Recipient Information

1. Recipient Name
UNIVERSITY OF NORTH CAROLINA AT CHAPEL HILL
104 AIRPORT DR STE 2200

CHAPEL HILL, NC 27599

2. Congressional District of Recipient
04

3. Payment System Identifier (ID)
1566001393A1

4. Employer Identification Number (EIN)
566001393

5. Data Universal Numbering System (DUNS)
608195277

6. Recipient's Unique Entity Identifier

7. Project Director or Principal Investigator
Noel Todd Brewer, PHD
Professor
ntb@unc.edu
(919) 966-3282

8. Authorized Official
Andrea Coghill
grants@unc.edu
919-962-3950

Federal Agency Information

9. Awarding Agency Contact Information
Sabrina Oasan

NATIONAL CANCER INSTITUTE
sabrina.oasan@nih.gov
240-276-6884

10. Program Official Contact Information
Sarah Kobrin

NATIONAL CANCER INSTITUTE
KOBRINS@MAIL.NIH.GOV
(240) 276-6931

Federal Award Information

11. Award Number
1P01CA250989-01A1

12. Unique Federal Award Identification Number (FAIN)
P01CA250989

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
Program Project – Improving Provider Announcement Communication Training (IMPACT)

15. Assistance Listing Number
93.393

16. Assistance Listing Program Title
Cancer Cause and Prevention Research

17. Award Action Type
New Competing

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information

19. Budget Period Start Date 09/23/2021 – **End Date** 08/31/2022	
20. Total Amount of Federal Funds Obligated by this Action	$2,381,047
20 a. Direct Cost Amount	$1,631,841
20 b. Indirect Cost Amount	$749,206
21. Authorized Carryover	$0
22. Offset	$0
23. Total Amount of Federal Funds Obligated this budget period	$2,381,047
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$2,381,047
26. Project Period Start Date 09/23/2021 – **End Date** 08/31/2026	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$2,381,047

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Dawn Walker

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

RESEARCH PROGRAM PROJECT
Department of Health and Human Services
National Institutes of Health

NATIONAL CANCER INSTITUTE

SECTION I – AWARD DATA – 1P01CA250989-01A1

Principal Investigator(s):
Noel Todd Brewer, PHD

Award e-mailed to: resadminosr@unc.edu

Dear Authorized Official:

The National Institutes of Health hereby awards a grant in the amount of $2,381,047 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to UNIV OF NORTH CAROLINA CHAPEL HILL in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Cancer Institute of the National Institutes of Health under Award Number P01CA250989. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Dawn Walker
Grants Management Officer
NATIONAL CANCER INSTITUTE

Additional information follows

Cumulative Award Calculations for this Budget Period (U.S. Dollars)

Salaries and Wages	$779,544
Fringe Benefits	$243,985
Personnel Costs (Subtotal)	$1,023,529
Consultant Services	$27,390
Materials & Supplies	$26,409
Travel	$20,584
Other	$130,684
Subawards/Consortium/Contractual Costs	$371,976
Publication Costs	$2,490
Tuition Remission	$28,779
Federal Direct Costs	$1,631,841
Federal F&A Costs	$749,206
Approved Budget	$2,381,047
Total Amount of Federal Funds Authorized (Federal Share)	$2,381,047
TOTAL FEDERAL AWARD AMOUNT	$2,381,047
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$2,381,047

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
1	$2,381,047	$2,381,047
2	FUTURE COSTS, RECOMMENDED COSTS	
3		
4		
5		

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

Fiscal Information:

Payment System Identifier:	1566001393A1
Document Number:	PCA250989A
PMS Account Type:	P (Subaccount)
Fiscal Year:	2021

IC	CAN	2021	2022	2023	2024	2025
CA	8479565	$2,381,047	FUTURE COSTS, RECOMMENDED COSTS			

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

NIH Administrative Data:
PCC: B9SC / **OC**: 41021 / **Released**: Walker, Dawn 09/14/2021
Award Processed: 09/23/2021 12:05:26 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 1P01CA250989-01A1

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

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SECTION III – STANDARD TERMS AND CONDITIONS – 1P01CA250989-01A1

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as

those included in appropriations acts.

c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2. As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

This institution is a signatory to the Federal Demonstration Partnership (FDP) Phase VII Agreement which requires active institutional participation in new or ongoing FDP demonstrations and pilots.

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This award is subject to the requirements of 2 CFR Part 25 for institutions to receive a Dun & Bradstreet Universal Numbering System (DUNS) number and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a DUNS requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) P01CA250989. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

This award provides support for one or more clinical trials. By law (Title VIII, Section 801 of Public Law 110-85), the "responsible party" must register "applicable clinical trials" on the ClinicalTrials.gov Protocol Registration System Information Website. NIH encourages registration of all trials whether required under the law or not. For more information, see http://grants.nih.gov/ClinicalTrials_fdaaa/

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System

(FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:

Additional Costs

SECTION IV – CA SPECIFIC AWARD CONDITIONS – 1P01CA250989-01A1

Clinical Trial Indicator: Yes

This award supports one or more NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

REQUIREMENT: This award is contingent upon the adjustment in Dr. Melissa Gilkey's effort as described in the updated Other Support/Correspondence dated 08/30/2021.

REQUIREMENT: The awardee must provide a interim progress report by 03/20/2022, via e-mail to the NCI Grants Management Specialist and Program Official for this award. The interim progress report should address recruitment updates.

INFORMATION: The funds in this award shall not be used to pay the salary of an individual at a rate in excess of Executive Level II ($199,300 in Fiscal Year 2021) per year effective January 3, 2021. See NIH Guide Notice: NOT-OD-21-057.

INFORMATION: In accordance with the National Cancer Institute's (NCI's) Fiscal Year (FY) 2021 funding policies, this award has been issued at 83% of the adjusted requested level*. Support recommended for future years has been adjusted accordingly.

*adjusted requested level: The requested level of support with adjustments made in accordance with the budget narrative in the summary statement and applicable grant policies.

INFORMATION: Although the budget period start date for this award is 9/23, this award includes funds for twelve months of support. Future year budget periods will cycle on 09/01. Allowable preaward costs may be charged to this award, in accordance with the conditions in the NIH Grants Policy Statement, and with institutional requirements for prior approval.

INFORMATION: This award, including the budget and the budget period, has been discussed between Sabrina Oasan of the National Cancer Institute and Andrea Cogdill on 08/30/2021.

INFORMATION: This award includes funds awarded for consortium activity. Consortia are to be established and administered as described in the NIH Grants Policy Statement (NIH GPS).

INFORMATION: This award involves Human Subjects Research. See "Assurance Requirements and Institutional Review Boards" under Part II, Subpart A, Human Subjects, in the NIH Grants Policy Statement, for specific requirements and recipient responsibilities related to the protection of human subjects, which are applicable to and are a term and condition of this award.

This award reflects the National Cancer Institute's acceptance of the certification that all key personnel have completed education on the protection of human subjects, in accordance the NIH Grants Policy Statement, "Education in the Protection of Human Research Subjects."

Any individual involved in the design and conduct of the study that is not included in the certification must satisfy this requirement prior to participating in the project. Failure to comply can result in the suspension and/or termination of this award, withholding of support of the continuation award, audit disallowances, and/or other appropriate action.

SPREADSHEET SUMMARY

AWARD NUMBER: 1P01CA250989-01A1

INSTITUTION: UNIV OF NORTH CAROLINA CHAPEL HILL

Budget	Year 1	Year 2	Year 3	Year 4	Year 5
Salaries and Wages	$779,544	FUTURE COSTS			
Fringe Benefits	$243,985				
Personnel Costs (Subtotal)	$1,023,529				
Consultant Services	$27,390				
Materials & Supplies	$26,409				
Travel	$20,584				
Other	$130,684				
Subawards/Consortium/Contractual Costs	$371,976				
Publication Costs	$2,490				
Tuition Remission	$28,779				
TOTAL FEDERAL DC	$1,631,841				
TOTAL FEDERAL F&A	$749,206				
TOTAL COST	$2,381,047				

Facilities and Administrative Costs	Year 1	Year 2	Year 3	Year 4	Year 5
F&A Cost Rate 1	55.5%	FUTURE COSTS			
F&A Cost Base 1	$1,349,921				
F&A Costs 1	$749,206				

PI: **Brewer, Noel Todd**	Title: Program Project – Improving Provider Announcement Communication Training (IMPACT)	
Received: 09/18/2020	FOA: PAR20-077	Council: 05/2021
Competition ID: FORMS-F	FOA Title: National Cancer Institute Program Project Applications (P01 Clinical Trial Optional)	
1 P01 CA250989-01A1	Dual:	Accession Number: 4493385
IPF: 578206	Organization: UNIV OF NORTH CAROLINA CHAPEL HILL	
Former Number: 1P01CA250989-01A1	Department: Health Behavior	
IRG/SRG: ZCA1 RPRB-L (M1)P	AIDS: N	Expedited: N
Subtotal Direct Costs (excludes consortium F&A) Year 1: 1,887,607 Year 2: Year 3: FUTURE COSTS Year 4: Year 5:	Animals: N Humans: Y Clinical Trial: Y Current HS Code: 30 HESC: N HFT: N	New Investigator: Early Stage Investigator:
Senior/Key Personnel:	*Organization:*	*Role Category:*
Noel Brewer	The University of North Carolina at Chapel Hill	PD/PI

APPLICATION FOR FEDERAL ASSISTANCE
SF 424 (R&R)

3. DATE RECEIVED BY STATE	**State Application Identifier**

1. TYPE OF SUBMISSION*

❍ Pre-application ❍ Application ● Changed/Corrected Application

4.a. Federal Identifier
CA250989

b. Agency Routing Number

2. DATE SUBMITTED
2020-09-18

Application Identifier

c. Previous Grants.gov Tracking Number
GRANT13205487

5. APPLICANT INFORMATION **Organizational DUNS*:** 608195277

Legal Name*: The University of North Carolina at Chapel Hill
Department: Office of Sponsored Research
Division: Research
Street1*: 104 Airport Drive
Street2: Campus Box 1350
City*: Chapel Hill
County: Orange
State*: NC: North Carolina
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: 27599-1350

Person to be contacted on matters involving this application
Prefix: First Name*: Andrea Middle Name: Last Name*: Coghill Suffix:
Position/Title: Grants Analyst
Street1*: 130 Mason Farm Road
Street2: CB 9525, Bioinformatics Bldg.
City*: Chapel Hill
County: Orange
State*: NC: North Carolina
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: 27599-9525
Phone Number*: (919) 962-3950 Fax Number: (919) 843-7094 Email: grants@unc.edu

6. EMPLOYER IDENTIFICATION NUMBER *(EIN) or (TIN)** 1-566001393-A1

7. TYPE OF APPLICANT* H: Public/State Controlled Institution of Higher Education

Other (Specify):
Small Business Organization Type ❍ Women Owned ❍ Socially and Economically Disadvantaged

8. TYPE OF APPLICATION*
❍ New ● Resubmission
❍ Renewal ❍ Continuation ❍ Revision

If Revision, mark appropriate box(es).
❍ A. Increase Award ❍ B. Decrease Award ❍ C. Increase Duration
❍ D. Decrease Duration ❍ E. Other *(specify)* :

Is this application being submitted to other agencies?* ❍Yes ●No What other Agencies?

9. NAME OF FEDERAL AGENCY*
National Institutes of Health

10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER
TITLE:

11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT*
Program Project – Improving Provider Announcement Communication Training (IMPACT)

12. PROPOSED PROJECT
Start Date* Ending Date*
07/01/2021 06/30/2026

13. CONGRESSIONAL DISTRICTS OF APPLICANT
NC-004

SF 424 (R&R) APPLICATION FOR FEDERAL ASSISTANCE

14. PROJECT DIRECTOR/PRINCIPAL INVESTIGATOR CONTACT INFORMATION

Prefix: First Name*: Noel Middle Name: T. Last Name*: Brewer Suffix:
Position/Title: Professor
Organization Name*: The University of North Carolina at Chapel Hill
Department: Health Behavior
Division: Gillings Sch. of Public Hlth
Street1*: 325 Rosenau Hall
Street2: CB 7440
City*: Chapel Hill
County: Orange
State*: NC: North Carolina
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: 27599-7440
Phone Number*: (919) 966-3282 Fax Number: (919) 966-2921 Email*: ntb@unc.edu

15. ESTIMATED PROJECT FUNDING

a. Total Federal Funds Requested*	$13,999,475.00
b. Total Non-Federal Funds*	$0.00
c. Total Federal & Non-Federal Funds*	$13,999,475.00
d. Estimated Program Income*	$0.00

16.IS APPLICATION SUBJECT TO REVIEW BY STATE EXECUTIVE ORDER 12372 PROCESS?*

a. YES ○ THIS PREAPPLICATION/APPLICATION WAS MADE AVAILABLE TO THE STATE EXECUTIVE ORDER 12372 PROCESS FOR REVIEW ON:
DATE:

b. NO ● PROGRAM IS NOT COVERED BY E.O. 12372; OR
○ PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW

17. By signing this application, I certify (1) to the statements contained in the list of certifications* and (2) that the statements herein are true, complete and accurate to the best of my knowledge. I also provide the required assurances * and agree to comply with any resulting terms if I accept an award. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. (U.S. Code, Title 18, Section 1001)

● I agree*

** The list of certifications and assurances, or an Internet site where you may obtain this list, is contained in the announcement or agency specific instructions.*

18. SFLLL or OTHER EXPLANATORY DOCUMENTATION File Name:

19. AUTHORIZED REPRESENTATIVE

Prefix: First Name*: Terry Middle Name: R Last Name*: Magnuson Suffix:
Position/Title*: Vice Chancellor for Research
Organization Name*: The University of North Carolina at Chapel Hill
Department: Office of Sponsored Research
Division: Research
Street1*: 104 Airport Dr. Ste. 2200
Street2: CB 1350
City*: Chapel Hill
County: Orange
State*: NC: North Carolina
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: 27599-1350
Phone Number*: (919) 966-3411 Fax Number: (919) 962-5011 Email*: resadminosr@unc.edu

Signature of Authorized Representative*
Terry R Magnuson

Date Signed*
09/18/2020

20. PRE-APPLICATION File Name:

21. COVER LETTER ATTACHMENT File Name:CoverLetterOverallrV21045711694.pdf

424 R&R and PHS-398 Specific
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Resource Sharing Plan(s) 864

Component Summary

Components	Component Project Title	Organization Name	Contact PD/PI Name or Project Lead Name
Overall	Program Project – Improving Provider Announcement Communication Training (IMPACT)	The University of North Carolina at Chapel Hill	Brewer, Noel T.
Admin-Core-001 (005)	Administrative Core – Improving Provider Announcement Communication Training (IMPACT)	The University of North Carolina at Chapel Hill	Brewer, Noel T.
Core-001 (006)	Intervention Core - Improving Provider Announcement Communication Training (IMPACT)	The University of North Carolina at Chapel Hill	Gilkey, Melissa
Core-002 (007)	Data Core – Improving Provider Announcement Communication Training (IMPACT)	The University of North Carolina at Chapel Hill	Gottfredson, Nisha Claire
Project-001 (001)	IMPACT Project 1 – The impact of standing orders support on HPV vaccine communication and uptake	The University of North Carolina at Chapel Hill	Brewer, Noel T.
Project-002 (002)	IMPACT Project 2 – The impact of clinic-level financial incentives on HPV vaccine communication and uptake	The University of North Carolina at Chapel Hill	Trogdon, Justin G.
Project-003 (003)	IMPACT Project 3 – Engaging clinical champions to improve HPV vaccine communication and uptake in healthcare systems	The University of North Carolina at Chapel Hill	Gilkey, Melissa
Project-004 (004)	IMPACT Project 4 – Budget impact, cost-effectiveness, and population outcomes of interventions to improve HPV vaccine communication and uptake in rural and nonrural communities	The University of North Carolina at Chapel Hill	Ozawa, Sachiko

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Project/Performance
Site Location(s) Summary

Applicant Organization	City	State/Province	Country
The University of North Carolina at Chapel Hill	Chapel Hill	NC	UNITED STATES

Organization Name	City	State/Province	Country	Component
AMGA Analytics, LLC	Alexandria	VA	UNITED STATES	Project-001 (001)
The Board of Regents of the University of Wisconsin System	Madison	WI	UNITED STATES	Project-003 (003)
The Ohio State University	Columbus	OH	UNITED STATES	Project-001 (001)
The University of North Carolina at Chapel Hill	Chapel Hill	NC	UNITED STATES	Admin-Core-001 (005)
The University of North Carolina at Chapel Hill	Chapel Hill	NC	UNITED STATES	Core-001 (006)
The University of North Carolina at Chapel Hill	Chapel Hill	NC	UNITED STATES	Core-002 (007)
The University of North Carolina at Chapel Hill	Chapel Hill	NC	UNITED STATES	Overall
The University of North Carolina at Chapel Hill	Chapel Hill	NC	UNITED STATES	Project-001 (001)
The University of North Carolina at Chapel Hill	Chapel Hill	NC	UNITED STATES	Project-002 (002)
The University of North Carolina at Chapel Hill	Chapel Hill	NC	UNITED STATES	Project-003 (003)
The University of North Carolina at Chapel Hill	Chapel Hill	NC	UNITED STATES	Project-004 (004)
Wake Forest University Health Sciences	Winston-Salem	NC	UNITED STATES	Core-001 (006)
WebMD	New York	NY	UNITED STATES	Core-002 (007)

Human Subjects
Clinical Trials
Vertebrate Animals
HESC
Human Fetal Tissue
Summary

Component	Human Subjects	Clinical Trial / Anticipated Clinical Trial	Vertebrate Animals	HESC	Human Fetal Tissue
Overall	Y	N	N	N	N
Admin-Core-001 (005)	N	N	N	N	N
Core-001 (006)	N	N	N	N	N
Core-002 (007)	Y	N	N	N	N
Project-001 (001)	Y	Y	N	N	N
Project-002 (002)	Y	Y	N	N	N
Project-003 (003)	Y	Y	N	N	N
Project-004 (004)	Y	N	N	N	N

Study Summary

Component	Study	Delayed Onset	Clinical Trial/Anticipated Clinical Trial	NIH Defined Phase III Clinical Trial
Core-002 (007)	Data Core: Improving Provider Announcement Communication Training (IMPACT)		No	
Project-001 (001)	The impact of standing orders support on HPV vaccine communication and uptake		Yes	No
Project-002 (002)	The impact of clinic-level financial incentives on HPV vaccine communication and uptake		Yes	No
Project-003 (003)	Engaging Clinical Champions to Improve HPV Vaccine Communication and Uptake in Healthcare Systems		Yes	No
Project-004 (004)	Budget impact, cost-effectiveness, and population outcomes of interventions to improve HPV vaccine communication and uptake in rural and nonrural communities		No	

Composite Application Budget Summary

Categories	Budget Period 1	Budget Period 2	Budget Period 3	Budget Period 4	Budget Period 5	TOTALS
Salary, Wages and Fringe Benefits	1,233,171	1,305,646	1,248,376	1,242,437	1,274,236	6,303,866
Equipment	0	0	0	0	0	0
Travel	24,800	32,000	31,500	24,000	35,300	147,600
Participant/Trainee Support Costs	0	0	0	0	0	0
Human Fetal Tissue Costs*						0
Other Direct Costs (excluding Consortium)	259,940	258,844	316,071	406,763	343,786	1,585,404
Consortium Costs	451,142	356,556	362,473	233,743	152,904	1,556,818
Direct Costs	1,969,053	1,953,046	1,958,420	1,906,943	1,806,226	9,593,688
Indirect Costs	892,572	866,381	866,334	903,990	876,510	4,405,787
Total Direct and Indirect Costs	2,861,625	2,819,427	2,824,754	2,810,933	2,682,736	**13,999,475**

*Human Fetal Tissue Costs, if present, are included in the budget summary for information only; the values have not been subtracted from "Other Direct Costs (excluding Consortium)"

Total Direct Costs less Consortium F&A

NIH policy (NOT-OD-05-004) allows applicants to exclude consortium/contractual F&A costs when determining if an application falls at or beneath any applicable direct cost limit. When a direct cost limit is specified in an FOA, the following table can be used to determine if your application falls within that limit.

Category	Budget Period 1	Budget Period 2	Budget Period 3	Budget Period 4	Budget Period 5	TOTALS
Total Direct Costs less Consortium F&A	1,887,607	1,843,681	1,850,628	1,833,410	1,753,146	**9,168,472**

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Component Budget Summary

Components	Categories	Budget Period 1	Budget Period 2	Budget Period 3	Budget Period 4	Budget Period 5	TOTALS
Admin-Core-001 (005)	Salary, Wages and Fringe Benefits	198,644	186,971	181,135	198,644	200,194	965,588
	Equipment	0	0	0	0	0	0
	Travel	6,000	6,000	6,000	6,000	6,000	30,000
	Participant/Trainee Support Costs	0	0	0	0	0	0
	Human Fetal Tissue Costs						0
	Other Direct Costs (excluding Consortium)	48,000	45,000	5,000	48,000	45,000	191,000
	Consortium Costs	0	0	0	0	0	0
	Direct Costs	252,644	237,971	192,135	252,644	251,194	1,186,588
	Indirect Costs	140,217	132,073	106,634	140,217	139,413	658,554
TOTALS	Total Direct and Indirect Costs	392,861	370,044	298,769	392,861	390,607	**1,845,142**
Core-001 (006)	Salary, Wages and Fringe Benefits	93,120	95,056	95,056	84,636	64,532	432,400
	Equipment	0	0	0	0	0	0
	Travel	8,800	0	0	0	11,800	20,600
	Participant/Trainee Support Costs	0	0	0	0	0	0
	Human Fetal Tissue Costs						0
	Other Direct Costs (excluding Consortium)	43,348	37,592	28,969	28,961	44,602	183,472
	Consortium Costs	62,699	62,711	62,724	62,736	62,749	313,619
	Direct Costs	207,967	195,359	186,749	176,333	183,683	950,091
	Indirect Costs	94,499	73,620	68,834	63,046	67,118	367,117

TOTALS	Total Direct and Indirect Costs	302,466	268,979	255,583	239,379	250,801	**1,317,208**
Core-002 (007)	Salary, Wages and Fringe Benefits	145,024	165,751	140,607	158,098	159,529	769,009
	Equipment	0	0	0	0	0	0
	Travel	0	0	0	0	0	0
	Participant/Trainee Support Costs	0	0	0	0	0	0
	Human Fetal Tissue Costs						0
	Other Direct Costs (excluding Consortium)	10,763	9,923	10,088	19,099	16,450	66,323
	Consortium Costs	206,386	0	0	0	0	206,386
	Direct Costs	362,173	175,674	150,695	177,197	175,979	1,041,718
	Indirect Costs	97,370	94,443	80,488	91,861	90,990	455,152
TOTALS	Total Direct and Indirect Costs	459,543	270,117	231,183	269,058	266,969	**1,496,870**
Project-001 (001)	Salary, Wages and Fringe Benefits	213,007	275,992	254,765	192,016	255,803	1,191,583
	Equipment	0	0	0	0	0	0
	Travel	3,000	3,000	3,000	3,000	3,000	15,000
	Participant/Trainee Support Costs	0	0	0	0	0	0
	Human Fetal Tissue Costs						0
	Other Direct Costs (excluding Consortium)	21,150	36,338	30,402	11,200	31,484	130,574
	Consortium Costs	52,555	71,374	77,278	47,832	17,964	267,003
	Direct Costs	289,712	386,704	365,445	254,048	308,251	1,604,160
	Indirect Costs	159,372	173,822	158,711	114,450	149,324	755,679
TOTALS	Total Direct and Indirect Costs	449,084	560,526	524,156	368,498	457,575	**2,359,839**
Project-002 (002)	Salary, Wages and Fringe Benefits	197,346	222,917	223,244	206,816	154,734	1,005,057

	Equipment	0	0	0	0	0	0
	Travel	1,500	6,000	5,500	1,500	1,500	16,000
	Participant/Trainee Support Costs	0	0	0	0	0	0
	Human Fetal Tissue Costs						0
	Other Direct Costs (excluding Consortium)	49,056	52,432	157,048	189,198	85,534	533,268
	Consortium Costs	0	0	0	0	0	0
	Direct Costs	247,902	281,349	385,792	397,514	241,768	1,554,325
	Indirect Costs	127,115	145,364	203,006	209,179	122,396	807,060
TOTALS	Total Direct and Indirect Costs	375,017	426,713	588,798	606,693	364,164	**2,361,385**
Project-003 (003)	Salary, Wages and Fringe Benefits	225,427	167,915	162,525	195,469	216,625	967,961
	Equipment	0	0	0	0	0	0
	Travel	4,500	13,000	13,000	7,500	6,000	44,000
	Participant/Trainee Support Costs	0	0	0	0	0	0
	Human Fetal Tissue Costs						0
	Other Direct Costs (excluding Consortium)	31,598	25,670	23,594	40,239	35,538	156,639
	Consortium Costs	129,502	222,471	222,471	123,175	72,191	769,810
	Direct Costs	391,027	429,056	421,590	366,383	330,354	1,938,410
	Indirect Costs	156,927	113,835	110,511	132,326	140,801	654,400
TOTALS	Total Direct and Indirect Costs	547,954	542,891	532,101	498,709	471,155	**2,592,810**
Project-004 (004)	Salary, Wages and Fringe Benefits	160,603	191,044	191,044	206,758	222,819	972,268
	Equipment	0	0	0	0	0	0
	Travel	1,000	4,000	4,000	6,000	7,000	22,000

	Participant/Trainee Support Costs	0	0	0	0	0	0
	Human Fetal Tissue Costs						0
	Other Direct Costs (excluding Consortium)	56,025	51,889	60,970	70,066	85,178	324,128
	Consortium Costs	0	0	0	0	0	0
	Direct Costs	217,628	246,933	256,014	282,824	314,997	1,318,396
	Indirect Costs	117,072	133,224	138,150	152,911	166,468	707,825
TOTALS	Total Direct and Indirect Costs	334,700	380,157	394,164	435,735	481,465	**2,026,221**
TOTALS		**2,861,625**	**2,819,427**	**2,824,754**	**2,810,933**	**2,682,736**	**13,999,475**

Categories Budget Summary

Categories	Components	Budget Period 1	Budget Period 2	Budget Period 3	Budget Period 4	Budget Period 5	TOTALS
R&R Budget - Senior/Key Person Funds Requested	Admin-Core-001 (005)	79,516	79,516	79,516	79,516	79,516	397,580
	Core-001 (006)	12,585	12,585	12,585	12,585	12,585	62,925
	Core-002 (007)	76,246	72,723	74,872	76,302	77,733	377,876
	Project-001 (001)	60,554	60,554	60,554	60,554	60,554	302,770
	Project-002 (002)	66,940	80,174	80,174	80,174	66,940	374,402
	Project-003 (003)	55,062	55,062	55,062	55,062	55,062	275,310
	Project-004 (004)	144,541	147,421	147,421	163,135	163,135	765,653
TOTALS		495,444	508,035	510,184	527,328	515,525	**2,556,516**
R&R Budget - Other Personnel Funds Requested	Admin-Core-001 (005)	119,128	107,455	101,619	119,128	120,678	568,008
	Core-001 (006)	80,535	82,471	82,471	72,051	51,947	369,475
	Core-002 (007)	68,778	93,028	65,735	81,796	81,796	391,133
	Project-001 (001)	152,453	215,438	194,211	131,462	195,249	888,813
	Project-002 (002)	130,406	142,743	143,070	126,642	87,794	630,655
	Project-003 (003)	170,365	112,853	107,463	140,407	161,563	692,651
	Project-004 (004)	16,062	43,623	43,623	43,623	59,684	206,615
TOTALS		737,727	797,611	738,192	715,109	758,711	**3,747,350**
R&R Budget - Section A & B. Total Salary, Wages and Fringe Benefits (A+B)	Admin-Core-001 (005)	198,644	186,971	181,135	198,644	200,194	965,588
	Core-001 (006)	93,120	95,056	95,056	84,636	64,532	432,400

	Core-002 (007)	145,024	165,751	140,607	158,098	159,529	769,009
	Project-001 (001)	213,007	275,992	254,765	192,016	255,803	1,191,583
	Project-002 (002)	197,346	222,917	223,244	206,816	154,734	1,005,057
	Project-003 (003)	225,427	167,915	162,525	195,469	216,625	967,961
	Project-004 (004)	160,603	191,044	191,044	206,758	222,819	972,268
TOTALS		1,233,171	1,305,646	1,248,376	1,242,437	1,274,236	**6,303,866**
R&R Budget - Section C. Total Equipment	Admin-Core-001 (005)	0	0	0	0	0	0
	Core-001 (006)	0	0	0	0	0	0
	Core-002 (007)	0	0	0	0	0	0
	Project-001 (001)	0	0	0	0	0	0
	Project-002 (002)	0	0	0	0	0	0
	Project-003 (003)	0	0	0	0	0	0
	Project-004 (004)	0	0	0	0	0	0
TOTALS		0	0	0	0	0	**0**
R&R Budget - Domestic Travel	Admin-Core-001 (005)	6,000	6,000	6,000	6,000	6,000	30,000
	Core-001 (006)	8,800	0	0	0	11,800	20,600
	Core-002 (007)	0	0	0	0	0	0
	Project-001 (001)	3,000	3,000	3,000	3,000	3,000	15,000
	Project-002 (002)	1,500	6,000	5,500	1,500	0	14,500
	Project-003 (003)	4,500	13,000	13,000	7,500	6,000	44,000
	Project-004 (004)	1,000	4,000	4,000	6,000	7,000	22,000
TOTALS		24,800	32,000	31,500	24,000	33,800	**146,100**

R&R Budget - Foreign Travel	Admin-Core-001 (005)	0	0	0	0	0	0
	Core-001 (006)	0	0	0	0	0	0
	Core-002 (007)	0	0	0	0	0	0
	Project-001 (001)	0	0	0	0	0	0
	Project-002 (002)	0	0	0	0	1,500	1,500
	Project-003 (003)	0	0	0	0	0	0
	Project-004 (004)	0	0	0	0	0	0
TOTALS		0	0	0	0	1,500	**1,500**
R&R Budget - Section D. Total Travel	Admin-Core-001 (005)	6,000	6,000	6,000	6,000	6,000	30,000
	Core-001 (006)	8,800	0	0	0	11,800	20,600
	Core-002 (007)	0	0	0	0	0	0
	Project-001 (001)	3,000	3,000	3,000	3,000	3,000	15,000
	Project-002 (002)	1,500	6,000	5,500	1,500	1,500	16,000
	Project-003 (003)	4,500	13,000	13,000	7,500	6,000	44,000
	Project-004 (004)	1,000	4,000	4,000	6,000	7,000	22,000
TOTALS		24,800	32,000	31,500	24,000	35,300	**147,600**
R&R Budget - Tuition/Fees/Health Insurance	Admin-Core-001 (005)	0	0	0	0	0	0
	Core-001 (006)	0	0	0	0	0	0
	Core-002 (007)	0	0	0	0	0	0
	Project-001 (001)	0	0	0	0	0	0
	Project-002 (002)	0	0	0	0	0	0
	Project-003 (003)	0	0	0	0	0	0

	Project-004 (004)	0	0	0	0	0	0
TOTALS		0	0	0	0	0	**0**
R&R Budget - Stipends	Admin-Core-001 (005)	0	0	0	0	0	0
	Core-001 (006)	0	0	0	0	0	0
	Core-002 (007)	0	0	0	0	0	0
	Project-001 (001)	0	0	0	0	0	0
	Project-002 (002)	0	0	0	0	0	0
	Project-003 (003)	0	0	0	0	0	0
	Project-004 (004)	0	0	0	0	0	0
TOTALS		0	0	0	0	0	**0**
R&R Budget - Trainee Travel	Admin-Core-001 (005)	0	0	0	0	0	0
	Core-001 (006)	0	0	0	0	0	0
	Core-002 (007)	0	0	0	0	0	0
	Project-001 (001)	0	0	0	0	0	0
	Project-002 (002)	0	0	0	0	0	0
	Project-003 (003)	0	0	0	0	0	0
	Project-004 (004)	0	0	0	0	0	0
TOTALS		0	0	0	0	0	**0**
R&R Budget - Subsistence	Admin-Core-001 (005)	0	0	0	0	0	0
	Core-001 (006)	0	0	0	0	0	0
	Core-002 (007)	0	0	0	0	0	0
	Project-001 (001)	0	0	0	0	0	0

	Project-002 (002)	0	0	0	0	0	0
	Project-003 (003)	0	0	0	0	0	0
	Project-004 (004)	0	0	0	0	0	0
TOTALS		0	0	0	0	0	**0**
R&R Budget - Other Participants/Trainee Support Costs	Admin-Core-001 (005)	0	0	0	0	0	0
	Core-001 (006)	0	0	0	0	0	0
	Core-002 (007)	0	0	0	0	0	0
	Project-001 (001)	0	0	0	0	0	0
	Project-002 (002)	0	0	0	0	0	0
	Project-003 (003)	0	0	0	0	0	0
	Project-004 (004)	0	0	0	0	0	0
TOTALS		0	0	0	0	0	**0**
R&R Budget - Section E. Total Participants/Trainee Support Costs	Admin-Core-001 (005)	0	0	0	0	0	0
	Core-001 (006)	0	0	0	0	0	0
	Core-002 (007)	0	0	0	0	0	0
	Project-001 (001)	0	0	0	0	0	0
	Project-002 (002)	0	0	0	0	0	0
	Project-003 (003)	0	0	0	0	0	0
	Project-004 (004)	0	0	0	0	0	0
TOTALS		0	0	0	0	0	**0**
R&R Budget - Materials and Supplies	Admin-Core-001 (005)	4,000	1,000	1,000	4,000	1,000	11,000
	Core-001 (006)	500	500	500	500	500	2,500

	Core-002 (007)	5,417	3,417	3,417	6,417	3,417	22,085
	Project-001 (001)	6,350	5,300	3,800	6,800	3,250	25,500
	Project-002 (002)	6,800	2,500	2,800	4,000	2,800	18,900
	Project-003 (003)	7,550	3,550	1,750	6,300	3,300	22,450
	Project-004 (004)	1,200	1,000	1,000	1,000	1,000	5,200
TOTALS		31,817	17,267	14,267	29,017	15,267	**107,635**
R&R Budget - Publication Costs	Admin-Core-001 (005)	0	0	0	0	0	0
	Core-001 (006)	0	0	0	0	0	0
	Core-002 (007)	0	0	0	0	0	0
	Project-001 (001)	1,500	1,500	3,000	3,000	6,000	15,000
	Project-002 (002)	0	1,500	1,500	1,500	1,500	6,000
	Project-003 (003)	1,500	1,500	1,500	4,500	4,500	13,500
	Project-004 (004)	0	0	0	0	1,500	1,500
TOTALS		3,000	4,500	6,000	9,000	13,500	**36,000**
R&R Budget - Consultant Services	Admin-Core-001 (005)	0	0	0	0	0	0
	Core-001 (006)	0	0	0	0	0	0
	Core-002 (007)	0	0	0	0	0	0
	Project-001 (001)	7,000	7,000	0	0	1,000	15,000
	Project-002 (002)	12,000	12,000	12,000	12,000	12,000	60,000
	Project-003 (003)	0	0	0	0	0	0
	Project-004 (004)	14,000	44,000	44,000	44,000	44,000	190,000
TOTALS		33,000	63,000	56,000	56,000	57,000	**265,000**

R&R Budget - ADP/Computer Services	Admin-Core-001 (005)	0	0	0	0	0	0
	Core-001 (006)	0	0	0	0	0	0
	Core-002 (007)	0	0	0	0	0	0
	Project-001 (001)	0	0	0	0	0	0
	Project-002 (002)	0	0	0	0	0	0
	Project-003 (003)	0	0	0	0	0	0
	Project-004 (004)	0	0	0	0	0	0
TOTALS		0	0	0	0	0	**0**
R&R Budget - Subawards/Consortium/Contractual Costs	Admin-Core-001 (005)	0	0	0	0	0	0
	Core-001 (006)	62,699	62,711	62,724	62,736	62,749	313,619
	Core-002 (007)	206,386	0	0	0	0	206,386
	Project-001 (001)	52,555	71,374	77,278	47,832	17,964	267,003
	Project-002 (002)	0	0	0	0	0	0
	Project-003 (003)	129,502	222,471	222,471	123,175	72,191	769,810
	Project-004 (004)	0	0	0	0	0	0
TOTALS		451,142	356,556	362,473	233,743	152,904	**1,556,818**
R&R Budget - Equipment or Facility Rental User Fees	Admin-Core-001 (005)	0	0	0	0	0	0
	Core-001 (006)	0	0	0	0	0	0
	Core-002 (007)	0	0	0	0	0	0
	Project-001 (001)	0	0	0	0	0	0
	Project-002 (002)	0	0	0	0	0	0

	Project-003 (003)	0	0	0	0	0	0
	Project-004 (004)	0	0	0	0	0	0
TOTALS		0	0	0	0	0	**0**
R&R Budget - Alterations and Renovations	Admin-Core-001 (005)	0	0	0	0	0	0
	Core-001 (006)	0	0	0	0	0	0
	Core-002 (007)	0	0	0	0	0	0
	Project-001 (001)	0	0	0	0	0	0
	Project-002 (002)	0	0	0	0	0	0
	Project-003 (003)	0	0	0	0	0	0
	Project-004 (004)	0	0	0	0	0	0
TOTALS		0	0	0	0	0	**0**
R&R Budget - Other Direct Cost 1	Admin-Core-001 (005)	44,000	44,000	4,000	44,000	44,000	180,000
	Core-001 (006)	42,848	37,092	28,469	28,461	44,102	180,972
	Core-002 (007)	5,346	5,506	5,671	11,682	12,033	40,238
	Project-001 (001)	6,300	2,138	2,202	1,400	21,234	33,274
	Project-002 (002)	18,866	19,432	20,015	20,615	21,234	100,162
	Project-003 (003)	3,773	1,477	20,344	4,783	4,468	34,845
	Project-004 (004)	6,688	6,889	7,095	7,308	15,055	43,035
TOTALS		127,821	116,534	87,796	118,249	162,126	**612,526**
R&R Budget - Other Direct Cost 2	Admin-Core-001 (005)	0	0	0	0	0	0
	Core-001 (006)	0	0	0	0	0	0
	Core-002 (007)	0	1,000	1,000	1,000	1,000	4,000

	Project-001 (001)	0	20,400	21,400	0	0	41,800
	Project-002 (002)	11,390	17,000	120,733	151,083	48,000	348,206
	Project-003 (003)	18,775	19,143	0	24,656	23,270	85,844
	Project-004 (004)	34,137	0	8,875	17,758	23,623	84,393
TOTALS		64,302	57,543	152,008	194,497	95,893	**564,243**
R&R Budget - Other Direct Cost 3	Admin-Core-001 (005)	0	0	0	0	0	0
	Core-001 (006)	0	0	0	0	0	0
	Core-002 (007)	0	0	0	0	0	0
	Project-001 (001)	0	0	0	0	0	0
	Project-002 (002)	0	0	0	0	0	0
	Project-003 (003)	0	0	0	0	0	0
	Project-004 (004)	0	0	0	0	0	0
TOTALS		0	0	0	0	0	**0**
R&R Budget - Section F. Total Other Direct Cost	Admin-Core-001 (005)	48,000	45,000	5,000	48,000	45,000	191,000
	Core-001 (006)	106,047	100,303	91,693	91,697	107,351	497,091
	Core-002 (007)	217,149	9,923	10,088	19,099	16,450	272,709
	Project-001 (001)	73,705	107,712	107,680	59,032	49,448	397,577
	Project-002 (002)	49,056	52,432	157,048	189,198	85,534	533,268
	Project-003 (003)	161,100	248,141	246,065	163,414	107,729	926,449
	Project-004 (004)	56,025	51,889	60,970	70,066	85,178	324,128
TOTALS		711,082	615,400	678,544	640,506	496,690	**3,142,222**
R&R Budget - Section G. Total Direct Cost (A thru F)	Admin-Core-001 (005)	252,644	237,971	192,135	252,644	251,194	1,186,588

	Core-001 (006)	207,967	195,359	186,749	176,333	183,683	950,091
	Core-002 (007)	362,173	175,674	150,695	177,197	175,979	1,041,718
	Project-001 (001)	289,712	386,704	365,445	254,048	308,251	1,604,160
	Project-002 (002)	247,902	281,349	385,792	397,514	241,768	1,554,325
	Project-003 (003)	391,027	429,056	421,590	366,383	330,354	1,938,410
	Project-004 (004)	217,628	246,933	256,014	282,824	314,997	1,318,396
TOTALS		1,969,053	1,953,046	1,958,420	1,906,943	1,806,226	**9,593,688**
R&R Budget - Section H. Indirect Costs	Admin-Core-001 (005)	140,217	132,073	106,634	140,217	139,413	658,554
	Core-001 (006)	94,499	73,620	68,834	63,046	67,118	367,117
	Core-002 (007)	97,370	94,443	80,488	91,861	90,990	455,152
	Project-001 (001)	159,372	173,822	158,711	114,450	149,324	755,679
	Project-002 (002)	127,115	145,364	203,006	209,179	122,396	807,060
	Project-003 (003)	156,927	113,835	110,511	132,326	140,801	654,400
	Project-004 (004)	117,072	133,224	138,150	152,911	166,468	707,825
TOTALS		892,572	866,381	866,334	903,990	876,510	**4,405,787**
R&R Budget - Section I. Total Direct and Indirect Costs (G +H)	Admin-Core-001 (005)	392,861	370,044	298,769	392,861	390,607	1,845,142
	Core-001 (006)	302,466	268,979	255,583	239,379	250,801	1,317,208
	Core-002 (007)	459,543	270,117	231,183	269,058	266,969	1,496,870
	Project-001 (001)	449,084	560,526	524,156	368,498	457,575	2,359,839
	Project-002 (002)	375,017	426,713	588,798	606,693	364,164	2,361,385
	Project-003 (003)	547,954	542,891	532,101	498,709	471,155	2,592,810
	Project-004 (004)	334,700	380,157	394,164	435,735	481,465	2,026,221

TOTALS		2,861,625	2,819,427	2,824,754	2,810,933	2,682,736	**13,999,475**

Senior/Key Personnel
Summary

Name	Organization	Role on Project	Components
Brewer, Noel T.	The University of North Carolina at Chapel Hill	PD/PI(Contact)	Overall
Birken, Sarah	Wake Forest University Health Sciences	Co-Investigator	Admin-Core-001 (005)
Birken, Sarah A.	Wake Forest University Health Sciences	Other: Core Lead	Core-001 (006)
Birken, Sarah A.	Wake Forest University Health Sciences	Co-Investigator	Project-001 (001)
Birken, Sarah A.	Wake Forest University Health Sciences	Co-Investigator	Project-002 (002)
Birken, Sarah A.	Wake Forest University Health Science	Co-Investigator	Project-003 (003)
Birken, Sarah A.	Wake Forest University Health Sciences	Co-Investigator	Project-004 (004)
Brewer, Noel T.	The University of North Carolina at Chapel Hill	Other: Core Lead	Admin-Core-001 (005)
Brewer, Noel T.	The University of North Carolina at Chapel Hill	Co-Investigator	Core-002 (007)
Brewer, Noel T.	The University of North Carolina at Chapel Hill	Other: Project Lead	Project-001 (001)
Ciemins, Elizabeth L.	AMGA Analytics, LLC	Other: Research Director	Project-001 (001)
Cox, Elizabeth D.	The Board of Regents of the University of Wisconsin System	Co-Investigator	Project-003 (003)
Darden, Paul	N/A	Consultant	Project-001 (001)
Gilkey, Melissa	The University of North Carolina at Chapel Hill	Co-Investigator	Admin-Core-001 (005)
Gilkey, Melissa	The University of North Carolina at Chapel Hill	Co-Investigator(Contact)	Core-001 (006)
Gilkey, Melissa	The University of North Carolina at Chapel Hill	Other: Project Lead	Project-003 (003)
Gottfredson, Nisha Claire	The University of North Carolina at Chapel Hill	Co-Investigator	Admin-Core-001 (005)
Gottfredson, Nisha Claire	The University of North Carolina at Chapel Hill	Other: Core Lead	Core-002 (007)
Hassmiller Lich, Kristen	The University of North Carolina at Chapel Hill	Co-Investigator	Project-004 (004)
Hernandez, Michelle L	The University of North Carolina at Chapel Hill	Co-Investigator	Project-002 (002)
Higgins, Colleen	N/A	Consultant	Project-004 (004)

Ibrahim, Joseph G.	The University of North Carolina at Chapel Hill	Co-Investigator	Core-002 (007)
Kim, Jane	N/A	Consultant	Project-004 (004)
Mansfield, Lisa N.	University of California Los Angeles	Consultant	Project-001 (001)
Mills, Sarah Denton	The University of North Carolina at Chapel Hill	Co-Investigator	Project-004 (004)
Myers, Evan	N/A	Consultant	Project-004 (004)
Oliver, Kristin	Icahn School of Medicine at Mount Sinai	Other: External Advisory Board	Admin-Core-001 (005)
Ozawa, Sachiko	The University of North Carolina at Chapel Hill	Co-Investigator	Admin-Core-001 (005)
Ozawa, Sachiko	The University of North Carolina at Chapel Hill	Other: Project Lead	Project-004 (004)
Reiter, Paul L.	The Ohio State University	Co-Investigator	Project-001 (001)
Rosen, Audrey	WebMD	Other: Project Oversight	Core-002 (007)
Savoy, Margot L.	Temple University Health System	Other: External Advisory Board	Admin-Core-001 (005)
Spees, Lisa	The University of North Carolina at Chapel Hill	Co-Investigator	Project-004 (004)
Spencer, Jennifer	N/A	Consultant	Project-004 (004)
Szilagyi, Peter	University of California Los Angeles	Other: External Advisory Board	Admin-Core-001 (005)
Thirumurthy, Harsha	N/A	Consultant	Project-002 (002)
Thomas, Tami L.	Florida International University	Other: External Advisory Board	Admin-Core-001 (005)
Trogdon, Justin G.	The University of North Carolina at Chapel Hill	Co-Investigator	Admin-Core-001 (005)
Trogdon, Justin G.	The University of North Carolina at Chapel Hill	Other: Co-Core Lead	Core-002 (007)
Trogdon, Justin G.	The University of North Carolina at Chapel Hill	Other: Project Lead	Project-002 (002)
Weiner, Bryan J	University of Washington	Other: Advisor	Core-001 (006)
Wheeler, Stephanie B	The University of North Carolina at Chapel Hill	Co-Investigator	Project-004 (004)
Wheeler, Stephanie B.	The University of North Carolina at Chapel Hill	Co-Investigator	Admin-Core-001 (005)
Yarbrough, Wendell	The University of North Carolina at Chapel Hill	Other: Other Significant Contributor	Admin-Core-001 (005)
Zakharkin, Stanislav	WebMD	Other: Statistical Lead	Core-002 (007)

OMB No. 0925-0001 and 0925-0002 (Rev. 03/2020 Approved Through 02/28/2023)

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: **Brewer, Noel Todd**

eRA COMMONS USER NAME (credential, e.g., agency login): eRA COMMONS USER NAME

POSITION TITLE: **Professor of Health Behavior**

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE	Completion Date	FIELD OF STUDY
University of California at Santa Cruz	BA	06/1992	Economics
Rutgers University, New Brunswick, NJ	MS	06/2000	Social Psychology
Rutgers University, New Brunswick, NJ	PhD	06/2002	Health and Social Psych
Rutgers University, New Brunswick, NJ	Postdoc	06/2004	Human Ecology

A. Personal Statement

As Principal Investigator, my role will be to oversee the grant activities for the proposed P01 Program Project "Improving Provider Announcement Communication Training" (IMPACT). I will also serve as Lead of the Administrative Core, Project Lead of Project 1, and Co-Investigator for the Data Core (Year 1). As an accomplished leader in HPV vaccine communication and an experienced administrator, I am well-suited to oversee the complex work of the Program Project. I presently chair the National HPV Vaccination Roundtable and regularly advises WHO, CDC and other organizations on vaccine communication. I have served in a leadership capacity as a member of the National Vaccine Advisory Committee working group on HPV vaccine, co-chair of a workshop for the President's Cancer Panel, and special advisor to the Chair of the Panel. I have successfully advocated for federal panels to make recommendations in 3 key areas that hold promise for addressing low HPV coverage: communication trainings for providers, quality improvement visits to clinics, and establishing viable alternative vaccination settings such as schools and pharmacies.

Additionally, I have extensive expertise leading multidisciplinary teams with cross-institution collaborations, including overseeing large center projects, and conducting complex research studies. Furthermore, I have extensive management experience gained while running my Health Cognitive Behavior Lab overseeing over 20 project managers, postdoctoral research associates, and graduate research assistants; directing Cervical Cancer-Free North Carolina; and serving as collaborative scientific lead for UNC's Research Center for Excellence in Clinical Preventive Services. I am an expert in provider communication and developer of the Announcement Approach Training on vaccine provider communication.

I am a strong fit for these roles due to my work as a behavioral scientist who studies how people think about risk and my experience as a leader of extensively multi- and transdisciplinary teams, including teams implementing the Announcement Approach Training is 12 states. This Program Project is an exciting project that will meaningfully make a significant contribution to cancer prevention by developing new evidence on effective strategies to improve provider communication and HPV vaccine uptake. I am delighted to lead this multidisciplinary team that has worked across disciplines from inception and will continue to do so through completion.

Relevant publications

1. Gilkey MB, Dayton AM, Moss JL, Sparks AC, Grimshaw AH, Bowling JM, **Brewer NT**. Increasing provision of adolescent vaccines in primary care: A randomized controlled trial. *Pediatrics*. 2014 Aug;134(2):e346-353. PMID: 25002671. PMCID: PMC4531274.

2. Gilkey MB, Moss JL, Roberts AJ, Dayton AM, Grimshaw AH, **Brewer NT**. Comparing in-person and webinar delivery of an immunization quality improvement program: A process evaluation of the Adolescent AFIX trial. *Implement Sci*. 2014 Feb 18;9:21. PMID: 24533515. PMCID: PMC3937058.
3. **Brewer NT**, Chapman GB, Rothman AJ, Leask J, Kempe A. Increasing vaccination: Putting psychological science into action. Psychol Sci Public Interest. 2017 Dec;18(3):149-207. PMID:29611455.
4. Malo TL, Hall ME, **Brewer NT**, Lathren CR, Gilkey MB. Why is announcement training more effective than conversation training for introducing HPV vaccination? A theory-based investigation. Implement Sci. 2018 Apr 19;13(1):57. PMID: 29673374. PMCID: PMC5907716.

B. Positions and Honors

Positions and Employment

2004-2010	Assistant Professor, Health Behavior and Health Education, Gillings School of Global Public Health, University of North Carolina at Chapel Hill
2005-	Member, Lineberger Comprehensive Cancer Center, University of North Carolina at Chapel Hill
2006-	Adjunct Professor, Psychology, University of North Carolina at Chapel Hill
2010-2016	Associate Professor, Health Behavior, Gillings School of Global Public Health, University of North Carolina at Chapel Hill
2016-	Professor, Health Behavior, Gillings School of Global Public Health, University of North Carolina at Chapel Hill

Other Experience

2007-2009	Editorial boards, *Annals of Behavioral Medicine* and *Health Psychology*
2007-2010	Ad hoc member, Study Section, NIH Psychosocial Risk and Disease Prevention
2008-2012	Ad hoc reviewer for NSF (Decision, Risk and Management Science Program); NIH-AHRQ; Social Sciences and Humanities Research Council of Canada; and Cancer Research UK
2009-2013	Member, Risk Communication Advisory Committee, Food and Drug Administration
2009-2013	Editorial board, *Medical Decision Making*
2009-2014	Editorial board, *Journal of Behavioral Medicine*
2009-2019	Associate Editor, *Health Psychology Review*
2014-	Chair, National HPV Vaccination Roundtable

Selected Honors

1999	American Psychological Association, Div. 38, Health Psychology Research Award
2001	Rutgers University Award for Outstanding Research in Social Psychology
2006, ’17, ‘19	Citation Award, Society for Behavioral Medicine
2010	Rutgers University Early Career Alumnus Award for Distinguished Accomplishments & Service
2011	Phillip and Ruth Hettleman Prize for Artistic and Scholarly Achievement by Young Faculty, University of North Carolina
2017, 2018	Highly Cited Researcher (top 1% globally), Clarivite, 2017 and 2018.

C. Contributions to Science

My research examines health behaviors that prevent cancer, including HPV vaccination, screening, and stopping smoking.

1. **HPV vaccination.** One line of my research has sought to understand and intervene on the problem of low HPV vaccination coverage in the US. In a widely-cited systematic review, I examined motivators of HPV vaccination acceptability. I have also conducted studies that identified important HPV vaccine attitudes among adult women, parents of adolescent girls and boys, gay and bisexual men, heterosexual men, adolescent boys, healthcare providers, and adults in Botswana and Kenya. Concerned about the continued low rates of HPV vaccine uptake in the US, I initiated research in 2011 in three areas that I believe hold promise for addressing low coverage: communication trainings for clinicians, quality improvement visits to clinics, and establishing the viability of alternative vaccination settings such as schools and pharmacies. As a member of the National Vaccine Advisory Committee working group on HPV vaccine and co-chair of a

workshop for the President's Cancer Panel, I successfully advocated for both federal panels to recommend these three approaches. I presently chair the National HPV Vaccination Roundtable.

a. **Brewer NT**, Hall ME, Malo TL, Gilkey MB, Quinn B, Lathren C. Announcements versus conversations to improve HPV vaccination coverage: a randomized trial. *Pediatrics*. 2017 Jan;139(1). PMID: 27940512. PMCID: PMC5192091.
b. **Brewer NT**, Gottlieb SL, Reiter PL, McRee AL, Liddon N, Markowitz L, Smith JS. Longitudinal predictors of human papillomavirus vaccine initiation among adolescent girls in a high-risk geographic area. *Sex Transm Dis*. 2011 Mar;38(3):197-204. PMID: 20838362. PMCID: PMC3025264.
c. Gilkey MB, Malo TL, Shah PD, Hall ME, **Brewer NT**. Quality of physician communication about human papillomavirus vaccine: findings from a national survey. *Cancer Epidemiol Biomarkers Prev*. 2015 Nov;24(11):1673-9. PMID: 26494764. PMCID: PMC4633386.
d. Spencer JC, Calo W, **Brewer NT**. Disparities and reverse disparities in HPV vaccination: A systematic review and meta-analysis. *Prev Med*. 2019 Jun;123:197-203. PMID: 30930259. PMCID: PMC6724708.

2. **Tobacco prevention and control.** A second line of my research examines how to communicate the harms of smoking. Several of my studies have established that pictorial warnings on cigarette packs effectively increase intentions to quit smoking and quit attempts and have been cited in FDA's proposed rule "Required Warnings for Cigarette Packages and Advertisements." Colleagues and I recently developed the Tobacco Warnings Model to explain the effects of tobacco product warnings. Through an ongoing program of research, we are establishing how the public thinks about the harmful chemicals in cigarette smoke and how best to communicate about those risks. Finally, colleagues and I have documented the increasing use of e-cigarettes through the first systematic review in that area and explored perceptions about the health risks of e-cigarettes relative to other tobacco products.

a. **Brewer NT**, Morgan JC, Baig SA, Mendel JR, Boynton MH, Pepper JK, Byron MJ, Noar SM, Agans RP, Ribisl KM. Public understanding of cigarette smoke constituents: three US surveys. *Tob Control*. 2016 Sep;26(5):592-599. PMID: 27924009. PMCID: PMC5495614.
b. **Brewer NT**, Parada JH, Hall MG, Boynton MH, Noar SM, Ribisl KM. Understanding why pictorial cigarette pack warnings increase quit attempts. *Ann Behav Med*. 2019 Mar 1;53(3):232-243. PMID: 29850764. PMCID: PMC6265120.
c. Pepper JK, Emery SL, Ribisl KM, Rini CM, **Brewer NT**. How risky is it to use e-cigarettes? Smokers' beliefs about their health risks from using novel and traditional tobacco products. *J Behav Med*. 2015 Apr;38(2):318-26. PMID: 25348584. PMCID: PMC4520302.
d. Noar SM, Hall MG, Francis DB, Ribisl KM, Pepper JK, **Brewer NT**. Pictorial cigarette pack warnings: a meta-analysis of experimental studies. *Tob Control*. 2016 May;25(3):341-54. PMID: 25948713. PMCID: PMC4636492.

3. **Cancer screening.** A third line of my research has identified what motivates people to get screened for breast cancer, cervical cancer, and colorectal cancer and how being screened affects them. My systematic reviews identified that false-positive mammogram results make some women less likely to screen and cause long-lasting harm to women's wellbeing. The US Preventive Services Task Force used my systematic review on the harms of breast cancer screening as one basis for their recommendation of less frequent breast cancer screening among women ages 40-49. Colleagues and I also developed tools for reducing errors in women's understanding of genomic tests results related to breast cancer recurrence risk (Oncotype DX) and ability to metabolize tamoxifen (CYP2D6).

a. Alber JM, **Brewer NT**, Melvin C, Yackle A, Smith JS, Ko LK, Crawford A, Glanz K. Reducing overuse of cervical cancer screening: A systematic review. *Prev Med*. 2018 Nov;116:51-59. PMID: 30149037.
b. **Brewer NT**, Richman AR, DeFrank JT, Reyna VF, Carey LA. Improving communication of breast cancer recurrence risk. *Breast Cancer Res Treat*. 2012 Jun;133(2):553-61. PMID: 21964579. PMCID: PMC3754448.

c. Sheridan SL, Sutkowi-Hemstreet A, Barclay C, **Brewer NT**, Dolor RJ, Gizlice Z, Lewis CL, Reuland DS, Golin CE, Kistler CE, Vu M, Harris R. A comparative effectiveness trial of alternate formats for presenting benefits and harms information for low-value screening services: A randomized clinical trial. *JAMA Intern Med.* 2016 Jan;176(1):31-41. PMID: 26720730.

d. Harris RP, Sheridan SL, Lewis CL, Barclay C, Vu MB, Kistler CE, Golin CE, DeFrank JT, **Brewer NT**. The harms of screening: a proposed taxonomy and application to lung cancer screening. *JAMA Intern Med.* 2014 Feb 1;174(2):281-5. PMID: 24322781.

4. **Risk perception and risk communication.** A unifying theme across all of my research is understanding how people appraise their own risk of harm and how best to communicate information about risks. My early work examined the *behavior motivation hypothesis* by demonstrating that perceived risk motivates health behaviors including vaccination. Colleagues and I later formulated the *risk reappraisal hypothesis* and established support for it by showing that engaging in protective behavior can cause people to reappraise (and lower) their perceptions of risk. My work with Dr. Neil Weinstein (Rutgers University) established standards for high-quality measurement of risk beliefs including using survey items that ask about risk perceptions contingent on previous behavior. My recent work has focused on affect and risk, including a meta-analysis showing that anticipated regret is a cognitive emotion that motivates health behaviors. Another line of research has shown that risk communication can elicit reactance, a set of emotions and cognitions that includes anger as a response to perceived threat to freedom, which then undermines the impact of the communication efforts. I served for four years on the FDA's Risk Communication Advisory Committee and co-edited the FDA's book on risk communication.

   a. **Brewer NT**, DeFrank JT, Gilkey MB. Anticipated regret and health behavior: a meta-analysis. *Health Psychol.* 2016 Nov;35(11):1264-1275. PMID: 27607136. PMCID: PMC5408743.

   b. **Brewer NT**, Weinstein ND, Cuite CL, Herrington JE. Risk perceptions and their relation to risk behavior. *Ann Behav Med.* 2004 Apr;27(2):125-30. PMID: 15026296.

   c. **Brewer NT**, Chapman GB, Gibbons FX, Gerrard M, McCaul KD, Weinstein ND. Meta-analysis of the relationship between risk perception and health behavior: the example of vaccination. *Health Psychol.* 2007 Mar;26(2):136-45. PMID: 17385964.

   d. Fischhoff B, **Brewer NT**, Downs J. Communicating risks and benefits: an evidence-based user's guide. Washington, DC: Federal Drug Administration. 2011.

Complete List of Published Work in MyBibliography
https://www.ncbi.nlm.nih.gov/myncbi/browse/collection/47354498
My 272 publications have been cited 8,323 times, and my h index is 46 (data from ISI Web of Science as of 2/8/20).

D. Additional Information: Research Support

Ongoing Research Support (PI/PD)

CDC: A180254 Brewer (co-PI) 8/01/17-8/31/20
Impact of AFIX and Physician-to-Physician Engagement on HPV Vaccination in Primary Care: An RCT
This trial evaluates the impact of quality improvement visits (AFIX) and physician to physician peer-communication training on HPV vaccination uptake.
Role: Co-principal Investigator

R01: DA048390-01A1 Brewer (PI) 7/1/2020-4/30/2025
Informing ENDS policies: Studying the impact of e-cigarette warnings on behavior
The project studies the impact of the current FDA e-cigarette warning and new warnings in an RCT.
Role: Principal Investigator

PRIVATE SUPPORT Brewer (PI) 7/1/2020-6/30/2021
Getting Pediatric Vaccination Back on Track in the US
The project characterizes drops in vaccine uptake associated with the Covid-19 pandemic and examines how providers are communicating with patients about safety during vaccine visits.

Role: Principal Investigator

Ongoing Research Support (Co-I)

R01: CA246600 Noar (PI) 9/17/19-8/31/22

Advancing Perceived Message Effectiveness: A New Measure for Youth Prevention Media Campaigns

The primary goal of the proposed project is to develop and validate an *effects* PME scale for adolescent tobacco prevention ads using rigorous scale development methods. Another goal is to compare the performance of this new scale to the FDA's *message* PME scale in a longitudinal validation experiment.

Role: Co-Investigator

Completed Research Support (past 3 years)

NIH: R01CA183891-01A1 Smith (PI) 4/01/15-3/31/20

Effect of HPV Self-Collection on Cervical Cancer Screening in High Risk Women

This study examined whether mailing HPV self-collection kits to high-risk women increases in-clinic cervical cancer screening.

Role: Co-Investigator

NIH: P50CA180907 Ribisl (PI) 9/01/13-8/31/19

Effective Communication on Tobacco Product Risk and FDA Authority

The Center conducted integrated research projects on communicating about cigarette smoke constituents to reduce initiation of tobacco use and increase quit attempts.

Role: Principal Investigator, Project 1

CDC: U48 DP005017-SIP Ammerman (PI) 9/30/16-9/29/19

Center for Health Promotion and Disease Prevention – Supplement

SIP 16-005 Communication strategies to increase HPV vaccine intentions

This multi-level study built on communication theory, clinical experience, and several years of research by our team to identify effective messages and to refine a step-by-step strategy for effectively recommending HPV vaccination for adolescents as part of national cancer prevention efforts.

Role: Principal Investigator

CDC: U48DP005017-01S8 Weiner (PI) 9/30/14-9/29/19

Cancer Prevention and Control Research Network and Collaborating Center

The proposed project accelerated adoption and implementation of evidence-based cancer prevention and control to significantly reduce cancer risk and cancer burden, especially among under-served populations.

Role: Co-Investigator

NIH: P30CA016086 S3 Sharpless (PI) 12/01/13-11/30/18

Cigarette Warning Labels: Research Synthesis and Impact on Smoking Behavior

In this supplement to an existing P30 grant, we meta-analyzed the existing experimental literature on cigarette pack warnings. In addition, we are conducting a large-scale RCT in which we label smokers' cigarette packs with text or graphic warnings to examine the impact on smoking behavior.

Role: Program Director

[Older completed grants not listed, including several R01 equivalent grants with Dr. Brewer as PI.]

OMB No. 0925-0001 and 0925-0002 (Rev. 03/2020 Approved Through 02/28/2023)

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: **Birken, Sarah Abigail**

eRA COMMONS USER NAME (credential, e.g., agency login): eRA COMMONS USER NAME

POSITION TITLE: **Associate Professor**

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
University of California, Berkeley, CA	BA	05/2002	Women's Studies
University of North Carolina, Chapel Hill, NC	MSPH	05/2006	Health Policy and Management
University of North Carolina, Chapel Hill, NC	PhD	05/2011	Health Policy and Management
University of North Carolina, Chapel Hill, NC	Postdoctoral	06/2014	Cancer Control and Prevention

A. Personal Statement

I am a health services researcher and implementation scientist whose work focuses on translating evidence-based interventions (EBIs) in cancer care into practice. My expertise positions me well to lead the IMPACT Program Project (P01) in understanding the adoption and implementation of the interventions to be tested in the proposed trials as Co-Lead of the Intervention Core. I will contribute my conceptual, content, and methodological expertise to the proposed P01.

Conceptual expertise. As Intervention Core Co-Lead, I will ensure that studies of the interventions' implementation are conceptually sound and substantively contribute to the field of implementation science. I am well-positioned to do this as Associate Professor in the Department of Implementation Science in the Wake Forest School of Medicine and co-editor of *The Handbook on Implementation Science*, which provides an overview of the field's history, key concepts, and methods.

Content and methodological expertise. My research has identified determinants of the implementation of EBIs in cancer care [1-2]. I have received funding to develop a change package to disseminate an approach to promote the implementation of EBIs in cancer care similar to HPV vaccination, and my work has focused on identifying and developing implementation strategies [3]. I am Faculty Lead of the Wake Forest Baptist Comprehensive Cancer Center's Qualitative and Patient-Reported Outcomes Shared Resource. I also have extensive experience in mixed-method studies similar to the proposed P01 studies.

1. **Birken, S. A.**, Presseau, J. P., Ellis, S., Gerstel, A., Mayer, D. M. (2014). Potential determinants of survivorship care plan use in US cancer programs: A qualitative study using the theoretical domains framework. Implementation Science. 10(1): 63. PMCID: PMC4236456.
2. **Birken, S. A.**, Deal, A. M., Mayer, D., Weiner, B. J. (2014). Following through: The consistency of survivorship care plan use in United States cancer programs. The Journal of Cancer Education. 29(4): 689-697. PMCID: PMC4148470.
3. Leeman, J., **Birken, S. A.**, Powell, B. J., Rohweder, C., Shea, C. M. (2017). Beyond "implementation strategies": Classifying the full range of strategies used in implementation science and practice. Implementation Science. 12(1):125. PMID: 29100551.

B. Positions and Honors

Positions and Employment

2007-2008 Research Assistant, Managing Overweight and/or Obesity for Veterans Everywhere! Program, Veterans Affairs National Center for Health Promotion & Disease Prevention
2007-2008 Research Assistant, Durham Veterans Affairs Medical Center – Health Services Research & Development
2008-2009 Project Manager, Council on Education for Public Health Self-Study, University of North Carolina at Chapel Hill School of Public Health
2010-2011 Evaluator, North Carolina Access to Care Initiative, Center for Health Policy at Duke University
2010-2011 Teaching Fellow, Doctoral Seminar in Organizational Theory and Health Care Organizations, University of North Carolina at Chapel Hill
2011-2014 Postdoctoral Fellow, Cancer Control Education Program, Lineberger Comprehensive Cancer Center, University of North Carolina at Chapel Hill
2014-2020 Assistant Professor, Department of Health Policy and Management, University of North Carolina at Chapel Hill School of Public Health
2015-2020 Associate Member, Lineberger Comprehensive Cancer Center, University of North Carolina at Chapel Hill School of Public Health
2017-2020 Director, Program on Implementation and Organization Research, and Research Fellow, Cecil G. Sheps Center for Health Services Research, University of North Carolina at Chapel Hill
2020- Associate Professor, Department of Implementation Science, Wake Forest School of Medicine, Winston-Salem, NC
2020- Faculty Lead, Qualitative and Patient-Reported Outcomes Shared Resource of the Wake Forest Baptist Comprehensive Cancer Center
2020- Member, Cancer Prevention and Control Program at the Wake Forest Baptist Comprehensive Cancer Center
2020- Adjunct Associate Professor, Department of Health Policy and Management, University of North Carolina at Chapel Hill School of Public Health
2020- Faculty, Multilevel Training Institute, National Cancer Institute, National Institutes of Health

Other Experience and Professional Memberships

2006- Member, Organization Theory in Health Care Association
2006- Article Referee, e.g., Implementation Science; BMC Cancer; BMC Health Services Research; PLOS ONE, The Lancet Oncology
2008-2009 Project Manager, Council on Education for Public Health Self-study, Gillings School of Global Public Health, University of North Carolina at Chapel Hill
2010- Member, Academy of Management Health Care Management Division
2012-2013 Survivorship Care Planning and Dissemination & Implementation Champion, National Cancer Institute's Grid-Enabled Measures Survivorship Care Plan team
2012- Reviewer, Applications for Training Institute for Dissemination and Implementation in Health, a National Institutes of Health initiative to train investigators in dissemination and implementation
2012- Reviewer, Annual Meeting of the Academy of Management
2013- Member, Cancer Research Network Communication and Dissemination Research Scientific Working Group
2014 Chair, Health Policy and Healthcare Reform Impacts on Healthcare Management session at the Annual Meeting of the Academy of Management
2014 Expert speaker, George Washington University's Ask the Expert Webinar on Conducting the Survivorship Care Plan Use Survey for the Center for Disease Prevention and Control's National Comprehensive Cancer Control Program Directors
2014 Expert panel member, Clarity out of Chaos: Synthesizing Implementation Findings. Veterans Affairs Center for Clinical Management Research, Ann Arbor VA HSR&D Center of Excellence
2014-2020 Member, Committee on the Status of Women, University of North Carolina at Chapel Hill
2015 Panel member, WISDOM (Women in Science Deserve Opportunities and Mentoring) Women's Leadership and Career Development Discussion, University of North Carolina at Chapel Hill
2015 Expert speaker, National Cancer Survivorship Resource Center's Ask the Expert Webinar on Community of Practice: Generation and Translation of Evidence GATE Project

2015-2020 Member, Social and Behavioral Health Subcommittee, Protocol Review Committee, Lineberger Comprehensive Cancer Center
2015-2020 Member, Society for Implementation Research Collaboration
2016-2018 Co-Chair, Survivorship Special Interest Group, George Washington Cancer Institute's PCORI-funded Generation and Translation of Evidence: An Oncology Community of Practice

Honors

2002 Phi Beta Kappa, University of California, Berkeley
2002 National Society of Collegiate Scholars
2004-2006 University Merit Assistantship, University of North Carolina at Chapel Hill
2005-2006 Delta Omega, University of North Carolina at Chapel Hill
2006 Moulton-Wong Scholarship in Health Policy, University of North Carolina at Chapel Hill
2006 Doctoral Competitive Merit Scholarship, University of North Carolina at Chapel Hill
2009 Winner, Best Graduate Student Poster in the Social Sciences and Humanities: An investment in health: Anticipating the cost of a usual source of care for children. Presented at the 2009 University of North Carolina at Chapel Hill Annual University Research Day.
2010 Winner, Health Care Management Division Best Paper Based on a Dissertation: Where the rubber meets the road: Middle managers' role in innovation implementation in health care organizations. Presented at the 2010 Academy of Management Annual Meeting. Montreal.
2011 Fellow, Training in Dissemination and Implementation Research in Health. National Cancer Institute. Chapel Hill, NC.
2014-2015 Outstanding Reviewer, Healthcare Management Division. Annual Meeting of the Academy of Management.
2014-2016 Fellow, Mentored Training for Dissemination and Implementation in Research in Cancer. National Cancer Institute. St. Louis, MO.
2015 Alumna Member, Delta Omega Theta Chapter. The Gillings School of Global Public Health, University of North Carolina at Chapel Hill.
2016 Emerging Scholar, Academy of Management Health Care Management Division's Emerging Scholars Consortium. Anaheim, CA.

C. Contributions to Science

1. **Implementation of interventions in cancer survivorship**. Survivorship care plans (SCPs) are written documents containing information regarding cancer diagnosis, treatment, surveillance plans, short- and long-term health effects, and health promotion. SCPs are widely recommended and, in some cases, required. My research has documented that, despite widespread recommendations and requirements and some evidence that SCPs are effective, SCP dissemination and implementation has been low, slow and sporadic [e.g., a]. Later work demonstrated that empirical evidence of SCP implementation is limited [b], prompting several studies to identify determinants of SCP implementation [e.g., c, d]. In one, I used behavior change theory to identify potential determinants of SCP implementation [c]; in another, I found that the quality of guidelines for SCP use is poor, possibly contributing to limited dissemination and implementation [d].
   a. **Birken, S. A.**, Mayer, D., Weiner, B. J. (2013). Survivorship care plan use: Prevalence and barriers. The Journal of Cancer Education, 28(2): 290-6. PMCID: PMC3665729.
   b. Mayer, D. K., **Birken, S. A.**, Check, D., Chen, R.C. (2014). Summing it up: An integrative review of survivorship care plans (2006-2013). Cancer. [Epub ahead of print]. PMCID: PMC4948720.
   c. **Birken, S. A.**, Presseau, J. P., Ellis, S., Gerstel, A., Mayer, D. M. (2014). Potential determinants of survivorship care plan use in US cancer programs: A qualitative study using the theoretical domains framework. Implementation Science. [Epub ahead of print]. PMCID: PMC4236456.
   d. **Birken, S. A.**, Ellis, S.D., Walker, J.S., DiMartino, L.D., Check, D.K., Gerstel, A.A., Mayer, D.K. (2015). Guidelines for the use of survivorship care plans: A systematic quality appraisal using the AGREE II instrument. Implementation Science, 10(1): 63. doi: 10.1186/s13012-015-0254-9. PMCID: PMC4425878.

2. **Multilevel determinants of evidence-based intervention (EBI) implementation in health care organizations**. I have advocated for the use of organizational theory for implementation science [a, b]. I have demonstrated that implementation researchers exhibit demand for frameworks that capture multilevel

determinants of implementation [c]. To address this unmet need, I have received funding to develop a framework comprised of organizational theories to promote their use among implementation scientists.

a. **Birken, S. A.**, Bunger, A. C., Powell, B. J., Turner, K., Clary, A., Klaman, S., Yu, Y., Whitaker, D. J., Self, S. B., Rostad, W., Chatham, J. R. S., Kirk, M. A., Shea, C. M., Haines, E. R., Weiner, B. J. (2017). Organizational theory for dissemination and implementation research. Implementation Science. 12(1):62. PMCID: PMC5427584.
b. **Birken S. A.**, Nilsen, P. (2018). Implementation science as an organizational process. *Health Care Management Review*. 43(3):181. PMCID: PMC29847510
c. **Birken, S. A.**, Powell, B. J., Presseau, J., Kirk, M.A., Lorencatto, F., Gould, N., Shea, C. M., Weiner, B. J., Francis, J. J., Yu, Y., Haines, E.R., Damschroder, L. (2016). Combined use of the Consolidated Framework for Implementation Research and the Theoretical Domains Framework: A systematic review. Implementation Science, 12:2. BioMed Central 'Highly Accessed' article. PMCID: PMC5217749.

3. **Middle managers' role in implementing evidence-based interventions (EBIs) in health care organizations**. My first empirical study on the topic demonstrated that middle managers' commitment influences the effectiveness with which EBIs are implemented in health care organizations [a]. The second empirical study found that top managers can leverage middle managers' commitment by supporting EBI implementation [b]. My 2012 article in *Implementation Science* proposed a theory of middle managers' role in implementing healthcare EBIs has been the most influential in promoting investigation on the topic, with 16,000+ views [c]. My research on middle managers has been widely disseminated to influence health care practice [e.g., d].
   a. **Birken, S. A.**, Lee, S-Y. D., Weiner, B. J., Chin, M. H., Schaefer, C. (2013). Improving the effectiveness of health care innovation implementation: middle managers as change agents. Medical Care Research and Review, 70:1. PMCID: PMC3727966.
   b. **Birken, S. A.**, Lee, S-Y. D., Weiner, B. J., Chin, M. H., Chiu, M., Schaefer, C. (2014). From strategy to action: How top managers' support increases middle managers' commitment to innovation implementation in healthcare organizations. Health Care Management Review, 40(2): 159-68. PMCID: PMC4141032.
   c. **Birken, S. A.**, Lee, S-Y. D., Weiner, B. J. (2012). Uncovering middle managers' role in innovation implementation in health care organizations. Implementation Science, 7:28. BioMed Central 'Highly Accessed' article. PMCID: PMC3372435.
   d. Mate, K. (2015) The managers and management we need to improve care. Audio program from the Institute for Healthcare Improvement. Available at http://www.ihi.org/resources/Pages/AudioandVideo/WIHIMiddleManagers.aspx.

4. **The selection and application of implementation science theories**. I have developed a tool to promote the selection of theories for implementation science. Based on my observation of substantial overlap between two implementation theories, my colleagues and I conducted a systematic review of studies that used both of the implementation theories to help explore their unique contributions and conceptual overlaps [a]. In a survey of 223 implementation scientists from 12 countries, my colleagues and I found that implementation scientists use a large number of criteria to select theories, but there is little consensus on which are most important [b]. Leveraging these findings, we developed a tool to promote researchers' and practitioners' selection of appropriate implementation science theories [c].
   a. **Birken, S. A.**, Powell, B. J., Presseau, J., Kirk, M.A., Lorencatto, F., Gould, N., Shea, C. M., Weiner, B. J., Francis, J. J., Yu, Y., Haines, E.R., Damschroder, L. (2016). Combined use of the Consolidated Framework for Implementation Research and the Theoretical Domains Framework: A systematic review. Implementation Science, 12:2. BioMed Central 'Highly Accessed' article. PMCID: PMC5217749.
   b. **Birken, S. A.**, Powell, B. J., Shea, C. M., Haines, E. R., Kirk, M. A., Leeman, J., Rohweder, C. L., Damschroder, L., Presseau, J. (2017). Criteria for selecting implementation science theories and frameworks: Results from an international survey. Implementation Science. 12(1):124. PMCID: PMC5663064.
   c. **Birken, S. A.**, Rohweder, C. L., Powell, B. J., Shea, C. M., Scott, J., Leeman, J., Grewe, M. E., Kirk, M. A., Damschroder, L., Aldridge, W. A., Haines, E. R., Straus, S., Presseau, J. (2018). T-CaST: an implementation theory comparison and selection tool. Implementation Science. 13(1):143. PMCID: PMC6251099.

Complete List of Published Work in MyBibliography:
http://www.ncbi.nlm.nih.gov/pubmed/?term=birken%2C+sarah

D. Research Support

Selected Ongoing Research Support

R01 CA240092 Wheeler & Rosenstein (PIs) 08/15/19-07/31/23
Addressing Cancer-Related Financial Toxicity in Rural Oncology Care Settings
The objectives of this project are: (1) to understand the practice-level determinants of FT-focused intervention implementation in rural oncology practices; (2) to explore the extent to which practice-level technical support and tailored coaching can optimize financial navigation (FN) intervention implementation in rural oncology practices; and (3) to evaluate the effects of FN implementation on patient- and practice-level outcomes in rural oncology practices.
Role: Co-Investigator

R18 HS027078 Jonas (PI) 09/30/19-09/29/22
Agency for Healthcare Research and Quality
STUN Alcohol Use Now is designed to rapidly spread primary care practice support structures that help small to medium-size primary care practices identify and provide appropriate services for people with unhealthy alcohol use. We use an adaptive randomized, controlled trial to evaluate the effect of primary care practice facilitation embedded telehealth services on evidence-based screening, counseling, and medication-assisted therapy in 135 primary care practices with 10 or fewer providers.

1 U48 DP006400-01 Wheeler (PI) 09/30/20-09/29/21
Comprehensive Cancer Control Collaborative of North Carolina (4CNC)
This workgroup is creating a framework comprised of constructs from organizational theories that may be relevant to predicting intervention implementation.
Role: Co-Investigator; Organizational Theory for Implementation Science workgroup lead

Selected Completed Research Support

WITHHELD PRIVATE SUPPORT Birken (PI) 08/01/17-07/01/20
The objective of this study is to develop PRIVATE SUPPORT, a change package intended to promote [redacted] implementation by offering cancer programs a comprehensive set of pragmatic tools for designing PRIVATE SUPPORT delivery systems.
Role: Principal Investigator

5UG1CA189823 Birken (PI) 07/30/18-07/01/19
Identifying strategies for comprehensive survivorship care plan implementation
The purpose of this study is to identify the features of cancer programs that have implemented survivorship care plans in a way that is likely to improve survivorship care delivery.
Role: Principal Investigator

UL1TR002489 Birken (PI) 09/01/16-10/01/17
Developing a Tool to Promote the Selection of Appropriate Implementation Frameworks and Theories
The goal of this study is to develop a user-friendly, disease-agnostic tool to guide model selection by engaging a community of implementation researchers and practitioners in the tool's testing and refinement.
Role: Principal Investigator

OMB No. 0925-0001 and 0925-0002 (Rev. 03/2020 Approved Through 02/28/2023)

BIOGRAPHICAL SKETCH

NAME: **Ciemins, Elizabeth L.**

eRA COMMONS USER NAME (credential, e.g., agency login): eRA COMMONS USER NAME

POSITION TITLE: **Vice President, Research and Analytics**

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE	Completion Date	FIELD OF STUDY
Wittenberg University	BA	06/1988	Psychology
University of California, Los Angeles	MA	12/1993	African Area Studies
University of California, Los Angeles	MPH	06/1994	Population & Family Health
University of California, Berkeley	PhD	05/2003	Health Services & Policy Analysis

A. Personal Statement

As part of the proposed P01 Program Project on for HPV vaccine communication, I will serve as the Research Director for AMGA's subcontract and oversee the recruitment and retention of healthcare systems for formative work, a randomized controlled trial on standing orders support, primary care professional surveys, and key informant interviews. I am well suited for this role because of my training in health services research and my current role as Vice President, Research and Analytics, with AMGA. This trade organization supports member health care systems through advocacy, education, and analytics, and includes a foundation that supports healthcare organizations in their efforts to enhance population health through learning collaboratives that translate into innovative practices. My team uses a clinical data repository to which ~25 member organizations contribute EHR data. Through comparative analytics and provocative visualization, the Research and Analytics team helps health care organizations move from volume- to value-based payment models with a population health focus.

I bring extensive experience to this project punctuated by my qualitative research, dissemination, and implementation expertise. I led a 3-year contract with the Agency for Healthcare Research and Quality to study the effect of health IT on workflow in the context of primary care redesign using a mixed methods approach. For this project in particular, I bring extensive experience in the area of vaccination. I have supported four learning collaboratives on immunizations, including one on HPV vaccine. I have publications on adult immunizations (see below), and I am currently and Advisor on AMGA's National Immunizations Campaign, a 5-year endeavor (2020–2025).

I am an experienced health services researcher, which is reflected in publications listed below. My research has been conducted in health system-embedded health services research centers, which are designed to test models of care to be translated into clinical practice. This explains the diversity of study during my post graduate career. As a seasoned health services researcher and co-investigator on this project, I will oversee and contribute to the qualitative and quantitative work planned for this study, ensuring that rigorous research methods are employed and followed throughout the project.

B. Positions and Honors

Positions and Employment

1988-1990 Health Education Specialist/Nutritionist, US Peace Corps, Niger, West Africa
1993-1994 Graduate Research Assistant, UCLA School of Public Health, Los Angeles, CA
Research Consultant, Pacific Institute for Women's Health, Los Angeles, CA
1994 Research Analyst, Division STD/HIV Prevention, CDC&P, Atlanta, GA
1994 Trainer Consultant, Mississippi Consortium Int'l Development, Niger, West Africa
1995-1997 Project Director, STD Program, LA County DHS, Los Angeles, CA

1997-1998 Epidemiologist, STD Prevention and Control Program, San Francisco City and County Health Department, San Francisco, CA
1999-2001 Epidemiologist, STD Control Branch, CA Department of Health Services, Berkeley, CA
2000 Graduate Student Instructor, UC Berkeley, School of Public Health, Berkeley, CA
2001 Graduate Research Assistant, UC Berkeley, School of Public Health, Berkeley, CA
2001-2003 Research Assistant, Center for Mental Health Services Research, Berkeley, CA
2002 Graduate Student Reader, UC Berkeley, School of Public Health, Berkeley, CA
2003 Graduate Student Instructor, UC Berkeley, School of Public Health, Berkeley, CA
2003-2005 Senior Research Analyst, United Behavioral Health, San Francisco, CA
2005-2008 Senior Health Services Researcher, Sutter Health Institute for Research & Education, San Francisco, CA
2007-2015 Research Director, Center for Translational Research, Billings Clinic, Billings, MT
2016-2017 Interim Research Director, Center for Clinical Translational Research, Billings Clinic, Billings, MT
2014-2015 Assistant Program Director for Scholarship, Internal Medicine Residency, Billings Clinic, Billings, MT
2008-- Faculty Affiliate, School of Public and Community Health Sciences, University of Montana, Missoula, MT
2008-- Part-time Faculty, Health Administration Program, Montana State University Billings, Billings, MT
2013-- Center Investigator, NINR Center of Excellence, Adaptive Leadership for Cognitive/Affective Symptom Science (ADAPT Center), Duke University School of Nursing, Durham, NC
2015 -2017 Director, Research & Analytics, AMGA, Alexandria, VA
2018 -2020 Senior Director, Research & Analytics, AMGA, Alexandria, VA
2020– Vice President, Research & Analytics, AMGA, Alexandria, VA

Selected Honors

1988 Wittenberg University College Honor Society; Alpha Lambda Delta Honor Society; Wittenberg University Alumni Scholar
1993 Title VI Language Award, UCLA, Los Angeles, CA
1998-2000 National Institutes of Mental Health Doctoral Traineeship, UC Berkeley, School of Public Health, Berkeley, CA
2001-2002 Wellness Fund Scholarship, UC Berkeley, School of Public Health, Berkeley, CA
2001-2003 NIAAA Pre-Doctoral Fellowship, Alcohol Research Group, Berkeley, CA
2002 Society for Professionals in Healthcare Scholarship Competition Essay Winner
2006 Bay Area Clinical Research Symposium, Finalist, Best Poster Presentation
2012 Montana Outstanding Chick in Science Award, MT State University Billings
2012 American Telemedicine Association Annual Conference, Recipient Best Poster Award

B. Contributions to Science

1. **Behavioral health.** My research has examined the impact of mental health parity law on utilization patterns for families with children and adolescents. My focus was on the economic impact of health policies and health care decision making. This was an important contribution to better understanding the behavioral economics of health care utilization decision making when making decisions for children, which differ from making decisions for one's own health.

   a. **Ciemins EL.** The effect of parity-induced copayment reductions on adolescent utilization of substance use services. *J Stud Alcohol.* 2004;65(6):731-735. PMID: 15700510.

   b. Azocar F, **Ciemins E,** Kelleher D. Behavioral health outreach: integrating medical and behavioral health care. *Psychiatr Serv.* 2006;57(12):1807-1808. PMID: 17158500.

2. **Palliative care.** Another important contribution my research has made is in the area of palliative care. The quantitative work on palliative care helped demonstrate the value of palliative care, including the associated cost savings, important in maintaining the availability of these crucial services. My qualitative

research subsequently focused on both the patient and provider perspectives and demonstrated palliative care as a prime example of a complex adaptive system.

a. **Ciemins EL,** Stuart B, Gerber R, Newman J, Bauman M. An Evaluation of the Advanced Illness Management (AIM) Program: Increasing hospice utilization in the San Francisco Bay area. *J Palliat Med.* 2006;9(6):1401-1411. PMID: 17187548.

b. **Ciemins EL,** Blum L, Nunley M, Lasher A, Newman JM. The economic and clinical impact of an inpatient palliative care consultation service: a multifaceted approach. *J Palliat Med.* 2007;10(6):1347-1355. PMID: 18095814.

c. **Ciemins EL**, Brant J, Kersten D, Mullette E, Dickerson D. A qualitative analysis of patient and family perspectives of palliative care. *J Palliat Med.* 2015;18(3):282-285. PMID: 25299983.

d. **Ciemins EL,** Brant J, Kersten D, Mullette E, Dickerson D. Why the Interdisciplinary Team Approach Works: Insights from Complexity Science. *J Palliat Med.* 2016;19(7):767-770. PMID: 27104490.

3. **Access to services.** I have addressed the issue of access to important health care services to individuals living in rural U.S. communities. I have tested and studied innovative models of delivering care for chronic conditions including the use of advanced practice providers and the translation of evidence-based practices from urban to rural settings through the use of telehealth technology. This diabetes-focused work well prepared me for the current proposed topic area of screening and treatment for prediabetes.

a. **Ciemins EL**, Coon PJ, Coombs NC, Holloway BL, Mullette EJ, Dudley WN. Intent-to-treat analysis of a simultaneous multisite telehealth diabetes prevention program. *BMJ Open Diabetes Res Care.* 2018;6:1-10. PMCID: PMC5922481.

b. **Ciemins EL**, Holloway B, Coon PJ, McCloskey-Armstrong T, Min SJ. Telemedicine and the mini-mental state examination: assessment from a distance. *Telemed J E Health,* 2009;15(4): 325-327. PMCID: PMC2956527.

c. **Ciemins EL**, Coon PJ, Fowles JB, Min SJ. Beyond health information technology: critical factors necessary for effective diabetes disease management. *J Diabetes Sci Technol* 2009;3(3): 452-460. PMCID: PMC2769861.

d. **Ciemins EL**, Coon PJ, Holloway B, Peck R, Min SJ. Using telehealth to provide diabetes care to patients in rural Montana: Findings from the PRISM Program. *Telemed J E Health* 2011;17(8): 596-602. PMCID: PMC3208251.

4. **IT and health care.** The integration and impact of health information technology (IT) on health care has been an important area of my research. An AHRQ-funded study to improve communication between rural and urban providers resulted in a video produced by John Snow, Inc. on behalf of AHRQ in their "AHRQ Success Story" series. Another important project I led sought to examine the impact of health IT on workflow in the context of primary care practice redesign. This work resulted in an AHRQ report, referenced below. Complexity science-informed approaches have proved to be significantly effective in supporting important change in health care, a real contribution to the literature that has lagged in providing successful evidence-based approaches to behavior change.

a. **Ciemins EL**, Mohl V, Ferrin C, Oley W. Advancing provider communication to improve transitions in patient care. AHRQ Health IT Success Stories. Video. 2014. https://healthit.ahrq.gov/ahrq-funded-projects/ambulatory-safety-and-quality-program/improving-provider-communication-improve-transitions-patient-care

b. Zheng K, **Ciemins E**, Lanham H, Lindberg C. Examining the Relationship Between Health IT and Ambulatory Care Workflow Redesign. (Prepared by Billings Clinic under Contract No. 290- 2010-0019I1). AHRQ Publication No. 15-0058-EF. Rockville, MD: Agency for Healthcare Research and Quality. July 2015. https://healthit.ahrq.gov/sites/default/files/docs/citation/examining-the-relationship-between-health-it-and-ambulatory-care-workflow-redesign-final-report.pdf

c. **Ciemins EL,** Coon PJ, Sorli C. An analysis of tools for diabetes self-management: Can smart phone technology keep up? *J Diabetes Sci Technol* 2010; 4(4): 958-960. PMID: 20663462

d. Lindberg C, Hatch M, Mohl V, Arce C, **Ciemins EL.** Embracing Uncertainty: Complexity Inspired Innovations at Billings Clinic. In Sturmberg & Martin (Eds.), Handbook of Systems and Complexity in Health. New York: Springer; 2012.

5. **Population health.** A focus of my research and analytics work at AMGA has been population health. Research in the area of preventive health care and chronic disease management has been a main focus of the work AMGA Analytics does to help our members achieve the quadruple aim. Below are a few publications demonstrating our work in this area.

   a. **Ciemins EL**, Joshi V, Cuddeback J, Kushner R, Horn D, Garvey T. Diagnosing obesity as a first step to weight loss: An observational study. *Obesity.* 2020. *(in press)*

   b. **Ciemins EL,** Jerry M, Powelson J, Leaver-Schmidt E, Joshi V, Chambers E, Casanova D, Kennedy JW, Penso J. An adult immunization best practices learning collaborative: Impact, scale up, and spread. *Population Health Management;* 2020. doi: 10.1089/pop.2019.0169 PMID: 31930932

   c. **Ciemins EL**, Mollis B, Brant JM, Hassell LA, Albritton S, Amoroso P, Lloyd A, Smith JM, Pflugeisen BM, Tuttle KR, Baldwin LM. Clinician engagement in research as a path toward the learning health system: A regional survey across the Northwestern United States. *Health Services Management Research*; 2020; 33(1): 33–42. doi: 10.1177/0951484819858830 PMID: 31422696

   d. **Ciemins EL,** Ritchey MD, Joshi VV, Loustalot F, Hannan J, Cuddeback J. Application of a tool to identify undiagnosed hypertension – United States, 2016. *Morbidity and Mortality Weekly Report;* 2018; 67 (29): 798-802. PMCID: PMC6065206

Complete List of Published Work
http://www.ncbi.nlm.nih.gov/sites/myncbi/1PydBzx5C0Qe/bibliograpahy/46160619/public/?sort=date&direction=ascending

D. Additional Information: Research Support and/or Scholastic Performance

Ongoing Research Support

CDC: Abt Associates, Inc. Subcontract No.50829 Shoemaker-Hunt (PI) 09/30/19 – 9/22/22
Understanding Chronic Pain Management including Opioid Prescribing in the Context of Clinical Practice Guidelines and Policies
Rigorous evaluation to understand how current clinical practice guidelines and national, state, local, or health system policies related to chronic pain management, opioid prescribing, and medication-assisted treatment (MAT) for opioid use disorder.
Role: Co-Investigator

CDC, American Cancer Society Nkonga (PI) 08/01/2019 – 7/31/22
The Impact of a National Best Practices Learning Collaborative on Adolescent HPV Vaccination Rates
AMGA and the National HPV Vaccination Roundtable are implementing a 24-month learning collaborative to improve HPV vaccination rates among 8 multispecialty medical groups and integrated delivery systems. Participating organizations are implementing interventions and strategies to improve rates and data on four performance measures stratified by sex. AMGA Analytics is leading the data specification, collection, and analysis.
Role: Co-PI

PRIVATE SUPPORT Larochelle (PI) 04/01/19 – 03/31/20 (no cost extension through 2020)
Impact of health insurance type and transitions on treatment for opioid use disorder
This project aims to use two large databases to understand the impact of insurance type and transitions on medication for opioid use disorder (MOUD) initiation, engagement, and retention. The intent is to support health insurance benefit design and policy initiative that lead to improved access to and treatment with lifesaving MOUD.
Role: Co-investigator

PRIVATE SUPPORT Ciemins (PI) 11/15/17 – 12/31/20

Cardiovascular Disease in Patients with Type 2 Diabetes: A Qualitative Analysis of Health Care Professionals

This project seeks to understand providers' knowledge, attitudes, and beliefs related to the 2019 ADA Standards of Care for type 2 diabetes. Physicians at 4 US health systems were surveyed and interviewed. The Consolidated Framework for Implementation Research (CFIR) framed questions regarding the treatment of patients with type 2 diabetes and cardiovascular disease (or at risk for developing cardiovascular disease) using the following domains: intervention characteristics, outer setting, inner health system setting, individual (clinician) characteristics, and processes. Interviewees were also asked to reflect on the survey findings.
Role: PI

PRIVATE SUPPORT Kent (PI) 05/01/17 – 04/30/19 – EXTENSION through 2020

Improving Diabetes Prevention with Benefit-Based Tailored Treatment: Disseminating Patient-Centered Estimates of Benefit

This project will disseminate a clinically actionable understanding of the variation in patient-centered estimates of benefits of diabetes prevention interventions based on a prediction model derived directly from the Diabetes Prevention Program (DPP) trial. Phase 1 will incorporate the DPP benefit prediction model into an electronic health record (EHR)-based tool easily accessible at the point of care, adapting it as necessary using stakeholder input. Phase 2 will disseminate the EHR-based tool to approximately 50 clinic sites within two health care provider organizations and evaluate its use and effects.
Role: Site Investigator

AHRQ: HHSP233201500015I Ciemins (PI) 11/01/15 – 10/31/20

Acceleration Change and Transformation in Organizations and Networks (ACTION) III.

The goal of ACTION III is to promote and accelerate the development, implementation, dissemination and sustainability of evidence-based innovation in health care delivery to measurably improve the effectiveness, safety, quality and efficiency of health care in the U.S.
Role: PI (Transferred PI to Brant after moving to AMGA)

OMB No. 0925-0001 and 0925-0002 (Rev. 03/2020 Approved Through 02/28/2023)

BIOGRAPHICAL SKETCH

NAME: **Cox, Elizabeth D.**

eRA COMMONS USER NAME (credential, e.g., agency login): eRA COMMONS USER NAME

POSITION TITLE: **Professor**

EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE	COMPLETION DATE	FIELD OF STUDY
West Virginia University, Morgantown, WV	BS	05/1987	Chemistry, Cum Laude
West Virginia University, Morgantown, WV	MD	05/1991	
University of Wisconsin, Madison, WI	MS	05/2001	Population Health Sciences
University of Wisconsin, Madison, WI	PHD	12/2006	Health Services Research
University of Wisconsin Children's Hospital, Madison, WI	Resident	06/1994	Department of Pediatrics, Internship & Residency
University of Wisconsin, Madison, WI	Fellow	06/2002	National Research Service Award Fellowship, Primary Care Research

A. Personal Statement

The overarching goal of this research is to reduce cancer burden by increasing human papillomavirus (HPV) vaccination. The proposed work will develop and evaluate new ways to scale up delivery of an evidence-based intervention to increase HPV vaccination rates in healthcare systems, by focusing on increasing the frequency and effectiveness of provider recommendations for the vaccine. My background as a practicing pediatrician and health services researcher as well as my expertise in developing, implementing, and evaluating interventions that support delivery of high quality pediatric care make me uniquely suited to serve as co-investigator. Highly relevant to this application, I have expertise with various study designs (e.g., observational, quasi-experimental, and randomized trials) and primary data collection techniques (e.g., interviews, surveys, billing data, and electronic health record abstraction) as well as clinical and comparative effectiveness research. As PI on multiple clinical trials and observational studies, I have engaged diverse stakeholders to seamlessly integrate rigorous research into real world healthcare. For example, I was PI of an AHRQ-funded 5-year R18 that successfully implemented the Family-Centered Rounds Checklist to provide safer and more engaging family-centered care for hospitalized children. More recently, as PI on a randomized trial funded by the Patient-Centered Outcomes Research Institute (PCORI), I led a multi-site team in implementing and evaluating novel methods for aligning clinic-based diabetes self-management resources to the unique needs of each child and family. I have also served three years as an advisor to the PCORI Improving Healthcare Systems Panel, focusing on novel ways to integrate efficacious interventions into clinical practice. My accomplishments reflect the expertise, leadership, and motivation necessary to successfully contribute to the proposed project. The investigative team includes complementary expertise in dissemination and implementation science, biostatistics, and HPV vaccination behavior required for success. We are well prepared to conduct this work and to advance uptake of HPV vaccination nationally.

1. **Cox ED**, Jacobsohn GC, Rajamanickam VP, Carayon P, Kelly MM, Wetterneck TB, Rathouz PJ, Brown RL. A family-centered rounds checklist, family engagement, and patient safety: a randomized trial. Pediatrics. 2017 May;139(5). pii: e20161688. PMID: 28557720; PMCID: PMC5404725.
2. Fiallo-Scharer R, Palta M, Chewning BA, Rajamanickam V, Wysocki T, Wetterneck TB, **Cox ED**. Impact of family-centered tailoring of pediatric diabetes self-management resources. 2019 Nov;20(7):1016-1024. PMID: 31355957; PMCID: PMC6827338.
3. Fiallo-Scharer R, Palta M, Chewning BA, Wysocki T, Wetterneck TB, **Cox ED**. Design and baseline data from a PCORI-funded randomized controlled trial of family-centered tailoring of diabetes self-management resources. Contemp Clin Trials. 2017 Apr;58:58-65. PMID: 2845019; PMCID: PMC5535788.
4. Benjamin JM, **Cox ED**, Trapskin PJ, Rajamanickam VP, Jorgenson RC, Weber HL, Pearson RE, Carayon P, Lubcke NL. Family-initiated dialogue about medications during family-centered rounds. Pediatrics. 2015 Jan;135(1):94-101. PMID: 25511116; PMCID: PMC4279061.

B. Positions and Honors

Positions and Employment

1994 - 2005 General Pediatrician, Locum Tenens/Private Practice

2002 - 2007	Assistant/Associate Scientist, University of Wisconsin, School of Medicine and Public Health, Center for Women's Health Research, Madison, WI
2007 - 2013	Assistant Professor, University of Wisconsin, School of Medicine and Public Health, Department of Pediatrics, Madison, WI
2007 - 2013	Assistant Professor (Program Faculty), University of Wisconsin, School of Medicine and Public Health, Department of Population Health Sciences, Madison, WI
2013 - 2017	Associate Professor with Tenure, University of Wisconsin, School of Medicine and Public Health, Department of Pediatrics, Madison, WI
2013 - 2017	Associate Professor with Tenure (Program Faculty), University of Wisconsin, School of Medicine and Public Health, Department of Population Health Science, Madison, WI
2017 -	Professor (Tenured), University of Wisconsin, School of Medicine and Public Health, Department of Pediatrics, Madison, WI
2017 -	Professor, University of Wisconsin, School of Medicine and Public Health, Department of Population Health Science, Madison, WI

Other Experience and Professional Memberships

2000 - 2006	Member, Academy Health
2008 -	Member, Academic Pediatric Association

Honors

2013	Pediatric Endocrine Society Presidential Research Award Mentor (Dr. Katie Fritz, mentee)
2013 - 2016	Improving Healthcare Systems Advisory Panel, Patient Centered Outcomes Research Institute
2014 - 2016	Physician Leadership Development Program, UW Medical Foundation

C. Contributions to Science

1. **Developing, implementing, evaluating, and disseminating interventions to address specific barriers to optimal health or healthcare, especially for vulnerable populations such as children, minorities, and those from lower socioeconomic groups.** One of the greatest highlights of my research career has been sharing the evidence that my research positively impacts the care of vulnerable populations. Specifically, in my AHRQ-funded project to engage families in rounds in the children's hospital, we demonstrated that our Family-Centered Rounds Checklist significantly improved the number of best practices performed during rounds on services receiving the intervention compared to children receiving usual care (a). To aid dissemination of this checklist, we developed the Family-Centered Rounds Toolkit (b), which has been featured in a Society for Hospital Medicine webinar and posted on PatientFamilyEngagement.org, and the AHRQ Innovations Exchange. Over 760 individuals have downloaded the toolkit. Our work was further able to demonstrate how engaging families during rounds improves pediatric medication safety (a, c). Also, in my early career, I received HRSA funding to develop and evaluate a curriculum that taught medical students how to identify and address the needs of vulnerable families in clinical settings (d).
   a. **Cox ED**, Jacobsohn GC, Rajamanickam VP, Carayon P, Kelly MM, Wetterneck TB, Rathouz PJ, Brown RL. A family-centered rounds checklist, family engagement, and patient safety: a randomized trial. Pediatrics. 2017 May;139(5):pii: e20161688. PMCID: PMC5404725
   b. **Cox ED**, Carayon P, Kelly MM, DuBenske LL, Wetterneck TB, Brown RL. The Family-Centered Rounds Toolkit. Madison. 2014. Available from: http://www.hipxchange.org/FamilyRounds.
   c. Benjamin JM, **Cox ED**, Trapskin PJ, Rajamanickam VP, Jorgenson RC, Weber HL, Pearson RE, Carayon P, Lubcke NL. Family-initiated dialogue about medications during family-centered rounds. Pediatrics. 2015 Jan;135(1):94-101. PMCID: PMC4279061.
   d. **Cox ED**, Koscik RL, Olson CA, Behrmann AT, McIntosh GC, Kokotailo PK. Clinical skills and self-efficacy after a curriculum on care for the underserved. Am J Prev Med. 2008 May;34(5):442-8. PMID: 18407013. PMCID Policy Exempt – Accepted Prior to April 7, 2008.

2. **Engaging patients, their families, and other stakeholders as partners to optimize the development and implementation of interventions to promote effective healthcare.** In a recent comparative effectiveness trial, we engaged children with type 1 diabetes as well as their parents, their providers, and advocacy representatives to guide the research. This approach ensured that the clinical trial fits seamlessly in the clinical setting and that the intervention meets the needs of real-world parents, children, and providers, which will ultimately enhance sustainability and dissemination (a, b, c). Results highlight the importance of stakeholder engagement to the successful recruitment and retention of study families over two years as well

as data completeness (a). Ultimately, we were able to demonstrate how tailoring of interventions to families' specific needs improved diabetes control, especially for youth with A1c values over 8.5% (a). In an AHRQ-funded study, I led a multidisciplinary team of physicians, systems engineers, and health services researchers in developing an intervention to enhance family engagement in children's hospital rounds. To develop the intervention, I proposed and carried out the stimulated recall interview process through which families and healthcare team members reviewed videos of their rounds to identify strategies that engage families during these rounds (d). Through a prioritization process with our stakeholders, 21 strategies were distilled into the 8-item Family-Centered Rounds Checklist. This checklist was then implemented across multiple units in our children's hospital with the ongoing support of parent and clinical stakeholders.

a. Fiallo-Scharer R, Palta M, Chewning BA, Rajamanickam V, Wysocki T, Wetterneck TB, **Cox ED**. Impact of family-centered tailoring of pediatric diabetes self-management resources. Pediatr Diabetes. 2019 Nov;20(7):1016-1024. PMCID: PMC6827338.
b. Fiallo-Scharer R, Palta M, Chewning BA, Wysocki T, Wetterneck TB, **Cox ED**. Design and baseline data from a PCORI-funded randomized controlled trial of family-centered tailoring of diabetes self-management resources. Contemp Clin Trials. 2017 Apr;58:58-65. PMCID: PMC5535788
c. **Cox ED**, Chewning BA, Fiallo-Scharer R, Palta M, Wetterneck TB, Wysocki T. Type 1 Diabetes Self-Management Resource Toolkit (T1D-SMART). Madison. 2017. Available from: http://www.hipxchange.org/T1DSMART.
d. Kelly MM, Xie A, Carayon P, DuBenske LL, Ehlenbach ML, **Cox ED**. Strategies for improving family engagement during family-centered rounds. J Hosp Med. 2013 Apr;8(4):201-207. PMCID: PMC3955089.

3. **Demonstrating how barriers to chronic illness self-management and patients' challenges in communicating with health care providers are related to socioeconomic factors such as rurality, income, race, and education.** This series of papers and numerous others have advanced our understanding of how these factors influence healthcare and communication with healthcare providers. The first of these papers demonstrated how satisfaction with care for children's chronic illnesses was associated with the communication style of the physician and by ongoing physician-family relationships (a). A second paper disentangled the influence of race and socioeconomic status on communication in a large sample of pediatric primary care visits, noting that even when adjusted for income and education, persistent racial disparities in communication existed during these visits (b). In the two papers focused on adherence to asthma medications among adults (c, d), we demonstrated how the active patient role is related to asthma outcomes among clients of a rural, federally qualified health center pharmacy and examined specific barriers to self-management in these populations. These papers emphasize the need for strategies that enhance communication as a mechanism to help vulnerable populations overcome barriers to healthy behaviors.
   a. Swedlund MP, Schumacher JB, Young HN, **Cox ED**. Effect of communication style and physician-family relationships on satisfaction with pediatric chronic disease care. Health Commun. 2012;27(5):498-505. PMCID: PMC3413374.
   b. **Cox ED**, Nackers KA, Young HN, Moreno MA, Levy JF, Mangione-Smith RM. Influence of race and socioeconomic status on engagement in pediatric primary care. Patient Educ Couns. 2012 Jun;87(3):319-326. PMCID: PMC3359403.
   c. Young HN, Larson TL, **Cox ED**, Moreno MA, Thorpe JM, MacKinnon NJ. The active patient role and asthma outcomes in an underserved rural community. J Rural Health. 2014 Spring;30(2):121-127. PMCID: PMC4327938.
   d. Young HN, Kanchanasuwan S, **Cox ED**, Moreno MM, Havican NS. Barriers to medication use in rural underserved patients with asthma. Res Social Adm Pharm. 2015 Nov-Dec;11(6):909-914. PMCID: PMC4478282.

4. **Development and validation of new measures of patient experiences in treating illness or receiving care, especially for vulnerable populations such as youth, minorities, and those with chronic illness.** To understand how patients experience chronic illness treatment or receiving healthcare, I have developed innovative methods for patient/parent report (a, b, and c). Specifically, I developed and validated a survey of the barriers to managing type 1 diabetes as experienced by children and adolescents with diabetes and their parents (a). This tool, Problem Recognition in Illness Self-Management (PRISM) functions as the core of an intervention that tailors diabetes self-management resources to specifically address each family's needs and is being evaluated in a multisite trial with 214 youth 8-16 years of age. I also developed and validated a tool to assess parent perceptions of the safety climate in children's hospitals (b), which was used as an outcome

measure in our trial to assess the impact of family participation in hospital rounds. Lastly, I collaborated with others to develop measures of Spanish-speaking patients' experience of pharmacy care for asthma (c).

a. **Cox ED**, Fritz KA, Hansen KW, Brown RL, Rajamanickam V, Wiles KE, Fate BH, Young HN, Moreno MA. Development and validation of PRISM: a survey tool to identify diabetes self-management barriers. Diabetes Res Clin Pract. 2014 Apr;104(1):126-135. PMCID: PMC3992923.
b. **Cox ED**, Carayon P, Hansen KW, Rajamanickam VP, Brown RL, Rathouz PJ, DuBenske LL, Kelly MM, Buel LA. Parent perceptions of children's hospital safety climate. BMJ Qual Saf. 2013 Aug;22(8):664-671. PMCID: PMC3724532.
c. Young HN, Hwang MJ, Dilworth TJ, Mott D, **Cox ED**, Moreno MA. Development and evaluation of an instrument to measure community pharmacists' self-efficacy beliefs about communicating with Spanish-speaking patients. Res Social Adm Pharm. 2011 Dec;7(4):330-337. PMCID: PMC4432470.

Complete List of Published Work in My Bibliography:
https://www.ncbi.nlm.nih.gov/myncbi/elizabeth.cox.2/bibliography/public/

D. Additional Information: Research Support and/or Scholastic Performance

Ongoing Research Support

U48 DP006383 (Ehrenthal, PI) 09/01/19 – 09/30/24
Expanding the Evidence-base for Prevention Strategies to Improve the Health of Women, Infants, and Families
Prevention Research Center in Maternal and Child Health
Centers for Disease Control and Prevention
This award creates a Prevention Research Center at University of Wisconsin and includes a core research project that evaluates the impact and sustainability of a depression intervention for diverse, vulnerable mothers.
Role: Core Research Faculty

U18 HS025297 (Cabana, PI) 12/01/16 – 11/30/22
Agency for Healthcare Research and Quality (AHRQ)
The IMPLEmenting MEasures NeTwork (IMPLEMENT) for Child Health Network
The project will use a multidisciplinary approach to assess the feasibility and usability of new asthma and sickle cell disease quality measures developed by the Pediatric Quality Measures Program Centers of Excellence.
Role: Consultant

WITHHELD (Brasier, PI) 04/19/19 – 03/31/22
PRIVATE SUPPORT
ICTR CAP Program of Research on Outcomes for Kids
The project delivered resources that equip researchers with skills to improve health and healthcare for children.
Role: Project PI

WITHHELD (Misra, PI) 09/01/19 – 08/31/21
PRIVATE SUPPORT
A Community Partnership for Patient-centered Outcomes Research in Diabetes in West Virginia
This project will generate stakeholder relationships and build capacity for a future comparative effectiveness trial of methods to prevent type 2 diabetes in rural Appalachia.
Role: Co-Investigator

WITHHELD (Roberts, PI) 08/01/20 – 07/31/21
PRIVATE SUPPORT
Engaging Families as Quality Partners in Community Nursing Homes
The goal of this project is to collaborate with nursing home residents and families to develop an intervention to support resident and family engagement in care as Quality Partners.
Role: Co-Investigator

WITHHELD (Cox/Roberts, Co-PIs) 07/01/18 – 06/30/21
PRIVATE SUPPORT
Engaging Families as Care Partners in Community Nursing Homes
This project will collaborate with nursing home leadership, staff, residents, and families to form a learning network to identify, synthesize, share, and implement effective strategies to engage families as care partners.

WITHHELD (Cox, PI) 07/01/18 – 04/30/21
PRIVATE SUPPORT
Building a Translational Research Pipeline to Personalize Diabetes Prevention and Treatment
This project will establish a data registry and biobank of individuals with diabetes as a next step toward delivering personalized diabetes care and facilitating interdisciplinary translational diabetes research at UW.

WITHHELD (Cox, PI) 05/01/20 – 04/30/21
PRIVATE SUPPORT
On-Time HPV Vaccination for Rural Wisconsin Youth
To create a metric of on-time HPV vaccination and to conduct stakeholder interviews to inform interventions that address low rates of on-time HPV vaccination in rural Wisconsin.

1-18-ICTS-026 (Cox, PI) 01/01/18 – 12/31/20
PRIVATE SUPPORT
Identifying Actionable Self-Management Barriers for Adults with T1D
This project aims to create a clinically-useful tool to identify self-management barriers for adults with T1D as a first step toward tailoring self-management interventions to these barriers to improve glycemic control and QOL.

WITHHELD (Thompsen, Project Lead) 01/01/19 – 12/31/20
PRIVATE SUPPORT
This collaborative project will develop a survivor-centric national research agenda focused on intimate partner violence and develop a toolkit to engage survivors and other stakeholders as research advisors.
Role: Engagement Lead

Completed Research Support

U19 AR069519 (Panepinto, PI) 09/01/15 – 06/29/20
NIH/NIAMS
Family McPROs in Pediatric Chronic Illness (Project 2)
Role: Project 2 Co-PI

U19 AR069519 (Forrest, PI) 10/01/18 – 05/31/20
NIH/NIAMS
Guidance for Use of Pediatric PROMIS Measures in Ambulatory Clinics
Role: PI for Infrastructure and Opportunities Award

WITHHELD (Cox, PI) 10/01/13 – 12/31/18
PRIVATE SUPPORT
Family-Centered Tailoring of Pediatric Diabetes Self-Management Resources

WITHHELD (Cox, PI) 05/01/17 – 09/30/18
PRIVATE SUPPORT
The Impact of Influential Life Events on Self-Management of Type 1 Diabetes in Adulthood

UL1 TR002373 (Drezner/Lemanske, MPIs) 09/01/17 – 09/30/18
University of Wisconsin Institute for Clinical and Translational Research (UW ICTR)
Engaging Stakeholders to Support Clinical Trials
Role: Project PI

WITHHELD (Misra, PI) 10/01/17 – 09/30/18
PRIVATE SUPPORT
A Patient-Centered Strategy to Improve Diabetes Prevention and Management in West Virginia
Role: Consultant

UL1 TR000427 (Drezner, PI; Ward, Project PI) 07/01/17 – 06/30/18
NIH/NCATS & University of Wisconsin Institute for Clinical & Translational Research (UW ICTR)
Faith and Academic Engagement in Developing a Faith-Based Depression Intervention
Role: Consultant

UL1 TR000427 (Drezner, PI; Brooks, Project PI) 05/01/17 – 04/30/18
NIH/NCATS & University of Wisconsin Institute for Clinical & Translational Research (UW ICTR)
Academic Effects of Concussion in the High School Athlete
Role: Senior Investigator

OMB No. 0925-0001 and 0925-0002 (Rev. 03/2020 Approved Through 02/28/2023)

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: **Darden, Paul M.**

eRA COMMONS USER NAME (credential, e.g., agency login): eRA COMMONS USER NAME

POSITION TITLE: **Professor**

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE	Completion Date	FIELD OF STUDY
University of Houston, Houston	BS	05/1976	Biophysical Science
University of Texas Southwestern Medical School, Dallas	MD	06/1981	Medicine
Children's Medical Center, Dallas	Intern/ Resident	06/1984	Pediatrics
McGill University/Montreal Children's Hospital, Montreal	Fellow	08/1987	Pediatric Epidemiology

A. Personal Statement

I am excited to be working with Dr. Brewer and this group of accomplished investigators on testing an intervention including standing orders and a communication strategy (Announcement Approach Training) and their effect on HPV vaccine acceptance. The emphasis on nurses is a much needed one in researching vaccine delivery. Vaccine delivery has been a focus of my research for over 20 years. I have looked at vaccine delivery in clinics through national and regional practice-based research networks, in Emergency Departments, and through large dataset analyses. I have been involved in practice-based research for many years at the national and local level. I served on the steering committee of the American Academy of Pediatrics (AAP) practice-based research network Pediatric Research in Office Settings (PROS) for almost 20 years. This included being an investigator or principal investigator on many immunization-related research projects including the Pediatric Immunization Delivery Study and Reducing Immunization Disparity Study. I was the founding network director for the South Carolina Pediatric Practice Research Network (SCPPRN) while on faculty at the Medical University of South Carolina. When I moved to Oklahoma 10 years ago in collaboration with the Oklahoma Chapter of the AAP and in conjunction with the Family Medicine-based Oklahoma Physicians Resource/Research Network, I founded and currently direct the Oklahoma Child Health Research Network (OCHRN). Clinically, I have lead the adoption of standing orders in both South Carolina and in Oklahoma practices that I oversee. In research around standing orders, I am a quality improvement and immunization delivery lead for the Academic Pediatric Association's Continuity Research Networks project "National Immunization Partnership with the APA." I am thrilled to serve as a consultant on the "The impact of standing orders support on HPV vaccine communication and uptake" project. I will gladly provide my expertise through team meetings and in-person meetings as needed.

Relevant publications

1. **Darden PM**, Taylor JA, Slora EJ, et al. Methodological issues in determining rates of childhood immunization in office practice. A study from pediatric research in office settings (PROS). *Arch Pediatr Adolesc Med*. 1996;150(10):1027-1031. PMID: 8859133.
2. Rand CM, Tyrrell H, Wallace-Bodeur R, Goldstein NPN, **Darden PM**, Humiston SG, Albertin CS, Stratbucker W, Schaffer SJ, Davis W, Szilagyi PG. A Learning Collaborative Model to Improve Human Papillomavirus Vaccination Rates in Primary Care. *Acad Pediatr*. 2018;18(2S): S46-S52. PMID 29502638.
3. Roberts JR, Freeland KD, Kolasa MS, McElligott JT, **Darden PM**. Do immunisation procedures match provider perception? A study from the South Carolina Pediatric Practice Research Network (SCPPRN). *Qual Prim Care*. 2011;19(3):147-154. PMID 21781430.

4. Roberts JR, Morella K, Dawley EH, Madden CA, Jacobson RM, Pope C, Davis B, Thompson D, O'Brien ES, **Darden PM**. Direct-to-Adolescent Text Messaging for Vaccine Reminders: What Will Parents Permit? *Vaccine* published online April 15, 2018. May 2018:36(20);2788-2793. PMID 29653849.

B. Positions and Honors

Positions and Employment

1987-1994	Assistant Professor, Department of Pediatrics (primary), Department of Biometry and Epidemiology (joint), Medical University of South Carolina (MUSC), Charleston, South Carolina
1994-2000	Associate Professor, Division of General Pediatrics, Department of Pediatrics (primary), Department of Biometry and Epidemiology (joint), MUSC, Charleston, SC
2000-2008	Professor with tenure, Division of General Pediatrics, Departments of Pediatrics (primary), Internal Medicine (joint, 2004) and of Biostatistics, Bioinformatics and Epidemiology (joint), MUSC, Charleston, South Carolina
1999-2008	Founding Director Academic Generalist/Health Services Research Fellowship, Center for Health Disparities Research, MUSC, Charleston, South Carolina
2005-2008	Founding Director, South Carolina Pediatric Practice Research Network (SCPPRN). MUSC Children's Hospital, Department of Pediatrics, MUSC, Charleston, South Carolina
2008-	Professor with tenure, Department of Pediatrics, University of Oklahoma Health Sciences Center (OUHSC), Oklahoma City, Oklahoma
2008-	Chief General and Community Pediatrics, Department of Pediatrics, OUHSC, Oklahoma City, Oklahoma
2009-	Founding Director, Oklahoma Child Health Research Network (OCHRN), OUHSC, Oklahoma City, Oklahoma
2010-	Full Member of the Graduate Faculty, Clinical and Translational Sciences, Graduate College, OUHSC, Oklahoma City, Oklahoma
2016-	Founding Director, Oklahoma Pediatric Clinical Trials Network (OPCTN) a site for the ECHO IDeA State Pediatric Clinical Trials Network, Oklahoma City, Oklahoma

Selected Honors and Awards

1996	Elected Communications Director, Academic Pediatric Association
2002	Elected President, Academic Pediatric Association
2002	Mitchell I. Rubin Research Award. Department of Pediatrics, MUSC
2005	Elected to the American Pediatric Society
2006	Chair Council on Pediatric Subspecialties
2008	CMRI James Paul Linn Chair in Pediatrics
2011	Outstanding Mentor Award, Academic Pediatric Association
2011	Fifth Annual Distinguished Lecture, Christus Santa Rosa Children's Hospital, San Antonio, Texas
2012	Visiting Professor, Department of Pediatric and Adolescent Medicine, Mayo Clinic, Rochester, Minnesota
2014	Margaret Q. Jenkins Lecture, Pediatric Grand Rounds, Department of Pediatrics, Medical University of South Carolina, Charleston, South Carolina
2015	Provost's Research Award (Senior Faculty), University of Oklahoma Health Sciences Center, Oklahoma City, Oklahoma
2015	Speaker of the Oklahoma House of Representatives (Hickman) Appointment to the Infant and Children's Advisory Committee to the Oklahoma State Board of Health and the Health Department (reappointed in 2018)
2019	George Lynn Cross Research Professorship, University of Oklahoma Health Sciences Center, Oklahoma City, Oklahoma

C. Contributions to Science

1. **Practice-based research.** I have a long-term involvement in Practice-based research at the national, regional and in collaboration with multiple practice-based research networks. I have been the lead or senior

author on projects including those involving referrals to specialists, childhood immunizations, and obesity. Of particular import was the investigation of the change from oral polio vaccine to the injected IPV. We examined in the AAP's PROS network whether there was a risk of decreasing immunization acceptance with particular attention to minority populations. This was a collaboration between PROS and the National Medical Association's (NMA) PedsNet

a. Stille CJ, Lockhart SA, Maertens JA, Madden CA, **Darden PM**. Adapting practice-based intervention research to electronic environments: opportunities and complexities at two institutions. *EGEMS (Wash DC)*. 2015;3(1):1111. Published 2015 Feb 10. PMID: 25848633.

b. McElligott JT, Roberts JR, O'Brien ES, Freeland KD, Kolasa MS, Stevenson J, **Darden PM**. Improving immunization rates at 18 months of age: implications for individual practices. *Public Health Rep*. 2011;126 Suppl 2(Suppl 2):33-38. PMID: 21812167.

c. Rand CM, Schaffer SJ, Dhepyasuwan N, Blumkin A, Albertin C, Serwint JR, **Darden PM**, Humiston SG, Mann KJ, Stratbucker W, Szilagyi PG. Provider Communication, Prompts, and Feedback to Improve HPV Vaccination Rates in Resident Clinics. *Pediatrics*. 2018;141(4):e20170498. PMID: 29540572.

d. Taylor JA, **Darden PM**, Brooks DA, Hendricks JW, Baker AE, Bocian AB, Wasserman RC. Impact of the change to inactivated poliovirus vaccine on the immunization status of young children in the United States: a study from pediatric research in office settings and the National Medical Association. *Pediatrics*. 2001;107(6):E90. PMID: 11389288.

2. **Vaccine delivery, methods.** Developing methods and new measurements have been a long-standing interest. Reference #4 is the first of several investigations examining the ways of measuring immunization rates in office practice, these methods have concentrated on defining an appropriate denominator in the practice settings. I have also led the examination of statistical methods for analyzing complex sampling design surveys. In addition, I have published on the way to combine multiple identified datasets to end with a de-identified HIPAA compliant dataset.

   a. Hale JJ, Thompson DM, **Darden PM.** Calculating Subset Weighted Analysis Using PROC SURVEYFREQ and GENMOD. *SAS Global Forum*. 2013; Paper 272-2013. http://support.sas.com/resources/papers/proceedings13/272-2013.pdf.

   b. **Darden PM**, Gustafson KK, Nietert PJ, Jacobson RM. Extra-immunization as a clinical indicator for fragmentation of care. *Public Health Rep*. 2011; 126 (Suppl 2), 48-59. PMID: 21812169

   c. Ang SC, **Darden PM.** HIPAA Compliance: Meeting Privacy Requirements in Combining Multiple Datasets using SAS Functions. *SAS Global Forum.* 2011; from http://support.sas.com/resources/papers/proceedings11/175-2011.pdf

   d. **Darden PM**, Taylor JA, Slora EJ, Hasemeier CM, Asmussen L, Recknor JC, Wasserman RC. Methodological issues in determining rates of childhood immunization in office practice. A study from Pediatric Research in Office Settings (PROS). *Arch Pediatr Adolesc Med.*1996; 150(10), 1027-1031.

3. **Vaccine delivery, childhood and adolescents.** Most recently using both large datasets and PBRN data we have examined adolescent vaccine delivery. The reasons, intent to vaccinate and provider recommendation. We have found that provider recommendation is highest for HPV vaccine in multiple measures despite the lowest uptake for that vaccine. Qualitative research has also helped in examination of communication.

   a. Pope CA, Escobar-Gomez M, Davis BH, Roberts JR, O'Brien ES, Hinton E, **Darden PM**. The challenge of tetradic relationships in medically interpreted pediatric primary care visits: A descriptive study of communication practices. *Patient Educ Couns*. 2016;99(4):542-548. PMID: 26796067.

   b. Roberts JR, Thompson D, Rogacki B, Hale JJ, Jacobson RM, Opel DJ, **Darden PM.** Vaccine hesitancy among parents of adolescents and its association with vaccine uptake. *Vaccine*. 2015;33(14):1748-1755. PMID: 25659278.

   c. **Darden PM**, Jacobson RM. Impact of a physician recommendation. *Hum Vaccin Immunother*. 2014;10(9):2632-2635. PMID: 25483503.

d. **Darden PM**, Thompson DM, Roberts JR, Hale JJ, Pope C, Naifeh M, Jacobson RM. Reasons for not vaccinating adolescents: National Immunization Survey of Teens, 2008-2010. *Pediatrics*. 2013;131(4):645-651. PMID: 23509163.

Complete List of Published Work in ScieENcv:
http://www.ncbi.nlm.nih.gov/sites/myncbi/paul%20m..darden.1/bibliograpahy/47375293/public/?sort=date&direction=ascending

D. Research Support

Ongoing Research Support

PRIVATE SUPPORT Fagnan, LJ (PI) 07/18-06/23
Rural Adolescent Vaccine Enterprise. Oregon Rural Practice-based Research Network, Oregon Health and Science University (recipient organization).
Role: Co-Investigator, Child Health and HPV vaccine delivery expert

8U24OD024957 Y Lee and J Snowden (PI) 09/18-08/20
Office of the Director, National Institutes of Health
Data Coordinating and Operations Center (DCOC) for the IDeA States Pediatric Clinical Trials Network, University of Arkansas for Medical Sciences (recipient organization).
Role: PM Darden, Leadership Committee

8U24OD024957 JY Lee and J Snowden (PI) 09/18-08/20
Office of the Director, National Institutes of Health
Data Coordinating and Operations Center (DCOC) for the IDeA States Pediatric Clinical Trials Network, University of Arkansas for Medical Sciences (recipient organization).
Role: PM Darden, Chair of the writing committee for the iAmHealthy protocol

Contract No. HHSN- 275201000003I Benjamin, DK (PI) 04/18-09/22
Eunice Kennedy Shriver National Institute of Child Health and Human Development
Pharmacokinetics of Understudied Drugs Administered to Children per Standard of Care. Duke Clinical Research Institute, Pediatric Trials Network.
Role: C Allen, PM Darden, site PIs

8UG1OD024950 Darden, PM (PI) 09/16-08/20
Office of the Director, National Institutes of Health.
The Oklahoma Pediatric Clinical Trials Network (OPCTN)
Role: PI and OPCTN Network Director

U54GM104938 James, JA (PI) 09/13-06/23
National Institute of General Medical Sciences, National Institutes of Health
Oklahoma Shared Clinical and Translational Resources
Role: PI of the Professional Development Core as of 12/1/2016

Completed Research Support

H23IP000950 Szilagyi, Rand (PI) 09/14-09/19
National Center for Immunization and Respiratory Diseases, Centers for Disease Control and Prevention (CDC-RFA-IP14-1405PPHF14). *National Immunization Partnership with the APA* (NIPA). Academic Pediatric Association - APA (recipient organization).
Role: Co-Investigator, CORNET (APA Continuity Clinic Research Network) Project Director, and expert on immunization delivery

PRIVATE SUPPORT Darden, PM (PI) 12/17-12/18
Increasing HPV Vaccination Uptake: An Intensive Communication Training Intervention to Improve Office Recommendations to Adolescents.
Role: PI

WITHHELD Darden, PM (PI) 09/11-09/17
PRIVATE SUPPORT
Training Faculty for Careers in Academic Primary Care
The goal of this project is to train faculty in Internal Medicine, Pediatrics and Family Medicine for academic careers. This is a collaboration between the Oklahoma City and Tulsa campuses of the University of Oklahoma
Role: PI and Program Director

P30 HS 021644 Mold, J (PI) 07/12-06/17
Agency for Healthcare Research and Quality
Establishing the Coordinated Consortium of Networks (CoCoNet2)
Role: Co-Investigator and Director Oklahoma Child Health Research Network (OCHRN)

OMB No. 0925-0001 and 0925-0002 (Rev. 03/2020 Approved Through 02/28/2023)

BIOGRAPHICAL SKETCH

NAME: **Gilkey, Melissa Blair**

eRA COMMONS USER NAME (credential, e.g., agency login): eRA COMMONS USER NAME

POSITION TITLE: **Associate Professor of Health Behavior**

EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE	Completion Date	FIELD OF STUDY
University of North Carolina at Chapel Hill	BA	05/1998	English
University of North Carolina School of Public Health	MPH	05/2005	Health Behavior and Health Education
Johns Hopkins Bloomberg School of Public Health	PhD	12/2011	Health, Behavior and Society
University of North Carolina Lineberger Comprehensive Cancer Center	Postdoctoral	08/2014	Cancer Control Education Program

A. Personal Statement

As a behavioral scientist specializing in cancer prevention research, I am excited to join this team of highly accomplished investigators in a study that aligns with my primary career goal to improve the delivery of HPV vaccine. My roles in the IMPACT Program Project (P01) will be to serve as: 1) Project Lead (PL) of Project 3 ("Engaging clinical champions to improve HPV vaccine communication and uptake"); 2) Co-Lead of the Intervention Core; and 3) Member of the Administrative Core's IMPACT Integration Committee. In these roles, I will draw from three primary sources of expertise:

Provider communication about HPV vaccination. I will advise on intervention content related to improving healthcare providers' communication about HPV vaccination. My qualifications for this role include extensive training in health communication theory, as well as experience leading a portfolio of federally-funded studies to characterize and improve providers' HPV vaccine recommendations. My publication record includes over 20 peer-reviewed papers examining the influence of provider communication on HPV vaccination.

Clinical interventions to improve HPV vaccination. In Project 3, I will conduct a randomized clinical trial with 40 primary care clinics to evaluate two interventions to improve HPV vaccine communication and uptake. I will also support intervention delivery in other projects through the Intervention Core. My qualifications for this role include leading: 1) an RCT with 25 clinics that engaged clinical champions to deliver HPV vaccine-related training; 2) an RCT with 91 clinics that used assessment and feedback to improve HPV vaccination via CDC's AFIX program; and 3) an ongoing RCT that has successfully recruited >250 clinics to evaluate the impact of AFIX and provider communication training on HPV vaccination. This work demonstrates my experience recruiting clinics and developing and evaluating interventions to improve HPV vaccination.

Methods. I will contribute methodological expertise in intervention evaluation. I have extensive experience using quantitative and qualitative methods to study the implementation of cancer prevention interventions, with a particular focus on conducting surveys and interviews with healthcare providers. My experience in implementation science includes formal training via NCI's Training Institute for Dissemination and Implementation Research in Health.

1. **Gilkey, M. B.**, Parks, M. J., Margolis, M. A., McRee, A. L., & Terk, J. V. (2019). Implementing evidence-based strategies to improve HPV vaccine delivery. *Pediatrics, 144*(1). PMCID: PMC6615521
2. **Gilkey, M. B.,** Dayton, A. M., Moss, J. L., Sparks, A. C., Grimshaw, A. H., Bowling, J. M., & Brewer, N. T. (2014). Increasing provision of adolescent vaccines in primary care: A randomized controlled trial. *Pediatrics, 134*(2), e346-353. PMCID: PMC4531274
3. **Gilkey, M. B.,** Moss, J. L., Roberts, A. J., Dayton, A. M., Grimshaw, A. H., & Brewer, N. T. (2014). Comparing in-person and webinar delivery of an immunization quality improvement program: A process evaluation of the adolescent AFIX trial. *Implementation Science*, 9, 21. PMCID: PMC3937058
4. **Gilkey, M. B.**, & McRee, A. L. (2016). Provider communication about HPV vaccination: A systematic review. *Human Vaccines & Immunotherapeutics, 12*(6), 1454-68. PMCID: PMC4964733

B. Positions and Honors

Positions and Employment

2003-2005 Research Assistant, University of North Carolina School of Public Health, Chapel Hill, NC
2005-2006 Evaluation Coordinator, California Pacific Medical Center, San Francisco, CA
2006-2010 Research Assistant, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD
2011-2014 Postdoctoral Research Associate, Cancer Control Education Program, University of North Carolina Lineberger Comprehensive Cancer Center, Chapel Hill, NC
2014-2017 Assistant Professor, Department of Population Medicine, Harvard Medical School & Harvard Pilgrim Health Care Institute, Boston, MA
2017-2020 Assistant Professor, Department of Health Behavior, University of North Carolina Gillings School of Global Public Health, Chapel Hill, NC
2020- Associate Professor, Department of Health Behavior, University of North Carolina Gillings School of Global Public Health, Chapel Hill, NC

Other Experience and Professional Memberships

2009- Member, American Public Health Association
2011- Member, Society of Behavioral Medicine
2011- Member, American Society of Preventive Oncology
2015-2017 Member, Dana-Farber/Harvard Cancer Center
2017- Member, UNC Lineberger Comprehensive Cancer Center

Honors

1998 Phi Beta Kappa, University of North Carolina, Chapel Hill, NC
2003-2005 University Merit Assistantship, University of North Carolina, Chapel Hill, NC
2006-2011 Sommer Scholarship, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD
2009-2010 Dean's Teaching Fellowship, Johns Hopkins University, Baltimore, MD
2013 Academic Pediatric Association Young Investigator Award
2016 Robert H. Ebert Fellowship, Harvard Medical School

C. Contribution to Science

1. **Provider communication about HPV vaccination.** My research has identified opportunities for improving communication about HPV vaccination. Although receiving a provider's recommendation has long been known to be one of the strongest predictors of HPV vaccination, until recently we have known less about how providers communicate about the vaccine. Based on a systematic review of the research literature and survey research with physicians and parents, I have led efforts to develop a conceptual framework of HPV vaccine "recommendation quality." This framework emphasizes the importance of specific communication practices such as timeliness (recommending HPV vaccine by age 12), urgency (recommending same-day vaccination), and consistency (delivering routine versus risk-based recommendations). In a national study of pediatricians and family physicians, we found that half of physicians reported using two or more low-quality communication practices. This finding is concerning given that, in a corresponding survey of parents, we found that lower-quality recommendations were associated with lower levels of HPV vaccine initiation and higher levels of HPV vaccine refusal and delay. Covered by the *New York Times*, *Washington Post*, and National Public Radio, this body of research has helped to sustain national interest in improving HPV vaccine delivery, while extending our focus from *whether* providers recommend HPV vaccine to *how* they can recommend it most effectively.
    a. **Gilkey, M. B.**, & McRee, A. L. (2016). Provider communication about HPV vaccination: A systematic review. *Human Vaccines & Immunotherapeutics, 12*(6), 1454-68. PMCID: PMC4964733
    b. **Gilkey, M. B.**, Calo, W. A., Moss, J. L., Shah, P. D., Marciniak, M. W., & Brewer, N. T. (2016). Provider communication and HPV vaccination: The impact of recommendation quality. *Vaccine, 34*(9), 1187-92. PMCID: PMC4944755
    c. **Gilkey, M. B.**, Moss, J. L., Coyne-Beasley, T., Hall, M. E., Shah, P. D., & Brewer, N. T. (2015). Physician communication about adolescent vaccination: How is human papillomavirus vaccine different? *Preventive Medicine, 77*, 181-185. PMCID: PMC4490050
    d. **Gilkey, M. B.**, Malo, T. L., Shah, P. D., Hall, M. E., & Brewer, N. T. (2015). Quality of physician communication about human papillomavirus vaccine: Findings from a national survey. *Cancer Epidemiology, Biomarkers & Prevention, 24*(11), 1673-1679. PMCID: PMC4633386

2. **Interventions to improve vaccine delivery systems.** My research in healthcare systems has contributed to efforts to improve vaccine delivery through the development and evaluation of multi-level interventions. Most recently, I completed a cluster randomized clinical trial with 25 clinics in a large pediatric healthcare system that identified novel strategies for scaling up an assessment and feedback intervention to improve HPV vaccination. I have also evaluated the CDC's AFIX (Assessment, Feedback, Incentives and eXchange) intervention, finding that this nationally-implemented program had less impact on HPV vaccination coverage than on coverage for other adolescent vaccines. This research has brought renewed attention to AFIX and is also the basis for a study that I currently co-lead to further develop and test AFIX in an RCT with over 250 primary care clinics in three states. Working in conjunction with state health departments and the CDC's national AFIX program office, we have developed HPV AFIX, an enhanced, HPV vaccine-specific version of the standard AFIX approach. These studies demonstrate my experience in recruiting primary care providers, delivering multi-level interventions, and evaluating implementation and vaccination outcomes.

   a. **Gilkey, M. B.**, Parks, M. J., Margolis, M. A., McRee, A. L., & Terk, J. V. (2019). Implementing evidence-based strategies to improve HPV vaccine delivery. *Pediatrics, 144*(1). PMCID: PMC6615521
   b. Calo, W. A., **Gilkey, M. B.**, Leeman, J., Heisler-MacKinnon, J. A., Averette, C., Sanchez, S., Kornides, M. L., & Brewer, N. T. (2019). Coaching primary care clinics for HPV vaccination quality improvement: Comparing in-person and webinar implementation. *Translational Behavioral Medicine, 9*(1):23-31. PMCID: PMC6305561
   c. **Gilkey, M. B.,** Dayton, A. M., Moss, J. L., Sparks, A. C., Grimshaw, A. H., Bowling, J. M., & Brewer, N. T. (2014). Increasing provision of adolescent vaccines in primary care: A randomized controlled trial. *Pediatrics, 134*(2), e346-353. PMCID: PMC4531274
   d. **Gilkey, M. B.,** Moss, J. L., Roberts, A. J., Dayton, A. M., Grimshaw, A. H., & Brewer, N. T. (2014). Comparing in-person and webinar delivery of an immunization quality improvement program: A process evaluation of the adolescent AFIX trial. *Implementation Science*, 9, 21. PMCID: PMC3937058

3. **Parental hesitancy toward HPV vaccination.** My research with parents seeks to understand vaccination decisions, with a special emphasis on vaccine hesitancy. My survey research has helped to characterize concerns that parents have about vaccinating their adolescents and to develop and test messages designed to effectively address those concerns. This work has included the development and validation of the Vaccination Confidence Scale, a brief measure for identifying parents at risk for refusing adolescent vaccines, including HPV vaccine. This body of research has helped to inform work by the National Vaccine Advisory Committee and others to improve surveillance of parental vaccine hesitancy nationally.

   a. **Gilkey, M. B.**, Zhou, M., McRee, A. L., Kornides, M. L., & Bridges, J. F. P. (2018). Parents' views on the best and worst reasons for guideline-consistent HPV vaccination. *Cancer Epidemiology, Biomarkers & Prevention, 27*(7), 762-67. PMCID: PMC6035066
   b. Kornides, M. L., McRee, A. L., & **Gilkey, M. B.** (2018). Parents who decline HPV vaccination: Who later accepts and why? *Academic Pediatrics, 18*(2S), S37-S43. PMCID: PMC5859546
   c. **Gilkey, M. B.**, Calo, W. A., Marciniak, M. W., & Brewer, N. T. (2017). Parents who refuse or delay HPV vaccine: Differences in vaccination behavior, beliefs, and clinical communication preferences. *Human Vaccines & Immunotherapeutics, 13*(3), 680-686. PMCID: PMC5360115
   d. **Gilkey, M. B.**, Reiter, P. L., Magnus, B. E., McRee, A. L., Dempsey, A. F., & Brewer, N. T. (2016). Validation of the Vaccination Confidence Scale: A brief measure to identify parents at risk for refusing adolescent vaccines. *Academic Pediatrics, 16*(1), 42-49. PMCID: PMC4715593

4. **Patient-centeredness and patient engagement.** My earliest research contributed to a growing understanding of and appreciation for the need for patient-centeredness and patient engagement. I am the co-editor of *Patient Advocacy for Healthcare Quality: Strategies for Achieving Patient-Centered Care*, an edited volume used in graduate training. In this capacity, I worked closely with leaders in the fields of patient-provider communication, medical education reform, and patient safety to create one of the first texts on the role that patients play in healthcare quality improvement. Following on this work, I conducted a qualitative interview study aimed at understanding the role of cancer survivors who participate in the peer review of grant proposals for the National Cancer Institute. Drawing from my background in health education and health promotion, I aimed to position this research to inform the nascent field of patient-centered outcomes research.

a. Earp, J. A., French, E. A., & **Gilkey, M. B.** (Eds.). (2007). *Patient advocacy for health care quality: Strategies for achieving patient-centered care*. Boston, MA: Jones & Bartlett. PMCID: Not applicable
b. **Gilkey, M. B.**, & Earp, J. A. (2009). Defining patient advocacy in the post-Quality Chasm era: Results of the University of North Carolina Patient Advocacy Survey. *North Carolina Medical Journal, 70*(2), 120-124. PMCID: Not applicable
c. French, E. A., **Gilkey, M. B.**, & Earp, J. A. (2009). Patient advocacy: Putting the vocabulary of patient-centered care into action. *North Carolina Medical Journal, 70*(2), 114-119. PMCID: Not applicable
d. **Gilkey, M. B.** (2014). Supporting cancer survivors' participation in peer review: Perspectives from NCI's CARRA program. *Journal of Cancer Survivorship, 8*(1), 114-120. PMCID: PMC3945408

Complete List of Published Work in MyBibliography:
https://www.ncbi.nlm.nih.gov/sites/myncbi/1LQs9gfEmiakh/bibliography/47161883/public/?sortby=pubDate&sdirection=descending

D. Research Support

Ongoing

[ ] (Gilkey) 03/01/2020-02/28/2022
PRIVATE SUPPORT
Engaging Specialty Care Teams to Help Families Discuss and Manage the Cost of Asthma Care
This study will develop and pilot a cost navigation intervention to support children with asthma and their families in the context of asthma specialty care.
Role: multi-Principal Investigator

WITHHELD (Gilkey) 01/01/2019-12/31/21
PRIVATE SUPPORT
Evaluating the Feasibility of a Mobile Coaching Intervention to Improve HPV Vaccine Delivery
This study will develop the prototype of a mobile application (app) to improve primary care providers' communication about HPV vaccine.
Role: Principal Investigator

R21 CA241518 (Gilkey) 09/20/2019-07/31/2021
NCI
Evaluating the Feasibility of a Mobile Coaching Intervention to Improve HPV Vaccine Delivery
This study will enhance and test the feasibility of using a mobile application (app) to improve primary care providers' communication about HPV vaccine.
Role: Principal Investigator

U01 IP001073 (Gilkey, Brewer) 08/01/2017-07/31/2021
CDC
Impact of AFIX and Physician-to-Physician Engagement on HPV Vaccination in Primary Care: An RCT
This trial will evaluate the effectiveness of two quality improvement strategies commonly used by state health departments to increase HPV vaccination coverage: AFIX and P2P. By establishing how and for whom AFIX and P2P are effective, this study seeks to increase options available to public health leaders for mobilizing resources to ensure that our nation's youth are protected from HPV-attributable cancers.
Role: multi-Principal Investigator

WITHHELD (Cox) 05/01/2020 – 04/30/2021
PRIVATE SUPPORT
On-Time HPV Vaccination for Rural Wisconsin Youth
This study will assess variation in on-time HPV vaccination among rural Wisconsin youth. We will also conduct key stakeholder interviews to inform interventions to increase uptake in this high-priority population.
Role: Consultant

PRIVATE SUPPORT (Galbraith) 07/1/20 – 01/31/21

Comparing Patient-Centered Outcomes for Adults and Children with Asthma in High-Deductible Health Plans with and without Preventive Drug Lists
The goal of this supplement is to evaluate the feasibility of using an online "chatbot" to help families affected by asthma navigate insurance-related challenges in the Covid-19 era.
Role: Co-Investigator

Completed (past 3 years)

PRIVATE SUPPORT (Galbraith) 03/01/2017-03/17/2020

Comparing Patient-Centered Outcomes for Adults and Children with Asthma in High-Deductible Health Plans with and without Preventive Drug Lists
The goal of this study was to understand how a novel value-based insurance strategy—preventive drug lists—affect families' ability to manage asthma care costs in the context of high deductible health plans.
Role: Co-Investigator

U48DP005017 SIP 16-005 (Brewer) 09/30/2016-9/29/2019
CDC
Communication Strategies to Increase HPV Vaccine Intentions
This study developed and tested strategies that primary care providers can use to address parents' HPV vaccine-related concerns with the goal of increasing their intention to vaccinate. We first tested a range of communication strategies via a national survey of parents of adolescents. We next integrated effective strategies into an existing communication training module, which we disseminated to primary care providers in partnership with state health departments.
Role: Co-Investigator

K22CA186979-01 (Gilkey) 09/17/2014 - 08/31/2018
National Cancer Institute
Improving Healthcare Providers' Communication about HPV Vaccine
The goal of this project was to identify communication characteristics associated with HPV vaccine delivery and use these findings to develop a training module aimed at enhancing providers' communication about HPV vaccination.
Role: Principal Investigator

OMB No. 0925-0001 and 0925-0002 (Rev. 03/2020 Approved Through 02/28/2023)

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: **Gottfredson, Nisha Claire**

eRA COMMONS USER NAME (credential, e.g., agency login): eRA COMMONS USER NAME

POSITION TITLE: **Assistant Professor**

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE	Completion Date	FIELD OF STUDY
Pitzer College, Claremont, California	BA	05/2006	Psychology & Mathematics
University of North Carolina, Chapel Hill	MA	08/2008	Quantitative Psychology
University of North Carolina, Chapel Hill	PhD	05/2011	Quantitative Psychology

A. Personal Statement

My roles in the proposed P01 Program Project, "Improving Provider Announcement Communication Training" (IMPACT) include being Co-Director of the Data Core, Co-Investigator on Project 1, and Co-Investigator of the Administrative Core. As a quantitative psychologist with extensive expertise working with complex, nested data structures and harmonizing measures across multiple studies, I am well positioned to oversee the Data Core in collaboration with the other Co-Director, Dr. Trogdon. I have previously served as the statistician for a NIH-funded initiative to integrate measures across several study sites. Currently, I am a co-investigator on a NIH-funded RCT that is using a stepped-wedge design to facilitate ethical and practical rollout of intervention services within the community. I have overseen collection of survey data from difficult-to-reach populations and I have expertise in addressing nonresponse statistically.

In addition to my methodological expertise, I study adolescent risk behavior with an emphasis on intergenerational transmission of risk. The Announcement Approach used in the proposed Program Project is innovative and effective. I developed a similar intervention to address the onset of alcohol use among early adolescents (Brief Intervention to Prevent Alcohol Socialization; BI-PAS). This intervention is a natural fit to serve as the control condition in Project 1, and as Co-Investigator, I will ensure that it is implemented correctly.

Finally, to enhance communication and synergy across Projects and Cores, I will also serve on IMPACT's Integration Committee comprised of our research project and core directors.

Relevant publications

Gottfredson, N.C.. Cole, V.T., Giordano, M.*, Bauer, D.J., Hussong, A.M., & Ennett, S.T. (2019). Simplifying the implementation of modern scale scoring methods with an automated R package: Automated Moderated Nonlinear Factor Analysis (aMNLFA). *Addictive Behaviors, 94,* 65-73. PMCID: PMC6483881.

Hussong, A., **Gottfredson, N.C.**, Bauer, D.J., Curran, P.J., Harroon, M., Chandler, R., Delaney, J., Altice, F., Beckwith, C., Feaster, D., Flynn, P., Gordon, M., Knight, K., Kuo, I., Ouellet, L., Quan, V., Seal, D., & Springer, S. (2019). Approaches for crating comparable measures of alcohol use symptoms: Harmonization with eight studies of criminal justice population. *Drug and Alcohol Dependence, 194,* 59-68. PMCID: PMC6312501.

Gottfredson, N. C., Sterba, S. K., & Jackson, K. (2017). Explicating the conditions under which multilevel multiple imputation mitigates bias resulting from random coefficient-dependent missing longitudinal data. *Prevention Science, 18*, 12-19. PMCID: PMC5235951

Hoyle, R. & **Gottfredson, N. C.** (2015). Sample size considerations in prevention research applications of multilevel modeling and structural equation modeling. *Prevention Science, 16,* 987-996. PMCID: PMC 4207737

B. Positions and Honors

Positions and Employment

2007-2009	Research Associate, Pacific Institute for Research and Evaluation, Chapel Hill, NC
2011-2013	Postdoctoral Researcher, Center for Developmental Epidemiology and Transdisciplinary Prevention Research Center, Duke University, Durham, NC
2012-	Consultant, Catalyst Behavioral Sciences, Miami, FL
2013	Statistician/Investigator, Frank Porter Graham Child Development Institute, Chapel Hill, NC
2013-	Adjunct Professor, Department of Psychology, University of North Carolina, Chapel Hill
2014-2015	Senior Investigator, Center for Developmental Science, Chapel Hill, NC
2015-	Assistant Professor, Department of Health Behavior, UNC Gillings School of Global Public Health, Chapel Hill, NC
2015-	Faculty Affiliate, Center for Developmental Science, Chapel Hill, NC

Other Experience

2005-	Member, Division 5, American Psychological Association
2009-2011	Representative for Quantitative Psychology, Science Student Council, American Psychological Association
2013-	Member, Division 50, American Psychological Association
2015-	Member, Society for Prevention Research
2016-	Member, Research Society on Alcoholism
2016	Member, Society for Behavioral Medicine
2019-	National Academy of Sciences Healthy Parenting in Primary Care Collaborative

Honors

2005	Sigma Xi Undergraduate Research Honors Society, Claremont Colleges
2005	Psi Chi Psychology Honors Society, Claremont Colleges
2006	Graduated with honors, Pitzer College
2009	Lyle V. Jones Award for Outstanding Scholarship and Citizenship as a Doctoral Student
2009	Society for Multivariate and Experiment Psychology Tanaka Award for Most Outstanding Paper published in the journal of *Multivariate Behavioral Research* in 2008
2019	Delta Omega National Public Health Honorary Society

C. Contributions to Science

As a quantitative psychologist with a background in developmental science and prevention science, my research contributions consist of a mixture of advances in the development and application of statistical methodology and improved understanding of the developmental etiology of behavioral disorders, including identification of prevention targets. I have authored over 70 peer-reviewed publications. In the manuscripts highlighted below, * indicates student authorship.

1. Advancing model fidelity and measurement quality within longitudinal models. Human behavior and theoretical models used to explain human behavior are complex and, often, difficult to measure. Quantitative models, particularly those involving latent variables, can be useful for providing insights into noisy and non-deterministic behavior. However, the models are only useful if they are constructed thoughtfully and only if they are robust to minor misspecification. I have contributed to the field of quantitative psychology by adapting latent variable models so that they are better suited to reality. For example, my dissertation and several subsequent publications focused on the problem of nonignorable missingness in longitudinal models. Whereas most analytic techniques assume ignorable missingness, this is often an unrealistic assumption. In this vein, I developed a shared parameter mixture model for handling nonignorable missingness. Other contributions have involved adapting confirmatory factor analysis models to accommodate differential item functioning and impact due to covariates and adapting the residual covariance structure of multilevel models to accommodate 'rolling' group membership over time.

a. **Gottfredson, N. C.**, Sterba, S. K., & Jackson, K. (2017). Explicating the conditions under which multilevel multiple imputation mitigates bias resulting from random coefficient-dependent missing longitudinal data. *Prevention Science, 18*, 12-19. PMCID: PMC5235951
b. Curran, P. J., Cole, V., Bauer, D. J., Hussong, A. M., & **Gottfredson, N. C.** (2016). Improving factor score estimation through the use of observed background characteristics. *Structural Equation Modeling: An Interdisciplinary Journal,* 1-18. PMCID: PMC5526637
c. **Gottfredson, N.C.**, Bauer, D.J., & Baldwin, S. (2014). Modeling change in the presence of non-randomly missing data: Evaluating a Shared Parameter Mixture Model. *Structural Equation Modeling, 21,* 196-209. PMCID: PMC4084916
d. Bauer, D.J., **Gottfredson, N.C.**, Dean, D., & Zucker, R. A. (2012). Analyzing repeated measures data on individuals nested within groups: Accounting for dynamic group effects. *Psychological Methods, 17,* 1-14. PMCID: PMC3638804

2. <u>Reducing barriers to implementation of statistical methodology</u>. Advances to quantitative models are only useful if they are implemented in applied research. Often, statistical advances go un-noticed and un-applied by researchers who would benefit from them. Some of my most useful contributions to science have been those that identify and remove barriers to implementing complex methods. For example, I developed a software package in R for researchers wishing to implement the moderated nonlinear factor analysis model to accommodate differential item functioning in complex data, I published a YouTube video demonstrating implementation of Directed Acyclic Graphs, and I developed a simple method for researchers to correct for bias resulting from small level 1 sample sizes in multilevel models.

a. **Gottfredson NC**, Cole VT, Giordano M, Bauer DJ, Hussong AM & Ennett ST. (2019). Simplifying the implementation of modern scale scoring methods with an automated R package: automated Moderated nonlinear factor analysis (aMNLFA). *Addict Behav, 94*, 65-73. PMCID: PMC6483881.
b. Wouk, K.G.*, Bauer, A.& **Gottfredson, N.C.** (2019. How to implement Directed Acyclic Graphs to reduce bias in addiction research. *Addictive Behaviors, 94,* 109-116. PMID: 30292573 / PMCID: Pending ***[Senior Author]***
c. **Gottfredson NC.** (2019). A straightforward approach for coping with unreliability of person means when parsing within-person and between-person effects in longitudinal studies. *Addict Behav*, *94*, 156-161. PMCID: PMC6435441.
d. Hoyle, R. & **Gottfredson, N. C.** (2015). Sample size considerations in prevention research applications of multilevel modeling and structural equation modeling. *Prevention Science, 16,* 987-996. PMCID: PMC 4207737

3. <u>Use of longitudinal, population-based samples to characterize the developmental etiology of psychological and behavioral phenotypes, and how these phenotypes relate to one another over time</u>. The developmental concept of “multifinality” posits that early experiences and environmental contexts may give rise to a variety of potential outcomes. The concept of “heterotypic discontinuity” suggests that the same underlying trait may be expressed differently at different stages of development. I have used large-scale panel data to provide insight into the developmental course of anxiety and depression, substance use and substance use disorder and eating disorders using the concepts of multifinality and heterotypic discontinuity. A shared internalizing process partially explains some of the comorbidities that have been observed in these mental and behavioral traits.

a. Yilmaz, Z., **Gottfredson, N.C.**, Zerwas, S., Bulik, C., & Micali, N. (2019). Developmental premorbid body mass index trajectories of adolescents with eating disorders. *Journal of the American Academy of Child and Adolescent Psychiatry, 58*, 191-199. PMCID: PMC6766404. ***[First two authors contributed equally]***
b. **Gottfredson, N.C.**, Rhodes, B.E.*, & Ennett, S.T. (2019). Demographic moderation of the prediction of adolescent alcohol involvement trajectories. *Prevention Science, 20*, 811-823. PMCID: PMC6395564.
c. Zerwas, S., Von Holle, A., Watson, H., **Gottfredson, N.C.**, & Bulik, C. M. (2014). Childhood anxiety trajectories and adolescent disordered eating: Findings from the NICHD study of early child care and youth development, *International Journal of Eating Disorders, 47*, 784-792. PMCID: PMC4425370

d. **Gottfredson, N. C.**, Foshee, V. A., Ennett, S. T., Habertick, B., & Smolen, A. (2014). Genetic heterogeneity in adolescents' depressive symptoms in response to victimization. *Journal of Clinical Child and Adolescent Psychology.* PMCID: PMC4229484

4. Identifying targets for relapse prevention. As PI of a NIDA-funded K01 award, I used a measurement burst design to investigate real-time precursors to drug cravings and lapses among individuals in recovery for addiction. I hypothesized that individuals who cope with cravings by using alternative substances, including tobacco and comfort food, would be less likely to experience a successful recovery. This was true for tobacco use but was not entirely true for food. Rather, after disaggregating within-person and between-person effects, it is evident that some individuals are predisposed toward both polysubstance use and "food addiction," and that there is no temporal association between cravings and consumption of unhealthy foods. Another study led by a student found that poor sleep quality increases drug cravings in real time, and that this effect may be mediated by diminished willpower.

a. Rhodes, B.E.* & **Gottfredson, N.C.** (2020, E-pub ahead of print). Effects of tobacco on affect and craving during opioid addiction and recovery: An ecological momentary assessment study. *Addictive Behaviors.* PMID: 32151892 / PMCID: Pending. **[Senior author]**
b. **Gottfredson, N.C.** & Sokol, R.L.* (2019). Explaining excessive weight gain during early recovery from addiction. *Substance Use & Misuse, 54,* 769-778. PMCID: PMC6474807.
c. Freeman, L.K.* & **Gottfredson, N.C.** (2018). Using ecological momentary assessment to assess the temporal relationship between sleep quality and cravings in individuals recovering from substance use disorders. *Addictive Behaviors, 83*, 95-101. PMCID: PMC7080296. ***[Senior Author]***

Complete List of Published Work in MyBibliography:
https://www.ncbi.nlm.nih.gov/pubmed/?term=Gottfredson+NC%5BAuthor%5D+or+Gottfredson+N%5BAuthor%5D

D. Additional Information: Research Support and/or Scholastic Performance
Ongoing Research Support

R01: CA246600 Noar (PI) 9/17/2019-8/31/2022
Advancing Perceived Message Effectiveness: A New Measure for Youth Prevention Media Campaigns
The primary goal of the proposed project is to develop and validate an *effects* PME scale for adolescent tobacco prevention ads using rigorous scale development methods. Another goal is to compare the performance of this new scale to the FDA's *message* PME scale in a longitudinal validation experiment.
Role: Co-Investigator

R01: MD012832 Kneipp (PI) 6/10/2019-1/31/2024
NC Works4Health: Reducing Chronic Disease Risk in Socioeconomically Disadvantaged, Unemployed Populations
Particularly for socioeconomically disadvantaged adults, unemployment can trigger a cascade of stress-related coping and behavioral processes that increase risk factors for chronic disease. Interventions to mitigate chronic disease risks while in employment programs at the individual level, and to provide supervisory supports at the employer level could have a positive, cumulative impact on reducing health inequities within communities.
Role: Co-Investigator

R01: HD093901 Stuebe (PI) 9/7/2018-7/31/2023
Mood, Mother, and Child: The Psychobiology of Dyadic Resilience
This study identifies the psychobiological underpinnings of resilience among mother-child dyads exposed to maternal depression, a common and morbid condition that impacts the health of more than 400,000 mother-infant dyads every year.
Role: Co-Investigator

R01: MH110186 Pettifor (PI) 4/22/2016-1/31/2021
Multilevel mechanisms of HIV acquisition in young South African women

The overall objective of this application is to determine the effect and mechanisms of effect of key social determinants measured at multiple levels (e.g., individual, household, and community) that influence HIV acquisition in young women in South Africa.
Role: Co-Investigator

Completed Research Support (past 3 years; selected)

K01: DA035153 Gottfredson (PI) 5/01/2014-4/30/2020
The Impact of Affect Regulatory Mechanisms and Binge Eating on Drug Recovery
The goal of the research supported by this early researcher career development award is to understand circumstances leading to compensatory binge eating in individuals recovering from substance dependence and to evaluate whether and how this behavior relates to relapse and recovery.
Role: Principal Investigator

R01: DA037215 Hussong (PI) 9/15/2014-8/31/2019
Peer Mechanisms in the Internalizing Pathway to Substance Use
This prospective study evaluates the role of peer social networks on the development of an internalizing pathway to substance use and disorder in a large adolescent sample.
Role: Co-Investigator

OMB No. 0925-0001 and 0925-0002 (Rev. 03/2020 Approved Through 02/28/2023)

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: **Lich, Kristen Hassmiller**

eRA COMMONS USER NAME (credential, e.g., agency login): eRA COMMONS USER NAME

POSITION TITLE: **Associate Professor**

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE	Completion Date	FIELD OF STUDY
University of Akron, Akron, OH	BS	12/1996	Psychology
University of Michigan, Ann Arbor, MI	MHSA	05/2000	Health Management & Policy
University of Michigan, Ann Arbor, MI	PhD	05/2007	Health Services Organization & Policy

A. Personal Statement

I am an Associate Professor of Health Policy and Management at the University of North Carolina at Chapel Hill. As a Co-Investigator on Project 4, I will assist with the engagement of stakeholders in the proposed modeling work and to aid in the visualization and dissemination of cost-effectiveness results. I specialize in the application of systems thinking, operations research, and complex systems simulation modeling to inform and improve the population-level impact of health care delivery, policy, and cross-sector collaboration seeking to improve health. As a methodologist, I have worked on a variety of problems, with a focus on system strengthening in each:

- understanding the complex factors affecting tobacco use to estimate the relative impacts of alternate approaches to reducing initiation and supporting cessation;
- optimizing acute care systems for transition-aged youth and adults with mental illness;
- evaluating the impact of behavioral risk factors on the spread of infectious disease and its control;
- studying and simulating disparities in colorectal cancer screening, and the impact, feasibility, and efficiency of alternate approaches to reducing them at the population-level;
- re-allocating resources to better support the translation of evidence-based practices into real world stroke outcomes among Veterans; and,
- supporting public-private collaborations to strengthen systems of care that span multiple organizations (for example, supporting families in the 6 months after a baby is born, or clinical/educational/social service systems serving families with children/youth with special health care needs).

My research passion is to advance the way we use system maps, models (both qualitative and quantitative) and local data with stakeholders to improve understanding of complex systems and to inform policy and practice. I have been invited to introduce and train on the use of systems science methods in a variety of settings, including the CDC, the World Health Organization, the NIH, and the Veterans Health Administration. I support numerous practice-based collaborations in doing this work, and have taught these methods at UNC, the University of Michigan, and at the NIH-sponsored Institute for Systems Science and Health, as well as to public health workforce through my role in both the National Maternal and Child Health Workforce Development Center and the Family Planning National Training Center.

B. Positions and Honors

Positions and Employment

2006 Instructor of Health Policy & Management, Gillings School of Global Public Health, The University of North Carolina at Chapel Hill, NC

2007- Associate Professor (current title) of Health Policy & Management, Gillings School of Global Public Health, The University of North Carolina at Chapel Hill, NC

2013- Systems Integration Core Lead, National Maternal and Child Health Workforce Development Center

Selected Honors

2015 Inaugural 2015 Systems Science Scholarship, AcademyHealth
2017 Robert H. DuRant Award for Statistical Rigor and Innovation in Adolescent Health Research, Society for Adolescent Health and Medicine

C. Contributions to Science

1. **Systems dynamic modeling in VA stroke care.** In the Veterans Administration (VA), a national accountable care organization, it is difficult to know how to allocate limited resources to best support the health of the Veteran population. Charged with guiding the prioritization of research and practice-based improvement efforts, I led a team working with the Stroke Quality Enhancement Research Initiative (QUERI) that turned to system dynamics modeling to first shape and then estimate the relative impact of 15 alternate intervention scenarios for translating best evidence into practice VA-wide would have on the quality of life of Veterans. The model guided decision making over time, taking into account Veteran risk profiles, characteristics of current practice, and best evidence on disease etiology and intervention.

    a. **K Hassmiller Lich**, Y Tian, CA Beadles, LS Williams, DM Bravata, EM Cheng, HB Bosworth, JB Homer, DB Matchar. Strategic Planning to Reduce the Burden of Stroke among Veterans: Using Simulation Modeling to Inform Decision Making. *Stroke.* 2014:45(7);2078-2084. PMCID: PMC4287261.
    b. Y Tian, **K Hassmiller Lich,** ND Osgood, K Eom, DB Matchar. Linked Sensitivity Analysis, Calibration, and Uncertainty Analysis Using a System Dynamics Model for Stroke Comparative Effectiveness Research. *Medical Decision Making*. 2016;36(8):1043-57. PMID: 27091379.
    c. CA Beadles, MA Kaufman, J Homer, E Cheng, LS Williams, DM Bravata, D Matchar, HB Bosworth, **K Hassmiller Lich** (presenter). Using System Dynamics Tools to Integrate Evidence into VA Stroke Care. Peer-reviewed oral presentation at the VA Health Services Research & Development National Meeting: Washington, DC; March 2011.

2. **Colorectal cancer (CRC) screening and control.** Colorectal cancer (CRC) screening is effective, but current rates are sub-optimal, particularly among vulnerable populations. There is little guidance available for policymakers about how to prioritize investment for effective interventions. We sought to leverage population-level data (claims, health services, behavioral/risk factor, cancer registry) to better understand current practice (who currently gets screened versus does not, with which screening modality) as well as the determinants of existing disparities. We used discrete choice experiments to disentangle patients' preferences for alternate intervention programs – for example, assessing the value of making screening cheaper versus offering greater choice in screening options versus decreasing driving time to screening locations. We conducted interviews with state and national-level decision makers to understand their preferences and concerns for competing intervention options. Finally, we integrated all of this understanding in individual-level computer simulation models to translate potential screening scenarios into population-level screening outcomes (and estimated disparities), cost, and health outcomes across the state of North Carolina. We have recently been re-funded to extend this work to additional states.

    a. **KM Hassmiller Lich**, DA Cornejo, ME Mayorga, M Pignone, FKL Tangka, LC Richardson, TM Kuo, AM Meyer, IJ Hall, JL Smith, TA Durham, SA Chall, TM Crutchfield, SB Wheeler. Cost-Effectiveness Analysis of Four Simulated Colorectal Cancer Screening Interventions, North Carolina. *Prev Chronic Dis*. 2017; 14:E18. PMCID: PMC5325466.
    b. SB Wheeler, TM Kuo, RK Goyal, AM Meyer, **K Hassmiller Lich**, EM Gillen, S Tyree, CL Lewis, TM Crutchfield, CE Martens, F Tanqka, L Richardson, MP Pignone. Regional variation in colorectal cancer testing and geographic availability of care in a publicly insured population. *Health Place*. 2014;29:114-123. PMID: 25063908.
    c. MP Pignone, TM Crutchfield, PM Brown, ST Hawley, JL Laping, CL Lewis, **K Hassmiller Lich**, LC Richardson, FK Tangka, SB Wheeler. Using a discrete choice experiment to inform the design of programs to promote colon cancer screening for vulnerable populations in North Carolina. *BMC Health Serv Res*. 2014;14:611. PMCID: PMC4267137.

3. **Asthma care and control.** Despite tremendous investment in improving care for asthmatic youth, we continue to observe sub-optimal control in practice. Systems thinking methods offer a rich tool for helping a group of diverse experts (research and practice-based) understand what limits real-world impact. We engaged a team of stakeholders using system dynamics methods to understand where care and effective control behaviors break down. What factors across socio-ecological levels most need to be targeted? In a line of work focused on asthma, we have integrated insights from population-level data, stakeholder engagement, and health behavior theory to enrich our understanding of how to develop better control interventions targeting parents/caregivers of asthmatic children.

    a. E Gillen, **K Hassmiller Lich,** KB Yeatts, ML Hernandez, TW Smith, MA Lewis. Social Ecology of Asthma: Engaging Stakeholders in Integrating Health Behavior Theories and Practice-Based Evidence through Systems Mapping. *Health Education & Behavior.* 2014;41(1):63-77. PMID: 23709516.
    b. **K Hassmiller Lich**, K Minyard, R Niles, G Dave, *E Gillen* (2014). System Dynamics and Community Health. In JG Burke & S Albert (Eds.), Emerging Methods in Community Public Health Research.
    c. **K Hassmiller Lich**, D Travers, W Psek, M Weinberger, K Yeatts, W Liao, SJ Lippmann, L Njord, A Waller. Emergency Department Visits Attributable to Asthma in North Carolina, 2008. *North Carolina Medical Journal.* 2013;74(1):9-17. PMID: 23530373.
    d. D Travers, **K Hassmiller Lich**, S Lippmann, M Weinberger, K Yeatts, W Liao, A Waller. Defining Emergency-Department Asthma Visits for Public Health Surveillance, North Carolina 2008-2009. *Preventing Chronic Disease.* 2014:11;E100-110. PMCID: PMC4060874.

4. **Incorporating stakeholders and decision makers in systems science methods.** I have supported the use of systems science methods to help diverse stakeholder groups and decision makers better understand the complex factors shaping outcomes they seek to impact. I have supported numerous students at all academic levels in using these methods as part of their theses and dissertations (Undergraduate, Masters, PhD, and DrPH). I have facilitated numerous research meetings making use of these methods, and have taught on the value of these methods to audiences at the Centers for Disease Control and Prevention, National Institutes of Health, and other national and international training meetings. Through a HRSA-funded Maternal and Child Health Workforce Development Center, initially funded in the fall of 2013, I lead training efforts in systems methods. In this role, I have worked extensively with nearly all US state and territorial teams representing public health, consumers, health care professionals, payers, and other governmental sectors seeking to improve disconnected systems of care.

    a. L Frerichs, **K Hassmiller Lich**, G Dave, G Corbie-Smith. Integrating Systems Science and Community-Based Participatory Research to Achieve Health Equity. *American Journal of Public Health.* 2016;106(2):215-222. PMCID: PMC4815818.
    b. L Frerichs, **K Hassmiller Lich**, M Funchess, M Burrell, C Cerulli, P Bidell, AM White. Applying Critical Race Theory to Group Model-Building Methods to Address Community Violence. *Progress in Community Health Partnerships.* 2016;10(3):443-459. PMID: 28230552. PMCID: PMC6052436.
    c. **K Hassmiller Lich**, E Ginexi, NP Osgood, P Mabry. A Call to Address Complexity and Dynamic Systems in Prevention Research. *Prevention Science.* 2013;14(3):279-289. PMID: 22983746.
    d. JP Morrissey**, K Hassmiller Lich**, R Anhang Price, J Mandelblatt. Computational modeling and multilevel cancer control interventions. *Journal of the National Cancer Institute.* 2012;2012(44):56-66. PMCID: PMC3482961.

Complete List of Published Work in MyBibliography:
https://www.ncbi.nlm.nih.gov/sites/myncbi/1xWamsi0xbkkc/bibliography/48047360/public/?sort=date&direction=descending.

D. Additional Information: Research Support

Ongoing Research Support

NIH: R15 MD011502-01 Apostolopoulos, Sönmez (Co-PIs) 01/19-12/22
Delineating Hispanic Immigrants' Allostatic Load Dynamics through Systems Modeling

Based on complex systems methodologies, the goal of the proposed study is to delineate how complex and interacting social, immigration, health, and labor policies and work and non-work environments influence low-skill/-pay service-sector Latino immigrant workers' excess allostatic load and associated syndemicity over time, and to identify high-leverage intervention points to reverse deteriorating trends.
Role: Co-Investigator

US DHHS HRSA, Maternal and Child Health Bureau (MCHB): No Number Cilenti (PI) 09/13-08/21
National Consolidated Center for MCH Workforce Development
The goal of the Workforce Development Center is to support State and Territorial Title V (MCH public health) workforce in ensuring optimal MCH outcomes in a time of funding restrictions, health care transformation, and ever increasing population need through the use of systems integration methods that address social and environmental determinants of health, engage stakeholders and consumers, align investments and demonstrate collaboration on the use of data. I lead the Systems Integration Core in developing and offering universal training (web-based self-directed), targeted training (live and web-based short courses), and intensive training (methodological consulting/advising) on practical systems science approaches. Phase 1 of the Center was 2013-2016; Phase 2 (current) is 2016-2021.
Role: Co-Investigator and core lead

US DHHS Office of Population Affairs: 37223.2017.0001 Webb (PI) 09/16-08/20
Family Planning National Training Center for Service Delivery Improvement
This Center is funded to support training and technical assistance for Federal recipients of Title X grants, who are supporting population-level family planning. I lead the UNC team, which focuses on providing coaching to grantees and their teams as they uncover adaptive challenges threatening their service system's ability to deliver quality family planning to anyone in need and grow the capacity to address such challenges in an ever-changing context. Another component to guiding our adaptive leadership and system improvement support is developing and validating adaptive leadership competencies and related assessment tools and online toolkits to guide family planning workforce in system improvement work in the face of uncertainty and change.
Role: UNC Subcontract PI

NIH: 1-UG3-CA233251-01 Reuland (PI) 09/18-09/19
Scaling Colorectal Cancer Screening Through Outreach, Referral, and Engagement (SCORE)
This project is innovative in combining outreach and in-reach evidence-based interventions and in its use of stakeholder engaged simulation modeling to inform sustainability of interventions to reduce CRC morbidity, mortality, and disparities in vulnerable communities.
Role: Co-Invstigator

CDC: SIP-14-010 Wheeler (PI) 09/15-09/19
Special Interest Project: Colorectal cancer screening in underserved communities in North Carolina
This project extends a completed CDC Special Interest Project with the same title, seeking to inform local, state, and national efforts to improve colorectal cancer screening practices, programs, and policies and to inform health targets. We will update and use the simulation model developed in that grant to develop several scenarios for what it would take to reach established screening targets (e.g., Healthy People 2020). We will also estimate the impact of failing to extend Medicaid eligibility in North Carolina.
Role: Co-investigator

OMB No. 0925-0001 and 0925-0002 (Rev. 03/2020 Approved Through 02/28/2023)

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: **Hernandez, Michelle L.**

eRA COMMONS USER NAME (credential, e.g., agency login): eRA COMMONS USER NAME

POSITION TITLE: **Associate Professor, Department of Pediatrics; Division of Allergy, Immunology & Rheumatology**

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
University of North Carolina Chapel Hill	BS	12/1997	Biology
University of North Carolina Chapel Hill	MD	05/2002	Medicine
University of North Carolina Chapel Hill		06/2005	Pediatrics
University of California San Diego		07/2007	Postdoctoral Fellowship in Allergy & Immunology

A. Personal Statement

I am a pediatric allergist and immunologist with expertise in translational and clinical research. My work to date has focused on a) understanding how inhaled pollutants exacerbate innate immune inflammatory responses in allergic asthma; b) testing novel, anti-inflammatory therapies, including IL-1 blockade with anakinra, to mitigate these complications; and c) testing patient-reported outcome measures and use of mobile health technology in adolescents with poorly-controlled asthma.

I have the expertise, training, and leadership experience to serve as your primary clinical partner on this proposal "The impact of clinic-level financial incentives on HPV vaccine communication and uptake." I have successfully led and collaborated with other basic and clinical investigators at UNC and other university systems, study coordination staff, and regulatory agencies. I serve as the Pediatric and Adolescent Director of the North Carolina Network Consortium and direct the NC Child Health Research Network, two practice-based research networks. I am also the Associate Director of Clinical Research and Director of the Clinical Research Unit for the Children's Research Institute for the UNC Department of Pediatrics. Selected publications based on investigator-initiated practice-based research studies are highlighted below:

Relevant publications

1. Todorich K, Bangdiwala S, Vadlamudi A, Alarcon L, **Hernandez M**. Assessing asthma in African American children using the Asthma Control Test and the Childhood Asthma Control Test. *Ann Allergy Asthma Immunol*. 2015 Jan 30. PMID: 25648566
2. Burbank AJ, Grabich SC, Todorich K, Frye M, Loughlin C, Duncan KE, Robinette C, Mills KH, Peden DB, Diaz-Sanchez D, **Hernandez ML**. Impact of Aeroallergen Sensitization on Asthma Control in African-American Teens with Persistent Asthma. *Ann Allergy Asthma Immunol* 2016, Oct;117(4):442-444. PMID: 27566861
3. Burbank AJ, Todorich K, Steele P, Rosen J, Zhou H, Frye M, Loughlin CE, Ivins S, Mills K, Dembnicki Massey L, Reeve BB, **Hernandez ML.** Age and African-American race impact the validity and reliability of The Asthma Control Test in persistent asthmatics. *Respir Res 2018, Aug 15;19(1):152*. PMID: 30111326
4. **Hernandez ML**, Dhingra R, Burbank AJ, Todorich K, Loughlin CE, Frye M, Duncan K, Robinette C, Mills K, Devlin RB, Peden DB, Diaz-Sanchez D. Low-level ozone has both respiratory & systemic

effects in African-American adolescents with asthma despite asthma controller therapy. *J Allergy Clin Immunol*. 2018 Dec;142(6):1974-1977. PMID: 30102937

B. Positions and Honors

Positions & Employment

2007-2010	Clinical Assistant Professor, Department of Pediatrics, Division of Allergy, Immunology, Rheumatology & Infectious Diseases, University of North Carolina at Chapel Hill.
2010-2016	Assistant Professor, Department of Pediatrics, Division of Allergy, Immunology, & Rheumatology, University of North Carolina at Chapel Hill.
2016-present	Associate Professor, Department of Pediatrics, Division of Allergy, Immunology, & Rheumatology, University of North Carolina at Chapel Hill.
2018-present	Pediatric and Adolescent Director, North Carolina Network Consortium
2018-present	Director, North Carolina Child Health Research Network
2019-present	Associate Director of Clinical Research, Children's Research Institute, UNC Department of Pediatrics
2020-present	Director, Clinical Research Unit, Children's Research Institute, UNC Department of Pediatrics

Other Experience and Professional Memberships

2002-present	American Academy of Pediatrics
2005-present	American Academy of Allergy, Asthma, and Immunology (AAAAI)
2013-present	American Thoracic Society
2013-present	Reviewer, The Journal of Allergy & Clinical Immunology
2015-2019	Section Editor: Allergies and the Environment, Current Allergy & Asthma Reports
2016-present	Member, Environmental and Occupational Respiratory Diseases Committee, AAAAI
2017-present	Clinical Sciences Working Group, AAAAI
2017-2018	AAAAI Leadership Mentorship Program
2011-present	Associate Director, NC Children's Allergy and Asthma Center
2015-present	Society for Pediatric Research
2017-present	Member, ECHO Airways Outcomes Working Group
2020-2026	Respiratory Integrative Biology and Translational Research Study Section Member

Scholarships and Awards

1998-2002	University of North Carolina Medical Alumni Association Scholarship, UNC School of Medicine
2004	University of North Carolina Hospitals, Housestaff Officer of the Year Award
2005	UNC Department of Pediatrics, The Floyd W. Denny Pediatric Society Resident Award
2005	Wake Medical Center, Resident of the Year Award
2013-2014	Academic Career Leadership Academy in Medicine program at the UNC School of Medicine
2014	AAAAI/ARTrust Gail G. Shapiro Clinical Faculty Award
2014	Alpha Omega Alpha
2016	Excellence in Teaching & Mentoring of Fellows Award, UNC Department of Pediatrics
2017-2019	Best Doctors in America

C. Contributions to Science

1. **Role of TLRs in resolution of otitis media:** My post-doctoral fellowship at the University of California San Diego was based out of an otolaryngology lab focused on the role of innate immunity in the resolution of otitis media. This topic was of particular interest to me as a pediatrician, as this is one of the most common medical problems in children. We found that an intact innate immune system is essential for fast resolution of infection in the middle ear after infection with *non-typeable H. influenzae*, and dysregulated immune defense and inflammatory responses may contribute to recurrent or chronic otitis in children.

    a. **Hernandez ML*,** Leichtle A*, Pak K, Ebmeyer J, Euteneuer E, Obonyo M, Guiney DG, Webster N, Broide DH, Ryan AF and Wasserman SI. MyD88 is required for the resolution of Otitis Media. *J*

Infect Dis. 2008 Dec 15;198(12):1862-9. *The two authors contributed equally to this work. *PMCID: PMC3584630*

b. Leichtle A*, **Hernandez M***, Pak K, Yamasaki K, Cheng CF, Webster NJ, Ryan AF, Wasserman SI. TLR4-mediated induction of TLR2 signaling is critical in the pathogenesis and resolution of otitis media. *Innate Immun*. 2009 August 15(4):205-15. *The authors contributed equally to this work. PMC3565845

c. Leichtle A*, **Hernandez M*,** Pak K, Yamasaki K, Radek K, Choung YH, MD, Euteneuer S, Gallo R, Ryan AF, Wasserman SI. CCL3 Overcomes the Bactericidal and Phagocytic Defect of Macrophages and Hastens Recovery from Experimental Otitis Media in TNF-/- Mice. *J Immunol*. 2010 Mar 15; 184(6): 3087-97. *The authors contributed equally to this work. NIHMS224551

d. **Hernandez M***; Leichtle A*; Pak K; Webster NJ; Wasserman SI; Ryan AF. The transcriptome of a complete episode of acute otitis media. *BMC Genomics*. 2015 Apr 3;16:259. *The authors contributed equally to this work. PMC4394589

2. **Effect of ozone and endotoxin on asthmatic airway inflammation:** Environmental exacerbations of asthma result from pollutant-induced stimulation of innate immunity to promote airway neutrophilic inflammation. Using inhaled LPS as a challenge agent to activate airway macrophages, we found that atopic asthmatics had decreased airway inflammatory cell recruitment and decreased IL-1β production compared to normal volunteers. However, with a controlled high dose ozone exposure, atopic asthmatics have an exaggerated IL-1β -driven airway inflammatory response. The site of the initial inflammatory trigger (i.e. macrophage activation such as with LPS or epithelial cell activation such as with ozone exposure) can dramatically alter airway inflammatory responses, and should be examined further as we identify therapeutics that can mitigate airway inflammation while preserving immune function.

a. **Hernandez M,** Zhou H, Zhou B, Robinette C, Crissman K, Hatch G, Alexis NE, Peden D. Combination treatment with high-dose vitamin C and alpha-tocopherol does not enhance respiratory-tract lining fluid vitamin C levels in asthmatics. *Inhalation Toxicol.* 21(3):173-81, 2009. PMID: 18932058

b. **Hernandez ML**, Lay JC, Harris BD, Esther Jr. CR , Brickey J, Bromberg PA, Diaz-Sanchez D, Devlin RB, Kleeberger SR, Alexis NE, Peden DB. Atopic Asthmatics but not atopics without asthma have enhanced inflammatory response to ozone. *J Allergy Clin Immunol*, 2010 Sep;126(3):537-44.e1 PMC2949284

c. **Hernandez M**, Brickey WJ, Alexis NE, Fry RC, Rager JE, Zhou B, Ting JP, Zhou H, Peden DB. Airway cells from atopic asthmatic patients exposed to ozone display an enhanced innate immune gene profile. *J Allergy Clin Immunol.* 2012 Jan;129(1):259-261.e2. PMC3254026

d. **Hernandez ML**, Dhingra R, Burbank AJ, Todorich K, Loughlin CE, Frye M, Duncan K, Robinette C, Mills K, Devlin RB, Peden DB, Diaz-Sanchez D. Low-level ozone has both respiratory & systemic effects in African-American adolescents with asthma despite asthma controller therapy. *J Allergy Clin Immunol*. 2018 Dec;142(6):1974-1977. PMID: 30102937

3. **Novel anti-inflammatory therapies against neutrophilic airway inflammation:** Oxidative stress is a common pathway to initiate neutrophilic airway inflammation from various environmental exposures, suggesting that anti-inflammatory approaches targeting oxidative stress and its sequelae can mitigate adverse health effects. My expertise is centered on the design on early phase clinical studies to test the safety and efficacy of novel therapies for the treatment of asthma and neutrophilic airway inflammation. Using well-characterized models of inhaled endotoxin, ozone, and allergen challenge in human volunteers, we have identified that the vitamin E isoform, gamma tocopherol, and the IL-1 receptor antagonist, anakinra, attenuate neutrophilic airway inflammation. We are testing the efficacy of anakinra on mitigating key features of asthma exacerbations using a model of inhaled allergen challenge.

a. **Hernandez ML**, Wagner JG, Kala A, Mills K, Wells HB, Alexis NE, Lay JC, Jiang Q, Zhang H, Zhou H, Peden DB. Vitamin E Gamma-tocopherol Reduces Airway Neutrophil Recruitment after Inhaled Endotoxin Challenge in Rats and in Healthy Volunteers. *Free Radic Biol Med.* 2013 Jul;60:56-62. PMC3654053

b. Mills K; Lay JC; Wu, W; Robinette C; Kesic, MJ; Dreskin MC; Peden DB; & **Hernandez ML**. Vitamin E, γ-tocopherol, diminishes ex vivo basophil response to dust mite allergen. *Allergy*, 2014 Apr;69(4):541-4.
c. **Hernandez ML**; Mills KM; Almond MT, K; Aleman, MM; Zhang, H; Zhou, H; and Peden, DB. Interleukin-1 receptor antagonist reduces endotoxin-induced airway inflammation in human volunteers. *J Allergy Clin Immunol* 2015 Feb;135(2):379-85. PMC4323893
d. Burbank AJ, Duran CG, Pan Y, Burns P, Jones S, Jian Q, Yang C, Jenkins S, Wells H, Alexis N, Kesimer M, Bennett WD, Zhou Z, Peden DB, and **Hernandez ML**. Gamma tocopherol-enriched supplement reduces sputum eosinophilia and endotoxin-induced sputum neutrophilia in volunteers with asthma. *J Allergy Clin Immunol. 2018* Apr;141(4):1231-1238. PMID: 28736267

Complete List of Published Work in MyBibliography:
https://www.ncbi.nlm.nih.gov/myncbi/1ZsK7gzVC9zkh/bibliography/public/

D. Additional Information: Research Support and/or Scholastic Performance

Ongoing Research Support

Active

R01 HL135235-01 (Hernandez) 08/15/17-6/30/22
NIH/NHLBI
IL-1 receptor blockade as a novel treatment for exacerbation of allergic airway responses in humans
Anakinra is a FDA-approved IL-1 receptor antagonist with a fast onset of action and short half-life. We are examining the effect of the IL-1 receptor antagonist, anakinra, as a rescue treatment for features of viral- and allergen-induced airway inflammatory response and airway hyper-reactivity in allergic volunteers.
Role: Principal Investigator

1915169 (Lobaton-NCSU) (Hernandez-PI UNC) 09/01/19-08/31/23
NSF
SCH: INT: Collaborative Research: A Data-Driven Approach to Enhancing Wearable Device Performance - An Early Asthma Exacerbation Detection Study
In this proposal, we aim to provide an innovative framework for characterizing the performance of wearable devices in the real-world based on contextual information of their usage and demonstrate the framework's value by enabling more reliable early detection of asthma exacerbations in young adults.
Role: UNC Site PI

2012-1067-05 (Hernandez) 9/1/12 -8/31/20
NSF/NCSU Subcontract
Nanosystems Engineering Research Center for Advanced Self-Powered Systems of Integrated Sensors and Technologies (ASSIST)
The focus of our subcontract is for UNC to provide the interface between the sensor development team and the medical research community. Dr. Hernandez will lead collaborative studies testing wearable personal environmental and health monitors in the controlled exposure chambers in the US EPA Health Studies Facility, and work with investigators on testing a portable spirometer device with adolescent asthmatics.
Role: Site Principal Investigator

UL1TR002489-01 (Buse) 03/30/18-02/28/23
NIH
UNC Clinical and Translational Science Award
Major Goals: A national consortium of medical research institutions, funded through Clinical and Translational Science Awards, is working together and shares a common vision: to improve the way biomedical research is conducted across the country, reduce the time it takes for laboratory discoveries to become treatments for patients, engage communities in clinical research efforts, and train the next generation of clinical and translational researchers.
Role: Co-Investigator

UH3OD023348 (O'Shea, Fry) (MPI) 09/1/2018 – 8/31/23
NIH

Environment, Epigenetics, Neurodevelopment & Health of Extremely Preterm Children
The goal of the ECHO Consortium is to identify exposures and mechanisms that link the environment in early life to childhood development and health outcomes. This proposal commits to the ECHO Consortium numerous resources from the Extremely Low Gestation Age Newborn (ELGAN) Study.
Role: Co-Investigator

U01HL130045 (Martinez) 7/1/18-4/30/21
Randomized, placebo-controlled, multicenter study to assess the efficacy, safety and tolerability of ORal Bacterial EXtract for the prevention of wheezing lower respiratory tract illness (ORBEX)
The Primary Prevention of Asthma and Wheezing in Children trial will test if Bronchovaxom, given to children at high risk for asthma, can prevent the development of persistent wheezing by age 3.5-4.5 years.
Role: Co-Investigator

PRIVATE SUPPORT

Completed Research Support (past 3 years)

WITHHELD

(Israel) 12/01/17-5/31/19
PREPARE (Patient Empowered Strategy to Reduce Asthma Morbidity in Highly Impacted Populations)
This multi-site pragmatic clinical trial examines the use of beclomethasone therapy as an adjunct to standard of care albuterol for the management of asthma symptoms in African-American and Hispanic patients with persistent asthma, with the goal of reducing asthma exacerbations requiring systemic corticosteroid therapy.
Role: UNC Site PI

OMB No. 0925-0001 and 0925-0002 (Rev. 03/2020 Approved Through 02/28/2023)

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: **Higgins, Colleen**

eRA COMMONS USER NAME (credential, e.g., agency login):

POSITION TITLE: **Independent Consultant**

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE	Completion Date	FIELD OF STUDY
University of California, San Diego	BA	12/2011	Philosophy
University of North Carolina, Chapel Hill, NC	MSPH	05/2018	Health Policy & Management

A. Personal Statement

I am a strong fit to consult with Drs. Ozawa and Wheeler and their team on the proposed HPV vaccination modeling research in Project 4. I am delighted to participate in this innovative multidisciplinary collaboration, and my experience building agent-based models has uniquely prepared me for my role. My research interests center on developing simulation models that facilitate good decision making by providing stakeholders with useful, well-analyzed health and economic evidence. With a focus on the issue of substandard and falsified antimalarial medicines in the global context, I have been working closely with Dr. Sachiko Ozawa and the Global Health Economics for Pharmacy team at the UNC Chapel Hill Eshelman School of Pharmacy to program agent-based models. The agent-based model we have developed is used to assess the impact, in terms of costs and health effects, of substandard and falsified antimalarial medications on a country-level basis. Beginning with the Democratic Republic of the Congo, I have been involved in programming, researching, and analyzing this model for five countries, adapting the code, inputs, and designs for each. During this time, I transitioned the existing model from NetLogo software to a customized program written in the Python programming language, improving speed and transparency.

My primary basis in economic modeling comes from a rigorous series of modeling courses during my master's studies at the UNC Gillings School of Global Public Health, which included training in the technical, statistical, and theoretical aspects of health economic decision modeling. In an advanced course, I gained direct experience by developing an agent-based model to understand the transmission and progression of pediatric strep throat to rheumatic heart disease in American Samoa. Learning to use the AnyLogic software as I built this model, I employed advanced techniques, like using GIS technology to simulate the movement of children between home and school. Out of interest, I explored the background workings of AnyLogic, learning Java basics in order to make my program run more smoothly. Concurrently, I started programming in Python, specifically focused on learning programming for data professionals. I interned for a German health economics institute where I worked on models measuring the social impact of innovative pharmaceuticals. I learned their modeling techniques within three months, and was asked to continue to work for the team remotely beyond the initial contract. I believe my modeling skills will be a great asset to this proposed project.

B. Positions and Honors

Positions and Employment

2017 Intern, Wirtschaftsforschung (WifOR) (German: 'Economics Research') Social Impact team, Darmstadt, Germany
2017 – 2018 Research Assistant, WifOR, remote
2018 - Independent Consultant, Global Health Economics for Pharmacy, UNC Chapel Hill

Other Experience

2016 – 2018 AcademyHealth Student Chapter: Communications Chair 2017, President 2018
2016 – 2018 AcademyHealth National Member

2019 - International Health Economics Association, Early Career Researcher Member

Honors

2017, 2018 Health Policy & Management departmental award in recognition of strong academic ability and potential to contribute to public health solutions

C. Contributions to Science

1. **Substandard and falsified medicines and impact of antimicrobial resistance.** Working with Dr. Ozawa, I have co-authored research articles on the impact of substandard and falsified antimalarials. My contributions include auditing, writing, and streamlining the code for the substandard and falsified antimalarial research impact (SAFARI) model, as well as researching inputs and contributing to manuscript writing. As a part of this process, I transitioned a model written in NetLogo to Python by developing a unique structure that governs the movements and data processing in the model. Instead of using object-oriented language which can be slow and non-transparent, I created my own method for manipulating arrays of data; writing my own functions to drive the entire program. The result is a direct and fully customizable agent-based model, without the use of interface software or built-in agent-based modeling functions. With the background programming completed and a data structure already conceptualized, the basis for the SAFARI model is ready to be used for our future modeling work.

    a. Ozawa S, Evans DR, **Higgins CR**, Laing SK, Awor P. Development of an agent-based model to assess the impact of substandard and falsified anti-malarials: Uganda case study. *Malaria journal*. 2019;18:5. PMID: 30626380. PMCID: PMC6327614.
    b. Evans DR, **Higgins CR**, Laing SK, Awor P, Ozawa S. Poor-quality antimalarials further health inequalities in Uganda. *Health Policy and Planning*. 2019 Dec 1;34(Supplement_3):iii36-iii47. PMID: 31816072 PMCID: PMC6901073
    c. Beargie SM, **Higgins CR**, Evans DR, Laing S, Erim D, Ozawa S. The economic impact of substandard and falsified antimalarial medications in Nigeria. *PloS One*. 2019 Aug 15;14(8):e0217910. PMID: 31415560. PMCID: PMC6695148.
    d. Ozawa S, **Higgins CR**, Yemeke T, Nwokike JI, Evans L, Hajjou M, Pribluda V. Importance of medicine quality in achieving universal health coverage. *PloS One*. 2020 Jul 9;15(7):e0232966. PMID: 32645019. PMCID: PMC7347121

D. Additional Information: Research Support

Ongoing Research Support

PRIVATE SUPPORT Ozawa (PI) 8/01/18 – 7/31/21

The aim of this study is to perform a systematic literature review and meta-analysis to examine the linkage between children's cognitive function and later outcomes in educational attainment, employment, and income.
Role: Co-Investigator

PRIVATE SUPPORT Ozawa (PI) 1/15/20 – 9/01/20

The aim of this study is to perform a return on investment analysis of risk-based post market surveillance of antibiotics and antimalarials in Tanzania.
Role: Co-Investigator

Completed Research Support (past 3 years)

PRIVATE SUPPORT Ozawa (PI) 3/01/19 – 6/28/19

Importance of Medicine Quality in Achieving Universal Health Coverage

The goal of this study is to investigate the role of medicine quality in the planning and development of Universal Health Coverage.
Role: Co-Investigator

OMB No. 0925-0001 and 0925-0002 (Rev. 03/2020 Approved Through 02/28/2023)

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: **Ibrahim, Joseph**

eRA COMMONS USER NAME (credential, e.g., agency login): eRA COMMONS USER NAME

POSITION TITLE: **Alumni Distinguished Professor**

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE	Completion Date	FIELD OF STUDY
University of Minnesota	BS	06/1983	Mathematics
University of Minnesota	MS	07/1988	Statistics
University of Minnesota	PhD	07/1988	Statistics

A. Personal Statement

Dr. Joseph Ibrahim, Alumni Distinguished Professor of biostatistics at UNC, is principal investigator of two National Institutes of Health (NIH) grants for developing statistical methodology related to cancer and genomics research. Dr. Ibrahim is the Director of the Biostatistics and Data Management Core at UNC's Lineberger Comprehensive Cancer Center. Dr. Ibrahim is currently the biostatistical core leader for the currently NIH funded breast SPORE and he is the Biostatistics Core Faculty Director of the Lineberger Comprehensive Cancer Center (LCCC) at UNC. Dr. Ibrahim's areas of research focus are Bayesian inference, missing data problems, medical imaging analysis, and genomics. He received his Ph.D. in statistics from the University of Minnesota in 1988. With over 26 years' experience working in cancer clinical trials, Ibrahim directs the UNC Laboratory for Innovative Clinical Trials. He is also the Director of Graduate Studies in UNC's Department of Biostatistics, as well as the Program Director of the cancer genomics training grant in the department. Ibrahim has served on several national committees and study sections, including being the Section Chair of the Section on Bayesian Statistical Science of the American Statistical Association and the Biostatistical Methods and Research Design (BMRD) NIH Study Section. He has also served as the Associate Editor for several statistical journals and is currently serving and the Editor of *JASA - Application and Case studies.* Dr. Ibrahim has published over 330 research papers, most in top statistical journals. He also has published two advanced graduate-level books on Bayesian survival analysis and Monte Carlo methods in Bayesian computation. He is an elected fellow of the American Statistical Association and the Institute of Mathematical Statistics, an elected fellow of the international society of Bayesian Analysis, an elected member of the International Statistical Institute.

For the past 22 years, Dr. Ibrahim, his students, and his co-workers, has been deeply engaged in cancer clinical trials and genomics research. In clinical trials, Dr. Ibrahim has developed methods for meta-analysis and network meta-analysis, adaptive methods for Bayesian design and analysis of clinical trials, and informative prior elicitation based on historical data for Bayesian clinical trials design and analysis. In genomics, Dr. Ibrahim has specifically examined statistical issues in motif discovery, gene expression analysis, eQTL, single cell sequencing, Chip-seq and RNA-seq analysis. Dr. Ibrahim has also been deeply invested in developing Bayesian survival analysis methods for cancer clinical trials and genomic data.

B. Positions and Honors

Positions:

1988-1994 Assistant Professor, Division of Statistics, Northern Illinois University
1994 Associate Professor, (with tenure), Division of Statistics, Northern Illinois University
1994-1996 Assistant Professor, Department of Biostatistics, Harvard University, and Department of Biostatistical Science, Dana-Farber Cancer Institute

1996-2002	Associate Professor, Department of Biostatistics, Harvard University, and Department of Biostatistical Science, Dana-Farber Cancer Institute
2002-	Professor (with tenure), Department of Biostatistics, University of North Carolina at Chapel Hill, Chapel Hill, NC
2006-	Alumni Distinguished Professor, Department of Biostatistics, University of North Carolina at Chapel Hill and Director of the Biostatistics and Data Management Core Facility of UNC Lineberger Comprehensive Cancer Center

Honors:

1999	Elected Fellow, American Statistical Association
2000	Elected Fellow, Institute of Mathematical Statistics
2000	Elected member, International Statistical Institute
2020	Elected Fellow of the International Society of Bayesian Analysis

C. Contribution to Science

1. **Missing Data Methods for Regression Models:** Dr. Ibrahim has developed the EM by the method of weights for handling missing responses and/or covariates in general regression models, and this methodology has a wide variety of applications in genomics data, big data, and survival analysis. Representative publications in missing data include:

   a. **Ibrahim, JG**, Lipsitz, SR, and Chen, MH, "Missing Covariates in Generalized Linear Models When the Missing Data Mechanism is Nonignorable," *Journal of the Royal Statistical Society, Series B*, 1999; **61**:173-190.
   b. **Ibrahim, JG**, Chu, H, and Chen, MH, "Missing Data in Clinical Studies: Issues and Methods," *Journal of Clinical Oncology*, 2012; **30**:3297-3303. PMC3948388
   c. Zhu, H**, Ibrahim**, JG, Chen, MH, "Diagnostic Measures for the Cox Regression Model with Missing Covariates," *Biometrika*, 2015; **102:**907-923. PMC4760115
   d. Wu, J, **Ibrahim, JG**, Chen, MH, Schifano, ED, and Fisher, JD, "Bayesian Modeling and Inference for Nonignorably Missing Longitudinal Binary Response Data with Applications to HIV Prevention Trials," *Statistica Sinica*, 2018; **28**:1929-1963. PMC6309964

2. **Informative Prior Elicitation Using the Power Prior:** Dr. Ibrahim's second fundamental contribution to science involves developed the so-called power prior, which is an informative prior constructed from historical data to be used in a Bayesian analysis. The power prior has major applications to the analysis of clinical trials data where raw historical data or summaries of historical data are typically available. The power prior has enjoyed widespread popularity in the design and analysis of clinical trials and has become a standard tool in software packages such as SAS and R as well as in textbooks. Some representative publications include:

   a. **Ibrahim, JG**, and Chen, MH, "Power Prior Distributions for Regression Models," *Statistical Science*, 2000; **15**:46-60.
   b. **Ibrahim, JG**, Chen, MH, and Sinha, D, "On Optimality Properties of the Power Prior," *Journal of the American Statistical Association*, 2003; **98**:204-213.
   c. **Ibrahim JG**, Chen, MH, Lakshminarayanan, M, Liu, GF, and Heyse, JF, "Bayesian Probability of Success for Clinical Trials Using Historical Data," *Statistics in Medicine*, 2015; **34**:249-264. PMC4676938
   d. **Ibrahim, JG**, Chen, MH, Gwon, Y, and Chen, F "The Power Prior: Theory and Applications," *Statistics in Medicine*, 2015; **34**:3724-3749. PMC4626399

3. **Bayesian Methods for Survival Analysis:** A third major contribution to science of Dr. Ibrahim is to Bayesian survival analysis, especially in connection to the development of the cure rate model for analyzing time to event data and the development of joint models for longitudinal and survival data with major applications in cancer vaccine studies, AIDS studies, and the analysis of quality of life in cancer clinical trials. Some representative publications include:

   a. **Ibrahim, JG**, Chu, H, and Chen, L, "Basic Concepts and Methods for Joint Models of Longitudinal and Survival Data," *Journal of Clinical Oncology*, 2010; **28**:2796-2801. PMC4503792.

b. Zhang, D, Chen, MH, **Ibrahim, JG**, Boye, ME, and Shen, W, "JMFit: A SAS Macro for Assessing Model Fit in Joint Models of Longitudinal and Survival Data," *Journal of Statistical Software*, 2016; **71**, doi: 10.18637/jss.v071.i03. PMC5015698
c. Zhang, D, Chen, MH, **Ibrahim, JG**, Boye, ME, and Shen, W, "Bayesian Model Assessment in Joint Modeling of Longitudinal and Survival Data with Applications to Cancer Clinical Trials," *Journal of Computational and Graphical Statistics*, 2017; **26**:121-133. PMC5321618
d. Wang, Y, **Ibrahim, JG**, Zhu, H, "Partial Least Squares for Functional Joint Models with an application to the Alzheimer's Disease Neuroimaging Initiative Study," *Biometrics*; 2020; in press.

4. **Bayesian Methods for Clinical Trials Design:** A fourth area of major contributions is in Bayesian clinical trials design, especially Bayesian designs that employ the power prior in the design. These types of designs have been recently developed and have enjoyed widespread success and impact for practitioners and applied researchers. They are becoming widely adopted in the pharmaceutical industry and in general statistical practice. Representative publications include:

a. Psioda, MA, Soukap, M, and **Ibrahim, JG**, "A Practical Bayesian Adaptive Design Incorporating Data from Historical Controls," *Statistics in Medicine*, 2018; **37**:4054-4070. PMC6327964
b. Psioda, MA, and **Ibrahim, JG**, "Bayesian Clinical Trial Design Using Historical Data that Inform the Treatment Effect," *Biostatistics*, 2019; **20**:400-415. PMC6587921
c. Psioda, MA, Hu, K, Zhang, Y, Pan, J, **Ibrahim, JG**, "Bayesian Design of Biosimilars Trials Involving Multiple Therapeutic Indications," *Biometrics*; 2020; in press. PMC7170751
d. Psioda, MA, Xu, J, Jiang, Q, Ke, C, Zhao, Y, and **Ibrahim, JG**, "Bayesian Adaptive Basket Trial Design Using Model Averaging," *Biostatistics*, 2020; in press.

5. **Methods for Meta-Analysis and Network Meta-Analysis:** Dr. Ibrahim has made major contributions to the Bayesian methods for meta-analysis (MA) and network meta-analysis (NMA). He has worked on novel methods for MA and NMA for aggregate and individual patient data (IPD) that accommodate high dimensional random effects, multivariate response variables, assessment of homogeneity and consistency, and heavy tailed distributions for MA and NMA data. Some representative publications include:

a. Yao, H, Kim, S, Chen, MH, **Ibrahim, JG**, Shah, AK, and Lin, J, "Bayesian Inference for Multivariate Meta-regression with Partially Observed Within-Study Sample Covariance Matrix," *Journal of the American Statistical Association*, 2015; **110**:528-544. PMC4524568
b. Ma, X, Lian, Q, Chu, H, **Ibrahim, JG**, Chen, Y, "A Bayesian Hierarchical Model for Network Meta-analysis of Multiple Diagnostic Tests," *Biostatistics*, 2018; **19**:71-86. PMC6454495
c. Li, H, Chen, MH, **Ibrahim, JG**, Kim, S, Shah, AK, Lin, J, Tershakovec, AM, "Bayesian Inference for Network Meta-Regression Using Multivariate Random Effects with Applications to Cholesterol Lowering Drugs," *Biostatistics*, 2019; **20**:499-516. PMCID: PMC6676556
d. **Ibrahim, JG**, Kim, S, Chen, MH, Shah, AK, Lin, J, "Bayesian Multivariate Skew Meta-Regression Models for Individual Patient Data," *Statistical Methods for Medical Research*, 2019; **28**:3415-3436. PMC6461541

MyNCBI Bibliography: https://www.ncbi.nlm.nih.gov/myncbi/joseph.ibrahim.1/bibliography/public/

D. Research Support

Ongoing Research Support

PRIVATE SUPPORT (Ibrahim) 7/31/2008 - 12/31/20

Supported Research Agreement with Amgen, Inc.
Sponsor and the University agree to undertake a joint statistical research and training in statistical practice project. Role: Principal Investigator

PRIVATE SUPPORT (Ibrahim) 7/1/2009 - 12/31/20

Methods for Interim Analysis with Incomplete Adjudication of Events

UNC-CH will perform off-site biostatistical data analysis of clinical trials in support of Merck's clinical development projects and publications/presentations of the results. UNC-CH will also develop relevant new statistical techniques for data analysis. Role: Principal Investigator

P01 CA142538 (Kosorok) 4/1/2015 - 3/31/21
National Cancer Institute
Statistical Methods for Cancer Clinical Trials - Project 1: Innovative Biomarker-Integrated Clinical Trial Design and Analysis
This research will provide valuable new designs and statistical methods. These new designs will provide efficient tools for facilitating biomarker discovery; for developing and validating biomarker-based therapies; and for improving the quality and efficiency of cancer clinical trials. Role: Co-Investigator

P01 CA142538 (Kosorok) 4/1/2015 - 3/31/21
National Cancer Institute
Statistical Methods for Cancer Clinical Trials - Project 2: Statistical Methods for Biomarkers and Patient Reported Outcomes in Cancer Trials
The primary goal of this project is to develop and evaluate new statistical methodology for the identification of patient reported outcomes, such as quality of life, in cancer clinical trials. We will also develop several novel statistical methods for establishing formal methods of decision making in cancer clinical trials.
Role: Project Leader

P01 CA142538 (Kosorok) 4/1/2015 - 3/31/21
National Cancer Institute
Statistical Methods for Cancer Clinical Trials - Core A: Administrative Core
The Administrative Core will provide essential administrative and scientific leadership, coordinating the investigators across three institutions into an effective team and facilitating integration of project research, effective dissemination of research results, and management of resources and logistics. Role: Core Contributor

R01 GM070335 (Ibrahim) 7/1/2016 - 6/30/21
National Institute of General Medical Sciences
Bayesian Approaches to Model Selection for Survival Data
In this proposal, we develop Bayesian methodology for high dimensional genomic data. The overarching theme in this proposal is that we develop several novel statistical methods for motif discovery in genomic sequence data. Role: Principal Investigator

P30 CA016086 (Earp, III) 12/1/2016 - 11/30/20
National Cancer Institute
Cancer Center Core Support Grant - Biostatistics and Data Management Core
This is a competing renewal for the Lineberger Comprehensive Cancer Center's Center Core Support Grant from NCI. This proposal includes support for nine scientific programs, 22 shared resources, three staff investigators and budgets for leadership, planning and evaluation, administration and developmental research.
Role: Faculty Director

P50 CA058223 (Perou) 9/1/2018 - 8/31/23
National Cancer Institute
SPORE in Breast Cancer- Core B: Biostatistics & Bioinformatics
Cancer biology and clinical medicine are increasingly dependent upon the management and analysis of data from sequencing, imaging, and mass spectrometry. The SPORE Bioinformatics and Biostatistics Resource will provide design and analysis expertise for all projects and will cover the future needs of developmental research projects and the career enhancement participants. Role: Co-Project Leader

R01 MH086633 (Ibrahim) 11/14/2018 - 6/30/21
University of Texas at Houston
Statistical Analysis of Biomedical Imaging Data in Curved Space

The project proposes to analyze imaging, behavioral, and clinical data from a longitudinal neuroimaging database on early brain development in high-risk children from the Conte study. New statistical methods are developed and verified by using extensive simulation studies and the Conte dataset.
Role: Principal Investigator

UG1 CA233333 (Perou) 3/1/2019 - 2/28/25
National Cancer Institute
UNITS: The UNC / UT National Clinical Trials Network Group Integrated Translational Science Production and Consultation Center
The adoption of genomic medicine in the clinic has incredible potential to clarify disease origins, improve diagnosis, and usher in the era of personalized medicine for cancer patients. In this proposal, we plan to provide methods, know how, and robust technologies, in association with clinical trial specimens, for tumor samples to be evaluated for genomic changes that may be targeted by molecular-based therapies.
Role: Biostatistician

Completed Research Support
P50 CA058223 (Earp, III) 9/14/2012 - 8/31/17
National Cancer Institute
SPORE in Breast Cancer: Core B: Genomics, Biostatsitics & Bioinformatics Core
Our projects are conceptually linked by studies of breast cancer molecular phenotypes, particularly those with the worst prognosis. This Core brings together all the needed expertise and tools for these computational challenges so that advances in breast cancer treatment can be made. Role: Co-Core Director

UL1 TR001111 (Buse) 9/26/2013 - 4/30/18
National Center for Advancing Translational Sciences
North Carolina Translational & Clinical Sciences Institute (NC TraCS) - Biostatistic Services
A national consortium of medical research institutions, funded through Clinical and Translational Science Awards, is working together and shares a common vision: to improve the way biomedical research is conducted across the country, reduce the time it takes for laboratory discoveries to become treatments for patients, engage communities in clinical research efforts, and train the next generation of clinical and translational researchers. Role: Biostatistician

U10 CA181009 (Hayes) 4/22/2014 - 2/28/19
National Institutes of Health
Network Group Integrated Translational Science Centers Application
In this proposal, we plan to provide methods and systems in association with clinical trials for tumor samples to be evaluated for specific changes that may be targeted in therapy. Role: Biostatistician

R01 MH086633 (Zhu) 7/1/2014 - 6/30/19
University of Texas at Houston
Statistical Analysis of Biomedical Imaging Data in Curved Space
The project proposes to analyze imaging, behavioral, and clinical data from a longitudinal neuroimaging database on early brain development in high-risk children from the Conte study. New statistical methods are developed and verified by using extensive simulation studies and the Conte dataset. Role: Subcontract PI

R41 CA213690 (Kaufmann) 8/1/2017 - 7/31/18
AsystBio LLC
STTR: AML-MutationCounter, an Improved Tool to Detect Residual and Recurrent Leukemia
The main goal of this study is to determine whether the AML-MutationCounter tool kit can detect low levels of leukemia. Role: Co-Investigator

OMB No. 0925-0001 and 0925-0002 (Rev. 03/2020 Approved Through 02/28/2023)

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: **Kim, Jane J.**

eRA COMMONS USER NAME (credential, e.g., agency login): eRA COMMONS USER NAME

POSITION TITLE: **Professor of Health Decision Science**

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
Dartmouth College, Hanover, NH	BA	05/95	Psychology
Harvard T.H. Chan School of Public Health, Boston, MA	MS	05/01	Health Policy & Management
Harvard University, Cambridge, MA	PhD	05/05	Health Policy/Decision Sciences

A. Personal Statement

As a consultant for Project 4 of the proposed IMPACT Program, my role will be to advise the development of the agent-based HPV transmission model and oversee the work of Dr. Jennifer Spencer, who is working with me as a post-doctoral fellow. I am the Dean for Academic Affairs and a professor of health decision science at the Harvard T.H. Chan School of Public Health. Trained in health policy and decision science, I apply a wide range of mathematical and statistical modeling tools to evaluate health policy issues related to women's health. Much of my research has focused on developing models to evaluate the clinical benefits and cost-effectiveness of cervical cancer prevention strategies in the U.S. and settings with very limited resources globally. My methodological interests include integrating different methods of operations research to inform health decision-making and service delivery and quantifying the impacts of budget and human resource constraints on program effectiveness and feasibility. The current project draws on my extensive experience in developing, calibrating, and validating mathematical models of HPV transmission and related cancers, leveraging epidemiological, clinical, and economic data from the U.S. setting.

1. **Kim JJ**, Tosteson ANA, Zauber AG, Sprague BL, Stout NK, Alagoz O, Trentham-Dietz A, Armstrong K, Pruitt SL, Rutter CM, on behalf of the PROSPR (Population-based Research Optimizing Screening through Personalized Regimens) consortium. Cancer models and real-world data: Better together. *J Natl Cancer Inst* 2015;108(2). pii: djv316. doi: 10.1093/jnci/djv316. PMCID: PMC4907359.
2. **Kim JJ**, Campos NG, Sy S, Burger EA, Cuzick J, Castle PE, Hunt WC, Waxman A, Wheeler CM on behalf of the New Mexico HPV Pap Registry Steering Committee. Inefficiencies and high-value improvements in current U.S. cervical cancer screening practice: A cost-effectiveness analysis. *Ann Intern Med* 2015; 163:589-597. doi: 10.7326/M15-0420. PMCID: PMC5104349.
3. Burger EA, Lee K, Saraiya M, Thompson TD, Chesson HW, Markowitz LE, **Kim JJ**. Racial and ethnic disparities in human papillomavirus-associated cancer burden with first-generation and second-generation human papillomavirus vaccines. *Cancer* 2016;122(13):2057-66. PMCID: PMC4911256.
4. Campos NG, Tsu V, Jeronimo J, Mvundura M, Lee K, **Kim JJ**. To expand coverage, or increase frequency: Quantifying the tradeoffs between equity and efficiency facing cervical cancer screening programs in low-resource settings. *Int J Cancer* 2017;140(6):1293-1305. PMCID: PMC5516173.

B. Positions and Honors

Positions and Employment

1995-1997	Research Coordinator, Psychopharmacology, Massachusetts General Hospital, Boston, MA
1997-1999	Research Administrator, Transkaryotic Therapies Inc., Cambridge, MA
1998-2000	Research Analyst, Bureau of Health Statistics, Research, and Evaluation, Massachusetts Department of Public Health, Boston, MA
2000-2005	Research Assistant, Harvard Center for Risk Analysis, Boston, MA
2005-2006	Research Associate, Harvard Initiative for Global Health, Cambridge, MA
2006-2013	Assistant Professor of Health Decision Science, Department of Health Policy and Management, Harvard T.H. Chan School of Public Health
2013-2016	Associate Professor of Health Decision Science, Department of Health Policy and Management, Harvard T.H. Chan School of Public Health
2016-Present	Professor of Health Decision Science, Department of Health Policy and Management, Harvard T.H. Chan School of Public Health
2020-Present	Dean for Academic Affairs, Harvard T.H. Chan School of Public Health

Other Experience and Professional Memberships

2000-Present	Member, Society for Medical Decision Making (Trustee since 2016)
2002-Present	Member, International Papillomavirus Society
2005-Present	Member, International Health Economics Association
2004-2009	Board Vice Chair, Massachusetts Asian and Pacific Islanders (MAP) for Health

Honors

2002	Lee Lusted Award for outstanding research, Society for Medical Decision Making
2004	Merit Fellowship for academic promise, Harvard University
2005	Lee Lusted Award for outstanding research, Society for Medical Decision Making
2005	Research Award for the top-ranked oral abstract, International Papillomavirus Society
2008	Best Referee of 2008, *British Medical Journal*
2009	Top Referee of 2009, *Annals of Internal Medicine*
2010	ASPH/Pfizer Young Investigator's Research Award Recipient
2012	Teaching citation award, Harvard T.H. Chan School of Public Health
2013	Burke Global Health Research Fellowship, Harvard Global Health Institute
2014	Mentoring award, Harvard T.H. Chan School of Public Health
2015	Top Referee of 2015, *Annals of Internal Medicine*

C. Contributions to Science

My main contributions to science have been in the area of improving health policy decision-making regarding cervical cancer control in the U.S. and globally using decision science methodology. These contributions include: (1) informing clinical guidelines for cervical cancer screening globally with respect to clinical benefits, costs, and cost-effectiveness; (2) informing HPV vaccine policy with respect to the cost-effectiveness of different target populations in the U.S.; and (3) developing and applying novel decision-analytic methodologies to address public health decisions.

1. **Informing clinical guidelines for cervical cancer screening globally with respect to clinical benefits, costs, and cost-effectiveness.** Advancements in HPV-related cancer epidemiology and medical technology for screening, detection and treatment of cervical disease provide a remarkable opportunity to improve upon secondary prevention efforts. However, they also pose significant challenges for decision-making due to the complex cancer natural history, the long time horizon from HPV acquisition to disease, and remaining knowledge gaps regarding long-term intervention effectiveness. Disease simulation models synthesize the best available data from multiple sources, extrapolate data beyond the time horizon of single studies, reflect parameter and process uncertainty, and identify factors most influential on outcomes. The following publications document the development and application of cervical cancer disease simulation models that have influenced clinical guidelines with respect to optimal and cost-effective cervical cancer screening strategies in the U.S. and globally.

a. **Kim JJ**, Burger EA, Regan C, Sy S. Screening for Cervical Cancer in Primary Care: A Decision Analysis for the US Preventive Services Task Force. *JAMA* 2018;320(7):706-714.
b. **Kim JJ**, Sharma M, Ortendahl J. Optimal interval for routine cytology screening in the United States. *JAMA Intern Med* 2013:173(3):241-2. PMCID: PMC3640804.
c. **Kim JJ**, Campos NG, Sy S, Burger EA, Cuzick J, Castle PE, Hunt WC, Waxman A, Wheeler CM on behalf of the New Mexico HPV Pap Registry Steering Committee. Inefficiencies and high-value improvements in current U.S. cervical cancer screening practice: A cost-effectiveness analysis. *Ann Intern Med* 2015; 163:589-597. doi: 10.7326/M15-0420. PMCID: PMC5104349.
d. **Kim JJ**, Burger EA, Sy S, Campos NG. Optimal cervical cancer screening in women vaccinated against human papillomavirus. *J Natl Cancer Inst* 2016;109(2). pii: djw216. PMCID: PMC5068562.

2. **Informing HPV vaccine policy with respect to the cost-effectiveness of different target populations in the U.S.** With the FDA approval of HPV vaccines in 2006, decisions regarding appropriate recommendations for routine and catch-up vaccination use were deliberated by the CDC and other major guidelines-making organizations in the U.S. Using a dynamic HPV transmission model and disease simulation models of all HPV-associated cancers in women and men (i.e., cervical, vulvar, vaginal, penile, anal, oropharyngeal), I evaluated the cost-effectiveness of HPV vaccination for different target populations and age groups. These publications describe analyses that were used to inform the U.S. Advisory Committee on Immunization Practices (ACIP), which makes vaccine policy recommendations to the CDC, directly contributing to the current U.S. HPV vaccination policy.
   a. **Kim JJ**, Goldie SJ. Health and economic implications of guidelines for HPV vaccination in the United States. *N Engl J Med* 2008; 359(8):821-32. PMCID: PMC3080183.
   b. **Kim JJ**, Goldie SJ. Cost-effectiveness of including boys in a human papillomavirus (HPV) vaccination program in the United States. *BMJ* 2009;339:b3884. PMCID: PMC2759438.
   c. **Kim JJ**, Ortendahl J, Goldie SJ. Cost-effectiveness of HPV vaccination and cervical cancer screening in women older than 30 years in the United States. *Ann Intern Med* 2009;151(8):538-45. PMCID: PMC2779121.
   d. **Kim JJ**. Targeted human papillomavirus vaccination of men who have sex with men in the USA: a cost-effectiveness modelling analysis. *Lancet Infect Dis* 2010;10(12):845-52. PMCID: PMC3982926.

3. **Decision science and mathematical modeling methodology.** Mathematical models are powerful tools in synthesizing available evidence and projecting long-term outcomes of real-world and hypothetical scenarios. They are increasingly used to inform health policy decisions for numerous public health problems worldwide. Novel methodologies are required to integrate data of variable quality and uncertainty, as well as to accommodate real-world conditions and interventions. The following publications document contributions to the literature on decision science and mathematical modeling methodology.
   a. **Kim JJ**, Salomon JA, Weinstein MC, Goldie SJ. Packaging health care services in a single cervical cancer screening visit for older women in resource-poor settings. *PLoS Med* 2006;3:e434. PMCID: PMC1635742.
   b. Campos NG, Castle PE, Schiffman M, **Kim JJ**. Policy implications of adjusting randomized trial data for economic evaluations: a demonstration from the ASCUS-LSIL Triage Study. *Med Decis Making* 2012;32(3):400-27. PMCID: PMC3647223.
   c. Verguet S, **Kim JJ**, Jamison DT. Extended cost-effectiveness analysis for health policy assessment: a tutorial. *Pharmacoecon* 2016;34(9):913-23. PMCID: PMC4980400.
   d. Menzies NA, Soeteman DI, Pandya A, **Kim JJ**. Bayesian Methods for Calibrating Health Policy Models: A Tutorial. *Pharmacoecon* 2017 Jun;35(6):613-624. doi: 10.1007/s40273-017-0494-4. PMCID: PMC5448142.

Complete List of Published Work in MyBibliography:
http://www.ncbi.nlm.nih.gov/sites/myncbi/jane.kim.1/bibliograpahy/43429423/public/?sort=date&direction=ascending

D. Additional Information: Research Support and/or Scholastic Performance

Ongoing Research Support

5U01CA199334 (PI: J Kim) 09/09/15-08/31/20
National Cancer Institute
CISNET: Comparative Modeling to Inform Cervical Cancer Control Policies (U01)
As part of the Cancer Intervention and Surveillance Modeling Network (CISNET), a group of established cervical cancer modelers from the U.S., Australia, and the Netherlands will engage in a formal collaboration of comparative modeling using a series of state-of-the-art mathematical models of HPV and cervical carcinogenesis. We will pursue analyses related to the historical impact of screening, the comparative effectiveness of current and anticipated HPV vaccination and screening strategies, the identification of optimal routes for reducing cervical cancer disparities, and the translation of clinical trial results to public health policy. Role: PI.

WITHHELD (PI: E Simpson) 01/01/18-09/30/21
PRIVATE SUPPORT
HPV 1-dose: Accelerating evidence and implementation
The overall goal of this proposal is to accelerate dissemination and broad use of HPV vaccines by national programs of LMICs with flexible dosing schedules that allow for considerations of 1-dose or 1-dose extended intervals. We will achieve this goal by compiling, systematically updating, synthesizing, utilizing, and disseminating the evidence base for use of 1-dose or 1-dose extended schedules for global policy discussions and guidance including perspectives from regional and country levels. Role: Co-Investigator (PI of Subcontract).

WITHHELD (PI: J Kim) 11/01/19-10/31/20
PRIVATE SUPPORT
Therapeutic Modeling
The goal of this study is to better understand the potential impact of therapeutic HPV interventions and identify the ideal characteristics of a potential therapeutic to accelerate HPV control and elimination efforts. Role: PI.

WITHHELD (PI: T Garske) 04/01/18-03/31/21
PRIVATE SUPPORT
VIMC: Vaccine Impact Modeling Consortium
The *Vaccine Impact Modeling Consortium* aims to develop a more sustainable, efficient and transparent approach to generating global disease burden and vaccine impact estimates across several research groups for multiple pathogens. The Harvard-HPV modeling group will use a three-tiered modeling approach in the VIMC analyses, to enable incorporation of herd immunity and cervical cancer disease natural history into its estimates of HPV vaccination impact in low- and middle-income countries. Role: Co-Investigator (PI of Subcontract).

WITHHELD (PI: J Kim) 08/01/17-07/31/21
PRIVATE SUPPORT
Ancillary Micro-Costing and Cost-Effectiveness Study for the Clinical Trial: "A Scientific Evaluation of One and Two Doses of the Bivalent and Nonavalent Prophylactic HPV Vaccines"
The goals of this project are to 1) estimate the financial and economic costs of a national clinic-based female human papillomavirus (HPV) vaccination program in Costa Rica under different roll-out scenarios using the Government's perspective, for each vaccine and dose regimen; and 2) evaluate the comparative long-term health and economic impact and value (i.e., cost-effectiveness) of each vaccine and dose regimen in the context of Costa Rica's cervical cancer prevention program. Role: PI. *Project currently paused, but will resume soon.*

5UH3CA189883 (PI: M Cremer) 09/01/17-08/31/20
National Cancer Institute/Cleveland Clinic
CryoPen: An Innovative Treatment of Cervical Pre-cancer in Low-Resource Settings
The goal of this project is to evaluate the comparative effectiveness of two cryotherapy methods and three post-treatment surveillance strategies for women with cervical pre-cancer in Colombia and Peru. We will

conduct assessments of the costs and cost-effectiveness of treating women with cervical pre-cancer with CryoPen versus N_2O-based cryotherapy, as well as the three post-surveillance screening techniques. Role: Co-Investigator (PI of Subcontract).

Completed Research Support

WITHHELD (PI: I Scarinci) 01/01/17-06/30/20
PRIVATE SUPPORT
Self-Sampling for HPV Testing in African American Women – Mississippi Delta
The goal of this randomized study is to examine the efficacy and costs of a patient-centered approach to cervical cancer screening (i.e., self-collection of cervical sample in the home) as compared to the current standard of care (i.e., Pap testing in the clinic) in increasing screening adherence among un/under-screened African American women in the Mississippi Delta. The study will employ community-based participatory research and decision science methods to assess the acceptability, affordability, and cost-effectiveness of interventions aiming to reduce health disparities among women with the highest cervical cancer burden in the U.S. Role: Co-Investigator (PI of Subcontract).

WITHHELD (PI: J Kim) 07/05/2019-12/05/2019
PRIVATE SUPPORT
Global Cost-Effectiveness of Cervical Cancer Elimination in 78 Low- and Middle-Income Countries
The goal of this project is to use our model to estimate the global cost-effectiveness of elimination for 78 low- and middle-income countries as part of the model comparison consortium through the World Health Organization. Role: PI.

WITHHELD (PI: J Kim) 10/27/16-06/30/19
PRIVATE SUPPORT
Health and Cost Impact of HPV Vaccination in Gavi Countries
The proposed work aims to use a mathematical modeling framework to integrate data on population demographics, disease burden, and intervention costs and effects to estimate the health and economic impact and cost-effectiveness of vaccination with emerging HPV vaccines and delivery approaches in Gavi countries. Role: PI.

WITHHELD (PI: V.Tsu) 08/01/14-02/28/18
PRIVATE SUPPORT
Cervical Cancer Prevention Project
The goal of this project is to evaluate the health and economic impact of cervical cancer screening algorithms in low-resource settings, including human papillomavirus (HPV) DNA testing with self-collected specimens, management strategies for women with positive screening test results, and alternative screening ages and frequencies in settings with varying epidemiologic profiles. Role: Co-Investigator (PI of subcontract).

HHSA29020120000l5i (PI: J Lin) 01/01/16-09/27/17
AHRQ/Kaiser Permanente
Evidence-based Practice Centers (EPCs) IV Program
To inform the US Preventive Services Task Force national guidelines on cervical cancer screening, the goal of this project was to lead the decision analysis integrating empirical data synthesized by the Evidence-Based Practice Center (i.e., Kaiser Permanente) and conducting model-based analyses of alternative cervical cancer screening strategies. Role: Co-Investigator (PI of Subcontract).

OMB No. 0925-0001 and 0925-0002 (Rev. 03/2020 Approved Through 02/28/2023)

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: **Mansfield, Lisa Nicole**

eRA COMMONS USER NAME (credential, e.g., agency login): eRA COMMONS USER NAME

POSITION TITLE: **Postdoctoral Fellow**

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Start Date MM/YYYY	Completion Date MM/YYYY	FIELD OF STUDY
Winston-Salem State University (Winston-Salem, NC)	BSN	08/2008	05/2012	Nursing
Winston-Salem State University (Winston-Salem, NC)	MSN	05/2014	05/2016	Nursing Education
Duke University (Durham, NC)	PhD	08/2016	05/2020	Nursing Research
University of California, Los Angeles (Los Angeles, CA)	Postdoctoral Fellow	07/2020	Present	General Internal Medicine/Health Services Research

A. Personal Statement

My role on the IMPACT P01 Program Project will be as a nurse consultant to ensure that the planned research is informed by and meets the needs of nurses working in primary care. My nursing career in primary care as a registered nurse, doctoral training in nursing, and research experiences in the field of HPV vaccination make me well suited to serve as a nurse consultant for the proposed research. Throughout my academic and research training, I have focused my research on improving HPV vaccination among racial/ethnic minority adolescents and bring expertise in health disparities, health prevention, using electronic health record data for research, conducting quantitative, qualitative, and mixed-methods analyses, and clinic recruitment strategies to the study team. My research has largely focused on exploring factors influencing HPV vaccination among adolescent girls and boys including the role that parents, healthcare providers, and social determinants of health play in initiating and completing the HPV vaccine. In my role as nurse consultant, I will provide Dr. Brewer and his team guidance related to the nurse's role in administering and communicating about HPV vaccine, maintaining clinic workflow while conducting research, and cultural perspectives on vaccination among racial/ethnic minority adolescents that may influence healthcare providers' communication about HPV vaccine. In addition, I practiced as a registered nurse in primary care for several years and bring clinical experience and a unique perspective to the study team of challenges nurses face when communicating and educating patients about vaccinations in practice. As a nurse consultant, I will use my previous training, career experience, and research expertise to support and guide Dr. Brewer and his team throughout the proposed study period.

Relevant publications

1. **Mansfield LN,** Onsomu EO, Merwin E, Hall NM, & Harper-Harrison A. Association between parental HPV knowledge and intentions to have their daughters vaccinated. *Western Journal of Nursing Research*, 2018 *40*(4), 481-501. doi:10.1177/0193945916682953. PMID: 28322641

B. Positions and Honors

Employment

2012– 2014 Staff Nurse, Orthopedic Unit, Vidant Medical Center, Greenville, NC

Professional Memberships

2011-2012	Secretary, Rho Lambda Chapter, Sigma Theta Tau International
2011-2012	Epsilon Tau Sigma School of Health Science Honors' Society
2012-	Alpha Kappa Alpha Sorority Incorporated
2016-	Southern Nursing Research Society (SNRS)
2017-	Sigma Theta Tau International, Honor Society of Nursing
2017-	Secretary, Beta Epsilon Chapter, Sigma Theta Tau

Honors

2008-2012	Dean's List, Winston-Salem State University, Winston-Salem, NC
2010	WSSU Honor's College Recipient, Winston-Salem State University, Winston-Salem, NC
2011-2012	President, Student Nurses' Association, Winston-Salem State University, Winston-Salem, NC
2016	Top Student Selected Poster, Presented to President of UNC System, Winston-Salem State University, Winston-Salem, NC
2016	Winston-Salem State University School of Health Science Graduate Student Achievement Award, Winston-Salem, NC

C. Contributions to Science

1. **Identification of Factors Influencing HPV Vaccination among U.S. Adolescents.** My early and ongoing work has explored barriers and facilitators to HPV vaccination among adolescent girls and boys. My preliminary studies include a paper focusing on the role of parents' knowledge in making decisions to initiate HPV vaccination for their daughters and a funded study of social determinants influencing vaccine completion among adolescent girls and boys (manuscripts in preparation from dissertation). These studies highlighted the important role healthcare providers play in providing HPV vaccine education to parents and adolescents. Furthermore, these studies revealed that multi-level factors influence adolescent's ability to initiate and complete the multidose HPV vaccine series. Identification of these factors has informed both clinic and community strategies to improve HPV vaccination among adolescents. I recently completed my predoctoral program in May 2020; therefore, the papers from my dissertation are not yet published.

    a. **Mansfield LN,** Onsomu EO, Merwin E, Hall NM, Harper-Harrison A. Association between parental HPV knowledge and intentions to have their daughters vaccinated. *Western Journal of Nursing Research*, 2018 *40*(4), 481-501. doi:10.1177/0193945916682953. PMID: 28322641

    b. **Mansfield LN,** Silva SG, Merwin EI, Chung RJ, Gonzalez-Guarda RM. Factors associated with HPV vaccine completion among adolescents. 2020. Manuscript in preparation.

    c. **Mansfield LN**, Merwin EI, Chung RJ, Silva SG, Gonzalez-Guarda RM. Multi-level determinants of HPV vaccine completion among adolescents: A mixed-method study. 2020. Manuscript in preparation.

    d. **Mansfield LN,** Vance A, Nikpour JA, Gonzalez-Guarda RM. HPV vaccination among U.S. adolescents: A socioecological systematic review. 2020. Manuscript in preparation.

Complete List of Published Work in MyBibliography:
https://www.ncbi.nlm.nih.gov/myncbi/1TGnfdRXTDcko/bibliography/public/

D. Additional Information: Research Support

Completed Research Support

NIH: 1F31NR018347-01 Mansfield (PI) 09/30/18-05/31/20
Social Determinants of HPV Vaccine Completion among Adolescents
Research Goal: To identify and describe the role that multi-level determinants (e.g. social determinants of health) play in influencing HPV completion among adolescents.
The National Institutes of Health and National Institute of Nursing Research
Role: Principal Investigator

PRIVATE SUPPORT 03/14/18-03/14/19
Factors Associated with HPV Vaccine Completion in a Pediatric Clinic

Research Goal: To assess the feasibility of collecting electronic health record (EHR) data, identify key study variables, and estimate effect sizes to appropriately power the larger F31 study.
Role: Principal Investigator

OMB No. 0925-0001 and 0925-0002 (Rev. 03/2020 Approved Through 02/28/2023)

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. DO NOT EXCEED FIVE PAGES.

NAME: **Mills, Sarah**

eRA COMMONS USER NAME: eRA COMMONS USER NAME

POSITION TITLE: **ASSISTANT PROFESSOR**

EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE	Completion Date	FIELD OF STUDY
Columbia University	BA	05/2010	Psychology, Hispanic Cultures
San Diego State University	MS	05/2013	Clinical Psychology
San Diego State University	MPH	05/2015	Epidemiology
San Diego State University/University of California, San Diego Joint Doctoral Program in Clinical Psychology	PHD	06/2017	Clinical Psychology
University of North Carolina at Chapel Hill	Postdoctoral Fellow	06/2019	Public Health

A. Personal Statement

My career goal is to eliminate socioeconomic and racial/ethnic disparities in in cancer-related health behaviors and outcomes, especially tobacco use and tobacco-related disease. My recent research has focused on 1) documenting socioeconomic and racial/ethnic disparities in the tobacco retail environment, and 2) identifying policies that can be used to reduce socioeconomic and racial/ethnic disparities in tobacco use.

Currently, I am developing a microsimulation model that will be used to estimate the impact of a national menthol cigarette ban policy on tobacco use, cardiovascular disease, and tobacco-related cancers. The impact of a menthol cigarette ban among low-income and racial/ethnic minority smokers is of particular interest given their high rates of menthol cigarette use. This work is conducted as part of my Mentored Research Scientist Career Development Award in Tobacco Regulatory Research (K01), funded by the National Cancer Institute. Prior to this work, for five years my research used a range of analytical methods to evaluate health measures among racial/ethnic minorities and patient populations with chronic disease, demonstrating my background in statistical modeling.

1. **Mills SD,** Henriksen L, Golden SD, Kurtzman R, Kong AY, Queen TL, Ribisl KM. Disparities in retail marketing for menthol cigarettes in the United States, 2015. *Health Place.* 2018 Jul 26;53:62-70. PubMed PMID: 30055469. PMCID: PMC6161357.
2. **Mills SD,** Golden SD, Henriksen L, Kong AY, Queen TL, Ribisl KM. Neighbourhood disparities in the price of the cheapest cigarettes in the USA. *J Epidemiol Community Health.* 2019 Sep;73(9):894-896. PMCID: PMC6689253
3. Ribisl KM, **Mills SD.** Explaining the rapid adoption of Tobacco 21 policies in the United States. *Am J Public Health.* 2019 109:1483-1485. PMID: 31577495. PMCID: PMC6775913
4. **Mills SD,** Golden SD, Queen TL, Kong AY, Ribisl KM. Are state-level income-based disparities in adult smoking declining? *Prev Med.* 2020 Feb 10;133:106019. PMID: 32057958 PMCID: PMC7415585.

B. Positions and Honors

Positions and Employment

2014 - 2015	Teaching Assistant, Multivariate Statistics, San Diego State University
2016	Instructor, Health Psychology, San Diego State University
2016 - 2017	Clinical Psychology Intern, University of California, Los Angeles
2017 - 2019	Postdoctoral Fellow, University of North Carolina at Chapel Hill
2019 - Present	Member, UNC Lineberger Comprehensive Cancer Center
2019 - Present	Assistant Professor, Gillings School of Global Public Health, University of North Carolina at Chapel Hill

Other Experience and Professional Memberships

2012 - 2014	Diversity Representative, Student Advisory Council, American Psychological Association Division 38 (Health Psychology)
2013 - 2016	Student Editor, The Score, newsletter for American Psychological Association Division 5 (Evaluation, Measurement, & Statistics)

Honors

2006 - 2010	Dean's List, Columbia University
2014	Inamori Fellow, San Diego State University
2015	Citation Award, Society of Behavioral Medicine
2016	Teaching Award, SDSU/UC San Diego Joint Doctoral Program in Clinical Psychology
2016	Health Equity Scholarship, American Psychosocial Oncology Society
2018	Trainee Award, American Society of Preventive Oncology
2020	3rd Place in University of Oxford Map the System Competition

C. Contribution to Science

1. **I have documented socioeconomic and racial/ethnic disparities in an emerging tobacco control policy area, the tobacco retail environment.** In a study of 2,124 tobacco retail outlets published in *Health & Place,* I found that retail marketing for menthol cigarettes is more common in neighborhoods with more youth, low-income, and African-American residents. This is one of the first national studies on this issue, and the first study to compare price promotions across the three leading menthol cigarette brands, Newport, Camel, and Marlboro. In another national study of tobacco retailers, I found that discount cigarettes are cheapest in neighborhoods with more youth and low-income residents, increasing access to these products in these neighborhoods.

    a. **Mills SD**, Henriksen L, Golden SD, Kurtzman R, Kong AY, Queen TL, Ribisl KM. Disparities in retail marketing for menthol cigarettes in the United States, 2015. Health Place. 2018 Jul 26;53:62-70. PubMed PMID: 30055469. PMCID: PMC6161357.

    b. **Mills SD**, Golden SD, Henriksen L, Kong AY, Queen TL, Ribisl KM. Neighbourhood disparities in the price of the cheapest cigarettes in the USA. J Epidemiol Community Health. 2019 Sep;73(9):894-896. PubMed PMID: 31122944; PubMed Central PMCID: PMC6689253

2. **I have evaluated the psychometric properties of health measures among samples of English- and Spanish-speaking Latinos and patients with chronic disease**. Evaluating the psychometric properties of health measures in diverse populations is critical to conducting valid and reliable health research. I have examined the psychometric properties of six health measures, including the widely-used Patient Health Questionnaire-4 and Generalized Anxiety Disorder-7 scales, measures of anxiety and depression, respectively, among English- and Spanish-speaking Latinos. My research evaluating health measures among patients with chronic disease has focused on important psychosocial constructs including perceived stress, helplessness, appearance anxiety, and appearance satisfaction.

    a. **Mills SD**, Fox RS, Pan TM, Malcarne VL, Roesch SC, Sadler GR. Psychometric Evaluation of the Patient Health Questionnaire-4 in Hispanic Americans. Hisp J Behav Sci. 2015 Nov;37(4):560-571. PubMed PMID: 29097834; PubMed Central PMCID: PMC5663318.

b. **Mills SD**, Fox RS, Malcarne VL, Roesch SC, Champagne BR, Sadler GR. The psychometric properties of the Generalized Anxiety Disorder-7 scale in Hispanic Americans with English or Spanish language preference. Cultur Divers Ethnic Minor Psychol. 2014 Jul;20(3):463-8. PubMed PMID: 25045957; PubMed Central PMCID: PMC4129392.
c. **Mills SD**, Kwakkenbos L, Carrier ME, Gholizadeh S, Fox RS, Jewett LR, Gottesman K, Roesch SC, Thombs BD, Malcarne VL. Validation of the Social Appearance Anxiety Scale in Patients with Systemic Sclerosis: A Scleroderma Patient-centered Intervention Network Cohort Study. Arthritis Care Res (Hoboken). 2018 Jan 17;PubMed PMID: 29342510.
d. Pan TM, **Mills SD**, Fox RS, Baik SH, Harry KM, Roesch SC, Sadler GR, Malcarne VL. The psychometric properties of the English and Spanish versions of the Life Orientation Test-Revised in Hispanic Americans. J Psychopathol Behav Assess. 2017 Dec;39(4):657-668. PMID: 29170597; PMCID: PMC5695875.

3. **I have contributed to the understanding of the construct of acculturation among Latinos and African Americans.** Acculturation refers to the extent to which racial/ethnic minorities engage in the values, beliefs, and practices of their own cultural traditions and those of the majority/dominant society. The study of acculturation is important because it allows for examination of how within-group differences play a role in health and health behaviors. I evaluated the psychometric properties of the Brief Acculturation Scale for Hispanics, a screener of acculturation, and determined that a single-item indicator of language preference may be an even more efficient, and similarly valid, measure of the construct. I also conducted the first systematic review to examine the relationship between acculturation and health behaviors among African Americans.

   a. **Mills SD**, Malcarne VL, Fox RS, Sadler Gr. Psychometric Evaluation of the Brief Acculturation Scale for Hispanic Americans. Hisp J Beh Sci. 2014 May 1l36(2):164-174. PubMed PMID: 25110387; NIHMSID: NIHMS609398; PubMed Central PMCID: PMC4125565.
   b. **Mills SD**, Fox RS, Gholizadeh S, Klonoff EA, Malcarne VL. Acculturation and health behaviors in African Americans: A systematic review. J Cross Cult Psychol. 2017 July;48(7):1073-1097. PMID: 30594322

Complete List of Published Work in My Bibliography:
https://www.ncbi.nlm.nih.gov/myncbi/sarah.mills.1/bibliography/56410243/public/

D. Additional Information: Research Support

Ongoing Research Support
Mentored Research Scientist Career Development Award in Tobacco Regulatory Research, National Cancer Institute
1K01CA242530-01
Mills, Sarah (PI): 08/01/19-7/31/24
Modeling the public health impact of a national menthol cigarette ban
This project uses microsimulation modeling to estimate the public health impact of national menthol cigarette ban on tobacco use, cardiovascular disease, and tobacco-related cancers.
Role: Principal Investigator

National Cancer Institute
1P01CA225597-01
Ribisl, Kurt M. (MPI); 8/01/2019-3/01/2023
ASPiRE Advancing Science and Practice in the Retail Environment
The Center's goal is to build a strong scientific evidence base for effective policies in the tobacco retail environment to help reduce tobacco use, tobacco-related disparities, and the public health burden of tobacco, including cancer.
Role: Co-Investigator

Completed Research Support (past 3 years)

T32 CA057726-26

Ribisl, Kurt M. (PI); 07/01/17-06/30/19

Cancer Control Education Program

This is a renewal of the R25T Cancer Control Education Program (CCEP) for Years 21-25. During the next 5 years, CCEP will continue to support five pre- and three postdoctoral fellows yearly and train them for careers in cancer prevention and control that emphasize multidisciplinary and collaborative research.

Role: Postdoctoral Fellow

OMB No. 0925-0001 and 0925-0002 (Rev. 03/2020 Approved Through 02/28/2023)

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: **Myers, Evan Robert**

eRA COMMONS USER NAME (credential, e.g., agency login): eRA COMMONS USER NAME

POSITION TITLE: **Walter L. Thomas Distinguished Professor of Obstetrics and Gynecology**

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE	Completion Date	FIELD OF STUDY
Harvard College, Cambridge, MA	BA	1983	History & Literature
Univ Pennsylvania, Philadelpha, PA	MD	1988	Medicine
Duke University Medical Center, Durham, NC		1992	Residency, OB/GYN
University of North Carolina, Chapel Hill, NC	MPH	1994	Epidemiology

A. Personal Statement

I am a Professor of Obstetrics and Gynecology in the Duke University School of Medicine and a trained Ob/Gyn clinician. As a consultant for Project 4, I will bring a clinical perspective to the modeling work in Aim 2. My demonstrated expertise in the application of quantitative methods, especially mathematical modeling and decision analysis, to problems in women's health, has prepared me to provide oversight and expertise on the development of the proposed HPV transmission model. Additionally, my experience with guidelines development, clinical decision support, and stakeholder engagement has prepared me to consult on the development of the proposed decision support tool. My work focuses primarily on the application of methods for evidence synthesis, including systematic review, meta-analysis, and simulation modeling to address important clinical, epidemiological, and policy questions in women's health, with a substantial proportion of that work in women's cancers. I also teach the course on decision and cost-effectiveness analysis in the Duke Clinical Research Training Program and have mentored fellows and junior faculty in other cancer-related fields in these topics. As part of the DCI's CCPS program, I collaborate with investigators across the DCI. I also serve as PI on an ongoing prospective registry of women undergoing treatment for uterine fibroids.

Relevant publications.

1. Ryser MD, **Myers ER**, Durrett R. HPV clearance and the neglected role of stochasticity. PLoS Comput Biol. 2015;11(3):e1004113. doi: 10.1371/journal.pcbi.1004113. PubMed PMID: 25769112; PMCID: 4358918.
2. Moss HA, Berchuck A, Neely ML, **Myers ER**, Havrilesky LJ. Estimating Cost-effectiveness of a Multimodal Ovarian Cancer Screening Program in the United States: Secondary Analysis of the UK Collaborative Trial of Ovarian Cancer Screening (UKCTOCS). JAMA Oncol. 2018;4(2):190-5. Epub 2017/12/10. doi: 10.1001/jamaoncol.2017.4211. PubMed PMID: 29222541; PMCID: PMC5838595.
3. **Myers ER**, Moorman P, Gierisch JM, Havrilesky LJ, Grimm LJ, Ghate S, Davidson B, Mongtomery RC, Crowley MJ, McCrory DC, Kendrick A, Sanders GD. Benefits and Harms of Breast Cancer Screening: A Systematic Review. JAMA : the journal of the American Medical Association. 2015;314(15):1615-34. doi: 10.1001/jama.2015.13183. PubMed PMID: 26501537.
4. Moss HA, Samimi G, Havrilesky LJ, Sherman ME, **Myers ER**. Estimating the number of potential family members eligible for BRCA1 and BRCA2 mutation testing in a "Traceback" approach. Genet Epidemiol. 2018;42(1):117-22. Epub 2017/12/02. doi: 10.1002/gepi.22095. PubMed PMID: 29193313.

B. Positions and Honors

Positions and Employment

1992-1994 Associate, Dept OB/GYN, Duke University; RWJ Clinical Scholar,UNC-Chapel Hill
1994-1996 Instructor, Dept OB/GYN, Beth Israel Hospital, Harvard Medical School
1996-2002 Assistant Professor, Dept OB/GYN, Duke University
1997-2001 Faculty, Center for Health Informatics, Duke University Medical Center

1997-2012	Faculty, Evidence-based Practice Center, Duke University Medical Center
1999-present	Faculty, Duke Clinical Research Institute
2001-2011	Chief, Division Clinical and Epidemiological Research, Dept OB/GYN, Duke 2002-2006
	Associate Professor, Dept OB/GYN, Duke University
2003-present	Adjunct Associate Professor, Dept Epidemiology, UNC School of Public Health
2006-2012	Professor, Dept OB/GYN, Duke University
2012-present	Walter L. Thomas Distinguished Professor, Dept OB/GYN, Duke University
2013-present	Faculty, Duke Evidence Synthesis Group

Public Advisory Committee Positions

2002-2007	NICHD, Reproduction, Andrology, and Gynecology Study Section
2002, 2011	Cervical Cancer Screening Guidelines, American Cancer Society
2012	Site Visitor, NCI Intramural Program, 2009, 2011, NICHD Intramural Program,
2011-2014	Centers for Disease Control and Prevention, Early Breast and Cervical Cancer Detection
	Program Advisory Committee

Selected Honors

1983	Phi Beta Kappa
1992	Alpha Omega Alpha
1995	New Faculty Teaching Award, Dept OB/GYN, Beth Israel Hospital
1996	Faculty Teaching Award, Dept OB/GYN, Beth Israel Hospital
1997, 1998	Distinguished Professor Award, Dept OB/GYN, Duke University
1999	Distinguished Educator Award, Association of Professors of Gynecology and Obstetrics

C. Contributions to Science

1. **Evidence synthesis and decision analysis.** Much of my work has involved combining systematic reviews and synthesis of evidence, largely through the AHRQ Evidence-based Practice Center program, often with a significant component based on computer simulation modeling, decision and cost-effectiveness analysis to identify research gaps, then working with collaborators to help directly address these gaps through primary data collection. The first EPC project was a review of methods for screening for cervical cancer, which included development of a model of the natural history of human papillomavirus infection and cervical carcinogenesis. This activity led to participation in the Phase III trials of the quadrivalent HPV vaccine (on the FUTURE II Steering Committee), and has continued with work supporting guidelines development for cervical cancer prevention. Note that one of my former post-doctoral and junior faculty trainees, Shalini Kulasingam, was first author on several of these papers.

    a. **Myers ER**, McCrory DC, Nanda K, Bastian L, Matchar DB. Mathematical model for the natural history of human papillomavirus infection and cervical carcinogenesis. American Journal of Epidemiology. 2000;151(12):1158-71. PubMed PMID: 10905528.
    b. Kulasingam SL, **Myers ER**. Potential health and economic impact of adding a human papillomavirus vaccine to screening programs. JAMA:2003;290(6):781-9. doi: 10.1001/jama.290.6.781. PubMed PMID: 12915431.G
    c. FUTURE II Study Group. Quadrivalent vaccine against human papillomavirus to prevent high-grade cervical lesions. The New England Journal of Medicine. 2007;356(19):1915-27. doi: 10.1056/NEJMoa061741. PubMed PMID: 17494925.
    d. Kulasingam SL, Havrilesky LJ, Ghebre R, **Myers ER**. Screening for cervical cancer: a modeling study for the US Preventive Services Task Force. Journal of Lower Genital Tract disease. 2013;17(2):193-202. doi: 10.1097/LGT.0b013e3182616241. PubMed PMID: 23519288; PMCID: 3608928.

2. **Management of uterine fibroids.** Another topic in women's health where initial work on a systematic review led to identification of research gaps and subsequent research to fill those gaps was management of uterine fibroids. Publication of the initial review led to collaboration with the Society for Interventional Radiology on a registry of patient undergoing uterine artery embolization, with subsequent work on prioritizing research needs, leading to the recent award of a large national multi-center comparative effectiveness research study on fibroids, for which I serve as overall PI.

a. **Myers ER**, Barber MD, Gustilo-Ashby T, Couchman G, Matchar DB, McCrory DC. Management of uterine leiomyomata: what do we really know? Obstetrics and gynecology. 2002;100(1):8-17. PubMed PMID: 12100798.
b. **Myers ER**, Goodwin S, Landow W, Mauro M, Peterson E, Pron G, Spies JB, Worthington-Kirsch R, Investigators F. Prospective data collection of a new procedure by a specialty society: the FIBROID registry. Obstetrics and gynecology. 2005;106(1):44-51. doi: 10.1097/01.AOG.0000165827.66541.dd. PubMed PMID: 15994616.
c. Goodwin SC, Spies JB, Worthington-Kirsch R, Peterson E, Pron G, Li S, **Myers ER**, Fibroid Registry for Outcomes Data Registry Steering C, Core Site I. Uterine artery embolization for treatment of leiomyomata: long-term outcomes from the FIBROID Registry. Obstetrics and gynecology. 2008;111(1):22-33. doi: 10.1097/01.AOG.0000296526.71749.c9. PubMed PMID: 18165389.
d. Wechter ME, Stewart EA, **Myers ER**, Kho RM, Wu JM. Leiomyoma-related hospitalization and surgery: prevalence and predicted growth based on population trends. American journal of obstetrics and gynecology. 2011;205(5):492 e1-5. doi: 10.1016/j.ajog.2011.07.008. PubMed PMID: 22035951; PMCID: 3746963.

3. **Management of adnexal masses**. Modeling work developed for another evidence report on management of adnexal masses led to ongoing work with Laura Havrilesky, who, at the time of the initial project, I was mentoring as part of a career development award from the American Association of Gynecologists and Obstetricians Foundation. This work has led to insights into the potential inherent limitations of screening for ovarian cancer as well as issues related to diagnosis, management, and quality of care.

a. Havrilesky LJ, Sanders GD, Kulasingam S, **Myers ER**. Reducing ovarian cancer mortality through screening: Is it possible, and can we afford it? Gynecologic oncology. 2008;111(2):179-87. doi: 10.1016/j.ygyno.2008.07.006. PubMed PMID: 18722004.
b. Wallace AH, Havrilesky LJ, Valea FA, Barnett JC, Berchuck A, **Myers ER**. Projecting the need for gynecologic oncologists for the next 40 years. Obstetrics and gynecology. 2010;116(6):1366-72. doi: 10.1097/AOG.0b013e3181fc3a22. PubMed PMID: 21099604.
c. Havrilesky LJ, Sanders GD, Kulasingam S, Chino JP, Berchuck A, Marks JR, **Myers ER**. Development of an ovarian cancer screening decision model that incorporates disease heterogeneity: implications for potential mortality reduction. Cancer. 2011;117(3):545-53. doi: 10.1002/cncr.25624. PubMed PMID: 21254049.
d. Havrilesky LJ, Dinan M, Sfakianos GP, Curtis LH, Barnett JC, Van Gorp T, **Myers ER**. Costs, effectiveness, and workload impact of management strategies for women with an adnexal mass. Journal of the National Cancer Institute. 2015;107(1):322. doi: 10.1093/jnci/dju322. PubMed PMID: 25515232.

Complete List of Published Work in MyBibliography:
http://www.ncbi.nlm.nih.gov/sites/myncbi/evan.myers.1/bibliography/48065881/public/?sort=date&direction=ascending.

D. Additional Information: Research Support

Ongoing Research Support

AHRQ: P50-HS023418 Myers (PI) 9/30/14-9/30/20
Comparing Options for Management: Patient-centered Results for Uterine Fibroids (COMPARE-UF)
The broad, long-term objective of this project is to enable patients with uterine fibroids (UF) to make informed decisions about management options based on the highest possible quality evidence. To help achieve this objective, we propose a multi-center registry of a geographically, racially, ethnically, and clinically diverse group of women who have received medical or surgical treatment for UF.
Role: Principal Investigator

PRIVATE SUPPORT Hwang (PI) 3/1/16-2/28/21
Comparison of Operative to Medical Endocrine Therapy (COMET) for Low Risk DCIS
This proposed research is funded by PRIVATE SUPPORT.

Role: Investigator

UVA/NIH: GB10416-154701 4/1/17-3/31/21
Exploring Factors Related to Racial Disparities in Ovarian Cancer Incidence and Survival
To pool existing observational datasets of ovarian cancer incidence and survival in order to better understand factors, including potentially modifiable factors, contributing to observed disparities between white and African-American women in ovarian cancer incidence (lower incidence in African-American women) and survival (poorer survival in African-American women)
Role: Site Principal Investigator

Completed Research Support (selected)
UNC-CH / NIH: 5111098/5R01-MD011680-02 Myers (PI) 7/1/18-6/30/19
Racial Differences in Treatment with Hysterectomy: a Multilevel Investigation
Goals of the overall project are to identify clinical, demographic, and other determinants of treatment choice that explain observed differences in hysterectomy rates between African-American and white women.
Role: Site PI

PRIVATE SUPPORT Schmidler (PI) 1/1/18-12/31/18
Exploring Value-Based Care from Various Perspectives
To illustrate differences in cost-effectiveness estimates for different interventions when the analytic perspective is changed using existing models for implantable cardiac defibrillators, preoperative testing for ovarian malignancy, and influenza vaccination during pregnancy.
Role: Co-Investigator

NIH: R01CA174634 Strickler (PI) 10/1/13-9/30/18
Molecular methods to improve cervical cancer screening in HIV+ women
This project will estimate sensitivity and specificity of a variety of novel molecular markers of HPV-related cervical neoplasia in a cohort of HIV+ women.
Role: Co-Investigator

OMB No. 0925-0001 and 0925-0002 (Rev. 03/2020 Approved Through 02/28/2023)

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: **Oliver, Kristin**

eRA COMMONS USER NAME (credential, e.g., agency login):

POSITION TITLE: **Assistant Professor**

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE	Completion Date	FIELD OF STUDY
McGill University, Montreal, Canada	BA	01/2000	Social Studies of Medicine
Johns Hopkins Bloomberg School of Public Health, Baltimore, MD	MHS	05/2003	Health Policy & Management
Goucher College, Towson, MD		05/2004	Post-Bacc Pre Med
Mount Sinai School of Medicine, New York, NY	MD	05/2008	Medicine
Mount Sinai Hospital, New York, NY		06/2011	General Pediatrics Residency
Mount Sinai Hospital, New York, NY		06/2013	Preventive Medicine Residency

A. Personal Statement

I have the expertise and motivation necessary to serve on the External Advisory Board for the proposed P01 Program Project “Improving Provider Announcement Communication Training” (IMPACT). My research focuses on immunization, quality improvement, and tobacco cessation. Over the past five years as a member of the American Academy of Pediatrics’ HPV Vaccination Expert Physician Panel I have become an expert in the areas of HPV immunization and health care provider education. I am now translating this expertise to answer research questions of my own, working at the NYC Department of Health and Mental Hygiene to identity factors associated with low immunization rates across the city, and conducting an evaluation of the effectiveness of health care provider outreach to pediatric offices to increase adolescent immunizations. As the Deputy Director of the General Preventive Medicine Residency Program and core faculty in the Graduate Program in Public Health, I dedicate much of my time to mentoring residents and MPH students in their research activities. Many of the resident projects focus on quality improvement for a smoking cessation clinic I helped develop at the Bronx VA Medical Center. My pediatric practice is at the Mount Sinai School Based Health Centers, located in a public elementary school in East Harlem. My patients come from neighborhoods with high poverty; high asthma rates and substantial barriers to receiving high quality health care. To address these needs I have led multiple quality improvement projects in our clinic with a focus on asthma, HPV and influenza immunization.

B. Positions and Honors

2002-2003 Health Care Analyst, US Government Accountability Office (GAO), Washington, DC
2003 Delta Omega Honorary Public Health Society, Johns Hopkins School Public Health
2011-2013 Attending, Department of Pediatrics, Montefiore Medical Center, NY
2012-2013 Chief Resident, Department of Preventive Medicine, Icahn School of Medicine, NY
2013-present Assistant Professor, Department of Environmental Medicine & Public Health, Icahn School of Medicine, NY
2013-present Assistant Professor, Department of Pediatrics, Icahn School of Medicine, NY
2013-present Course Director, Graduate Program in Public Health, Icahn School of Medicine, NY
2013-2014 Director of Employee Wellness, Mount Sinai Hospital, NY
2014-present Member, HPV Expert Physician Panel, American Academy of Pediatrics

2015-present Chair, Academic Advisory Committee, Graduate Program in Public Health, Icahn School of Medicine, NY
2015-present Deputy Director, General Preventive Medicine Residency, Icahn School of Medicine, NY
2017-present Steering Committee Member, National HPV Vaccination Roundtable

C. Contributions to Science

As a board certified pediatrician and preventive medicine physician, my contributions to science have focused on vaccine preventable diseases and tobacco cessation. As a member of the American Academy of Pediatrics' HPV expert physician panel, I am developing and promoting successful strategies to increase rates of HPV immunization that target both physicians and patients. As the Director of Employee Wellness for Mount Sinai Hospital I was responsible for developing the hospital's tobacco cessation program and enhancing tobacco cessation screening and services in the hospital's inpatient and outpatient settings.

a. **Oliver K**, McCorkel C, Pister I, Majid N, Benkel D, Zucker J. Improving HPV Vaccine Delivery at School-Based Health Centers. *Human Vaccin Immunother*. 2019;15(7-8):1870-1877. PMID: 30735468. doi: 10.1080/21645515.2019.1578596.

b. Nobel T, Rajupet S, Sigel K, **Oliver K**. Using Veterans Affairs Medical Center (VAMC) data to identify missed opportunities for HPV vaccination. *Human Vaccin Immunother*. 2019;15(7-8):1878-1883. PMID: 30681403. doi: 10.1080/21645515.2018.1559684.

c. Laitman B, **Oliver K**, Genden E. Medical Student Knowledge of Human Papillomavirus-Positive Head and Neck Cancer. *JAMA Otolaryngol Head Neck Surg*. 2018 Apr 1;144(4):380-382. PMID: 29423502. PMCID: PMC5876804. doi: 10.1001/jamaoto.2017.3089.

d. **Oliver K**, Frawley A, Garland E. HPV vaccination: Population approaches for improving rates. *Hum Vaccin Immunother*. 2016 Jun 2;12(6):1589-93. PMID: 2680685. PMCID: PMC4964670. doi:10.1080/21645515.2016.1139253.

D. Additional Information: Research Support

None.

OMB No. 0925-0001 and 0925-0002 (Rev. 03/2020 Approved Through 02/28/2023)

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: **Ozawa, Sachiko**

eRA COMMONS USER NAME (credential, e.g., agency login): eRA COMMONS USER NAME

POSITION TITLE: **Associate Professor**

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE	Completion Date	FIELD OF STUDY
Georgetown University, Washington, DC	BSFS	05/2003	Science, Technology and International Affairs
Johns Hopkins, Baltimore, MD	MHS	05/2007	International Health, Health Systems
Johns Hopkins, Baltimore, MD	PhD	03/2010	International Health, Health Systems & Health Economics

A. Personal Statement

As Project Co-Lead of Project 4, "Budget impact, cost-effectiveness, and population outcomes of interventions to improve HPV vaccine communication and uptake in rural and nonrural communities," my role will be to oversee the grant activities for the proposed HPV modeling work. I will also serve as the contact Project Lead for Project 4, and will be responsible for communications with the funding agency and for the overall administrative functions of the project. Additionally, to enhance communication and synergy across the Program, I will serve on IMPACT's Integration Committee comprised of all research project and core directors. My expertise in vaccine economics, with a background in global health and training in mathematical modeling and health policy research, makes me a strong fit for these roles. I am an Associate Professor of Maternal Child Health and Practice Advancement and Clinical Education in the UNC Eshelman School of Pharmacy. I currently lead the Global Health Economics for Pharmacy (GHEP) team at University of North Carolina at Chapel Hill where my research focuses on estimating the global impact of vaccines and substandard and falsified medicines. I have published 60 articles in peer-reviewed journals, including 40 articles as corresponding author and over 25 articles on vaccination. I have been PI of 15 projects totaling more than $4.5 million in research funding, as well as Co-Investigator on numerous other grants. I have successfully administered projects, collaborated with multidisciplinary researchers, and produced several peer-reviewed publications from each project. I have the expertise, leadership, training and motivation necessary to successfully carry out this proposed research project.

My research is best known in the area of the value of vaccines. I was the PI for over 5 years of the Decade of Vaccine Economics project, a multi-million dollar project funded by the Bill and Melinda Gates Foundation (BMGF), which estimated the return on investment from childhood immunization across 94 low- and middle-income countries (LMICs) during the decade. My research findings have been used by BMGF, World Health Organization (WHO), UNICEF and Gavi (the Vaccine Alliance) to advocate for vaccine introduction and coverage increases in LMICs. Specifically, my work has been instrumental in securing the funding replenishment for Gavi of $7.5 billion for 2016-2020 and has contributed to the Addis declaration signed by 20 health ministers at the Ministerial Conference on Immunization in Africa in 2016 to increase the use of vaccines in preventing infectious diseases. This work was presented at the National Press Club, became *Health Affairs*' top 10 most read articles in 2016, was tweeted by Bill Gates and cited in the 2017 Gates' annual letter. Moreover, I led the team to model the economic burden of adult vaccine-preventable diseases in the United States, which became among *Health Affairs*' top 10 most read articles in 2016. This work was reported by the Washington Post, Forbes, and other news media, and continues to be used by the Centers for Disease Control and Prevention (CDC), and by the US Department of Health and Human Services (HSS).

Relevant publications

1. **Ozawa S**, Portnoy A, Getaneh H, Clark S, Knoll M, Bishai D, Yang HK, Patwardhan P. Modeling the economic burden of adult vaccine-preventable diseases in the United States. *Health Affairs (Millwood)*. 2016 Nov 1; 35(11): 1-9. PMID: 27733424 *Health Affairs' Top 10 Most Read Articles of 2016.

2. **Ozawa S**, Clark S, Portnoy A, Grewal S, Brenzel L, Walker D. Return on investment from childhood immunizations in low- and middle-income countries, 2011-20. *Health Affairs (Millwood)*. 2016 Feb; 35(2):199-207. PMID: 26858370. *Health Affairs' Top 10 Most Read Articles of 2016.
3. **Ozawa S**[§], Yemeke T, Evans D, Pallas S, Wallace A, Lee BY. Defining hard-to-reach populations for vaccination. *Vaccine*. 2019 Aug 7. pii: S0264-410X(19)30858-8. PMID: 31400910.
4. Portnoy A, Clark S, **Ozawa S**, Jit M. The impact of vaccination on gender equity: Conceptual framework and human papillomavirus (HPV) vaccine case study. *International Journal for Equity in Health*. 2020 Jan 14; 19(1):10. PMID: 31937328 PMCID: PMC6961353.

B. Positions and Honors

Positions and Employment

2005-09 Consultant, Health Nutrition & Population Unit, Human Development Network, The World Bank
2007-10 Graduate Research Assistant, Department of International Health, The Johns Hopkins Bloomberg School of Public Health
2009 Dean's Teaching Fellow, Undergraduate Program in Public Health Studies, Zanvyl Krieger School of Arts and Sciences, The Johns Hopkins University
2010-16 Assistant Scientist, Department of International Health, The Johns Hopkins Bloomberg School of Public Health; Health Economist, International Vaccine Access Center
2016-Present Associate Professor, Division of Practice Advancement and Clinical Education, UNC Eshelman School of Pharmacy, University of North Carolina at Chapel Hill
Adjunct Associate Professor, Department of Maternal and Child Health, UNC Gillings School of Global Public Health, University of North Carolina at Chapel Hill

Other Experience

2005- Member, American Public Health Association, Global Health Council
2006- Member, International Health Economics Association, American Society of Health Economists, Society of Medical Decision Making
2012- Member, Health Systems Global
2014 Ad hoc reviewer, Committee on Identifying and Prioritizing Preventive Vaccines for Development, Review of National Academies Report: Ranking Vaccines: Applications of a Prioritization Software Tool, Institute of Medicine and National Academy of Engineering
2015-17 Member of WHO Strategic Advisory Group of Experts (SAGE) Global Vaccine Action Plan (GVAP) Working Group on Demand for Immunization
2016- Member of the Scientific Committee Review Panel of International Health Economics Association (iHEA)
2017- Elected Co-Chair, Medicines in Health Systems Thematic Working Group, Health Systems Global

Selected Honors

2003 Magna Cum Laude, Georgetown University
Phi Beta Kappa National Honors Society, Georgetown University
2005 Designation as Associate in Risk Management, Insurance Institute of America
2006 Departmental Full-Tuition Scholarship for PhD in Health Systems
2007 *Delta Omega Public Health Honors Society*, Johns Hopkins University
Dean's Alumni Advisory Council Scholarship; Global Field Experience Fund Award
2008 The Dean's Teaching Fellowship, Johns Hopkins University
Baker, Reinke, Taylor Scholarship in International Health
2009 New Investigator Award in Global Health, Global Health Council
The Ruth Rice Puffer Award; Nancy Stephens Student Support Award
2010 Faculty Pilot Grants in Global Health: 2010 Winner, Johns Hopkins Center for Global Health
The Toyota Foundation Research Grant Award
2011 & 2012 Teaching Excellence Recognition, Johns Hopkins School of Public Health
2020 Junior Faculty Development Award, the University of North Carolina at Chapel Hill

C. Contribution to Science

1. **Estimating the value of vaccines globally.** One line of my research has sought to generate evidence on the broad benefits of vaccination for non-health decision makers. In a widely-cited systematic review, I examined the cost-effectiveness and economic benefits of vaccines. I led the development of various economic models to estimate the return on investment of childhood immunizations across 10 antigens and 94 countries over a decade. This work has been referenced frequently by decision makers (Ministers of Health, Ministers of Finance, parliamentarians, Gavi, UNICEF, WHO, Bill and Melinda Gates Foundation) and tweeted by Bill Gates. I have estimated the economic impact of vaccinations across many countries including the US, demonstrating averted treatment costs and saved productivity losses from vaccination.

    a. **Ozawa S**, Portnoy A, Getaneh H, Clark S, Knoll M, Bishai D, Yang HK, Patwardhan P. Modeling the economic burden of adult vaccine-preventable diseases in the United States. *Health Affairs (Millwood).* 2016 Nov 1; 35(11): 1-9. PMID: 27733424. *Health Affairs' Top 10 Most Read Articles of 2016.
    b. **Ozawa S**, Clark S, Portnoy A, Grewal S, Brenzel L, Walker D. Return on investment from childhood immunizations in low- and middle-income countries, 2011-20. Health Affairs (Millwood). 2016 Feb;35(2):199-207. PMID: 26858370. *Health Affairs' Top 10 Most Read Articles of 2016.
    c. **Ozawa S**, Clark S, Portnoy A, Grewal S, Stack M, Sinha A, Mirelman A, Franklin H, Friberg I, Tam Y, Walker N, Clark A, Ferrari M, Sweet S, Goldie S, Vynnycky E, Reef S, Grant G, Garske T, Li M, Hansen P, Johnson H, Walker D. Estimated economic impact of vaccinations in 73 low- and middle-income countries, 2001-2020. Bulletin of the World Health Organization. 2017;95(9):629-638. PMID: 28867843. PMCID: PMC5578376.
    d. **Ozawa S**, Mirrelman A, Stack M, Walker D, Levine OS. Cost-Effectiveness and Economic Benefits of Vaccines in Low- and Middle- Income Countries: A Systematic Review. *Vaccine*. 2012 Dec; 31(1):96-108. PMID: 23142307

2. **Reaching 'the last mile' to improve immunization coverage.** A second line of my research has sought to understand and intervene on the problem of low immunization coverage among hard-to-reach populations, also known as reaching 'the last mile'. This work has included reviews of definitions of hard-to-reach populations for vaccination and examining costs of interventions to increase immunization coverage. I have examined the economic value of targeting hard-to-reach populations for vaccination and parents' preferences for interventions to improve immunization coverage.

    a. **Ozawa S**, Yemeke T, Evans D, Pallas S, Wallace A, Lee BY. Defining hard-to-reach populations for vaccination. *Vaccine*. 2019 Aug 7. pii:S0264-410X(19)30858-8. PMID: 31400910.
    b. **Ozawa S**. Yemeke TT, Thompson KM. Systematic review of the incremental costs of interventions that increase immunization coverage. *Vaccine*. 2018 Jun 14; 36:3641-9. PMID: 29754699.
    c. **Ozawa S**, Zhou M, Wonodi C, Chen H, Bridges J. Parents' preferences for interventions to improve childhood immunization uptake in northern Nigeria. *Vaccine*. 2018 May 11; 36(20):2833-2841. PMID: 29661582.
    d. Lee B, Brown S, Haidari L, Clark S, Abimbola T, Pallas S, Wallace A, Mitgang E, Leonard J, Bartsch S, Yemeke T, Zenkov E, **Ozawa S**. Economic value of vaccinating geographically hard-to-reach populations with measles vaccine: A modelling application in Kenya. *Vaccine*. 2019 Apr; 37(17): 2377-86. PMID: 30922700 PMCID: PMC6487493.

3. **Agent-based modeling on substandard and falsified medicines and impact of antimicrobial resistance.** A third line of my research has examined the impact of medicine quality using agent-based modeling. I led the development of mathematical simulation models to examine the impact of substandard and falsified medicines and the resulting impact of antimicrobial resistance in the Democratic Republic of Congo, Uganda and Nigeria. To parameterize model inputs, I also led a well-cited systematic review and meta-analysis of the prevalence and economic impact of substandard and falsified medicines.

    a. **Ozawa S,** Haynie D, Bessias S, Laing S, Yemeke T, Evans D. Modeling the economic impact of substandard and falsified antimalarials in the Democratic Republic of Congo. *American Journal of Tropical Medicine and Hygiene*. 2019 May;100(5):1149-1157. PMID: 30675851 PMCID: PMC6493946.

b. **Ozawa S**, Evans D, Higgins C, Laing S, Awor P. Development of an agent-based model to assess the impact of substandard and falsified anti-malarials: Uganda case study. *Malaria Journal*. 2019 Jan 9;18(1):5. PMID: 30626380. PMCID: PMC6327614.
c. **Ozawa S**, Evans D, Bessias S, Haynie D, Yemeke T, Laing S, Herrington J. Prevalence and estimated economic burden of substandard and falsified medicines in low- and middle-income countries: A systematic review and meta-analysis. *Jama Network Open*. 2018 Aug 3; 1(4):e181662. PMID: 30646106. PMCID: PMC6324280.
d. Beargie S, Higgins C, Evans D, Laing S, Erim D, **Ozawa S**. The economic impact of substandard and falsified antimalarial medications in Nigeria. *PLoS One*. 2019 Aug 15; 14(8):e0217910. PMID: 31415560 PMCID: PMC6695148.

4. **Examination of trust in vaccines and the health system.** My PhD dissertation was on the measurement of trust, which I have continued to be interested in as an important predictor of vaccination uptake, care seeking, treatment adherence, and health outcomes. I have reviewed trust measures, developed a tool to build informed trust, and explored pathways for building trust in vaccines and the health system.

a. **Ozawa S**, Villar-Uribe M, Evans D, Kulkarni V, Por I. Building informed trust: developing an educational tool for injection practices and health insurance in Cambodia. *Health Policy and Planning.* 2018 Nov 1; 33(9):1009-17. PMID: 30312416.
b. **Ozawa S**, Paina L, Qiu M. Exploring pathways for building trust in vaccines and strengthening health system resilience. *BMC Health Services Research.* 2016 Nov 15; 6(Suppl 7):639. PMID: 28185595. PMCID: PMC5123384.
c. **Ozawa S**, Sripad P. How do you measure trust in the health system? A systematic review of the literature. *Social Science & Medicine*. 2013 Aug; 91:10-14. PMID: 23849233.
d. **Ozawa S**, Stack M. Public Trust and Vaccine Acceptance – International Perspectives. *Human Vaccines & Immunotherapeutics.* 2013 Aug; 9(8):1774-8. PMID: 23733039.

5. **Costing studies on vaccines.** Costing studies are important to estimate adequate resources that are needed to successfully carry out programs and forecast future requests for financial resources. I have conducted various economic studies examining costs of vaccination programs or costs of vaccine-preventable diseases to build the groundwork for economic evaluations.

a. Portnoy A, **Ozawa S**, Grewal S, Norman B, Rajgopal J, Gorham K, Brown S, Lee B. Costs of vaccine programs across 94 low- and middle-income countries. *Vaccine*. 2015 May 7; 33S: A99-A108. PMID: 25919184.
b. **Ozawa S**, Grewal S, Portnoy A, Sinha A, Arilotta R, Stack M, Brenzel L. Funding gap for immunization across 94 low- and middle-income countries. *Vaccine*. 2016 Dec 7; 34(50): 6408-6416. PMID: 28029541.
c. **Ozawa S**, Stack ML, Bishai DM, Mirelman A, Friberg IK, Niessen L, Walker DG, Levine OS. During the 'decade of vaccines,' the lives of 6.4 million children valued at $231 billion could be saved. *Health Affairs (Millwood)*. 2011 Jun; 30(6):1010-20. PMID: 21653951.
d. Stack ML, **Ozawa S**, Bishai DM, Mirrelman A, Tam Y, Niessen L, Walker DG, Levine OS. Estimated economic benefits during the 'decade of vaccines' include treatment savings, gains in labor productivity. *Health Affairs (Millwood).* 2011 Jun; 30(6):1021-8. PMID: 21653952.

Complete List of Published Work in my bibliography (59 total):
https://www.ncbi.nlm.nih.gov/myncbi/1RY1_w344uR5k/bibliography/public/

D. Additional Information: Research Support

Ongoing Research Support

PRIVATE SUPPORT — Ozawa (PI) — 2/20-1/22

Fellowship in Quality of Medical Products
This project establishes a new fellowship program between UNC and USP for fellows to conduct research examining economic incentives to improve the quality of medical products. Role: Principal Investigator

U.S. Agency for International Development Ozawa (PI) 7/20-6/21
Return on Investment on Nutrition Investments
The purpose of this research is to estimate USAID's return on investment of nutrition interventions to assess the value of USAID's historical and future investments in reducing undernutrition in low- and middle-income countries. Role: Principal Investigator

PRIVATE SUPPORT Ozawa (PI) 1/20-10/20
Return on Investment of Risk-Based Post Market Surveillance
The purpose of this research is to develop a business case for strengthening national regulatory authorities to conduct risk-based post market surveillance to counter the threat of substandard and falsified medicines. Role: Principal Investigator

PRIVATE SUPPORT Ozawa (PI) 1/20-12/20
UNC Junior Faculty Development Award
The purpose of this research is to estimate the health and economic impact of buying antibiotics from illicit online pharmacies. Role: Principal Investigator

PRIVATE SUPPORT Omer (PI) 8/18-7/21
Estimating the Impact of Maternal Flu Immunization
The purpose of this research is to estimate the impact of maternal flu immunization on economic productivity gains by examining the linkage between children's cognitive function, educational attainment and employment outcomes. Role: Co-Investigator

Completed Research Support (past 3 years)
PRIVATE SUPPORT Ozawa (PI) 3/19-6/19
Importance of Medicine Quality in Achieving Universal Health Coverage
The purpose of this research is to develop a white paper on the importance of medicine quality of essential medicines in low- and middle-income countries toward achieving universal health coverage.
Role: Principal Investigator

Center for Disease Control and Prevention (CDC) Lee (PI) 8/18-6/19
Hard-to-reach Populations Bridging the Gaps for Immunization (H2R BTG)
The purpose of this research is to identify the gaps in literature on populations that are hard-to-reach for immunization, including the mechanisms that make individuals hard-to-reach, economic impact of not reaching them and interventions to reach them. Role: Co-Investigator

PRIVATE SUPPORT Ozawa (PI) 3/17-9/17
Estimation of financial resource requirements for achieving maternal and neo-natal tetanus elimination
The purpose of this research is to develop an investment case that presents the cost-effectiveness of maternal and neo-natal tetanus elimination and comprehensively shows the resource requirements needed for achieving maternal and neo-natal tetanus elimination. Role: Principal Investigator

OMB No. 0925-0001 and 0925-0002 (Rev. 03/2020 Approved Through 02/28/2023)

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. DO NOT EXCEED FIVE PAGES.

NAME: **Reiter, Paul L**

eRA COMMONS USER NAME (credential, e.g., agency login): eRA COMMONS USER NAME

POSITION TITLE: **Associate Professor**

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)*

INSTITUTION AND LOCATION	DEGREE (if applicable)	Completion Date MM/YYYY	FIELD OF STUDY
Bowling Green State University, Bowling Green, OH	BS	05/2001	Biology
University of Minnesota, Minneapolis, MN	MPH	05/2004	Epidemiology
The Ohio State University, Columbus, OH	PhD	06/2008	Epidemiology
University of North Carolina, Chapel Hill, NC	Postdoctoral Fellowship	07/2011	Cancer Control Education Program

A. Personal Statement

As an epidemiologist with extensive experience in the behavioral sciences, I am committed to improving vaccination and cancer screening behaviors. I am particularly interested in identifying the determinants of engaging in these behaviors and then developing and testing interventions to increase their use. I will serve as a co-investigator on this project and work in close collaboration with Dr. Noel Brewer and the rest of the study team. In doing so, I will be highly involved with the development and implementation of the intervention and data collection activities. Given my training and expertise, I believe I am well-qualified to serve in this role. The primary focus of my work over the last decade has been on assessing and increasing HPV vaccination among adolescents and young adults. I currently serve as the multi-PI of an R37 project (originally awarded as an R01) to test a mobile health (mHealth) intervention to increase HPV vaccination among young sexual minority men. I also have experience in working with health clinics to implement interventions, as evidenced by my current role as project multi-PI on a P01 award to implement cervical cancer prevention interventions in health clinics in four Appalachian states. I also possess expertise in data collection methodologies. I recently served as Director of the Behavioral Measurement Shared Resource at The Ohio State University Comprehensive Cancer Center and as co-leader of the Recruitment, Survey, and Retention Core for the OSU Center for Excellence in Regulatory Tobacco Science. My past work has resulted in over 110 publications since 2008, and I have a long history of successful collaboration with Dr. Brewer. The proposed study will build upon our previous work together and will rigorously develop and test clinic-based interventions to increase HPV vaccination.

Relevant publications

1. **Reiter PL**, Shoben AB, McDonough D, Ruffin MT, Steinau M, Unger ER, Paskett ED, Katz ML. Results of a Pilot Study of a Mail-Based Human Papillomavirus Self-Testing Program for Underscreened Women From Appalachian Ohio. *Sex Transm Dis.* 2019; 46(3): 185-190. PubMed PMID: 30461597; PMCID: PMC637501.
2. **Reiter PL**, Katz ML, Bauermeister JA, Shoben AB, Paskett ED, McRee AL. Increasing human papillomavirus vaccination among young gay and bisexual men: a randomized pilot trial of the Outsmart HPV intervention. *LGBT Health.* 2018; 5(5): 325-9. PubMed PMID: 29979642; PMCID: PMC6034390.
3. **Reiter PL**, McRee AL, Pepper JK, Gilkey MB, Galbraith KV, Brewer NT. Longitudinal predictors of human papillomavirus vaccination among a national sample of adolescent males. *Am J Public Health.* 2013 Aug;103(8):1419-27. PubMed PMID: 23763402; PMCID: PMC3725571.
4. **Reiter PL**, Stubbs B, Panozzo CA, Whitesell D, Brewer NT. HPV and HPV vaccine education intervention: effects on parents, healthcare staff, and school staff. *Cancer Epidemiol Biomarkers Prev.* 2011 Nov;20(11):2354-61. PubMed PMID: 21949110; PMCID: PMC3210879.

B. Positions and Honors

Positions and Employment

2011-2012 Associate Director, Behavioral Measurement Shared Resource, Comprehensive Cancer Center, The Ohio State University, Columbus, OH
2011-2016 Assistant Professor, Division of Cancer Prevention and Control, The Ohio State University, Columbus, OH
2013-2016 Executive Officer, Cancer Control Program, Alliance for Clinical Trials in Oncology, Columbus, OH
2016-2018 Associate Professor, Division of Cancer Prevention and Control, The Ohio State University, Columbus, OH
2012-2018 Director, Behavioral Measurement Shared Resource, Comprehensive Cancer Center, The Ohio State University, Columbus, OH
2011- Member, Cancer Control Program, Comprehensive Cancer Center, The Ohio State University, Columbus, OH
2018- Associate Professor, Division of Health Behavior and Health Promotion, The Ohio State University, Columbus, OH

Other Experience and Professional Memberships

2014-2017 Editorial Board Member, PLOS ONE
2015-2018 Chair, Best Practices Task Group, National HPV Vaccination Roundtable
2008- Member, American Public Health Association
2009- Member, Society of Behavioral Medicine
2010- Member, American Society of Preventive Oncology

C. Contributions to Science

My research is focused on the determinants of vaccination and cancer screening behaviors and establishing evidence for successful interventions.

1. **HPV Vaccination Behaviors.** Over the last several years, I have performed seminal work on determining HPV vaccine coverage among US residents. This work has involved several primary data collection efforts and conducting secondary analyses of large datasets. Findings have produced novel data that offer important insight into HPV vaccine coverage and determinants of vaccination, and these findings have been used to inform interventions to increase HPV vaccination. I also helped develop the Carolina HPV Immunization Attitudes and Beliefs Scale (CHIAS), which has become a widely used scale for measuring attitudes and beliefs about HPV vaccination. This past work is important to the proposed program project since its focus is on promoting HPV vaccination.

    a. **Reiter PL**, Brewer NT, Gilkey MB, Katz ML, Paskett ED, Smith JS. Early adoption of the human papillomavirus vaccine among Hispanic adolescent males in the United States. *Cancer*. 2014 Oct 15;120(20):3200-7. PMID: 24948439; PMCID: PMC4321105.
    b. **Reiter PL**, McRee AL, Pepper JK, Gilkey MB, Galbraith KV, Brewer NT. Longitudinal predictors of human papillomavirus vaccination among a national sample of adolescent males. Am J Public Health. 2013 Aug;103(8):1419-27. PMID: 23763402; PMCID: PMC3725571.
    c. **Reiter PL**, Katz ML, Paskett ED. HPV vaccination among adolescent females from Appalachia: implications for cervical cancer disparities. *Cancer Epidemiol Biomarkers Prev*. 2012 Dec;21(12):2220-30. PMID: 23136141; PMCID: PMC3518634.
    d. McRee AL, Brewer NT, **Reiter PL**, Gottlieb SL, Smith JS. The Carolina HPV immunization attitudes and beliefs scale (CHIAS): scale development and associations with intentions to vaccinate. *Sex Transm Dis.* 2010 Apr;37(4):234-9. PMID: 19940807.

2. **Developing and Testing Interventions.** I have developed and tested several behavioral interventions to improve cancer screening and vaccination behaviors. These interventions have targeted individuals, healthcare providers, and health clinics and have involved a variety of approaches. Current and recent work includes interventions promoting HPV self-testing at home among women from Appalachia, HPV vaccination among gay and bisexual men, HPV vaccination among college students, and colorectal cancer screening for individuals at high-risk for colorectal cancer. For these projects, I have led or co-led the development and implementation of the interventions, which has provided me with experience that will be

highly useful for developing and implementing the intervention in the proposed study.

a. **Reiter PL**, Shoben AB, McDonough D, Ruffin MT, Steinau M, Unger ER, Paskett ED, Katz ML. Results of a Pilot Study of a Mail-Based Human Papillomavirus Self-Testing Program for Underscreened Women From Appalachian Ohio. Sex Transm Dis. 2019; 46(3): 185-190. PMID: 30461597; PMCID: PMC637501.

b. **Reiter PL**, Katz ML, Bauermeister JA, Shoben AB, Paskett ED, McRee AL. Increasing human papillomavirus vaccination among young gay and bisexual men: a randomized pilot trial of the Outsmart HPV intervention. LGBT Health. 2018; 5(5): 325-9. PMID: 29979642; PMCID: PMC6034390.

c. Presser BE, Katz ML, Shoben AB, Moore D, Ruffin MT, Paskett ED, **Reiter PL**. Effects of an education intervention about HPV self-testing for healthcare providers and staff. J Cancer Educ. 2018; 33(5): 954-9. PMID: 28074444; PMCID: PMC5503812.

d. **Reiter PL**, Stubbs B, Panozzo CA, Whitesell D, Brewer NT. HPV and HPV vaccine education intervention: effects on parents, healthcare staff, and school staff. Cancer Epidemiol Biomarkers Prev. 2011 Nov;20(11):2354-61. PMID: 21949110; PMCID: PMC3210879.

3. **Qualitative and Quantitative Data Collection.** I have expertise in both qualitative and quantitative data collection methods. *Qualitatively*, I have moderated qualitative data collection sessions (e.g., focus groups) for both formative research and program evaluation. Recently, I served as moderator for all of the focus groups that were conducted in developing an HPV vaccine intervention for young sexual minority men. In other projects, I have led qualitative data collection sessions involving adolescents, parents, adult patients, and healthcare providers. *Quantitatively*, I have developed highly sophisticated survey instruments for administration via several routes, including mail, telephone, and online. For these surveys, I was also highly involved in developing and implementing data collection protocols, designing data tracking systems, monitoring data quality, and identifying and implementing innovative solutions to data collection issues. I recently served as Director of the BMSR and co-leader of the Recruitment, Survey, and Retention Core for the OSU Center for Excellence in Regulatory Tobacco Science. Both of these positions involved extensive data collection activities.

a. Katz ML, Zimmermann BJ, Moore D, Paskett ED, **Reiter PL**. Perspectives from healthcare providers and women about completing human papillomavirus (HPV) self-testing at home. Women Health. 2017 Nov-Dec;57(10):1161-77. PMID: 27700693; PMCID: PMC5949215.

b. **Reiter PL**, McRee AL. Cervical cancer screening (Pap testing) behaviours and acceptability of human papillomavirus self-testing among lesbian and bisexual women aged 21-26 years in the USA. J Fam Plann Reprod Health Care. 2015 Oct;41(4):259-64. PMID: 25385868; PMCID: PMC5253697.

c. **Reiter PL**, Broder-Oldach B, Wewers ME, Klein EG, Paskett ED, Katz ML. Appalachian residents' perspectives on new U.S. cigarette warning labels. J Community Health. 2012; 37(6): 1269-1278. PMID: 22527659; PMCID: PMC3430827.

d. **Reiter PL**, McRee AL, Kadis JA, Brewer NT. HPV vaccine and adolescent males. Vaccine. 2011 Aug 5;29(34):5595-602. PMID: 21704104; PMCID: PMC3143221.

4. **Cancer Prevention Behaviors.** In addition to HPV vaccination, I have performed extensive work over the last several years on measuring and assessing cancer prevention behaviors among US residents. Much of this work has focused on cancer screening behaviors, as well as outcomes related to tobacco use. Findings have produced novel data that have highlighted engagement in these behaviors and identified existing disparities by demographic characteristics (e.g., age, race/ethnicity, socioeconomic status, etc.). Further, much of this work has been conducted among residents of rural areas, which are geographic regions that often experience cancer-related disparities.

a. Katz ML, **Reiter PL**, Young GS, Pennell ML, Tatum CM, Paskett ED. Adherence to multiple cancer screening tests among women living in Appalachia Ohio. *Cancer Epidemiol Biomarkers Prev.* 2015 Oct;24(10):1489-94. PMID: 26282630; PMCID: PMC4592467.

b. Pepper JK, **Reiter PL**, McRee AL, Cameron LD, Gilkey MB, Brewer NT. Adolescent males' awareness of and willingness to try electronic cigarettes. *J Adolesc Health.* 2013 Feb;52(2):144-50. PMID: 23332477; PMCID: PMC3569032.

c. Pepper JK, Cameron LD, **Reiter PL**, McRee AL, Brewer NT. Non-smoking male adolescents' reactions

to cigarette warnings. *PLoS One.* 2013;8(8):e65533. PMID: 23950861; PMCID: PMC3737223.

d. **Reiter PL**, Wewers ME, Paskett ED, Klein EG, Katz ML. Ohio Appalachian residents' views on smoke-free laws and cigarette warning labels. *Rural and Remote Health.* 2012; 12(1): 1945. PMID: 22300190; PMCID: PMC3881177.

Complete List of Published Work in My Bibliography:
http://www.ncbi.nlm.nih.gov/myncbi/paul.reiter.1/bibliography/44488419/public/?sort=date&direction=ascending

D. Additional Information: Research Support

Ongoing Research Support

NCI: P01 CA229143 Paskett (PI) 04/11/19-03/31/24
Improving Uptake of Cervical Cancer Prevention Services in Appalachia
This Program Project is addressing the burden of cervical cancer in Appalachia through the delivery of a clinic-based integrated prevention program that focuses on the major causes of cervical cancer.
Role: Multi-PI for Project 3

NCI: R37 CA226682 (originally awarded as R01 CA226682) Reiter, McRee (PIs) 04/01/18-03/31/22
A Randomized Controlled Trial of an HPV Vaccine Intervention for Young Sexual Minority Men
This study is comprehensively evaluating *Outsmart HPV*, an innovative mobile health HPV vaccine intervention that was recently developed for young sexual minority men.
Role: Multi-PI

NIMHD: R21 MD012800 Reiter (PI) 08/22/18-03/31/21 (NCE)
A Secondary Analysis to Identify HPV Vaccination Disparities across Hispanic Subgroups in the United States
This study is examining how HPV vaccination differs across various Hispanic subgroups in the United States.
Role: PI

NCI: UH3 CA233282 Dignan (PI) 09/19/18-08/31/23
Accelerating Colorectal Cancer Screening through Implementation Science (ACCSIS) in Appalachia
This project aims to increase screening for colorectal cancer in central Appalachia.
Role: Co-Investigator

NIA: R21 AG061496 Katz (PI) 02/15/19-12/31/20
Using Audio and Video Brochures in a Mail-Based FIT Outreach Intervention
This project will develop and pilot test a mail-based intervention to improve colorectal cancer screening.
Role: Co-Investigator

Completed Research Support (past 3 years)

PRIVATE SUPPORT

Katz, Reiter (PIs) 06/01/15-12/31/18
An HPV Vaccine mHealth Intervention for College Students
This project developed an education intervention to increase HPV vaccination among college students.
Role: Multi-PI

NCI: P50 CA180908 Wewers, Shields (PIs) 09/01/13-08/31/18
OSU Center for Excellence in Regulatory Tobacco Science (OSU-CERTS)
The overall theme of OSU-CERTS was to understand the reasons for underlying tobacco-product preferences and how these reasons influence use in an environment of ever-changing diverse types of tobacco products.
Role: Co-Investigator (Co-Director of the Recruitment, Survey, and Retention Core)

NCI: R21 CA194831 Reiter,McRee (PIs) 07/01/15-06/30/18 (NCE)
Increasing HPV Vaccine Coverage among Young Adult Gay and Bisexual Men
This study developed and pilot tested an HPV vaccine intervention for gay and bisexual men.
Role: Multi-PI

NCI: R03 CA198115 Reiter, McRee (PIs) 07/07/15-06/30/18 (NCE)

HPV Infection among Sexual Minority Women in the United States

This project determined the prevalence of HPV infection among sexual minority women in the United States.
Role: Multi-PI

OMB No. 0925-0001 and 0925-0002 (Rev. 03/2020 Approved Through 02/28/2023)

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: **Rosen, Audrey**

eRA COMMONS USER NAME (credential, e.g., agency login):

POSITION TITLE: **Vice President Market Research**

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE	Completion Date	FIELD OF STUDY
SUNY Stony Brook University Stony Brook, NY	BA	5/1980	Psychology
Adelphi University Garden City NY	MBA	01/1982	Organizational Behavior

A. Personal Statement

With over 30+ years of experience working with custom research, household panel and syndicated research, as well as integration and analysis of data sources such as behavioral data and digital information and survey research, I will provide leadership to the WebMD team who will manage the programming and data collection efforts. My 30+ years of experience includes directing large- and small-scale research and evaluation studies, managing project staff, overseeing million dollar plus project budgets, and ensuring that projects were completed on schedule and within budget. I have served as a project executive for a wide variety of projects across multiple verticals including pharmaceutical, health insurance, medical technology, retail and consumer packaged goods.

Prior to joining WebMD in 2017, I worked for Knowledge Networks starting in its infancy (in 2000) through our sale to Gfk in 2012 and then remained with GfK through much of 2016. Knowledge Networks and Knowledge panel were known in the industry as innovators in building a representative panel of the US population first leveraging RDD phone recruiting and then utilizing Address based sampling approaches.

B. Positions and Honors

Positions and Employment

1986 - 1989	Senior Project Director, NPD research consumer diary panel division (division sold to Nielsen in 1989)
1989 - 2000	Vice President Group Account Director, Nielsen Market Research
2000 - 2016	Executive Vice President Custom and Behavioral Research, Managing Director Market Opportunity, Innovation and Trends, Knowledge Networks (sold to Gfk in 2012)
2017 - Current	Vice President Market Research, WebMD – Medscape professional services

C. Contributions

1. I provide custom research oversight and data collection services primarily to commercial entities that have a need for high quality health care professional research data and analysis services. I have expertise in multiple verticals including health care, consumer packaged goods, retail and media. I am experienced with several modes of research data collection, including web-based surveys, telephone interviewing (TDI's) and in-person interviewing. I have lead market research teams of over 75 employees responsible for the research and analysis for many Fortune 100 organizations.
    - In process of validating and recruiting physicians in EU5 plus Canada in order to launch a new global health care professional panel for WebMD/Medscape

- Part of 8 person executive team at Knowledge Networks participating in the presentation and sale of Knowledge Networks to potential acquirers
- Lead development and roll out of Hispanic Knowledge Networks panel (including both acculturated and Spanish speaking household)
- Lead in creation, productization and roll-out of unique methodology to optimize consumer choice in consumer goods and retail
- Collaborated with ComScore to build a product that linked online viewing behavior to shopper card data providing the client the ability to evaluate the impact of online communication on in-store purchasing behavior

D. Additional Information: Research Support

None.

OMB No. 0925-0001 and 0925-0002 (Rev. 03/2020 Approved Through 02/28/2023)

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: **Savoy, Margot Latrese**

eRA COMMONS USER NAME (credential, e.g., agency login):

POSITION TITLE: **Associate Professor, Family & Community Medicine**

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE	Completion Date	FIELD OF STUDY
University of Maryland, College Park	BS	05/1998	Neurobiology & Physiology
University of Maryland, Baltimore	MD	05/2002	Medicine
Crozer-Keystone Family Medicine Residency Program		6/2005	Family Medicine
University of North Carolina, Chapel Hill Gillings School of Global Public Health	MPH	05/2008	Public Health Leadership (Public Health Practice)
Michigan State University Primary Care	Faculty Development	05/2008	
Thomas Jefferson University/EPaD Geriatric Education Center Interdisciplinary	Faculty Development	05/2010	
American Academy of Family Physicians Vaccine	Science Fellowship	03/2012	

A. Personal Statement

I have the expertise, leadership, training, expertise and motivation necessary to serve on the External Advisory Board for the proposed P01 Program Project “Improving Provider Announcement Communication Training” (IMPACT). I am an Associate Professor and Chair of Family and Community Medicine at Temple University’s Lewis Katz School of Medicine. I am a family physician who cares for patients across ages and in a diverse range of ambulatory and inpatient settings. My clinical work focuses on prevention and management of chronic diseases with an interest in immunizations, diabetes and cardiovascular diseases using patient-centered and evidenced-based approaches. My research focuses on quality improvement, health disparities, social determinants of health, patient safety and health policy. I have successfully led local and national collaborative efforts to assist clinicians in providing optimal care using a patient-centered population health approach including optimizing communication with patients around HPV vaccination, use of community-based pre-diabetes prevention programs and leveraging private/public partnerships via the Million Hearts® Delaware campaign. My current work includes connecting African American women with researchers in an effort to understand Triple Negative Breast Cancer in Delaware and working with the PCORI Stakeholder Advisory Group to develop training materials to ensure patients and researchers are able to work most effectively as co-researchers. The current application builds logically on my prior work as a clinician and researcher.

Relevant publications

1. **Savoy M**, O'Gurek D, Brown-James A. Sexual Health History: Techniques and Tips. *Am Fam Physician*. 2020;101(5):286-293.
2. **Savoy M**. IDx-DR for Diabetic Retinopathy Screening. *Am Fam Physician*. 2020;101(5):307-308.
3. Leasy M, O'Gurek DT, **Savoy ML**. Unlocking Clues to Current Health in Past History: Childhood Trauma and Healing. *Fam Pract Manag*. 2019 Mar/Apr;26(2):5-10.

4. Loehr J, **Savoy M**. Strategies for Addressing and Overcoming Vaccine Hesitancy. *Am Fam Physician*. 2016 Jul 15;94(2):94-6.

B. Positions and Honors

Positions & Employment

Academic

2005-2008 Community Preceptor, Lewis Katz School of Medicine, Temple University, Philadelphia, PA
2007-2008 Community Preceptor, Crozer-Keystone Family Practice Residency Program, Springfield, PA
2010-2018 Clinical Assistant Professor, Sidney Kimmel Medical College, Thomas Jefferson University, Philadelphia, PA
2008-2018 Core faculty, Christiana Care Health System Family Medicine Residency Program, Wilmington, DE
2018- Associate Professor, Temple University Physicians, Philadelphia, PA

Hospital

2005-2008 Attending Physician, Crozer-Keystone Health Access Network, Springfield, PA
2006-2015 Attending Physician, Pennsylvania Department of Health STD clinic, Chester PA
2008-2018 Attending Physician, Christiana Care Health System, Wilmington, DE
2018- Attending Physician, Lewis Katz School of Medicine, Temple University, Philadelphia, PA

Other Experience and Professional Memberships

2006- Society of Teachers of Family Medicine
2006-2008 PA Department of Public Welfare Family Planning Waiver Task Force
2008-2014 Board member, Southeast Pennsylvania Area Health Education Council
2008-2018 Committee member (various roles), Christiana Care Health System
2009- American Public Health Association
2011- Member, Immunization Coalition of Delaware
2011-2014 Advisory Council member, Quality Insights of Delaware
2012- Member (various roles), American Academy of Family Physicians
2012- Westside Family Healthcare Board of Directors Quality Improvement Committee member
2012-2015 Million Hearts® Delaware Clinical Prevention Sub-committee Chair
2013- Medical Society of Delaware
2016- Immunization Action Coalition Advisory Board
2017-2018 Committee member, EBright Health ACO

Honors

1997 Health Careers Enhancement Program for Minorities at Case Western Reserve University School of Medicine Outstanding Scholarship Award 1997
1999 Fogarty Minority International Research Traineeship
2004 American Academy of Family Physicians Minority Scholarship
2005 American Academy of Family Physicians Resident Scholarly Project Honorable Mention
2005 Pennsylvania Academy of Family Physicians Annual Research Day 1st place in Poster Category
2005 Crozer-Keystone Family Practice Residency Program Senior Scholarly Project Award
2005 Crozer-Keystone Family Practice Residency Program Resident of the Year
2011 Christiana Care Health System Medical Dental Staff Rising Star award recipient
2013 Delaware Academy of Family Physicians Teacher of the Year
2015 Delaware Academy of Family Physicians President's Recognition
2017 Delaware Academy of Family Physicians President's Recognition
2018 Friend of the Delaware Academy of Family Physicians

C. Contributions to Science

1. **Quality Improvement.** My publications in quality improvement span a wide range mostly ambulatory projects occurring typically with residency teaching practices in urban or suburban areas. Initially focused on developing practices into patient-centered medical homes, my later work focused on expanding that model to improve vaccination rates, communication with patients via the patient portal and leveraging the QI model to embed patient safety science concepts in the practice.

   a. Dressler R, Consiglio-Ward L, Moore C, **Savoy M**, Aboff, B, Salam T, Jordan, J, Collier, V. Safety Science as Second Nature - Training Residents to Use Best Practices Instinctively to Keep Patients Safe. *Physician Executive Journal*: 2014 May/June; 40(3):66-69. PMID: 24964553.

   b. **Savoy, M**. An Opportunity for Improvement: Adolescent Administration of the Human Papillomavirus Vaccine. *Delaware Medical Journal*. 2014 February: 86(2):53-5. PMID: 24783718.

   c. **Savoy M**, Hammond JA, Castellano L. Implementing a patient portal at the family medicine center. *Delaware Medical Journal*. 2015 Mar;87(3):81-4. PMID: 25985541.

   d. **Savoy M**. Navigating Conflict While Constructing Your Patient-Centered Medical Home. *Physician Executive Journal*: 2014 January; 40(1):28-32. PMID: 24575699.

2. **Health Disparities & Social Determination of Health.** Much of my published work around health disparities and SDOH focuses on assisting clinicians in identifying opportunities or gaps in care or communication and implementing solutions to improve the care provided by the patient. Given the focus of this research project is around shared decision-making and communication, I've highlighted a sample of my previous publications that focus on those areas.

   a. Lin K, O'Gurek DT, Rich R, **Savoy ML**. How to Help Your Patients Choose Wisely. *Fam Pract Manag*. 2015 Jul-Aug;22(4):28-34. PubMed PMID: 26176506.

   b. Epling JW, **Savoy ML**, Temte JL, Schoof BK, Campos-Outcalt D. When vaccine misconceptions jeopardize public health. *J Fam Pract*. 2014 Dec;63(12):E1-7. Review. PMID: 25486317.

   c. Weinberg JL, Guarino JM, **Savoy ML**, Horton T, Reed J. Identifying Differences in Communication Technology Preferences Across the Lifespan. *Journal of the American Geriatrics Society*. 11/2012; 60(11):2176-2177. PMID: 23148426.

   d. Loehr J, **Savoy M**. Strategies for Addressing and Overcoming Vaccine Hesitancy. *Am Fam Physician*. 2016 Jul 15;94(2):94-6.

3. **Patient Safety.** In addition to the quality improvement publications noted earlier, my more recent work has focused on improving patient safety during transitions of care and in the ambulatory setting. The sample of recent work noted below focuses on previous work seeking tools for use in outpatient practices to identify preventable adverse events as well as identifying strategies to improve communication and reduce preventable hospitalizations.

   a. Davis J, N Harrington, H Bittner Fagan, **M Savoy**. The Accuracy of Trigger Tools to Preventable Adverse Events in Primary Care: A Systematic Review. *J Am Board Fam Med*. 2018 Jan-Feb;31(1):113-125. PMID: 29330246

   b. Davis J, Bittner-Fagan H, **Savoy M**. Improving Patient Safety: Common Outpatient Medical Errors. *FP Essent*. 2017 Dec;463:11-15. Review. PMID: 29210554

   c. Bittner-Fagan H, Davis J, **Savoy M**. Improving Patient Safety: Improving Communication. *FP Essent*. 2017 Dec;463:27-33. Review. PMID: 29210557

   d. **Savoy M**, Davis J, Bittner-Fagan H. Improving Patient Safety: Prevention of Hospital Readmission. *FP Essent*. 2017 Dec;463:21-26. PMID: 29210556

4. **Health Policy.** As a former chair and member of the AAFP Commission on Health of the Public and Science and liaison to many organizations on behalf of the AAFP, I have drafted a number of clinical polices for adoption. I am currently a member of the AAFP Board of Directors and ADFM board of

directors. While these policies are not published under my name, I've included samples of the publications I've prepared to explain the work to the wider family medicine population. I recently completed service on the ISDA Lyme Disease guideline panel and the recommendations are currently in press.

a. **Savoy M**. ACIP Releases 2018 Childhood Immunization Recommendations. *Am Fam Physician*. 2018 Feb 15;97(4):278. PMID: 29671520.
b. **Savoy M**. ACIP Releases 2018 Adult Immunization Recommendations. *Am Fam Physician*. 2018 Feb 15;97(4):279-280. PMID: 29671519.
c. **Savoy M**. Differences Between the AAFP Atrial Fibrillation Guideline and the AHA/ACC/HRS Guideline American Family Physician. *Am Fam Physician* (e-pub ahead of print; August, 2017) http://www.aafp.org/dam/AAFP/documents/journals/afp/AFibEditorial.pdf

Pub-Med bibliography:
https://www.ncbi.nlm.nih.gov/sites/myncbi/1xaJtaHpjCHAq/bibliography/53889042/public/?sort=date&direction=ascending

A summary of additional publications can be located on my Temple bio:
https://medicine.temple.edu/margot-savoy

D. Additional Information: Research Support and/or Scholastic Performance

Ongoing Research Support

n/a

Completed Research Support

n/a

OMB No. 0925-0001 and 0925-0002 (Rev. 03/2020 Approved Through 02/28/2023)

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: **Spees, Lisa P**

eRA COMMONS USER NAME (credential, e.g., agency login): eRA COMMONS USER NAME

POSITION TITLE: **Assistant Professor**

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
Emory University, Atlanta, GA	BA	05/2009	History
Emory University, Atlanta, GA	MA	05/2009	History
Wake Forest University Winston-Salem, NC	MS	05/2010	Management
University of North Carolina, Chapel Hill, NC	PhD	05/2016	Public Policy
Cecil G. Sheps Center for Health Services Research, University of North Carolina, Chapel Hill, NC	Postdoc	07/2018	Health Services Research
Lineberger Comprehensive Cancer Center, University of North Carolina, Chapel Hill, NC	Postdoc	07/2020	Cancer Care Quality

A. Personal Statement

I am an Assistant Professor in the Department of Health Policy and Management at the University of North Carolina at Chapel Hill (UNC-CH). As a health services researcher, my research has focused on examining disparities among cancer populations and identifying the multi-level barriers to care among medically underserved cancer populations. Relevant to the proposed Project 4 is my research expertise in urban/rural disparities. In previous projects, I explored the long-standing belief that urban-rural health disparities are due to the longer distances rural patients must travel to receive care by examining whether distance to care influences cervical cancer patients' access to guideline-concordant treatment. For this project, I was awarded a $2000 grant from the North Carolina Translational and Clinical Sciences Institute and a $50,000 Developmental Research Award from Lineberger Comprehensive Cancer Center. From this research, I first-authored two manuscripts, one of which was chosen as a "Highlight" article in the journal, *Cancer Epidemiology, Biomarkers & Prevention.* Additionally, I have worked with collaborators at the National Cancer Institute to identify multi-level barriers to genomic testing in a nationally-representative survey of medical oncologists. Our results showed that oncologists practicing in rural areas were more like to face barriers at both the individual- and organizational-level, compared to oncologists practicing in urban areas. Additionally, I have strong research collaborations with Dr. Stephanie Wheeler (Co-Lead) and Dr. Sarah Birken (Co-I). I have developed and led a project (with Drs. Birken and Wheeler as Co-Is) to identify the multilevel determinants of de-implementation of low-value urologic imaging of prostate cancer and asymptomatic microscopic hematuria patients. This mixed methods study will comprehensively conceptualize individual and organizational determinants of de-implementation of low-value imaging by combining use of the Theoretical Domains Framework (TDF) and the Consolidated Framework for Implementation Research (CFIR). Due to the novel study design, this project has been chosen to be a case study in an article detailing how to effectively identify the multilevel determinants of de-implementation in addition to being exemplified in a book chapter on mixed methods for a handbook on implementation science. My expertise in urban/rural disparities, and my interest in implementation science, I am well-positioned to contribute to the current proposal.

Relevant publications.

1. **Spees LP**, Wheeler, SB, Weinberger, M, Mahesh V, Baggett C, Zhou X, Petermann VM, Brewster WR. Evaluating the urban-rural paradox: The complicated relationship between distance and receipt of guideline-concordant care among cervical cancer patients. *Gynecol Oncol.* 2019 Jan;152(1):112-118. doi: 10.1016/j.ygyno.2018.11.010. PMCID: PMC6321781.
2. **Spees LP**, Brewster WR, Weinberger, M, Mahesh V, Baggett C, Zhou X, Peterman VM, Wheeler, SB. Examining urban and rural differences in how distance to care influences the initiation and completion of treatment among insured cervical cancer patients. *Cancer Epidemiol Biomarkers Prev.* 2019 May;28(5):882-889. doi: 10.1158/1055-9965.EPI-18-0945. PMCID: PMC6500480.
3. **Spees LP**, Roberts MC, Freedman AN, Butler E, Klein WM, Prabhu Das I, de Moor J. Involving Patients and Their Families in Deciding to Use Next Generation Sequencing: Results from a Nationally Representative Survey of U.S. Oncologists. *Patient Educ Couns*. 2020 Mar 3;S0738-3991(20)30116-6. doi: 10.1016/j.pec.2020.03.001.

B. Positions and Honors

Positions and Employment

2007-2008 Research Assistant, Department of History, Emory University, Atlanta, GA
2009 Summer Associate in Global Entrepreneurship, Public Forum Institute, Washington, DC
2010-2016 Predoctoral Trainee, Carolina Population Center, University of North Carolina at Chapel Hill, Chapel Hill, NC
2010-2016 Graduate Student, Department of Public Policy, University of North Carolina at Chapel Hill (UNC), Chapel Hill, NC
2015-2016 Research Assistant, Department of Epidemiology, Harvard T.H. Chan School of Public Health, Boston, MA
2016-2018 Consultant, International Training and Education Center for Health, University of Washington, Gaborone, Botswana
2016-2018 NRSA Postdoctoral Research Fellow, Cecil G. Sheps Center for Health Services Research, University of North Carolina at Chapel Hill, Chapel Hill, NC
2018- 2020 Cancer Care Quality Postdoctoral Research Fellow, Lineberger Comprehensive Cancer Center, University of North Carolina at Chapel Hill, Chapel Hill, NC
2020- Associate Member, Lineberger Comprehensive Cancer Center, University of North Carolina at Chapel Hill, Chapel Hill, NC
2020- Assistant Professor, Department of Health Policy and Management, Gillings School of Global Public Health, University of North Carolina at Chapel Hill, Chapel Hill, NC

Grants and Fellowships

2008 Scholarly Inquiry and Research at Emory Independent Research Grant, Emory University ($2,500)
2011-2012 Carolina Population Center Predoctoral Traineeship, University of North Carolina at Chapel Hill ($9,150)
2010-2016 Chancellor Fellowship, Royster Society of Fellows, University of North Carolina at Chapel Hill ($65,900)
2017-2018 NCTraCS Pilot Grant, University of North Carolina at Chapel Hill ($2,000)
2017-2018 Developmental Pilot Research Award, University of North Carolina at Chapel Hill ($50,000)
2020-2021 Developmental Pilot Research Award, University of North Carolina at Chapel Hill ($50,000)

Other Experience

2010-2016 Member, Royster Society of Fellows, University of North Carolina at Chapel Hill
2010-2016 Member, Population Association of America
2010-2017 Member, Association for Public Policy Analysis and Management
2012- Ad hoc reviewer, *Educational Research Journal*
2013- Ad hoc reviewer, *Latino/a Psychology*
2014- Ad hoc reviewer, *Sociological Inquiry*
2017- Reviewer, *Families, Systems, and Health*
2019- Reviewer, *Journal of Rural Health*

2019- Reviewer, *Cancer Epidemiology*
2019- Reviewer, *International Journal of Cancer*

Selected Honors

2007 Phi Alpha Theta, History Honors Society, Emory University
2009 B.A. awarded with high honors, Emory University
2009 Partial scholarship, 1-year Masters scholarship, Wake Forest University School of Business
2010 Beta Sigma Gamma, Business Honors Society, Wake Forest University School of Business
2010 M.A. awarded with honors, University School of Business
2010 Inducted into Royster Society of Fellows; UNC Graduate School
2010-2016 Predoctoral Fellowship, Carolina Population Center, University of North Carolina at Chapel Hill, Chapel Hill, NC (5T32HD716833)
2012-2013 Teaching Assistant of the Year Award, University of North Carolina at Chapel Hill, Department of Public Policy
2013-2014 Teaching Assistant of the Year Award, University of North Carolina at Chapel Hill, Department of Public Policy
2013 Poster Session Winner, Annual meeting of the Population Association of America
2013 Travel Award, American Education Research Association Institute on Statistical Analysis: Causal Inference
2014 Robert E. Bryan Public Service Award (for Amigas En Salud), University of North Carolina at Chapel Hill
2016 Funded for 1-month visit, International Training and Education Center for Health, University of Washington, Gaborone, Botswana
2016-2018 National Service Research Award Post-Doctoral Traineeship, University of North Carolina at Chapel Hill (5T32HS000032-28)
2018-2020 Post-Doctoral Traineeship, Lineberger Comprehensive Cancer Center, University of North Carolina at Chapel Hill (5T32CA116339)
2019 Postdoctoral Award for Research Excellence, University of North Carolina at Chapel Hill
2020 Cancer Outcomes Research Program Travel Award, Lineberger Comprehensive Cancer Center, University of North Carolina at Chapel Hill

C. Contributions to Science

1. **Urban/rural disparities in access to cancer care**. During my postdoctoral fellowship at the Sheps Center for Health Services Research at UNC, I led a project examining the urban-rural disparities in the timing and treatment of cervical cancer patients. This project challenged the long-standing belief that urban-rural health disparities were due to the longer distances rural patients must travel to receive care. Our findings demonstrated that geographic distance independently influenced receipt of high-quality treatment among urban and rural cancer patients. More specifically, we found that urban patients were more likely to find distance to be a significant barrier to treatment whereas rural patients did not find distance to be a barrier to treatment. These results have significant implications for future interventions focused on reducing urban/rural cancer disparities; simply extending services and opportunities that exist and work well in urban environments will be insufficient since the underlying social determinants of poor cancer outcomes in rural areas differ from those in urban areas.

    a. **Spees LP**, Wheeler, SB, Weinberger, M, Mahesh V, Baggett C, Zhou X, Petermann VM, Brewster WR. Evaluating the urban-rural paradox: The complicated relationship between distance and receipt of guideline-concordant care among cervical cancer patients. Gynecol Oncol. 2019 Jan;152(1):112-118. doi: 10.1016/j.ygyno.2018.11.010. PMCID: PMC6321781.
    b. **Spees LP**, Brewster WR, Weinberger, M, Mahesh V, Baggett C, Zhou X, Peterman VM, Wheeler, SB. Examining urban and rural differences in how distance to care influences the initiation and completion of treatment among insured cervical cancer patients. Cancer Epidemiol Biomarkers Prev. 2019 May;28(5):882-889. doi: 10.1158/1055-9965.EPI-18-0945. PMCID: PMC6500480.

2. **Cervical cancer screening among medically underserved populations**. I am part of a team evaluating the effect of at-home HPV self-tests compared to in-clinic scheduling assistance for cervical cancer

screening among underscreened or never screened women in North Carolina. From this project, I published a protocol article. Additionally, I was the senior author of a systematic review examining the screening preferences of medically underserved populations. We found that consistent preferences for HPV self-testing over traditional Pap testing highlight a key potential mechanism for increasing cervical cancer screening uptake among medically underserved populations. Additionally, preferences for gender- and language-concordant providers underscore the need for continued efforts toward expanding diversity among medical professionals.

a. **Spees LP**, Des Marais AC, Wheeler SB, Hudgens MG, Doughty S, Brewer NT, Smith JS. Impact of human papillomavirus (HPV) self-collection on subsequent cervical cancer screening completion among under-screened women: MyBodyMyTest-3 Protocol for a randomized controlled trial. *Trials*. 2019;20(1):788. doi: 10.1186/s13063-019-3959-2. PMCID: PMC6935089.
b. Biddell CB, O'Leary MO, Wheeler SB, **Spees LP**. Variation in Cervical Cancer Screening Preferences Among Medically Underserved Individuals in the US: A Systematic Review. (forthcoming in *Cancer Epidemiol Biomarkers Prev*).

3. **Improving clinical care for hematopoietic stem cell transplant recipients (HSCTs).** At Duke University, I was a co-investigator and senior methodologist on a project examining changes in the clinical care of patients receiving HSCTs, a treatment being used to treat a growing number of malignant and non-malignant conditions in adults and children. Data for this project came from several sources, including chart review, Duke's HSCT patient registry, and the Duke Enterprise Data Unified Content Explorer (DEDUCE), which includes administrative and clinical information. Results from this project have showed that how advances in the diagnosis and treatment of infections such as aspergillosis has improved survival over time. We also determined that strategies targeted at preventing and treating adenovirus, cytomegalovirus, and graft-versus-host-disease are still needed.

a. **Spees LP**, Kelly MS, Vinesett R, Stokhuyzen A, McGill L, Proia AD, Jenkins K, Arshad A, Seed PC, Martin PL. Utility of autopsy among pediatric allogeneic hematopoietic stem cell transplant recipients: one last chance to learn? *Biol Blood Marrow Transplant.* 2018 Sep;24(9):1861-1865. doi: 10.1016/j.bbmt.2018.05.030. PMCID: PMC6163060.
b. **Spees LP**, Martin PL, Kurtzberg J, Stokhuyzen A, McGill L, Prasad VK, Driscoll TA, Parikh SH, Page KM, Vinesett R, Severyn C, Sung AD, Proia AD, Jenkins K, Arshad M, Steinbach WJ, Seed PC, Kelly MS. Reduced mortality after umbilical cord transplantation in children over a 20-year period (1995-2014). *Biol Blood Marrow Transplant.* 2019 Apr;25(4):756-763. doi: 10.1016/j.bbmt.2018.11.018. PMCID: PMC6453734.
c. Akinboyo I, Young R, **Spees LP**, Heston S, Smith MJ, Chang Y, McGill LE, Martin PL, Jenkins K, Lugo DJ, Hazen KC, Seed PC, Kelly MS. Microbiology and Risk Factors for Hospital-Associated Bloodstream Infections among Pediatric Hematopoietic Stem Cell Transplant Recipients. *Open Forum Infect Dis.* 2020 Mar 16;7(4):ofaa093. doi: 10.1093/ofid/ofaa093. PMCID: PMC7141603.
d. Tanaka JS, Young RR, Heston SM, Jenkins K, **Spees LP**, Sung AD, Corbet K, Thompson JC, Bohannon L, Martin PL, Stokhuyzen A, Vinesett R, Ward DV, Bhattarai SK, Bucci V, Arshad M, Seed PC, Kelly MS. Anaerobic antibiotics and the risk of graft-versus-host disease after allogeneic hematopoietic stem cell transplantation. *Biol Blood Marrow Transplant.* 2020 Jul 16;S1083-8791(20)30442-0. PMID: 32682948.

Complete List of Published Work in MyBibliography
https://www.ncbi.nlm.nih.gov/sites/myncbi/1biSx9gKxoCkX/bibliography/50910851/public/?sort=date&direction=ascending

D. Additional Information: Research Support and/or Scholastic Performance

NCI: 1-R01-CA240092-01 Wheeler, Rosenstein (Co-PIs) 07/2019 – 07/2023
Addressing Cancer-Related Financial Toxicity in Rural Oncology Care Settings
The objectives of this application are to: (1) understand the rural oncology practice context to optimize tailored strategies to support financial navigation (FN) implementation; (2) assess FN intervention implementation in

rural oncology practices; and (3) evaluate the effects of FN implementation on patient outcomes, including financial toxicity (FT) and health-related quality of life, in rural oncology practices.
Role: Co-I

NCI: 1-R01-CA183891-01A1 Smith (PI) 07/2020 – 12/2020
Effect of HPV Self-collection on Cervical Cancer Screening in High Risk Women
This study employs a randomized controlled trial to investigate whether cervical cancer screening among underscreened women could be improved with testing for human papillomavirus (HPV) using at-home self-collection kits delivered by mail. This study further explores the cost-effectiveness of such an intervention.
Role: Co-I

NCI: 1-R01-CA226842-01A1 Dinan (PI) 07/2020 – 12/2023
Disparities in the Use of Oral Anticancer Agents in Kidney Cancer
This award uses three complementary data sources to study modifiable barriers to optimal oral anticancer agents (OAA) utilization and adherence at the level of patients, providers, facilities, and region.
Role: Co-I

PRIVATE SUPPORT Wheeler (PI) 07/2020-08/2020
Developing and validating a risk stratification framework for breast cancer survivors
We will develop and validate a risk stratification framework, beginning with breast cancer survivors who constitute the largest share of cancer survivors who may benefit from such risk stratification, in response to the American Cancer Society Request for Proposal (RFP) to provide Coordination and Technical Assistance for the 2018 Patient Navigation & the Cancer Care Delivery Modeling Study.
Role: Co-I

Completed Research Support (past 3 years)
NIH: 5T32 CA116339 Basch, Wheeler, Chen (Co-PIs) 09/2018-05/2020
Cancer Care Quality Training Program (CCQTP) T-32 Postdoctoral Traineeship
This traineeship is a joint appointment between the Lineberger Comprehensive Cancer Center and the UNC Gillings Department of Health Policy and Management.
Role: Post-doctoral Fellow

NIH: 5T32 HS000032 Carey (PI) 09/2016-07/2018
National Research Service Award (NRSA) Institutional Health Services Research Training Program
This traineeship, funded by the Agency for Healthcare Research and Quality (AHRQ), is sponsored by the Cecil G. Sheps Center for Health Services Research.
Role: Post-doctoral Fellow

OMB No. 0925-0001 and 0925-0002 (Rev. 03/2020 Approved Through 02/28/2023)

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: **Spencer, Jennifer**

eRA COMMONS USER NAME (credential, e.g., agency login): eRA COMMONS USER NAME

POSITION TITLE: **Postdoctoral Research Fellow**

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE	Completion Date	FIELD OF STUDY
North Carolina State University, Raleigh, NC	BS	05/2009	Zoology
University of North Carolina, Chapel Hill, NC	OTH	05/2016	Health Policy & Management
University of North Carolina, Chapel Hill, NC	PhD	08/2019	Health Policy & Management

A. Personal Statement

As a consultant for Project 4, my role will be to provide modeling expertise on the development, testing, and visualization of the proposed dynamic HPV transmission model. I am a postdoctoral fellow in the Training in Oncology Population Sciences (TOPS) program at Dana Farber/Harvard Cancer Center. My research uses decision science methods to explore issues of cancer care equity, with a focus in HPV vaccination. In collaboration with Dr. Wheeler, I have worked on projects exploring racial, socioeconomic, and geographic disparities in breast cancer. I have also done substantial work in decision modeling with Dr. Wheeler, including leading a project comparing treatments for abnormal uterine bleeding and acting as a mentor on several student projects developed as part of our introductory modeling course that have been published or submitted for publication. Dr. Wheeler was the chair of my dissertation, which used a dynamic model of HPV transmission and vaccination to model current and future HPV cancer disparities between low-poverty and high-poverty US counties. Through this model I evaluated the potential effect of current vaccination rates, the cost-effectiveness of vaccination in both low- and high-poverty settings, and identified cost-effective strategies for increasing HPV vaccine uptake. For this work, I received the Marci K. Campbell Dissertation Award, awarded by the Lineberger Cancer Center for outstanding dissertation work in cancer population sciences. This work will help to inform the agent-based transmission model proposed in Aim 2 of this project. Further, in my current postdoctoral position, under the mentorship of Dr. Jane Kim, I have continued to strengthen my modeling skills across multiple projects while maintaining an emphasis on health equity through a project focused on HPV vaccination and HPV transmission among sexual minority populations. I have a strong history of collaboration with Dr. Wheeler and will be able to contribute to the proposed study through expertise on the development, testing, and visualization of the dynamic HPV model.

B. Positions and Honors

Positions and Employment

2015-2019 Research Assistant, University of North Carolina at Chapel Hill, Dept. Health Policy and Management
2017-2018 Teaching Assistant: Techniques for the Economic Evaluation of Healthcare, University of North Carolina at Chapel Hill, Dept. Health Policy & Management
2019-2019 Teaching Fellow: Operations Research for Healthcare Systems, University of North Carolina at Chapel Hill, Department of Health Policy and Management
2019- Postdoctoral Fellow, Dana Farber/Harvard Cancer Center, Boston, MA

Other Experience and Professional Memberships

2015 - Member, Disparities Interest Group, AcademyHealth
2016-2017 Treasurer, AcademyHealth UNC Student Chapter
2016 - Member, Society for Medical Decision Making

2019 - 2020	Communications Committee Chair, Harvard TH Chan School of Public Health Postdoctoral Association
2020-	President, Harvard TH Chan School of Public Health Postdoctoral Association

Selected Honors

2016	2nd Place, Presenting Research in Compelling Ways-Student Competition, AcademyHealth Annual Research Meeting
2017	Student Travel Award, Geographic Management of Cancer Health Disparities Program (GMaP) Region 1-South
2017	First Place: Cancer Communication Poster-Research, Center for Disease Control National Cancer Conference
2018	Cancer Outcomes Travel Award, Lineberger Comprehensive Cancer Center
2018	Harry T Philips Award for Outstanding Teaching by a Doctoral Student, Department of Health Policy and Management, University of North Carolina
2018	Scholar-in-Training Travel Award, NCI Center to Reduce Cancer Health Disparities
2019	Marci Kramish Campbell Dissertation Award, Lineberger Comprehensive Cancer Center
2019	Inductee- Theta Chapter, Delta Omega Honorary Society in Public Health
2019	Best Oral Presentation – Celebration of Early Career Researchers, Dana Farber/Harvard Cancer Center

C. Contributions to Science

1. **My research evaluates effective and efficient uses of healthcare resources through decision modeling.** As healthcare costs continue to rise and healthcare decision making becomes increasingly complex, decision science modeling offers crucial insight through comparison of multiple potential interventions when randomized controlled trials would be infeasible or would not capture costs and outcomes over the relevant time horizon of interest. My work thus far has modeled treatment options with respect to both patient-centered outcomes (quality of life, complication rates) and priorities from the healthcare system and health policy perspective, including cost-effectiveness.

    a. **Spencer JC**, Louie M, Moulder JK, Ellis V, Schiff LD, Toubia T, Siedhoff MT, Wheeler SB. Cost-effectiveness of treatments for heavy menstrual bleeding. Am J Obstet Gynecol. 2017 Nov;217(5):574.e1-574.e9. PubMed PMID: 28754438.

    b. James HJ, James TW, Wheeler SB, **Spencer JC**, Baron TH. Cost-effectiveness of endoscopic ultrasound-directed transgastric ERCP compared with device-assisted and laparoscopic-assisted ERCP in patients with Roux-en-Y anatomy. Endoscopy. 2019 Jun 26;PubMed PMID: 31242509.

    c. Wheeler SB, **Spencer J**, Rotter J. Toward Value in Health Care: Perspectives, Priorities, and Policy. N C Med J. 2018 Jan-Feb;79(1):62-65. PubMed PMID: 29439109.

    d. Louie M, **Spencer J,** Wheeler S, Ellis V, Toubia T, Schiff LD, Siedhoff MT, Moulder JK. Comparison of the levonorgestrel-releasing intrauterine system, hysterectomy, and endometrial ablation for heavy menstrual bleeding in a decision analysis model. Int J Gynaecol Obstet. 2017 Nov;139(2):121-129. PubMed PMID: 28796898.

2. **My research identifies underlying causes of persistent cancer disparities and strategies for improving cancer health equity**. Cancer in the US is characterized by wide and persistent disparities in incidence and mortality. Systemic barriers to accessing quality prevention, screening, and treatment exist for multiple traditionally marginalized populations, including racial, ethnic, and sexual minorities as well as those who are socioeconomically disadvantaged. My work has focused on identifying fundamental causes of health disparities as well as strategies to improve cancer health equity. This has included using advanced econometric methods to understand rural/urban health disparities in the US as well as several studies specific to breast cancer which explore disparate cancer outcomes by race, income, rurality, and the intersection of these characteristics.

a. **Spencer JC**, Wheeler SB, Rotter JS, Holmes GM. Decomposing Mortality Disparities in Urban and Rural U.S. Counties. Health Serv Res. 2018 Dec;53(6):4310-4331. PubMed PMID: 29845634; PubMed Central PMCID: PMC6232410.
b. **Spencer JC**, Reeve BB, Troester MA, Wheeler SB. Factors Associated with Endocrine Therapy Non-Adherence in Breast Cancer Survivors. Psycho-Oncology. 2020 Feb 11; PubMed PMID: 32048400.
c. **Spencer JC**, Rotter JS, Eberth JM, Zahnd WE, Vanderpool RC, Ko LK, Davis MM, Troester MA, Olshan AF, Wheeler SB. Employment changes following breast cancer diagnosis: the effects of race and place. J Natl Cancer Inst. 2019 Oct 10; PubMed PMID: 31599949.
d. Wheeler SB, **Spencer JC**, Pinheiro LC, Carey LA, Olshan AF, Reeder-Hayes KE. Financial Impact of Breast Cancer in Black Versus White Women. J Clin Oncol. 2018 Jun 10;36(17):1695-1701. PubMed PMID: 29668368; PubMed Central PMCID: PMC5993169.

3. **My research explores patterns of HPV vaccination use and long-term implications of HPV vaccine for traditionally marginalized populations.** HPV vaccination offers tremendous potential to reduce cancer, but uptake has been low in the US. HPV vaccination has important implications for health disparities, as many of the cancers that it prevents occur disproportionately in traditionally marginalized populations. My previous research in HPV vaccine disparities includes a meta-analysis synthesizing more than 100 studies reporting racial differences in HPV vaccine uptake, identification of predictive factors associated with follow-through of subsequent HPV vaccine doses, and a modeling study evaluating the cost-effectiveness of strategies to increase HPV vaccination rates in the US.

a. **Spencer JC**, Calo WA, Brewer NT. Disparities and reverse disparities in HPV vaccination: A systematic review and meta-analysis. Prev Med. 2019 Mar 29;123:197-203. PubMed PMID: 30930259.
b. **Spencer JC**, Brewer NT, Trogdon JG, Wheeler SB, Dusetzina SB. Predictors of Human Papillomavirus Vaccine Follow-Through Among Privately Insured US Patients. Am J Public Health. 2018 Jul;108(7):946-950. PubMed PMID: 29771616; PubMed Central PMCID: PMC5993378.
c. **Spencer JC**, Brewer NT, Trogdon JG, Weinberger M, Coyne-Beasley T, Wheeler SB. (2019) "Cost Effectiveness of Strategies to Increase HPV Vaccination". Pediatrics. 2020. *Accepted.*

Complete List of Published Work in My Bibliography:
https://www.ncbi.nlm.nih.gov/myncbi/jenny.spencer.1/bibliography/public/

D. Additional Information: Research Support and/or Scholastic Performance

Ongoing Research Support

WITHHELD — Spencer, Jennifer (PI) — 05/2020-04/2021
PRIVATE SUPPORT
"Incorporating Sexual Minority Populations in HPV Vaccine Modeling"
This pilot funding will support data acquisition and analysis for describing and modeling sexual behavior and HPV transmission rates among sexual minority men in the US.
Role: Primary Investigator

WITHHELD — Kim, Jane (PI) — 11/2019-10/2020
PRIVATE SUPPORT
"Therapeutic HPV Vaccine Modeling"
The goal of this study is to better understand the potential impact of therapeutic HPV interventions in both a low-income and high-income setting and to identify the ideal characteristics of a potential therapeutic to accelerate HPV control and elimination efforts.
Role: Postdoctoral Research Fellow

NIH: 2-T32-CA092203-1 — Krieger, Schrag (Co-PIs) — 07/2019-06/2021
National Cancer Institute

“Training in Oncology Population Sciences”
The Training in Oncology Population Sciences program is a T-32 Postdoctoral traineeship sponsored by the Dana Farber/Harvard Cancer Center.
Role: Postdoctoral Research Fellow

Completed Research Support

NIH: 2-T32-CA116339-11 Basch, Wheeler, Chen (Co-PIs) 09/2018-05/2019
National Cancer Institute
“Cancer Care Quality Training Program”
The Cancer Care Quality Training Program (CCQTP) is a T-32 Predoctoral Traineeship at the Lineberger Comprehensive Cancer Center, UNC-CH.
Role: Predoctoral Trainee

NIH: 5-R25-CA116339-10 Basch, Wheeler, Chen (Co-PIs) 09/2017-09/2018
National Cancer Institute
“Cancer Care Quality Training Program”
The Cancer Care Quality Training Program (CCQTP) is a R-25 Predoctoral Traineeship at the Lineberger Comprehensive Cancer Center, UNC-CH.
Role: Predoctoral Trainee

OMB No. 0925-0001 and 0925-0002 (Rev. 03/2020 Approved Through 02/28/2023)

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: **Szilagyi, Peter G.**

eRA COMMONS USER NAME (credential, e.g., agency login): eRA COMMONS USER NAME

POSITION TITLE: **Professor of Pediatrics and Vice Chair for Clinical Research**

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE	MM/YY	FIELD OF STUDY
Dartmouth College	BA	06/1977	Psychology
University of Rochester, NY	MD	06/1981	Medicine
University of Rochester, NY	MPH	06/1987	Public Health

A. Personal Statement

I am Professor of Pediatrics and Executive Vice-Chair in the Department of Pediatrics at the University of California, Los Angeles (UCLA). I have led studies on immunization delivery for 25+ years. My team has contributed substantially to strategies to improve immunization delivery such as practice-based interventions, reminder/recall, the development and evaluation of the US adolescent immunization strategy, universal influenza and rotavirus vaccination, vaccine financing (leading to the Vaccines for Children (VFC) Program), and strategies to reduce disparities in vaccination rates. Our work has been used extensively by CDC, the Advisory Committee on Immunization Practices (ACIP), IOM, the American Academy of Pediatrics and other bodies responsible for the US's immunization system. Most recently I have become interested in testing and implementing strategies that can be scaled up widely to entire populations. This proposal by Dr. Brewer and colleagues is scalable. I am happy to advise on this Program.

I have been a leader of large practice-based vaccination delivery studies. For the past 8 years I have led a set of practice intervention studies to raise HPV vaccination rates (>250 practices across the US); interventions include training providers in HPV vaccine communication skills, EHR/nurse prompts, performance feedback, and standing orders. These studies ranged from RCTs to QI-based studies. Several have noted moderate effectiveness in improving HPV vaccination rates and reducing missed opportunities for vaccinations. I have >20 years of experience in practice-based research. In 2008 I led the development of the University of Rochester's Greater Rochester Practice-based Research Network (pediatric, internal medicine, and family medicine practices) which assists with >50 studies per year. I am MPI of an NIH-funded RCT (the STOP-HPV study) involving 50 pediatric practices across the U.S., testing sequentially 3 interventions (and then testing the bundle). This study is in the field. I am also a practicing primary care pediatrician; I administer vaccines. Thus, I have the experience and understanding of primary care to consult on this proposal. In addition to addressing HPV vaccinations, I also have substantial experience with other studies to raise immunization rates. One set of studies involves patient reminder-recall. Others involve practice-based quality improvement. Others involve single or multi-component interventions.

Finally, I am an expert in dissemination/implementation. Between 1995 and 2014 I directed a county-wide reminder, recall and outreach program which raised child and adolescent vaccination rates in the Rochester area, reduced disparities, and was funded by the community for 20 years. I am a UCLA CTSI leader with a focus on child health research and community engagement. This R01 proposal combines rigorous methods of pragmatic RCTs with implementation science to improve HPV vaccination rates and to develop a sustainable, scalable model for the US. I am at the forefront of national immunization vaccine policy as a voting member of ACIP, and I serve as chair of ACIP's HPV Vaccine Workgroup. Thus I have the content expertise to serve on the External Advisory Board for the proposed P01 Program Project "Improving Provider Announcement Communication Training" (IMPACT).

B. Positions and Honors

Professional Experience (selected, since 1999)

1999-2014 Chief, Division of General Pediatrics and Professor of Pediatrics
2004-2014 Co-Director, Greater Rochester Practice-Based Research Network
2005-2014 Director, General Pediatrics Academic Fellowship Program
2006-2014 Associate Director, Community Engagement, CTSI
2009-present Editor-in-Chief: *Academic Pediatrics*
2014-present Vice Chair for Clinical Research and leader of "Special Populations" at UCLA's CTSI
2016-present Executive Vice-Chair of Pediatrics, UCLA

Honors (selected)

2002 Academic Pediatrics Association (APA) Lifetime National Research Award Recipient
2004 CDC: Honor for #1 practice-based immunization quality improvement program in US
2004 Howard Berman Prize for physician who most improved Rochester community health
2006 Junior Faculty Mentoring Award (a major mentoring award at the University of Rochester)
2010 Dr. David Satcher Community Health Improvement Award, University of Rochester
2010 NIH Health Services Organization and Delivery Study Section (HSOD); served to 2015
2014 Appointed to MACPAC- Medicaid & CHIP Payment & Access Commission, advises HHS and Congress
2015 Leadership team of the national CTSA Task Force on Lifecourse Research
2016 Appointed to the Advisory Committee on Immunization Practices (ACIP)

Professional Memberships (selected)

1989-present Academic Pediatric Association President (2008), Board member since 2004, Multiple leadership positions since 1995, Editor-in-Chief of *Academic Pediatrics*
1994-present Society for Pediatric Research (SPR)
1999-present American Pediatric Society (APS)
1987-present American Academy of Pediatrics (multiple roles over the past 25 years)

C. Contributions to Science

1. **Strategies to Improve HPV Immunization Rates – Focus on Practice-Based Interventions.** I am MPI of a CDC-funded U01 grant focused on practice-based interventions to improve HPV vaccination rates. We are working with two large practice-based research networks (PBRNs): the Academic Pediatric Association's (APA's) Continuity Clinic Research Network (CORNET) and the National Improvement Partnership Network (NIPN). We work with >75 practices/year using a quality-improvement framework to study provider prompts, training in HPV vaccine communication skills, standing orders, and office redesign. We've noted moderate impact on raising HPV vaccination rates. I am also MPI with Alex Fiks MD MPH on the STOP-HPV trial, an NIH-funded R01 study with the American Academy of Pediatrics (AAP's) Pediatric Practice in Office Settings (PROS) PBRN. This study tests, sequentially, provider training in communication skills, provider performance feedback, and provider prompts (and then the bundle). We are in the field with 50 practices. Over 25 years I have performed dozens of immunization studies in practices, ranging from assessing provider, patient and practice factors related to vaccination coverage, to RCTs testing prompts, methods to reduce missed opportunities, reminder/recall, and other interventions. I and my group speak widely on improving immunization coverage (>25 grand rounds/year); recognizing that a multi-pronged strategy is needed to raise HPV vaccination rates.

    a. **Szilagyi PG**, Humiston SG, Gallivan S, et al. Effectiveness of A City-Wide Patient Immunization Navigator Program in Improving Adolescent Immunizations and Preventive Care Visit Rate. *Arch Pediatr Adolesc Med*. 2011; 165: 547-553. PMID: 21646588.
    b. **Szilagyi PG,** SJ, Humiston SG, Rand C, Schaffer S, Vincelli P, Dhepyasun N, Blumkin A, Curtiss R. The Effect of Provider Prompts on Adolescent Immunization Rates: A Randomized Trial. *Academic Pediatrics*. 2015 Mar-Apr;15(2):149-57. doi: 10.1016/j.acap.2014.10.006. PMID: 25748976.
    c. Rand CM, Schaffer SJ, Dhepyasuwan N, Blumkin A, Albertin C, Serwint JR, Darden PM, Humiston SG, Mann KJ, Stratbucker W, **Szilagyi PG**. Provider communication, prompts, and feedback to improve HPV vaccination rates in resident clinics. *Pediatrics*. 2018 Mar 14:e20170498. PMID: 29540572.

d. Rand CM, Tyrrell H, Wallace-Brodeur R, Goldstein NP, Darden PM, Humiston SG, Albertin CS, Stratbucker W, Schaffer SJ, Davis W, **Szilagyi PG**. A learning collaborative model to improve HPV vaccination rates in primary care. *Academic Pediatrics*. 2018 Mar 1;18(2):S46-52. PMID: 29502638.

2. **Strategies to Improve Immunization Rates In General.** For >25 years I have led one of the most impactful US research groups studying methods to improve childhood, adolescent, and adult immunization rates. Our group has been continuously funded since 1987. Major contributions have included: (a) development of a widely-used model of barriers to immunization delivery (the Immunization Barrier Model); (b) investigations of the benefit of patient reminder/recall in improving child, adolescent, and adult immunization rates; (c) characterization of the concept of missed opportunities for immunizations and multiple RCTs to reduce missed opportunities and implement office practice changes; (d) studies on financial barriers to immunization delivery; (e) national leadership on the development and dissemination of the adolescent immunization platform; (f) national leadership on universal influenza vaccination recommendations with studies on improving influenza vaccination rates; and (g) incorporation of technology (immunization registries, EHRs, autodialers, text messages) to increase immunization rates. I have presented reports at Advisory Committee on Immunization Practices (ACIP) and IOM workgroups, CDC conferences and seminars, and special meetings focused on adolescent and influenza immunizations. These four references show my breadth of research in raising immunization rates:

   a. **Szilagyi PG**, Rickert D, McLaurin J, Tan L, Britto M, Francis A, Dunne E, Rand CM. Delivering Adolescent Vaccinations in the Medical Home: A New Era? *Pediatrics.* 121(Supplement): S15-S24, 2008. PMID: 18174317.
   b. **Szilagyi PG,** SJ, Humiston SG, Rand C, Schaffer S, Vincelli P, Dhepyasun N, Blumkin A, Curtiss R. The Effect of Provider Prompts on Adolescent Immunization Rates: A Randomized Trial. *Academic Pediatrics*. 2015 Mar-Apr;15(2):149-57. doi: 10.1016/j.acap.2014.10.006. PMID: 25748976.
   c. Rand C, **Szilagyi PG**, Vincelli P, Goldstein N, Blumkin A. Effects of Phone and Text Message Reminders on Completion of the Human Papillomavirus Vaccine Series. *Journal of Adolescent Health*. 2016 Sep. (Ref: Ms. No. JAH3084-17MAY16R1).
   d. **Szilagyi PG**, Schaffer S, Rand CM, Goldstein NPN, Hightower AD, Younge M, Eagan A, Blumkin A, Albertin CS, DiBetetto K, Concannon C, Vincelli P, Yoo B, Humiston S. Impact of elementary school-located influenza vaccinations: A stepped wedge trial across a community. *Vaccine.* 2018. 36:2861-2869. PMID: 29678459.

3. **Practice-based Research.** I have performed practice-based research since the 1980's, mostly focused on improving immunization delivery. I have also mentored dozens of faculty and fellows to conduct practice-based research. In 2008, as part of the University of Rochester's CTSI application, I helped design and then co-directed for 7 years the Greater Rochester Practice-based Research Network (GR-PBRN), working with 75 pediatric, family medicine, and internal medicine primary care practices. Nationally, I have been highly involved in the APA's Continuity Clinic Research Network and have conducted several practice-based interventions within this network. I am MPI of a CDC-funded U01 grant involving the Academic Pediatric Association (APA), that is focused on improving practice's HPV vaccine delivery and strengthening provider recommendations for the vaccine. Over the past 4 years we have worked with >250 practices across the US. Finally I am corresponding MPI of a NCI-funded practice-based research study (the STOP-HPV Trial) to test, in a sequential RCT format, the impact of training in provider communication skills, performance feedback, and provider prompts on HPV vaccination rates; this study involves 50 practices.

   a. Gibson K, Campbell T, Fiscella K, McInerny T, Swanger C, **Szilagyi P**. Physician Perspectives on Incentives to Participate in Practice-based Research.*The Journal of the American Board of Family Medicine.* 3(4) 52-454, 2010. PMID: 20616287. PMCID: PMC3000687.
   b. Poehling KA, Fairbrother G, Yuwei Z, Donauer S, Umiker D, Edwards K, Staat M, Prill MM, Finelli, L, Allred N, Bardenheier B, **Szilagyi PG**. Practice and Child Characteristics Associated with Influenza Vaccine Uptake in Young Children. *Pediatrics.* 126(4) 665-673, 2010. PMID: 20819893. PMCID: PMC3673003.
   c. Humiston SG, Serwint JR, **Szilagyi PG** et al. Increasing Adolescent Immunization Rates in Primary Care: Strategies Physicians Use and Would Consider Implementing. *Clinical Pediatrics*. 2013. 52(8):706-716. PMID: 23580625.

d. Halterman JS, Fagnano M, Tremblay PJ, Fisher SG, Wang H, Rand C, **Szilagyi PG**, Butz A. Prompting asthma intervention in Rochester-uniting parents and providers (PAIR-UP): A randomized trial. *JAMA Pediatr*. 2014 Oct;168(10):e141983. PMID: 25288141. PMCID: PMC4232370.

4. **Translational Science and Dissemination**. I have been instrumental in bolstering the field of pediatric translational research. I published an operational definition for pediatric research of T1-T4 research (Ref. #2 below). I have also been actively involved in local and national CTSA-based research in an attempt to enhance the rigor and impact of both child health translational research and community-engaged research. I adopted decades ago a population-based approach to research, with an attempt to study immunization delivery in generalizable settings involving primary care practices, schools, and other settings.

   a. **Szilagyi PG**. Translational Research and Pediatrics. *Academic Pediatrics*. 2009; 9:71–80. PMID: 19329097.
   b. Huskins WC, Sullivan CD, Wang J, ….**Szilagyi PG**, Purucker M, Barkin SL. Tracking the impact of the National Institutes of Health Clinical and Translational Science Awards on child health research: developing and evaluating a measurement strategy. *Pediatric Research, 2012;* 1-6. PMID: 22398699.
   c. **Szilagyi PG**, Shone LP, Dozier AM, Newton GL, Green T, Bennett NM. Evaluating community engagement in an academic medical center. *Academic Medicine.* 2014; 89:1-11. PMID: 24556768. PMCID: PMC4028444.
   d. Jacobson Vann JC, Jacobson RM, Coyne-Beasley T, Asafu-Adjei JK, **Szilagyi PG**. Patient reminder and recall interventions to improve immunization rates. *Cochrane Database Syst Rev*. 2018. PMCID: PMC6491344.

5. **Evidence to Changing Health Policy.** I have contributed to changes in health policy in two major areas—immunization delivery and health insurance. My team's immunization-delivery research contributed (together with a large body of literature) to the following changes in immunization policy: Vaccines for Children (studies showing cost-barriers and problems with referring children to public health clinics led to the VFC program which finances immunization delivery for half of America's children); influenza vaccination (studies showing large burden from influenza and changes in practices that would be needed led to universal vaccination recommendation); rotavirus vaccination (studies showing large burden of disease led to universal recommendations); Adolescent (particularly HPV) immunizations (studies demonstrating high receptivity to the new vaccine by parents and providers alike, but warnings about practice-based challenges. I am on the AAP's Committee on Child Health Finance, and very involved with AAP-related immunization policies which affect primary care pediatrics. As a voting member of the ACIP, I encounter, on nearly a daily basis, the intersection of research, scientific evidence, and immunization policy.

   a. **Szilagyi PG**, Schuster MA, Cheng TL. The scientific evidence for child health insurance. *Academic Pediatrics.* 9(1):4-6, 2009. PMID: 19329084. PMCID: PMC4571275.
   b. **Szilagyi PG**, Rand CM, McLaurin J, et al. Delivering adolescent vaccinations in the medical home: a new era? *Pediatrics* 2008;121 Suppl 1:S15-24. PMID: 18174317.
   c. Jacobson Vann JC, Jacobson RM, Coyne-Beasley T, Asafu-Adjei JK, **Szilagyi PG**. Patient reminder and recall interventions to improve immunization rates. *Cochrane Database Syst Rev*. 2018. PMCID: PMC6491344.
   d. Robinson CL, Romero JR, Kempe A, Pellegrini C, **Szilagyi P**. Advisory Committee on Immunization Practices Recommended Immunization Schedule for Children and Adolescents Aged 18 Years or Younger—United States, 2018. *Morbidity and Mortality Weekly Report*. 2018 Feb 9;67(5):156. PMID: 29420458. PMCID: PMC5812475.

Complete List of Published Work in MyBibliography (245 publications)
http://www.ncbi.nlm.nih.gov/myncbi/browse/collection/47321246

D. Additional Information: Research Support and/or Scholastic Performance

Ongoing Research Support

UL1TR001881 (Dubinet, PI) NIH (NCATS)	Szilagyi (Co-I)	07/01/2016–06/30/2021

Clinical and Translational Science Institute (CTSI)
Aims: For the Special Populations section of the CTSI-- Integrate special populations into UCLA's research enterprise to ensure that breakthroughs are quickly translated to the benefit of society and its subpopulations.
Role: Co-Investigators (with Catherine Sarkisian, UCLA)

R01 CA202261-01A1 (Szilagyi, Fiks MPIs) 09/01/2016-08/31/2021
NIH (NCI)
Improving HPV Vaccination Delivery in Pediatric Primary Care: The STOP-HPV Trial
Aims: Improve HPV vaccinations via practice-based changes using 3 sequential RCTs: testing communication skills training, performance feedback, and provider prompts.
Role: Corresponding MPI (Alex Fiks is MPI, Children's Hospital of Philadelphia)

R01 HD088586-01 (Coker PI) Szilagyi (Co-I) 07/01/2016 – 06/30/2021
NIH
Well-Child Care Clinical Practice Redesign: A Parent Coach-Led Model of Care for Young Children
Aims: The goal of this proposed project is to conduct a large randomized trial of a new model of Parent Coach led well-child care among low-income families with young children.
Role: Co-Investigator

1U01IP001049-01 (Weinberg PI) Szilagyi (Co-I) 09/01/2016 – 09/29/2021
CDC
Rochester New Vaccine Surveillance Network (NVSN)
Aims: Assess the burden of acute respiratory viruses including influenza and acute gastrointestinal viruses using prospective surveillance, and assess vaccine effectiveness for influenza and rotavirus vaccines.
Role: Co-Investigator

1 R01 AI135029-01 (Szilagyi PI) Szilagyi (PI) 01/16/2018 – 12/31/2022
NIH (NIAID)
Improving Influenza Vaccination Delivery In a Health System by the Electronic Health Records Patient Portal
Aims: Assess the impact of patient portal based reminders about influenza vaccination plus portal advances upon adult and child influenza vaccination rates, using successive randomized controlled trials.
Role: PI

OMB No. 0925-0001 and 0925-0002 (Rev. 03/2020 Approved Through 02/28/2023)

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. DO NOT EXCEED FIVE PAGES.

NAME: **Thirumurthy, Harsha**

eRA COMMONS USER NAME (credential, e.g., agency login): eRA COMMONS USER NAME

POSITION TITLE: **Associate Professor**

EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
Oberlin College, Oberlin, OH	BA	05/1998	Economics, Physics
Yale University, New Haven, CT	MA	05/2002	Economics
Yale University	MPhil	05/2003	Economics
Yale University	PhD	12/2006	Economics

A. Personal Statement

I am an economist whose research has focused on human behavior and tested various behavioral interventions to promote healthy behaviors in low- and middle-income settings. My research interests include the development and testing of innovative HIV prevention interventions that leverage new technologies and insights from behavioral economics. I have also led studies that use non-experimental methods to assess the effects of large-scale health initiatives on population health and economic outcomes. My recent research has tested economic interventions to increase utilization of HIV prevention services such as medical male circumcision, HIV testing, and adherence to HIV treatment. I have published over 100 articles in economics and biomedical journals. I am currently PI of NIH-funded R01 projects on HIV self-testing and the use of incentives to promote HIV testing. I have formed close collaborations with clinicians, epidemiologists, social scientists, and policymakers in various research projects. Outside my research activities, I have served on the program committee of the International AIDS Conference and I provide ongoing service as Chair of the Population Sciences Subcommittee at NICHD. In addition, I am Associate Director of the Center for Health Incentives and Behavioral Economics (CHIBE) at the University of Pennsylvania, where I lead global health initiatives. I am highly enthusiastic about contributing to the proposed project.

1. **Thirumurthy H**, Masters SH, Napierala Mavedzenge S, Maman S, Omanga E, Agot K. Promoting male partner HIV testing and safer sexual decision making through secondary distribution of self-tests by HIV-negative female sex workers and women receiving antenatal and post-partum care in Kenya: a cohort study. *The Lancet HIV* 2016; 3(6):e266-74. doi: 10.1016/S2352-3018(16)00041-2. PMCID: 5488644.
2. **Thirumurthy H**, Masters SH, Rao S, Bronson MA, Lanham M, Omanga E, Evens E, Agot K. Effect of providing conditional economic compensation on uptake of voluntary medical male circumcision in Kenya: a randomized clinical trial. *JAMA* 2014; 312(7):703-711. PMCID: 4268484.
3. Zivin JG, Goldstein M, **Thirumurthy H**. AIDS treatment and intrahousehold resource allocation: Children's nutrition and schooling in Kenya. *Journal of Public Economics* 2009; 93:1008-1015. PMCID: 3238680.
4. **Thirumurthy H**, Zivin JG, Goldstein M. The economic impact of AIDS treatment: labor supply in Western Kenya. *Journal of Human Resources* 2008; 43(3):511-52. PMCID: 3237059.

B. Positions and Honors

Positions and Employment

2006-2007 Post-Doctoral Fellow, Center for Global Development, Washington, DC
2007-2014 Assistant Professor of Health Economics, Department of Health Policy and Management Gillings School of Global Public Health, University of North Carolina at Chapel Hill (UNC-CH)
2008- Faculty Fellow, Carolina Population Center, UNC-CH

2009-	Elected Affiliate, Bureau for Research and Economic Analysis of Development (BREAD)
2009-2011	Economist, The World Bank, Washington, DC (on leave from UNC-CH)
2015-2017	Associate Professor, Department of Health Policy and Management, Gillings School of Global Public Health, UNC-CH
2017-present	Associate Professor, Department of Medical Ethics and Health Policy, Perelman School of Medicine, University of Pennsylvania
2017-present	Associate Director, Center for Health Incentives and Behavioral Economics (CHIBE)

Other Experience and Professional Memberships

2006-	Member, American Economic Association
2007-	Member, Population Association of America
2012	Ad hoc peer reviewer, NIH Social Science and Population Studies Study Section
2012-13	Program committee member, Population Association of America Annual Meeting, Detroit
2012-13	Program committee member, 2013 International Aids Society (IAS) Conference, Kuala Lumpur
2013	Program committee member, Population Association of America Annual Meeting
2015	Ad hoc peer reviewer, NIMH/NIAID AIDS and AIDS Related Research Special Emphasis Panel
2015-16	Program committee member, 2016 International Aids Society (IAS) Conference, Durban
2015-2018	Chartered member, NICHD Population Sciences Subcommittee Study Section
2019-present	Chair, NICHD Population Sciences Subcommittee Study Section

Honors

1998	Joel Dean Prize in Economics, Oberlin College
1998	Carl E. Howe Prize in Physics, Oberlin College
1998	Phi Beta Kappa
1998	Sigma Xi
2000	Honorable Mention, National Science Foundation Graduate Fellowship Competition
2005	John F. Enders Fellowship, Yale University
2007	New Investigator in Global Health Award, Global Health Council

C. Contribution to Science

1. **Evaluation of the economic impacts of investments in health in developing countries**. Determining the causal effects of health on various socio-economic outcomes has been an important objective of research in development and health economics. This is an empirically challenging task because health status is often poorly measured in household socio-economic surveys and the possibility of reverse causality (economic status influences health) can lead to biased estimates. I have used novel study designs and primary data to make notable scientific contributions while also addressing an important policy question regarding the returns to investments in health. My research has generated among the first estimates of the economic impacts of health interventions such as HIV treatment. My publications in leading economics and biomedical journals have been cited widely and I have given numerous talks on this topic internationally.

   a) Jakubowski A, Snyman K, Kwarisiima D, Sang N, Burger R, Balzer L, Clark T, Chamie G, Shade S, Cohen C, Bukusi E, Charlebois E, Kamya M, Petersen M, Havlir D, **Thirumurthy H**. High CD4 counts associated with better economic outcomes for HIV-positive adults and their HIV-negative household members in the SEARCH Trial. *PLOS One* 2018 Jun; 13(6):e0198912. PMCID: 6019679.
   b) Jakubowski AE, Stearns SC, Angeles G, Kruk ME, **Thirumurthy H**. The US President's Malaria Initiative and under-five child mortality in sub-Saharan Africa. *PLOS Medicine* 2017 June; 14(6): e1002319. PMCID: 5469567.
   c) **Thirumurthy H**, Zivin JG, Goldstein M. The economic impact of AIDS treatment: labor supply in Western Kenya. *Journal of Human Resources* 2008; 43(3):511-52. PMCID: 3237059.
   d) **Thirumurthy H**, Jafri A, Srinivas G, Arumugam V, Saravanan RM, Ponnumsamy M, Raghavan S, Merson M, Kallolikar S. Two-year impacts on employment and income among adults receiving antiretroviral therapy in Tamil Nadu, India: a cohort study. *AIDS* 2011; 25:239-46. PMID: 21150560.

2. **Application of economics and psychology to the study of health behavior**. Despite the growing toolbox of highly efficacious biomedical interventions for preventing and treating HIV/AIDS, behavioral factors have limited their effectiveness when implemented at scale. My research has developed and tested

novel interventions to modify these behavioral factors. With support from an NICHD K01 award and other grants, I have used insights from economics and psychology to study a wide range of health behaviors, including adherence to HIV treatment, uptake of medical male circumcision, and utilization of antenatal care. I led the first randomized controlled trial (RCT) of text messages to improve medication adherence in Africa (published in *AIDS* and cited over 450 times). I have also been PI or key investigator in multiple RCTs of economic incentives to promote various health behaviors and published them in leading journals such as *JAMA* and *The Lancet HIV*.

a) Moscoe E, Agot K, **Thirumurthy H**. Effect of a Prize-Linked Savings Intervention on Savings and Healthy Behaviors Among Men in Kenya: A Randomized Clinical Trial. *JAMA Network Open* 2019 Sept; 2(9):e1911162. PMCID: 6745050
b) **Thirumurthy H**, Ndyabakira A, Marson K, Emperador D, Kamya M, Havlir D, Kwarisiima D, Chamie G. Financial incentives for achieving and maintaining viral suppression among HIV-positive adults in Uganda: a randomised controlled trial. *The Lancet HIV* 2019; 6(3): PE155-E163. PMCID: 6421075.
c) **Thirumurthy H**, Masters SH, Rao S, Bronson MA, Lanham M, Omanga E, Evens E, Agot K. Effect of providing conditional economic compensation on uptake of voluntary medical male circumcision in Kenya: a randomized clinical trial. *JAMA* 2014; 312(7):703-711. PMCID: 4268484.
d) Pop-Eleches C*****, **Thirumurthy H***, Habyarmina J*****, Graff Zivin J, Goldstein M, DeWalque D, MacKeen L, Haberer J, Sidle J, Ngare D, Bangsberg D. Mobile phone technologies improve adherence to antiretroviral treatment in resource-limited settings: a randomized controlled trial of text message reminders. *AIDS* 2011; 25(6):825-834. PMCID: 3718389. (*) *shared first-authorship.*

3. **Innovative strategies for promoting HIV testing uptake in sub-Saharan Africa.** There is an urgent need to increase the uptake of HIV testing in sub-Saharan Africa, particularly among men. Whereas early diagnosis and treatment reduces transmission as well as mortality, late diagnosis is common and is a major contributor to high rates of early mortality in African HIV care programs. I have served as PI or Investigator on studies of multiple HIV testing modalities in east Africa and am keenly interested in identifying innovative ways to promote HIV testing uptake. HIV self-testing (HIVST) is an especially innovative and important intervention as it shows potential to increase testing coverage in hard-to-reach segments of the population and countries in Africa are developing policies to scale-up its availability. I have completed two prominent studies on HIV self-testing and am leading or contributing to several ongoing HIVST studies. I am also PI of a project in Uganda that seeks to promote HIV testing among men using economic incentives.

a) Masters SH, Agot K, Obonyo B, Napierala Mavedzenge S, Maman S, **Thirumurthy H**. Promoting partner testing and couples testing through secondary distribution of HIV self-tests by women: a randomized trial. *PLOS Medicine* 2016; 13(11): e1002166. PMCID: 5100966.
b) **Thirumurthy H**, Masters SH, Napierala Mavedzenge S, Maman S, Omanga E, Agot K. Promoting male partner testing and safer sexual decision-making through secondary distribution of HIV self-tests by HIV-uninfected female sex workers and women receiving antenatal and postpartum care in Kenya: a cohort study. *The Lancet HIV* 2016; 3(6): e266–e274. PMCID: 5488644.
c) Chamie G, Clark TD, Kabami J, Kadede K, Ssemmondo E, Burger R, Kwarisiima D, Sang N, Jain V, **Thirumurthy H**, Liegler T, Balzer L, Petersen ML, Cohen C, Bukusi EA, Kamya, MR, Havlir DV, Charlebois ED. A “hybrid” mobile HIV testing approach for population-wide HIV testing in rural East Africa. *The Lancet HIV* 2016; 3(3):e111–e119. PMCID: 4780220.
d) Lee R, Cui R, Muessig KE, **Thirumurthy H**, Tucker JD. Incentivizing HIV/STI testing: a systematic review of the literature. *AIDS and Behavior* 2014; 18(5):905-12. PMCID: 3966986.

4. **Measurement of subjective expectations about survival to advanced ages.** Individuals’ expectations about future health and longevity have been hypothesized as important determinants of individuals’ decisions to invest in physical and human capital. In developing countries, however, relatively few population-level studies have elicited individuals’ expectations about longevity. Particularly in sub-Saharan Africa, there have been strikingly few studies examining associations between HIV/AIDS and individuals’ subjective expectations about life expectancy. In a large, ongoing NIH-funded cluster-randomized trial of early HIV treatment in rural Kenya and Uganda, I am leading efforts to collect data on individuals’ subjective expectations about future health (including mortality) and economic well-being.

a) Ndyabakira A, Chamie G, Emperador D, Marson K, Kamya MR, Havlir DV, Kwarisiima D, **Thirumurthy H**. Men's Beliefs About the Likelihood of Serodiscordance in Couples with an HIV-Positive Partner:

Survey Evidence from Rural Uganda. *AIDS and Behavior* 2019 May; [Epub ahead of print]. PMCID: 31073946

b) **Thirumurthy H**, Jakubowski A, Camlin CS, Kabami J, CHarlebois EC. Expectations about future health and longevity in Kenyan and Ugandan communities receiving a universal test-and-treat intervention. *AIDS Care* 2016; 28 Suppl 3:90-8. PMCID: 5443252.

URL for my full list of publications:
http://www.ncbi.nlm.nih.gov/pubmed/?term=thirumurthy+harsha

D. Research Support

NIH/NIMH R01MH120176 **(Camlin/Thirumurthy)** **09/01/19-06/30/24**
Self-Test Strategies and Linkage Incentives to Improve ART and PrEP Uptake in Men
Goals: This study will test combination behavioral and biomedical interventions to improve the HIV prevention and care cascades in a population of mobile men in western Kenya. The intervention strategy is to recruit and train highly socially-connected men to distribute HIV self-tests and provide linkage support to men in their close social networks.
Role: MPI

NIH/NIA P30AG034546 **(Volpp)** **09/15/19-05/31/24**
Penn Roybal Center on Behavioral Economics and Health
Goals: The Center facilitates and supports research that advances translation of behavioral economic concepts to improve health behaviors and health care delivery.
Role: Co-Investigator

PRIVATE SUPPORT **(Thirumurthy)** **10/16/18-12/31/22**
Leveraging social and sexual networks to reach young men with HIV testing and linkage services
Goals: This project will form partnerships with organizations delivering HIV prevention services in sub-Saharan Africa and ultimately test behavioral economics interventions to promote HIV testing and associated behaviors among young men in settings with high HIV prevalence.
Role: PI

NIH/NIMH R01MH111602 **(Thirumurthy)** **09/15/16-06/30/21**
Secondary distribution of HIV self-tests by female sex workers: an innovative strategy for promoting male partner testing and reducing HIV risk
Goals: This study is a randomized trial that will assess whether provision of multiple HIV self-tests to female sex workers in Kenya is effective in promoting greater awareness of HIV status in high risk, hard-to-reach segments of the population and also facilitating safer sexual decision-making.
Role: PI

NIH/NIMH R01MH105254 **(Thirumurthy/Chamie)** **09/08/15-07/31/20**
Innovative incentive strategies for sustainable HIV testing and linkage to care
Goals: This study will implement and evaluate novel incentive-based interventions to increase HIV testing among high-risk men in Uganda and promote linkage to care and viral suppression among HIV-infected adults.
Role: MPI

NIH/NIAAA U01AA026221 **(Chamie)** **09/15/17–08/31/22**
Interventions to reduce alcohol use and increase adherence to TB preventive therapy among HIV/TB co-infected drinkers
Goals: This study to optimize isoniazid (INH) preventive therapy in HIV/TB co-infected drinkers in Uganda will test low-cost strategies to reduce alcohol use and increase adherence.
Role: Investigator

NIH/NIMH R01MH116736 **(Turan)** **04/01/18-03/31/23**
Testing Strategies for Couple Engagement in PMTCT and Family Health in Kenya
Goals: This study is a three-arm couple-randomized controlled trial among pregnant women attending antenatal clinics and their primary male partners. Couples will be randomized to home-based couple visits, multiple HIV self-test kits, or the standard care of male partner invitation letters. The study will assess impacts of the intervention on multiple health behaviors and health outcomes.

Role: Investigator

Completed Research Support

PRIVATE SUPPORT **(Thirumurthy)** **09/01/18-08/31/19**
Prize-linked savings initiatives for promoting better health and economic outcomes in Kenya
Goals: This pilot project will assess the feasibility and acceptability of an innovative prize-linked savings intervention. It will also generate vital preliminary data on likely effect sizes and develop recruitment procedures and data collection tools – all of which will be useful for a larger randomized trial that will rigorously test the effect intervention on health and economic outcomes.
Role: PI

NIH/NICHD R03HD086497 **(Thirumurthy)** **07/25/16-06/30/19**
Assessing the effect of household member mortality on mental health outcomes using longitudinal data from South Africa
Goals: Explore and assess trends in mental health in South Africa over a 7-year period, including transitions into or out of poor mental health. In addition, the project aims to determine patterns in depression before and after the mortality of a household member and identify the causal effect of accidental household member mortality on depression.
Role: PI

NIH/NIAID U01AI099959 **(Havlir/Kamya)** **07/01/14-06/30/18**
Sustainable East Africa Research on Community Health (SEARCH) Trial
Goals: SEARCH is a cluster randomized trial of the "test and treat" strategy in 32 communities of roughly 10,000 persons each, in Uganda and Kenya. SEARCH aims to test innovative community based interventions that lead to the elimination of HIV in rural communities in East Africa using a multi-disease approach.
Role: Investigator

PRIVATE SUPPORT **(Mohanan/Thirumurthy)** **10/27/15-03/31/19**
Effect of Information and Facilitation for Social Accountability
Goals: Estimate the impact of social accountability interventions in 120 villages in Uttar Pradesh on health and governance outcomes. The project tests the effect of providing information on rights, entitlements, and responsibilities of key service providers, in order to inform a large scale implementation of social accountability in the state.
Role: Co-PI

NIH/NIMH R01MH107330 **(Cohen/Weiser)** **05/07/15-04/30/20**
Shamba Maisha: Agricultural intervention for food security and HIV health outcomes in Kenya
Goals: Randomized controlled trial to test whether providing microfinance and agricultural inputs improves food security and promotes better treatment adherence among HIV-infected persons in the Nyanza region of Kenya.
Role: Investigator

NIH/NIMH R01MH109309 **(Haberer/Baeten)** **06/22/16-04/30/22**
Next Generation Real-time Monitoring for PrEP Adherence in Young Kenyan Women
Goals: Use the next-generation electronic pill bottle called Wisepill to explore the combination of real-time adherence monitoring with real-time adherence feedback, triangulated with real-time assessment of sexual risk behavior. We will study young HIV-uninfected Kenyan women initiating PrEP.
Role: Co-Investigator

OMB No. 0925-0001 and 0925-0002 (Rev. 03/2020 Approved Through 02/28/2023)

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: **Thomas, Tami Lynn**

eRA COMMONS USER NAME (credential, e.g., agency login): eRA COMMONS USER NAME

POSITION TITLE: **Professor of Nursing**

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE	Completion Date	FIELD OF STUDY
University of Florida, Gainesville, FL	BSN	06/1996	Nursing
University of Florida, Gainesville, FL	MSN	12/1998	Nursing
University of Florida, Gainesville, FL	PhD	08/2006	Nursing/Minor Epidem.

A. Personal Statement

My past research experience has prepared me to contribute to this submission in the role of member on the External Advisory Board (EAB) of this P01 proposal titled "Improving Provider Announcement Communication Training" (IMPACT). My nursing career and research in health promotion and health disparities has focused on parents who reside in underserved areas and engagement of these communities where access to healthcare and research study implementation is a challenge. I have experience conducting controlled trials and intervention research in nursing and other disciplines. I have disseminated my study results broadly in well-respected peer reviewed publications across disciplines, including clinical and policy audiences for use in evidenced-based practice. My research trajectory has also been enhanced by interdisciplinary collaboration and transdisciplinary approaches to nursing research and health disparities, specifically behavioral science. My collaborations include projects with colleagues trained in Qualitative Methods, African American Diaspora studies, Public Health, Epidemiology, Statistics, Psychometrics, Instrument Development and Psychology. Through these collaborations and my appointed membership to the Steering Board of the National HPV Vaccine Round Table sponsored by the Centers for Disease Control and Prevention with the American Cancer Society and election to NAPNAP, National Immunization Special Interest groups and the Atlanta Clinical Translational Science Institute (ACTSI) Community Engaged Research Program (CERP); I have developed expertise and collaborative relationships that will guide the above named proposal if funded. I will draw on the experience I have gained conducting research with rural vulnerable communities.

Relevant publications

1. **Thomas, T.,** Caldera, M. & Maurer, J. (2019) Invited Manuscript: A Short Report: Parents HPV Vaccine Knowledge in Rural South Florida. *Human Vaccines & Immunotherapeutics,* 15(7-8):1666-1671. doi: 10.1080/21645515.2019.1600986.
2. **Thomas, T.,** Strickland, O. & Higgins, M. (2017). Mothers, Fathers, Sons and Human Papillomavirus Immunization Practices. *Family and Community Health,* 40(3), 278-287. doi:10.1097/FCH.0000000000000104.
3. **Thomas, T**., Blumling, A. & Delaney, A. (2015). The Influence of Religiosity and Spirituality on Rural Parents' Health Decision-Making and Human Papillomavirus Vaccine. *Advances in Nursing Science,* 38(4):E1-E12. PMCID: PMC4629515. doi: 10.1097/ANS.0000000000000094.
4. **Thomas, T**., Strickland, O, DiClemente, R., Haber, M. & Higgins, M. (2012). Rural African American Parents' Knowledge and Decisions about HPV Vaccination. T*he Journal of Nursing Scholarship,* 44:4, 358–367. PMCID: PMC3952034. doi: 10.1111/j.1547-5069.2012.01479.x.

B. Positions and Honors

Positions and Employment

1996-1998	Service Director, Maternal/Child Services, Shands Healthcare, Gainesville, Florida
1998-2000	Coordinator, Clinical Programs, University of Florida, College of Medicine, Division of General Pediatrics
2000-2005	Coordinator, Research Programs/Services, University of Florida, College of Medicine, Pediatric Nephrology, R01 funded Recurrent Urinary Tract Infections in Women
2005-2006	ARNP, Student Health Care Center, University of Florida, College of Medicine, Department of Community and Family Health
2005-2006	Research Associate and Site Coordinator, University of Florida, Addictive Health Behaviors Research Institute, R01 Funded Project Fitness
2006-2008	Assistant Professor, Florida International University, College of Nursing and Health Sciences, Miami, Florida
2008-2010	Assistant Professor, Medical College of Georgia, School of Nursing, Center for Nursing Research, Augusta, Georgia
2010-15	Assistant Professor, Nell Hodgson Woodruff School of Nursing, Emory University, Atlanta, Georgia
2015-17	Adjunct Professor, Nell Hodgson Woodruff School of Nursing, Emory University, Atlanta, Georgia
2015-19	Associate Professor of Nursing , Nicole Wertheim College of Nursing and Health Sciences, Florida International University, Miami, Florida.
2019-present	Professor of Nursing , Nicole Wertheim College of Nursing and Health Sciences, Florida International University, Miami, Florida.

Selected Honors

1994	Nurse of Excellence, Neonatal Intensive Care Unit, Alachua General Hospital
1996	Appointed Chairperson Nursing Evaluation Council and Nursing Practice Council, Shands
1997	Recognition for Planning the Take a Girl to the Game Program (T.A.G.G.) UFAA
1997	Appointed Executive Member of Community Partners for the City of Gainesville
2005	Recipient of the Joseph and Lillian A. Damon II Scholarship for doctoral studies
2007	Faculty Advisor – Sigma Theta Tau Phi Rho Chapter
2007	Florida Nurses Foundation, Blanche Case Research Award 2007 Sigma Theta Tau, Phi Rho Chapter, Research Award
2007	Academic Partner of the Year, Florida International University, University Health Services
2009	Robert Wood Johnson Foundation Nursing Faculty Scholar, Cohort II
2010	Excellence in Research, Sigma Theta Tau International, Augusta, GA Chapter
2011	Associate Member, (Cancer Prevention and Control) Winship Cancer Institute
2012	Excellence Award for Research Faculty/Student Collaboration, Emory University, Nell Hodgson Woodruff School of Nursing
2012	Awarded National Institutes of Health Loan Repayment Award for Research in Health Disparities
2012	Selected as a Member of the Early Career Reviewer (ECR) program at the Center for Scientific Review (CSR), National Institute of Health
2013	Fellow in the American Association of Nurse Practitioners (FAANP)
2014	Fellow in the American Academy of Nursing (FAAN)
2014	Appointment to Steering Board of the National HPV Vaccine Round Table

C. Contributions to Science

1. **Identification of Intervention Points to Increase Human Papillomavirus (HPV) Vaccination in Underserved Communities.** Over the past 12 years I have made substantive contributions to research literature regarding HPV Vaccination and the understanding and acceptability of the HPV vaccine by parents living in underserved communities. My preliminary studies include seven funded studies focusing on the HPV vaccine and parents. Noticeable gaps in the evidence for effective culturally competent interventions with parents to increase HPV vaccination were noted in these reviews and my study findings revealed that a parent's decision to vaccinate is complex, and preventing HPV should focus on cancer

prevention. Identification of these intervention points and linkages to parental understanding or lack of understanding regarding HPV vaccination are being use in clinical practice and in both clinical and community engaged research studies.

a. **Thomas, T.L.,** Stephens, D., Johnson-Mallard, V. & Higgins, M. (2016). Young Hispanic Men and Human papillomavirus Vaccine Choices, *Journal of Transcultural Nursing, 27(2):103-8.* PMCID: PMC4237692. doi: 10.1177/1043659614526759.
b. **Thomas, T.,** Strickland, O., DiClemente, R., & Higgins, M. (2013). An Opportunity for Cancer Prevention During Preadolescence and Adolescence: Stopping HPV Related Cancer through HPV Vaccination. *Special Supplement to the Journal of Adolescent Health*, 52;S60-S68. PMCID: PMC3990258. doi: 10.1016/j.jadohealth.2012.08.011.
c. **Thomas, T** & Snell, S. (2013). Vaccinate boys with the HPV vaccine? Really? *Journal For Specialists in Pediatric Nursing,* 165–169. DOI:org/10.1111/jspn.12025.
d. **Thomas, T**. (2008). The New Human Papillomavirus (HPV) Vaccine: Pros and Cons for Pediatric and Adolescent Health. *Pediatric Nursing, 34* (5) p 429-431. PMID: 19051848.

2. **Development of HPV Vaccine Measures for use in clinical practice and research to screen for knowledge, motivation, behavioral skills, and HPV vaccine series completion.** While the HPV vaccine was approved in 2006, there were no instruments available for use in clinical nursing practice or research. In 2007, I developed items and pilot tested an instrument that was subsequently used in four funded grants that focused on parents and HPV vaccination. The instrument was psychometrically tested and is now being used in both nursing practice and nursing research. In 2013, I developed, again in a similar process an instrument to be used with students. This instrument was vetted, used in two studies and was also psychometrically tested. It is being published this year for use in student populations. The outcome and use of these instruments has changed nursing practice and both are used widely in nursing research and in doctorate of nursing practice programs to increase HPV vaccine uptake.

a. **Thomas, T.**, Dalmida, S. & Higgins, M. (2015). The Student Human Papillomavirus Survey: Nurse Led Instrument Development and Psychometric Testing to Increase HPV Vaccine Series Completion in Young Adults. *The Journal of Nursing Measurement*, *24*(2), 226-244. PMCID: PMC4991555. doi: 10.1891/1061- 3749.24.2.226.
b. **Thomas, T.**, Strickland, O., DiClemente, R., Higgins, M., Williams, B. & Hickey, K. (2013). Parental Human Papillomavirus Vaccine Survey (PHPVS): Nurse led instrument development and psychometric testing for use in research and primary care screening. *Journal of Nursing Measurement, (21),* 1, 096-109. PMCID: PMC3952023.

3. **Effects of Culture on Health Promotion, Health Disparities and subsequent HPV Vaccination.** While Advanced Practice Nursing has continued to embraced evidenced based practice and care for the underserved, my work identified the essential need to determine the effects of culture on nursing approaches and care of communities from diverse backgrounds. During the past 12 years, my research teams and I have continued to disseminate findings from pilot studies to improve both the interactions between healthcare providers including nurses to increase the understanding of the patient's experience and the reasons why patients and families may or may not access healthcare. These findings have been cited widely in both practice and research literature and are being used to refine clinical approaches to patient problems, improve health promotion efforts and reduce health disparities.

a. **Thomas, T**., Yarandi, H., Dalmida, S., Frados, A., & Klienert, K. (2015). Cross Cultural Differences and Sexual Risk taking Behavior of Emerging Adults. *The Journal of Transcultural Nursing*, 26 (1), 64-72. PMCID: PMC4182167. doi: 10.1177/1043659614524791.
b. Stephens, D. P., **Thomas, T**., Easton, A. (2016). Identifying Health Beliefs Influencing Hispanic College Men's Willingness to Vaccinate against HPV. *American Journal of Sexuality Education*, 11(4): 267-286. doi.org/10.1080/15546128.2016.1198733.
c. **Thomas, T**. & Freeman, A. (2011). Project Genesis: Self-Reported Religiosity, Spirituality and Sexual Risk Taking in Young African-American Women Attending a Historically African American College

(HBCU). *Journal of the National Black Nurses Association*, 22(1), 27-35. Additionally cited in IBCSR Research.

d. **Thomas, T.**, Stephens, D. & Blanchard, B. (2010). Hip Hop, Health and HPV: Using Wireless Technology to Increase Human Papillomavirus (HPV) Vaccination Uptake. *The Journal for Nurse Practitioner*s, (6)6, 464-470.

Complete List of Published Work in MyBibliography

http://www.ncbi.nlm.nih.gov/sites/myncbi/tami.thomas.1/bibliography/46907180/public/?sort=date&direction=ascending

D. Additional Information: Research Support

Ongoing Research Support

PRIVATE SUPPORT

Regionally Underserved Sexual Assault Nurse Examiner (RUSANE) program

This 1.5 million dollar three year award will trained registered nurses to function as sexual assault nurse examiners in rural and underserved areas of south Florida. Along with community leaders, law enforcement and the state attorney's office this award will use process and outcome measures to improve community safety, increase reporting of sexual assaults and increase prosecution of violent offenders.
Role: Project Director

PRIVATE SUPPORT

Advanced Nursing Education Workforce (ANEW): A Program for Minority Nursing Graduate Students who serve the Rural and Underserved

This 1.7 million dollar four year award provides traineeships for graduate nursing students. These students then work in rural areas to understand rural culture and the challenges of these communities and families. Using process and outcome measures this project is not only increasing the APRN knowledge but informing future practice. This grant is also enhancing the applicant pool in these rural clinics and students, once graduated and achieving board certification, are serving in these rural isolated communities.
Role: Project Director

NIH: 1R03NR013558-01

Tailoring an Intervention with Parents in Rural Areas to Reduce HPV Transmission

Research Goal: Conduct a qualitative study with parents residing in rural areas with children ages 9 to 13 years of age to substantiate findings from an earlier quantitative study and begin to develop an intervention to increase HPV vaccination in rural areas where health disparities exist.
Role: Principal Investigator

PRIVATE SUPPORT

Prevalence and Correlates of HPV vaccination in Rural Georgia

Research Goal: Conducted a descriptive study in three rural counties in southeastern Georgia to determine parents' knowledge, attitudes, beliefs, and choices to vaccinate their children ages 9 to 13 years with the HPV vaccine. This led to instrument development and future collaborations with the Centers for Disease Control and Winship Cancer Institute.
Role: Principal Investigator

OMB No. 0925-0001 and 0925-0002 (Rev. 03/2020 Approved Through 02/28/2023)

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: **Trogdon, Justin G.**

eRA COMMONS USER NAME (credential, e.g., agency login): eRA COMMONS USER NAME

POSITION TITLE: **Professor of Health Policy and Management**

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
Baylor University, Waco, TX	BA	05/1999	Economics
Duke University, Durham, NC	MA	05/2001	Economics
Duke University, Durham, NC	PhD	05/2004	Economics

A. Personal Statement

As Project Lead, my role will be to oversee the grant activities for the proposed project "The impact of clinic-level financial incentives on HPV vaccine communication and uptake." I will also serve as Co-Lead of the Data Core. As an accomplished researcher in HPV vaccination and an experienced administrator, I am well-suited to direct the complex work of the proposed project. I am the Director for Cancer Health Economics Initiatives for the Cancer Outcomes Research Program of the Lineberger Comprehensive Cancer Center. I conduct research on the quality, utilization and cost of cancer care and prevention. My HPV vaccine research includes geospatial analysis of HPV vaccination patterns and vaccine providers, time series estimates of the effects of the release of the latest version of the HPV vaccine, analysis of claims and survey data to assess the effects of state-level policies on HPV vaccination, and costing and cost-effectiveness modelling of interventions to increase HPV vaccination. I am also conducting an economic evaluation for a NIH-funded randomized clinical trial of an intervention in North Carolina to improve communication about sex, sexually transmitted infections, and the HPV vaccination among providers, parents, and pre-teens. I have used state immunization information systems to explore geospatial patterns of HPV vaccination and HPV providers within North Carolina and Texas and to investigate the take-up of the newly approved nine-valent HPV vaccine. I also have experience using electronic health record data to evaluate clinic-level interventions to improve quality metrics in North Carolina primary care clinics.

I am a strong fit for these roles due to my work as a health economist who studies the effects of incentives and my experience as a leader of multi- and transdisciplinary teams, including teams including clinicians, statisticians, and health services researchers. This Program Project is an exciting project that will make a significant contribution to cancer prevention by developing new evidence on effective strategies to improve provider communication and HPV vaccine uptake. In summary, my expertise and experience in economics and HPV vaccination have prepared me to lead the proposed project.

Relevant publications

1. Shah PD, **Trogdon JG**, Golden SD, Golin CE, Marciniak MW, Brewer NT. Impact of pharmacists on access to vaccine providers: a geospatial analysis. The Milbank Quarterly 2018;96(3):568-592. PubMed PMID: 30203603.
2. Spencer JC, Brewer NT, **Trogdon JG**, Wheeler SB, Dusetzina SB. Predictors of HPV vaccine follow-through among privately insured patients. American Journal of Public Health 2018;108(7):946-950. PubMed PMID: 29771616.

3. **Trogdon JG**, Shafer P, Lindsay B, Coyne-Beasley T. Impact of introduction of the 9-valent human papillomavirus vaccine on vaccination coverage of youth in North Carolina. Vaccine 2018;36(10):1304-1309. PubMed PMID: 29395530.
4. **Trogdon JG**, Ahn T. Geo-spatial patterns in human papillomavirus vaccination uptake: evidence from uninsured and publicly-insured children in North Carolina. Cancer Epidemiology, Biomarkers & Prevention 2015;24(3):1-8. PubMed PMID: 25576528.

B. Positions and Honors

Positions and Employment

2001-2004	Research Assistant, Center for Health Policy, Law and Management, Duke University, Durham, NC
2004-2005	Lecturer, School of Economics, University of Adelaide, Australia
2006-2011	Visiting Lecturer, Department of Economics, Duke University, Durham, NC
2006-2011	Research Economist, RTI International, Research Triangle Park, NC
2012-2013	Senior Economist, RTI International, Research Triangle Park, NC
2013-2019	Associate Professor, Department of Health Policy and Management, Gillings School of Global Public Health, University of North Carolina at Chapel Hill, Chapel Hill, NC
2014-	Member, University of North Carolina at Chapel Hill, Lineberger Comprehensive Cancer Center
2019-	Director for Cancer Health Economics Initiatives for the Cancer Outcomes Research Program, University of North Carolina at Chapel Hill, Lineberger Comprehensive Cancer Center
2019-	Professor, Department of Health Policy and Management, Gillings School of Global Public Health, University of North Carolina at Chapel Hill, Chapel Hill, NC

Honors

1999	Phi Beta Kappa
1999-2000	Duke University Fellowship
2009	RTI Early Career Author Award
2011-2012	RTI Highly Cited Paper Award
2009-2012	RTI Highly Published Author Award
2011	System Dynamics Society's 2011 Applications Award
2011	Nominated for the 2011 Charles C. Shepard Science Award, Centers for Disease Control and Prevention

C. Contributions to Science

1. **My research identifies diseases and payers that drive health care expenditures and motivates policies to contain costs.** Diseases and risk factors place economic burden on patients and society through direct medical costs and indirect costs such as lost productivity from missed work. By quantifying the economic burden, policy makers will know where current resources are being spent and be able to support initiatives to reduce the burden. My research on the economic burden of chronic disease has helped shape the discipline and policy at the national and state levels. Our papers for the economic burden of obesity are some of the most cited in the literature, including in the Supreme Court decision on the Affordable Care Act. Thousands of public health professionals from across the country have used our cost calculators for chronic disease (Chronic Disease Cost Calculator) and obesity (Obesity Cost Calculator). We developed a statistical approach that avoids double counting when jointly estimating the burden of several diseases, which has been used by the Centers for Disease Control and Prevention and by the American Heart Association in their annual *Statistical Updates'* projections of cardiovascular disease costs. I served as the primary investigator or co-investigator in all these studies:
    a. Tangka FK, **Trogdon JG**, Ekwueme DU, Guy GP Jr, Nwaise I, et al. State-level cancer treatment costs: how much and who pays? Cancer. 2013 Jun 15;119(12):2309-16. PubMed PMID: 23559348.

b. Heidenreich PA, **Trogdon JG**, Khavjou OA, Butler J, Dracup K, et al. Forecasting the future of cardiovascular disease in the United States: a policy statement from the American Heart Association. Circulation. 2011 Mar 1;123(8):933-44. PubMed PMID: 21262990.
c. Finkelstein EA, **Trogdon JG**, Cohen JW, Dietz W. Annual medical spending attributable to obesity: payer-and service-specific estimates. Health Aff (Millwood). 2009 Sep-Oct;28(5):w822-31. PubMed PMID: 19635784.
d. **Trogdon JG**, Finkelstein EA, Hoerger TJ. Use of econometric models to estimate expenditure shares. Health Serv Res. 2008 Aug;43(4):1442-52. PubMed PMID: 18248403; PubMed Central PMCID: PMC2517274.

2. **My research evaluates whether policies and interventions provide good value to society.** Efficient allocation of resources requires that the incremental health benefit from a policy or intervention is equal to the incremental cost of the program. Economic evaluation, including cost and cost-effectiveness analysis, demonstrates whether interventions provide improved health to the public at a reasonable cost. My work in this area has evaluated the cost and cost-effectiveness of several programs designed to improve care for chronic conditions including a cost analysis for the National Breast and Cervical Cancer Early Detection Program (NBCCEDP), the nation's largest organized cancer screening program, the Communities Putting Prevention to Work initiative, and two different approaches to improve care for hypertension (patient-education and physician training). I served as the primary investigator or co-investigator in all these studies.
    a. Khavjou OA, Honeycutt AA, Hoerger TJ, **Trogdon JG**, Cash AJ. Collecting costs of community prevention programs: communities putting prevention to work initiative. Am J Prev Med. 2014 Aug;47(2):160-5. PubMed PMID: 24746039.
    b. **Trogdon JG**, Ekwueme DU, Subramanian S, Crouse W. Economies of scale in federally-funded state-organized public health programs: results from the National Breast and Cervical Cancer Early Detection Programs. Health Care Manag Sci. 2014 Dec;17(4):321-30. PubMed PMID: 24326873.
    c. **Trogdon JG**, Larsen B, Larsen D, Salas W, Snell M. Cost-effectiveness evaluation of a collaborative patient education hypertension intervention in Utah. J Clin Hypertens (Greenwich). 2012 Nov;14(11):760-6. PubMed PMID: 23126347.
    d. **Trogdon JG**, Allaire BT, Egan BM, Lackland DT, Masters D. Training providers in hypertension guidelines: cost-effectiveness evaluation of a continuing medical education program in South Carolina. Am Heart J. 2011 Oct;162(4):786-793.e1. PubMed PMID: 21982674.

3. **My research uses novel statistical and simulation models to estimate the effects of polices.** Policy makers need to know if the policies they implement are having the desired effect, and if not, whether changes to the policy will change the outcomes. Answering these questions can be extremely difficult using real-world data. I have used a variety of novel statistical models to address these issues. I estimated a structural model of hospital choice and treatment outcomes for heart attacks to simulate changes in certificate-of-need policies that limit expansion of services in markets where the service is already offered. I have also used non-structural models (e.g., propensity matching and instrumental variables) to estimate the effect of surgery for heart attack patients, peers' obesity on adolescents' obesity, influenza vaccination on asthma-related expenditures, and provider education on their patients' blood pressure, among other topics. Computer simulation models can also be used to simulate the effect of policies on health and health care markets. I led a series of contracts in which we built a large system dynamics model of cardiovascular disease. I have also used agent-based modeling to simulate the effect of weight-loss interventions in a social network where obesity depends on obesity of one's peers. I served as the primary investigator or co-investigator in all these studies.
    a. Hirsch G, Homer J, **Trogdon J**, Wile K, Orenstein D. Using simulation to compare 4 categories of intervention for reducing cardiovascular disease risks. Am J Public Health. 2014 Jul;104(7):1187-95. PubMed PMID: 24832142; PubMed Central PMCID: PMC4056242.
    b. Khwaja A, Picone GA, Salm M, **Trogdon JG**. A comparison of treatment effects estimators using a structural model of AMI treatment choices and severity of illness information from hospital charts. Journal of applied econometrics (Chichester, England). 2011; 26(5):825-853.
    c. **Trogdon JG**. Demand for and regulation of cardiac services. International economic review. 2009; 50(4):1183-1204.

d. **Trogdon JG**, Nonnemaker J, Pais J. Peer effects in adolescent overweight. J Health Econ. 2008 Sep;27(5):1388-99. PubMed PMID: 18565605.

Complete List of Published Work in MyBibliography:

http://www.ncbi.nlm.nih.gov/sites/myncbi/1VWO6ghRwjb5j/bibliography/47337871/public/?sort=date&direction=descending. My 98 publications have been cited 6,521 times and my h-index is 23. These data are from ISI Web of Science as of 3/12/20.

D. Additional Information: Research Support and/or Scholastic Performance

Ongoing Research Support

Award Number 1RO1CA23735701 (Wheeler and Reeder-Hayes) 09/01/19-08/31/24
National Institutes of Health
"Optimizing Endocrine Therapy Adherence through Motivational Interviewing and Text Interventions"
The objective of this application is to conduct a multisite randomized clinical trial of text message reminders, telephone-based motivational interviewing, or the combination of both, versus usual care, to improve endocrine therapy adherence among breast cancer survivors.
Role: Co-Investigator

Award Number 1R01HL137929 (Ward) 08/15/18-07/31/22
National Institutes of Health
"A hybrid effectiveness-implementation trial of Go NAPSACC: a childcare-based obesity prevention program"
This study will evaluate the effectiveness of the Go NAPSACC online program on childcare centers' practices and compare Enhanced vs. Basic implementation strategies impact on centers' attempts to change, completeness of their efforts, continued use of the change process, and cost-effectiveness.
Role: Co-Investigator

Award Number 1R01HS025723 (Bushnell and Trogdon) 08/01/18-05/31/22
Agency for Healthcare Research and Quality
"Affordability and Efficiency for COMprehensive Post-Acute Stroke Services (COMPASS)"
By investigating the return on investment to post-acute stroke services, this study will evaluate the financial incentives for hospital systems to adopt and sustain such activities. In addition, the results will inform the design of alternative payment models for post-acute stroke services that achieve lower cost without sacrificing quality of care.
Role: Co-PI

PRIVATE SUPPORT (Wheeler) 04/01/19-8/31/20
"Developing and validating a risk stratification framework for breast cancer survivors"
We propose to develop and validate a risk stratification framework, beginning with breast cancer survivors who constitute the largest share of cancer survivors who may benefit from such risk stratification.
Role: Co-Investigator

Completed Research Support (past 3 years)

Award Number 1R01AG050733 (Trogdon) 09/01/16-05/31/20
National Institute on Aging
"Cancer, Care Coordination, and Medication Use for Multiple Chronic Conditions"
By investigating patterns of care coordination and medication use for multiple chronic conditions among older cancer patients, this study will identify gaps in medication use during cancer treatment and in the transition to survivorship. It will highlight the effects of policies, including the nation's largest medical home program, to improve the management of multiple chronic conditions among older, complex cancer patients.
Role: PI

Award Number 5R18 HS023912-02 (Cykert) 05/01/15-12/31/19
Agency for Healthcare Research and Quality

“Facilitation, Spread and Translation of Patient-Centered Evidence in NC Practices”
The major goal of this project is to evaluate the effect of onsite practice facilitation on performance of effective, evidence-based, patient -centered cardiovascular disease prevention measures in small primary care practices. We will also assess the effect of facilitation on organizational change process measures using a stepped-wedge, stratified, cluster randomized study design.
Role: Co-Investigator

Award Number U48 DP005017 SIP 17-004 (Trogdon and Wheeler) 09/30/17-09/29/19
Centers for Disease Control and Prevention
“Assessing the Lifetime Economic Burden in Younger, Midlife, and Older Women with Metastatic Breast Cancer”
The overall goal of this study is to assess the economic burden of metastatic breast cancer across the lifetime and to evaluate the cost effectiveness of alternative clinical pathways for metastatic breast cancer.
Role: Co-PI

Agreement Number 15IPA1504755 (Trogdon) 07/01/15-06/30/19
Centers for Disease Control and Prevention
“Economic Analysis of Cancer Prevention and Control”
Dr. Trogdon will work with economists in the Division of Cancer Prevention and Control to analyze the Medical Expenditure Panel Survey and National Breast and Cervical Cancer Early Detection Program data for a number of studies.
Role: PI

Award Number R01AI113305 (Cates) 08/15/14-08/14/18
National Institute of Allergy and Infectious Diseases
“Normalizing Preteen HPV Vaccination with Practice-based Communication Strategies”
The overall objective is to assess the extent to which providers, parents and preteens respond to these proactive communication strategies by vaccinating preteen girls and boys.
Role: Co-Investigator

SIP 14-0132 (Kneipp) 09/30/14-09/29/18
Centers for Disease Control and Prevention
“SIP 14-032: Testing the Effects of the CDSMP among Lower-Wage Workers”
The purpose of the proposed research is to extend the Chronic Disease Self-Management Program to lower-wage populations aged 40-64 years by partnering with public libraries and employment support networks in select North Carolina counties.
Role: Co-Investigator

OMB No. 0925-0001 and 0925-0002 (Rev. 03/2020 Approved Through 02/28/2023)

BIOGRAPHICAL SKETCH

NAME: **Weiner, Bryan J.**

eRA COMMONS USER NAME (credential, e.g., agency login): eRA COMMONS USER NAME

POSITION TITLE: **Professor**

EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE	Completion Date	FIELD OF STUDY
University of California, Santa Cruz, CA	B.A	06/1989	Psychology
University of Michigan, Ann Arbor, MI	M.A.	06/1992	Psychology
University of Michigan, Ann Arbor, MI	Ph.D.	06/1994	Psychology

A. Personal Statement

I have the expertise and experience to successfully carry out my role as a senior scientific advisor to the Intervention Core of the proposed Program Project "Improving Provider Announcement Communication Training (IMPACT)." My research on the implementation of public health interventions, in particular cancer control interventions and health services research position me well for this role. In the proposed Program Project, I will contribute my expertise in organizational change theory to ensure that the interventions are effectively and sustainably adapted and implemented. An organizational psychologist by training, my research focuses on the adoption, implementation, and sustainment of innovations and evidence-based practices in health care organizations. Over the past 25 years, I have examined a wide range of innovations including quality improvement practices, care management practices, patient safety practices, clinical information systems, as well as evidence-based clinical practices in cancer, diabetes, and cardiovascular disease. I currently serve as Principal Investigator (MPI) of a newly funded research center (P50CA244432) to develop and refine novel methods for optimizing the implementation of evidence-based interventions in cancer control. In prior work, I have used implementation science frameworks and quantitative, qualitative, and mixed methods to identify implementation barriers and facilitators, evaluate implementation strategies, examine processes that contribute to implementation success, and analyze multilevel factors associated with implementation outcomes. I also have experience developing, testing, and evaluating measures of implementation determinants, processes, and outcomes.

1. **Weiner B.J.**, Lewis C.C., Stanick C., Powell B.J., Dorsey CN, Clary A.S., Boynton MH, Halko H. Psychometric assessment of three newly developed implementation outcome measures. Implement Sci. 2017;12:108. PMCID: PMC5576104

2. Powell B.J., Fernandez M.E., Williams N.J., Aarons G.A., Beidas R.S., Lewis C.C., McHugh S.M., Mittman B.S., **Weiner B.J**. Enhancing the impact of implementation strategies: a research agenda. Front. Public Health. 2019 Jan 22;7:3. PMCID: PMC6350272

3. Lewis C.C., Klasnja P., Powell B.J., Lyon A.R., Tuzzio L., Jones S., Walsh-Bailey C., **Weiner B.J**. From confusion to causality: advancing understanding of mechanisms of change in implementation science. Front. Public Health. 2018 May 7;6:136. PMCID: PMC5949843

4. Shea C.M., Jacobs S.R., Esserman D.A., Bruce K., **Weiner B.J**. Organizational readiness for implementing change: a psychometric assessment of a new measure. Implement Sci. 2014 Jan 10;9(1):7. PMCID: PMC3904699

B. Positions and Honors

Positions and Employment

1995 – 1999 Assistant Professor, Tulane University
1999 – 2005 Assistant Professor, University of North Carolina at Chapel Hill, Chapel Hill, NC

2001 – 2016	Research Fellow, Cecil G. Sheps Center for Health Services Research
2001 – 2016	Director, Program on Healthcare Organization, Cecil G. Sheps Center for Health Services Research
2005 – 2010	Associate Professor, University of North Carolina at Chapel Hill, Chapel Hill, NC
2006 – 2016	Member, Lineberger Comprehensive Cancer Center, University of North Carolina at Chapel Hill
2010 – 2016	Professor, University of North Carolina at Chapel Hill, Chapel Hill, NC
2012 – 2016	Deputy Director for Research, Cecil G. Sheps Center for Health Services Research
2015 – 2016	Senior Research Fellow, Cecil G. Sheps Center for Health Services Research
2016 –	Professor, Department of Global Health, University of Washington, Seattle, WA
2016 –	Professor, Department of Health Services, University of Washington, Seattle, WA

Honors

1991 – 1993	National Institute of Mental Health (NIMH) Predoctoral Fellowship.
1993 – 1994	Agency for Health Care Policy and Research (AHCPR) Postdoctoral Fellowship in Health Services Research.
1996 – 1998	Kellogg Foundation Community Care Networks SM Governance Fellowship.
1997	The Governance Institute and Modern Healthcare Governance Fellowship.
2000	John D. Thompson Prize for Young Investigators. Awarded by Association of University Programs in Health Administration.

C. Contributions to Science

1. Organizational determinants of innovation in healthcare. My research has advanced implementation science by creating new knowledge about the organizational determinants of effective implementation of innovations in health care. My early work focused on the organizational factors associated with quality improvement (QI) implementation and outcomes. My research showed that the scope of QI implementation is positively associated with hospital quality, patient safety, and financial performance. These studies were important because they provided evidence to support the Institute of Medicine's (2001) call for systems-based approaches for providing safer, higher quality care. In subsequent work, I examined the implementation, impact, sustainability, and business case of a federally funded provider-based research network (PBRN). Study results provided the NIH with timely information about what it takes to implement and sustain PBRNs and what it can expect from PBRNs as a strategy for disseminating evidence-based clinical services in community practice settings. I recently completed an evaluation that tested the effectiveness of primary care practice support as a strategy for implementing evidence-based cardiovascular disease prevention and treatment in primary care practices (1R18HS02391, PI: Cykert).

a. **Weiner B.J.**, Alexander J.A., Shortell S.M., Baker L.C., Becker M., Geppert J.J. Quality improvement implementation and hospital performance on quality indicators. Health Serv Res. 2006 Apr;41(2):307-34. PMCID: PMC1702526
b. **Weiner B.J.**, Alexander J.A., Baker L.C., Shortell S.M., Becker M. Quality improvement implementation and hospital performance on patient safety indicators. Med Care Res Rev. 2006 Feb;63(1):29-57. PMID: 16686072
c. Teal R., Bergmire D.M., Johnston M., **Weiner B.J**. Implementing community-based provider participation in research: an empirical study. Implement Sci 2012, 7:41. PMCID: PMC3482599.
d. **Weiner B.J.**, Pignone M.P., DuBard C.A., Lefebvre A., Suttie J.L., Freburger J.K., Cykert S. Advancing heart health in North Carolina Primary Care: The Heart Health NOW Study Protocol. Implement Sci. 2015 Nov 14;10:160. PMCID: PMC4650518.

2. Developing new theories in implementation science. I have advanced implementation science by introducing and developing new theories. My 2009 article in *Health Education Research,* presenting a theory of the organizational determinants of the effective implementation of complex innovations, made an important theoretical contribution in a field dominated by individual-level theories of innovation adoption, which do not apply well to implementation of complex innovations requiring collective, coordinated behavior change. My 2009 article in *Implementation Science*, in which I develop a theory of organizational readiness for change, is their most viewed article ever (320,000+ views). In my 2011 article "The meaning and measurement of implementation climate" I explored the often under-theorized "construct implementation climate", which

nonetheless figures prominently in several frameworks and models. I am currently updating a systematic review and critical analysis of the conceptualization and measurement of organizational readiness for change in health services and other fields.

a. **Weiner B.J.**, Lewis M.A., Linnan L.A. Using organization theory to understand the determinants of effective implementation of worksite health promotion programs. Health Educ Res. 2009 Apr;24(2):292-305. PMID: 18469319
b. **Weiner B.J.**, Amick H., Lee S-Y. Conceptualization and measurement of organizational readiness for change: a review of the literature in health services research and other fields. Med Care Res Rev. 2008 Aug;65(4):379-436. PMID: 18511812
c. **Weiner B.J**. A theory of organizational readiness for change. Implement Sci. 2009 Oct;4:67. PMCID: PMC2770024.
d. **Weiner B.J.**, Belden C.M., Bergmire D.M., Johnston M. The meaning and measurement of implementation climate. Implement Sci. 2011 July 22;6:78. PMCID: PMC3224582.

3. Use of qualitative methods. I have sought to advance implementation science through the use of qualitative methods and proposal of strategies to increase qualitative method use. In my 2011 paper in *Medical Care Research Review,* I reviewed the use and benefit of qualitative methods in health services and management research and proposed strategies to increase qualitative method use. Moreover, I have utilized qualitative and mixed methods to enhance our understanding of the application of organizational theory to the implementation of evidence-based practices. The use and advancement of qualitative methods is an essential tool in facilitating the measurement of important implementation constructs that lack valid and reliable measurement tools.

a. **Weiner B.J.**, Amick H.A., Lund J.L., Lee S.Y.D., Hoff T.J. Use of qualitative methods in published health services and management research: a ten-year review. Med Care Res Rev 2011 Feb; 68(1): 3-33. PMCID: PMC3102584
b. **Weiner B.J.**, Haynes-Maslow L., Kahwati L.C., Kinsinger L., Campbell M.K.. Implementing the MOVE! Weight Management Program in the Veterans Health Administration, 2007-2010: a qualitative study. Prev Chronic Dis 2012 Jan; 9: E16. PMCID: PMC3277396.
c. Zullig L.L., Vanderburg S.B., Muiruri C., Abernethy A., **Weiner B.J.**, Bartlett J., Oneko O., Lisasi E., Oresto M., Zafar S.Y. Sustainability of cancer registration in the Kilimanjaro region of Tanzania - a qualitative assessment. World Health Popul 2014;15(1):21-30. PMCID: PMC4114571.

4. Advances in measurement. Finally, I have sought to advance measurement in the field of implementation science. I have developed and tested new measures of organizational readiness for change and implementation climate. In addition, I have participated in a large-scale effort to evaluate the psychometric properties of more than 400 instruments measuring 37 constructs appearing in the Consolidated Framework for Implementation Research. I recently developed and tested new measures of three implementation outcomes: acceptability, appropriateness, and feasibility (1R01MH106510, PI: Lewis). This work is important because it puts the emerging field of implementation science on a firmer measurement foundation. Without reliable, valid, and pragmatic measures, the field cannot produce cumulative knowledge about implementation barriers, facilitators, processes, or generate sound evidence about which implementation strategies work best, when, and for whom.

a. Shea C.M., Jacobs S.R., Esserman D.A., Bruce K., **Weiner B.J**. Organizational readiness for implementing change: a psychometric assessment of a new measure. Implement Sci. 2014 Jan 10;9(1):7. PMCID: PMC3904699
b. Jacobs S.J., **Weiner B.J.**, Bunger A.C. Context matters: measuring implementation climate among individuals and groups. Implement Sci. 2014 Apr 17;9:46. PMCID: PMC4012549
c. Martinez R.G., Lewis C.C., **Weiner B.J**. Instrumentation issues in implementation science. Implement Sci. 2014 Sep 4;9:118. PMCID: PMC4164742
d. **Weiner B.J.**, Lewis C.C., Stanick C., Powell B.J., Dorsey C.N., Clary A.S., Boynton M.H., Halko H. Psychometric assessment of three newly developed implementation outcome measures. Implement Sci. 2017;12:108. PMCID: PMC5576104

Complete list of published work in MyNCBI
https://www.ncbi.nlm.nih.gov/sites/myncbi/bryan.weiner.1/collections/49443645/public/

D. Research Support
Ongoing Research Support

5R01AI134130 Farquhar (PI) 07/01/17 – 06/30/22
NAIAD
Implementing Assisted Partner Services to HIV Test and Treat Men in Western Kenya
The overarching goal is to demonstrate using implementation science methods that assisted partner services (aPS) is a safe and effective strategy to increase the proportion of men living with HIV who know their serostatus and engage in HIV treatment. Role: Investigator

K12HL137940 Au, Curtis, Weiner (PI) 09/01/17-08/31/22
NHLBI
University of Washington Implementation Science Training Program (UW-ISTP)
The University of Washington Implementation Sciences Training Program (UW-ISTP) proposes to recruit and train a new generation of researchers focused on the science of dissemination and implementation in pulmonary critical care and palliative care. Role: MPI

1U01TR002008-01 Shelley (PI) 08/17/17 – 6/30/21
NCATS
Measure development to accelerate the translation of evidence based clinical guidelines into practice
This research center will work to improve symptom control and reduce symptom disparities during curative and palliative treatment for cancers through the deployment of an integrated symptom monitoring and management system. Role: Investigator

U24CA221936-01 Li, Barlow, Zheng (MPI) 04/15/18 – 03/31/23
National Cancer Institute
Coordinating Center for Population-based Research to Optimize the Screening Process
Provide admin coordination for PROSPR network/guidance in development of PROSPR's governance, organization, policies/procedures; Lead development of common conceptualization and measures for: Assessing role of systems-level factors impacting screening process, assessing screening quality; Facilitate trans-PROSPR research comparing screening process across at least 2 organ sites; Develop/implement processes and procedures to share data with qualified investigators outside of network. Role: Investigator

1R01HD092449-01A1 Fernandes, Sherr (MPI) 05/07/18-04/30/23
National Institutes of Health
Spreading the Integrated District Evidence-to-Action Program for Neonatal Mortality Reduction (IDEAs) in Mozambique
This project evaluates the scale-up a health systems intervention (modified and enhanced audit and feedback) to improve implementation of evidence-based Ministry of Health guidelines in Mozambique, and uses the RE-AIM framework to assess the intervention's reach, effectiveness, adoption, implementation and maintenance to inform further national scale-up. Role: Investigator

2T32HS013853 Grembowski, Weiner (MPI) 07/01/18-06/30/23
AHRQ
Health Services Research Training Program at the University of Washington
The Health Services Research Training Program at the University of Washington recruits and trains scholars at the pre-doctoral level to conduct health services research. Role: MPI

1R01NS106560 Vavilala, Bell (MPI) 01/01/19 – 12/31/23
NIH
Implementation Fidelity and Benefits of the Critical Care Pediatric Guideline Adherence and Outcomes Program in Traumatic Brain Injury
Evidenced-based pediatric TBI guidelines exist but TBI guideline adherence is low. We developed a new Pediatric Guideline Adherence and Outcomes (PEGASUS) program to increase TBI guideline adherence. We propose to test if the PEGASUS program improves TBI guideline adherence and outcomes. Role: Investigator

R01NR018161 Curtis (PI) 09/01/18 – 08/31/22
NINR
Evaluating effectiveness of a communication facilitator to reduce distress and improve goal concordant care for critical ill patients and their families: a randomized trial
Testing a nurse facilitator-led intervention to improve communication between ICU patients and their families and their providers; it focuses focus on transitions in care that include the ICU stay, discharge from the ICU, and the immediate post-hospitalization period. Role: Investigator

1P50CA244432 Weiner, Hannon, Lewis (MPI) 09/20/19 – 08/31/24
NCI
Optimizing Implementation in Cancer Control: OPTICC
The OPTICC Center seeks to improve cancer outcomes by developing, testing, and refining innovative methods for optimizing the implementation of evidenced-based interventions (EBIs) in community and clinical settings for a wide range of cancers across the cancer care continuum. Role: MPI

1R01HL142412 Gimbel-Sherr (PI) 05/1/19 – 04/30/24
NHLBI
Systems Analysis and Improvement Approach to Optimize the Hypertension Diagnosis and Care Cascade for HIV-infected Individuals (SAIA-HTN)
Evaluating an evidence-based intervention to improve chronic care services (SAIA) for hypertension detection and management in people living with HIV, building evidence on how to achieve rapid, sustainable and scalable improvements in services improving population health in resource-limited countries. Role: Investigator

R01AG062441 Curtis, Engelberg (MPI) 04/1/19 – 03/31/24
NIH/NIA
Using the Electronic Health Record to Identify and Promote Goals-of-Care Communication for Older Patients with Serious Illness
Two linked and innovative randomized trials to evaluate a novel intervention that promotes and enhances goals-of-care discussions for hospitalized patients with serious chronic illness. Role: Investigator

3R01HD089850-04S1 John-Stewart (MPI) 07/1/19 – 06/30/21
NICHHD
Transitioning From Pediatric To Adult HIV Care in Kenya – Administrative Supplement
We are evaluating a novel adolescent transition package (ATP) in a cluster-randomized trial in the parent R01. In parallel with the clinical trial, this administrative supplement proposes to systematically determine how health care workers adapt, implement and integrate the ATP into practice and determine cost-effectiveness of the ATP. Role: Investigator

PRIVATE SUPPORT Stout (PI) 03/01/19 – 02/28/21
Dissemination of a Community Health Worker program from the Guidelines to Practice (G2P) project
Scaling up the successful PHSKC community health worker asthma intervention across Washington state by engaging stakeholders, developing and delivering support tools for CHWs and supervisors, and measuring and evaluating sustainability during scale-up. Evaluation of this project will use the RE-AIM model's framework (Reach, Effectiveness, Adoption, Implementation and Maintenance). Role: Investigator

Completed Research Support (past three years)
Completed research support is available by request

OMB No. 0925-0001 and 0925-0002 (Rev. 03/2020 Approved Through 02/28/2023)

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: **Wheeler, Stephanie B.**

eRA COMMONS USER NAME (credential, e.g., agency login): eRA COMMONS USER NAME

POSITION TITLE: **Professor of Health Policy & Management**

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE	Completion Date	FIELD OF STUDY
College of Charleston, SC	BS	05/2003	Biology
College of Charleston, SC	BA	05/2003	Theatre
University of Cape Town, South Africa	MPH	06/2007	Public Health
The University of North Carolina at Chapel Hill, NC	PhD	05/2010	Health Policy & Management

A. Personal Statement

As a health services researcher and decision scientist, my research is focused on understanding cancer care quality, access, equity, and value. Strong and noteworthy aspects of my research portfolio are: compiling and linking 'big data' from various sources to enhance decision making around complex healthcare issues; studying determinants of effective implementation of evidence-based interventions, including interventions to optimize cancer outcomes; and employing systems science and decision science methods. My work has been funded by more than $20 million in research grants, including multiple investigator-initiated awards for which I serve as PI/MPI. Currently, I lead two R01s funded by NCI focused on: 1) testing motivational interviewing and text message reminder interventions to improve oral oncologic medication adherence in racially diverse women, and 2) studying implementation of financial navigation in rural hospitals to reduce financial toxicity. I also lead the implementation outcomes evaluation and cost-effectiveness assessment for two ongoing awards funded by NCI focused on mailed outreach interventions to improve cancer screening in community health centers. And I lead a study funded by ACS focused on risk stratification of cancer survivors using machine learning methods. My expertise in implementation science and decision science has informed multiple other efforts focused on optimizing cancer care delivery and outcomes. I currently lead the Coordinating Center of the CDC-funded Cancer Prevention and Control Research Network (CPCRN) which focuses on leveraging implementation science to enhance cancer prevention and control in communities, and I co-lead the NCI-funded T32 Cancer Care Quality Training Program at UNC. Within CPCRN, I currently lead a workgroup focused on mathematical modeling of the impact of evidence-based interventions to decrease cancer burden in underserved populations. This work contributed to development of a simulation-guided, web-based decision support tool to aid decision makers in selecting among multiple cancer screening interventions. In the current P01, I will be responsible for co-leading with Dr. Ozawa Project 4, which builds upon my expertise developing simulation models to compare interventions to reduce cancer morbidity and mortality and using results from those simulation models to inform healthcare decisions and implementation planning. Additionally, to enhance communication and synergy between the projects and cores, I will serve on IMPACT's Integration Committee comprised of all project and core directors. This work will continue my successful collaboration with Drs. Brewer and Trogdon over many years and leverage substantial research support and infrastructure provided by the UNC Lineberger Comprehensive Cancer Center and UNC Gillings School of Global Public Health to reduce the burden of HPV-associated cancers.

B. Positions and Honors

Positions and Employment

2006-2010 Research Assistant, UNC-CH, Health Policy and Management
2007-2009 Research Fellow, Family Health International (FHI), Applied Research Division
2008-2009 Research Assistant, Medical University of South Carolina, Health Administration and Policy
2008-2010 AHRQ T32 Pre-doctoral Trainee, UNC-CH, Sheps Center for Health Services Research
2010-2013 AHRQ K12 Comparative Effectiveness Research Career Development Scholar, UNC-CH
2010-2016 Assistant Professor, UNC-CH, Health Policy and Management

2010-	Member, UNC-CH, Lineberger Comprehensive Cancer Center
2010-	Research Fellow, UNC-CH, Sheps Center for Health Services Research
2011-2015	Cancer Disparities Trainee, UNC-CH, Center for Health Promotion & Disease Prevention
2015-	Associate Professor with tenure, UNC-CH, Health Policy and Management
2019-	Professor with tenure, UNC-CH, Health Policy and Management
2019-	Associate Director of Community Outreach and Engagement, UNC-CH, Lineberger Comprehensive Cancer Center

Selected Honors

2004-2005	Rotary International Academic-Ambassadorial Scholar (South Africa)
2006-2007	Academic Merit Fellowship, UNC-CH Graduate School
2008	American Public Health Association (APHA) Student Assembly Scholarship
2009	Harry T. Phillips Award for Outstanding Teaching by a Doctoral Student, UNC-CH
2009	Academy Health Most Outstanding Abstract Award, Annual Research Meeting
2010	Delta Omega Award for Academic Excellence, Theta Chapter, UNC-CH
2010	Jean G. Yates Outstanding Doctoral Student Award, UNC-CH
2015	Merit Award, Conquer Cancer Foundation of American Society for Clinical Oncology (ASCO)
2017	Early Career Award, Association of Schools and Programs in Public Health (ASPPH)
2017	Distinguished Alumni Award, College of Charleston
2017	Hettleman Prize for Scholarly Achievement, UNC-CH
2020	Honors College at the College of Charleston Most Distinguished Alumni Award

C. Contributions to Science

1. Economic analyses for healthcare decision support. A key contribution to science is systematically evaluating healthcare service utilization and cost, as well as cost-effectiveness and perceived value of care across diverse patient populations, most notably in cancer. Estimating the costs of cancer-focused treatments as well as the potential cost-effectiveness of those treatments are key aspects of my work. Often, this has involved creating mathematical simulation models to project longer term impact and to characterize uncertainty. In addition, my work in cancer economics includes characterizing financial toxicity, value/preference tradeoffs, and care navigation experiences for cancer patients and survivors. This methodological interest of mine is grounded in my doctoral training in econometrics with a concentration in decision sciences, as well as my ongoing role teaching economic evaluation at the graduate level and serving as concentration lead in Decisions Sciences and Outcomes Research within the Department of Health Policy and Management. I have served as methodological expert on many multidisciplinary teams to conduct economic and decision analyses that enhance medical decision-making in a variety of settings.

a. **Wheeler SB**, Spencer JC, Pinheiro LC, Carey LA, Olshan AF, Reeder-Hayes KE. Financial Impact of Breast Cancer in Black Versus White Women. J Clin Oncol. 2018 Apr 18:JCO2017776310. doi: 10.1200/JCO.2017.77.6310. PMC5993169
b. Tran AQ, Erim DO, Sullivan SA, Cole AL, Barber EL, Kim KH, Gehrig PA, **Wheeler SB**. Cost effectiveness of neoadjuvant chemotherapy followed by interval cytoreductive surgery versus primary cytoreductive surgery for patients with advanced stage ovarian cancer during the initial treatment phase. Gynecol Oncol. 2017 Dec 19. pii: S0090-8258(17)31598-6. doi: 10.1016/j.ygyno.2017.12.015. PMC6002777
c. Hassmiller Lich K, Cornejo DA, Mayorga ME, Pignone M, Tangka FK, Richardson LC, Kuo TM, Meyer AM, Hall IJ, Smith JL, Durham TA, Chall SA, Crutchfield TM, **Wheeler SB**. Cost-Effectiveness Analysis of Four Simulated Colorectal Cancer Screening Interventions, North Carolina. Prev Chronic Dis. 2017 Feb 23;14:E18. doi: 10.5888/pcd14.160158. PMC5325466
d. Rutstein SE, Siedhoff MT, Geller EJ, Doll KM, Wu JM, Clarke-Pearson DL, **Wheeler SB**. Cost-Effectiveness of Laparoscopic Hysterectomy With Morcellation Compared With Abdominal Hysterectomy for Presumed Myomas. J Minim Invasive Gynecol. 2016 Feb 1;23(2):223-33. doi: 10.1016/j.jmig.2015.09.025. PMC4744549

2. Designing, targeting, evaluating, implementing and disseminating interventions and policies to improve health outcomes in specific sub-populations. My work includes evaluating policies and behavioral interventions to optimize cancer outcomes in vulnerable sub-populations; using secondary and contextual data to identify regions where interventions and policies are most needed; adapting and fitting evidence-based interventions and policies to local contexts; evaluating implementation strategies that most enable local adoption of evidence-based interventions, and coordinating dissemination efforts more broadly as

PI of the Cancer Prevention and Control Research Network Coordinating Center. This work has stemmed from a growing appreciation that evidence-based interventions are vastly underused, despite decades of accumulated evidence, that one-size-fits-all strategies are not likely to be successful in diverse settings, contexts, and sub-populations, and that disparities are likely to be exacerbated if we haven't carefully considered where the greatest need lies and thoughtfully studied the implementation context. My writing has suggested that meaningfully addressing persistent health outcomes disparities will require focused and tailored intervention and implementation planning, leveraging local data.

a. **Wheeler SB** and Basch EM. Translating cancer surveillance data into effective public health interventions. JAMA. 2017 Jan 24; 317(4):365-367. 10.1001/jama.2016.20326. PMID: 28118434
b. **Wheeler SB**, Davis MM. "Taking the Bull by the Horns": Four Principles to Align Public Health, Primary Care, and Community Efforts to Improve Rural Cancer Control. J Rural Health. 2017 Sep;33(4):345-349. doi: 10.1111/jrh.12263. Epub 2017 Sep 14. PMC5824432
c. Peppercorn J, Horick N, Houck K, Rabin J, Villagra V, Lyman GH, **Wheeler SB**. Impact of the elimination of cost sharing for mammographic breast cancer screening among rural US women: A natural experiment. Cancer. 2017 Jul 1;123(13):2506-2515. doi: 10.1002/cncr.30629. Epub 2017 Feb 14. PubMed PMID: 28195644.
d. Spencer JC, **Wheeler SB**. A systematic review of Motivational Interviewing interventions in cancer patients and survivors. Patient Educ Couns. 2016 Jul;99(7):1099-1105. doi: 10.1016/j.pec.2016.02.003. Epub 2016 Feb 8. Review. PubMed PMID: 26879805.

3. Geographic and health system structural/organizational determinants of cancer outcomes. A key contribution to science is understanding geographic and health system determinants of health outcomes. Health system factors include those at the physician (e.g., provider specialty, age, race/ethnicity, board certification), facility (e.g., type, size, profit status, procedural volume, teaching status), and broader contextual (e.g., location/rurality, dispersion, and availability of health services, health care financing, dissemination of primary care medical homes) levels. A large portion of my research has helped to elucidate the role of such factors and policies in cancer treatment and outcomes. For example, we have documented the importance of distance to care on patient-level variation in the receipt of guideline-recommended colorectal cancer testing, radiation therapy and chemotherapy among breast cancer patients, and specialty urologist care in prostate cancer. Other studies I have led or contributed to have suggested opportunities to 'move the needle' towards improving cancer outcomes for all through innovative care models (e.g., primary care medical homes), provider-based initiatives, research networks, and systems-level change, such as health insurance expansion.

a. Davis MM, Renfro S, Pham R, Hassmiller Lich K, Shannon J, Coronado GD, **Wheeler SB**. Geographic and population-level disparities in colorectal cancer testing: A multilevel analysis of Medicaid and commercial claims data. Prev Med. 2017 Aug;101:44-52. doi: 10.1016/j.ypmed.2017.05.001. Epub 2017 May 13. PMC6067672
b. **Wheeler SB**, Kuo TM, Goyal RK, Meyer AM, Hassmiller Lich K, et al. Regional variation in colorectal cancer testing and geographic availability of care in a publicly insured population. Health & Place. 2014 Sep;29:114-23. PMC5824429
c. **Wheeler SB**, Kohler RE, Goyal RK, Lich KH, Lin CC, et al. Is medical home enrollment associated with receipt of guideline-concordant follow-up care among low-income breast cancer survivors?. Med Care. 2013 Jun;51(6):494-502. PMC6067673
d. **Wheeler SB**, Carpenter WR, Peppercorn J, Schenck AP, Weinberger M, et al. Structural/organizational characteristics of health services partly explain racial variation in timeliness of radiation therapy among elderly breast cancer patients. Breast Cancer Res Treat. 2012 May;133(1):333-45. PMC5824428

4. Quality of, and access to, cancer care in underserved populations. One of my key contributions to science is measuring the quality of, and access to, guideline-concordant care for vulnerable groups, including minority populations. My work has demonstrated that in many underserved populations (e.g., low income, racial/ethnic minorities, rural-dwelling persons), disparities in cancer care persist, despite access to health insurance and geographic availability of relevant health care providers.

a. **Wheeler SB**, Spencer J, Pinheiro LC, Murphy CC, Earp JA, Carey L, Olshan A, Tse CK, Bell ME, Weinberger M, Reeder-Hayes KE. Endocrine Therapy Nonadherence and Discontinuation in Black and White Women. J Natl Cancer Inst. 2018 Sep 20. doi: 10.1093/jnci/djy136. PMID: 30239824
b. Roberts MC, Weinberger M, Dusetzina SB, Dinan MA, Reeder-Hayes KE, Carey LA, Troester MA, **Wheeler SB**. Racial Variation in the Uptake of Oncotype DX Testing for Early-Stage Breast Cancer. J

Clinical Oncology. 2016 Jan 10;34(2):130-8. doi: 10.1200/JCO.2015.63.2489. Epub 2015 Nov 23. PMC4872005

c. **Wheeler SB**, Kohler RE, Reeder-Hayes KE, Goyal RK, Lich KH, et al. Endocrine therapy initiation among Medicaid-insured breast cancer survivors with hormone receptor-positive tumors. J Cancer Surviv. 2014 Dec;8(4):603-10. PMC4970579

d. Reeder-Hayes KE, Meyer AM, Dusetzina SB, Liu H, **Wheeler SB**. Racial disparities in initiation of adjuvant endocrine therapy of early breast cancer. Breast Cancer Res Treat. 2014 Jun;145(3):743-51. PMC5499377

5. Patient-reported measures of health-related preferences, quality of life, and barriers/facilitators to healthy behaviors. Another aspect of my research is focused on understanding the patient experience and ensuring that patient voices are considered in designing public health programs, interventions, and policies. This work has included preference elicitation through discrete choice experiments, assessment of health-related quality of life, and patient perceptions of barriers/facilitators to healthy behaviors and risk-benefit tradeoffs. This work has been influential in helping to demonstrate sub-population specific changes in health-related quality of life that occur with transitions in care (such as during cancer treatment and survivorship), as well as to suggest opportunities for tailored behavioral interventions that take into account heterogeneity in patients' preferences and perceptions. Such attention to the patient experience helps to ensure feasibility, acceptability, and sustainability of public health policies and programs, particularly in high-risk sub-groups.

a. Kohler RE, Gopal S, Lee CN, Weiner BJ, Reeve BB, **Wheeler SB**. Breast Cancer Knowledge, Behaviors, and Preferences in Malawi: Implications for Early Detection Interventions From a Discrete Choice Experiment. J Glob Oncol. 2017 Apr 21;3(5):480-489. doi: 10.1200/JGO.2016.005371. eCollection 2017 Oct. PubMed PMID: 29094086; PMC5646878

b. Kohler RE, Lee CN, Gopal S, Reeve BB, Weiner BJ, **Wheeler SB**. Developing a discrete choice experiment in Malawi: eliciting preferences for breast cancer early detection services. Patient Prefer Adherence. 2015 Oct 14;9:1459-72. doi: 10.2147/PPA.S87341. eCollection 2015. PMC4612134

c. Pignone MP, Crutchfield TM, Brown PM, Hawley ST, Laping JL… **Wheeler SB**. Using a discrete choice experiment to inform the design of programs to promote colon cancer screening for vulnerable populations in North Carolina. BMC Health Services Research. 2014 Nov 30;14:611. PMC4267137

d. Pinheiro LC, **Wheeler SB**, Chen RC, Mayer DK, Lyons JC, et al. The effects of cancer and racial disparities in health-related quality of life among older Americans: A case-control, population-based study. Cancer. 2014 Dec 18;PubMed PMID: 25522692.

Complete List of Published Work in MyBibliography (from 145 publications):
https://www.ncbi.nlm.nih.gov/myncbi/1xwd3woRmhgkt/bibliography/public/

D. Additional Information: Research Support

Ongoing Research Support

1-R01-CA240092-01 (Wheeler/Rosenstein) 09/01/2019 – 08/31/2024
National Cancer Institute
Addressing Cancer-Related Financial Toxicity In Rural Oncology Care Settings
Research objectives are to: (1) understand the practice-level determinants of FT-focused intervention implementation in 5 rural oncology practices; (2) explore the extent to which practice-level technical support and tailored coaching can optimize FN intervention implementation in 5 rural oncology practices; and (3) evaluate the effects of FN implementation on patient- and practice-level outcomes.
Role: Co-PI with Rosenstein, Contact PI

1-R01-CA237357-01 (Wheeler/Reeder-Hayes) 09/01/2019 – 08/31/2024
National Cancer Institute
Optimizing Endocrine Therapy Adherence in Motivational Interviewing and Text Interventions
The long-term goal of this research is to improve survival and reduce disparities in hormone receptor positive breast cancer by optimizing the delivery of widely available, highly effective and cost-effective ET through interventions to support ET adherence.
Role: Co-PI with Reeder-Hayes, Contact PI

WITHHELD **(Wheeler)** 05/01/2019 – 08/31/2020
PRIVATE SUPPORT
Developing and validating a risk stratification framework for breast cancer survivors

The goal of this work is to develop and validate a risk stratification framework for breast cancer survivors, in response to the American Cancer Society's RFA to provide Coordination and Technical Assistance for the 2018 Patient Navigation & the Cancer Care Delivery Modeling Study. Role: PI

1-R01-CA226842-01A1 (Dinan) 01/01/2019 – 12/31/2023
National Cancer Institute
Disparities in the Use of Oral Anticancer Agents in Kidney Cancer
This study uses three complementary data sources from patients of diverse ages, insurance, geography, and racial backgrounds to study modifiable barriers to optimal oral anticancer agent utilization and adherence at the level of patients, providers, facilities, and region.
Role: Sub-Contractual Site PI

1-UH3-CA233251-01 (Reuland) 09/01/2018-08/31/2023
National Cancer Institute
Scaling Colorectal Cancer Screening Through Outreach, Referral, and Engagement (SCORE)
This project combines outreach and in-reach evidence-based interventions and stakeholder engaged systems science methods to inform sustainability of interventions to improve CRC outcomes in NC.
Role: Co-I

5-T32-CA116339-11 (Basch/Wheeler) 09/01/2018-08/31/2023
National Cancer Institute
Cancer Care Quality Research Training Program
This program trains a cadre of clinician and non-clinician scientists at the pre-doctoral and post-doctoral level to work collaboratively in multidisciplinary teams to improve the quality of cancer care.
Role: PI

1R01 CA183891-01A1 (Smith) 4/9/2015-3/31/2021
National Institutes of Health
Effect of HPV Self-collection on Cervical Cancer Screening in High Risk Women
This study employs a randomized controlled trial to investigate whether cervical cancer screening among under-screened women could be improved with testing for human papillomavirus (HPV) using at-home self-collection kits delivered by mail. This study further explores the cost-effectiveness of such an intervention.
Role: Co-I

5-U48-DP006400-SIP (Wheeler/Leeman/Brenner) 10/1/2014-9/30/2024
Centers for Disease Control and Prevention
Cancer Prevention and Control Research Network
UNC is home to the Cancer Prevention and Control Research Network (CPCRN) coordinating center (PI: Wheeler) and to one of eight collaborating centers that comprise the network - the Comprehensive Cancer Control Collaboration, NC (4CNC; Leeman, PI). CPCRN centers undertake site-based and cross-site projects to accelerate the adoption and implementation of evidence-based cancer prevention and control interventions.
Role: PI

3-P30-CA016086 (Earp) 07/1/2019-11/30/2020
National Cancer Institute
Administrative Supplement for Strengthening Research, Training, and Outreach Capacity of the Geographic Management of Cancer Health Disparities Program (GMaP)
This supplement is intended to enhance capacity in the areas of disparities research, underrepresented investigator/trainee recruitment and career/professional development, communication/dissemination, and evaluation as part of building region-based "hubs" for the support of cancer health disparities research.
Role: UNC Site Program Director, Region 1 South

3-P30-CA016086 (Earp) 12/1/2015-11/30/2020
National Cancer Institute
Cancer Center Support Grant
This grant supports the Lineberger Comprehensive Cancer Center (LCCC), the largest research entity at UNC. LCCC forms the nexus of researchers focused on understanding and identifying the mechanisms leading to the prevention and early detection and treatment of cancer, with a focus on the state of NC.
Role: Associate Director of Community Outreach and Engagement

OMB No. 0925-0001 and 0925-0002 (Rev. 03/2020 Approved Through 02/28/2023)

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: **Yarbrough, Wendell G.**

eRA COMMONS USER NAME (credential, e.g., agency login): eRA COMMONS USER NAME

POSITION TITLE: **Thomas J. Dark Distinguished Professor and Chair, Otolaryngology-HNS**

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE	Completion Date	FIELD OF STUDY
University of North Carolina at Chapel Hill, NC	AB Honors	05/1985	Zoology/Chemistry
University of North Carolina at Chapel Hill, NC	MD Honors	05/1989	Medicine
University of North Carolina at Chapel Hill, NC	Board Certified	05/1995	Otolaryngology
Vanderbilt University, Nashville, TN	MMHC	09/2010	Business

A. Personal Statement

I am a surgeon-scientist active in head & neck cancer research for more than two decades. I was recently appointed Chair of Otolaryngology at the University of North Carolina at Chapel Hill where we established The Head & Neck Oncology Lab in the Lineberger Cancer Center at UNC. The Head & Neck Oncology Lab continues to focus on human papillomavirus-associated (HPV+) head and neck squamous cell cancer (HNSCC) with the goal of developing new therapies based on molecular vulnerabilities of HPV-associated HNSCC.

I have both a longstanding clinical interest in the HPV head and neck cancer epidemic, as well as a lab studying the biology and therapy of HPV oral cancer. Given my expertise, I am well suited and motivated to serve on the External Advisory Board for the proposed P01 Program Project "Improving Provider Announcement Communication Training" (IMPACT). This is a great and important effort, and I am happy to serve.

B. Positions and Honors

Positions and Employment

2004-2010 Assistant Professor, Health Behavior and Health Education, Gillings School of Global Public Health, University of North Carolina at Chapel Hill
1989-1994 Intern/Resident, Depts. of Surgery/Otolaryngology, UNC Hospitals, Chapel Hill, North Carolina
1993-1994 Chief Resident, Division of Otolaryngology UNC School of Medicine, Chapel Hill, North Carolina
1994-1996 Fellow Surgical Oncology (Edison Liu, M.D.) UNC School of Medicine, Chapel Hill, North Carolina
1994-1996 Clinical Instructor (non-tenured), Div. Otolaryngology, UNC Hospitals, Chapel Hill, North Carolina
1996-2001 Assistant Professor, Div. Otolaryngology, UNC School of Medicine, Chapel Hill, North Carolina
2000-2001 Assistant Professor, Biochem. & Biophysics, UNC School of Medicine, Chapel Hill, North Carolina
2001-2003 Associate Professor, Dept. Otolaryngology, UNC School of Medicine, Chapel Hill, North Carolina
2001-2003 Associate Professor, Dept. Biochemistry & Biophysics, UNC School of Medicine, Chapel Hill, NC
2001-2003 Associate Professor, Curr. in Gen. & Molecular Biology, UNC School of Medicine, Chapel Hill, NC

2002-2004	Vice Chair, Head and Neck Comm., American College of Surgeons Oncology Group (ACOSOG)
2003-2012	Associate Professor, Dept. of Otolaryngology, Vanderbilt University, Nashville, Tennessee
2003-2012	Associate Professor, Dept. Cancer Biology, Vanderbilt University, Nashville, Tennessee
2003-7/2012	Director, Barry Baker Laboratory for Head & Neck Oncology, Vanderbilt University, Nashville, TN
2006-7/2012	Ingram Prof. of Cancer Res., Vanderbilt Ingram Cancer Ctr, Vanderbilt University, Nashville, TN
2009-7/2012	Co-Leader Thoracic and Head & Neck Program, Vanderbilt Ingram Cancer Center, Nashville, TN
2012-7/2012	Professor, Depts. of Otolaryngology and Cancer Biology, Vanderbilt University, Nashville, TN
2012-2018	Professor & Chief, Otolaryngology, Dept. of Surgery, Yale School of Medicine, New Haven, CT
2012-2018	Director, Head & Neck Disease Center Smilow Cancer Hospital, New Haven, CT
2012-2018	Co-Director, Virology and other Infection-Assoc. CA Program, Yale Cancer Ctr, New Haven, CT
2018-	Thomas J. Dark Distinguished Professor and Chair Otolaryngology, UNC-Chapel Hill, NC

Honors/Service

1981-85	John Motley Morehead Scholar, University of North Carolina
1985	Graduation with Honors Chemistry and Outstanding Senior Student Majoring in Chemistry
1989	Deborah C. Leary Award for the Outstanding Medical Student Research Paper
1989	Graduation with Honors and Distinction, UNC School of Medicine
1994	Nathan A. Womack Scholar for outstanding surgical resident at UNC Hospitals
2000	Jefferson Pilot Fellowship for outstanding Assistant Professor in the School of Medicine at UNC
2002	Mosher Award for the outstanding thesis for The Triologic Society
2003-08	Ad Hoc Reviewer Cancer Molecular Pathobiology (CAMP) Study Section, NIH
2004-07	Member- Head and Neck Surgery & Oncology Committee, AAO/HNS
2004, 06	Ad Hoc Reviewer-ZRG1 ONC-Z/Basic Mechanisms of Cancer Therapeutics (BMCT)
2004	Distinguished Service Award, AAO-HNS Foundation
2004-07	Senior Examiner, American Board of Otolaryngology
2005-06	Ad Hoc Reviewer- ZDE1 PZ (65) Special Emphasis Panel
2007	Ad Hoc Reviewer Cancer Research UK 2007
2007-2012	Reviewer-DSR NIDCR Special Grants Review Committee
2007-2009	Head and Neck Surgery Education Committee, American Academy Otolaryngology (AAO-HNS)
2007-2010	Head and Neck Surgery and Oncology Committee, AAO-HNS
2010	Guest Reviewer, Board of Scientific Counselors, NIDCD
2007-10; 11-	Editorial Board, *Head & Neck*
2015, 2017	Guest Reviewer, Study Section Special Emphasis Panel ZCA1 TCRB-D, NIH PAR 14-285
2015-	Editorial Board, *Laryngoscopy Investigative Otolaryngology*
2015-	Editorial Board, *Cancers of the Head and Neck*
2017-	Council, American Head and Neck Society
2017	Chair, Study Section Special Emphasis Panel ZDE1 CF, NIDCR RFA-DE-18-004

C. Contribution to Science

To describe my contributions to science, accomplishments have been categorized into the research areas that have been and remain the focus of our lab, namely: 1) Head and neck squamous cell carcinoma (HNSCC), 2) Salivary carcinoma, and 3) Cell cycle, p53, and NF-□B

1. **Head and neck squamous cell carcinoma (HNSCC)** – HNSCC is the most common cancer of the upper aerodigestive tract, and the incidence of HPV-associated HNSCC has dramatically increased in the U.S., so that now its incidence has surpassed that of uterine cervical cancer. Immuno-oncologic therapy has great promise, but currently only ~18% of HPV+ HNSCC patients respond to approved immune checkpoint inhibitors. We reported distinct gene expression patterns in HPV(+) vs. HPV-negative head and neck squamous cell carcinoma (HNSCC) and described increased PIK3CA mutations in HPV-associated tumors. We also reported distinct proteomic patterns in HNSCC based on HPV status and found pathways that were differentially activated including DNA damage and proliferation. We were a part of the TCGA project and I was on the writing. More recently, I have focused on unique vulnerabilities of HPV (+) HNSCC

and mechanisms of HPV carcinogenesis. We reported that HPV+ HNSCC are hypermethylated and that demethylation is toxic to these tumors causing DNA double strand breaks and decreased clonogenic survival that is dependent on APOBEC3B (A3B). Using TCGA data, we recently reported that HPV-associated head and neck cancers have mutations in two genes (TRAF3/CYLD), and that the presence of these mutations correlates with improved survival and the absence of HPV genome integration.

a. Hajek M, Sewell A, Kaech S, Burtness B, **Yarborough WG**, Issaeva N. TRAF3/CYLD mutations identify a distinct subset of human papillomavirus-associated head and neck squamous cell carcinoma, *Cancer,* 123(10):1778-1790, 2017. PMCID: PMC5419871.
b. Biktasova AK, Hajek M, Sewell AB, Gary CS, Bellinger G, Deshpande H, Bhatia A, Burtness B, Judson B, Mehra S, **Yarbrough W**, Issaeva N. Demethylation therapy as a targeted treatment for human papilloma virus-associated head and neck cancer, *Clinical cancer research*, 2017. PMID: 28916527.
c. Cancer Genome Atlas Network. Comprehensive genomic characterization of head and neck squamous cell carcinomas, *Nature,* 517(7536):576-82, 2015. PMCID: PMC4311405.
d. Chung CH, Parker JS, Karaca G, Wu J, Funkhouser WK, Moore D, Butterfoss D, Xiang D, Zanation A, Yin X, Shockley WW, Weissler MC, Dressler LG, Shores CG, **Yarbrough WG**, Perou CM. Molecular classification of head and neck squamous cell carcinomas using patterns of gene expression, *Cancer Cell,* 5(5):489-500; May 2004. PMID: 15144956.

2. **Salivary carcinoma** – Salivary cancers are an orphan disease, but remain a significant cause of morbidity and mortality for affected patients. Many of these tumors are have high recurrence rates and current there are no effective therapies besides surgical resection and post-operative radiation for most histologies. Over just the last several years, we have established a group to address this tumor type and worked broadly to create a consortium of academic centers to provide viable specimens for culture, modeling and banking. Using these specimens and patient-derived xenografts, we have focused on cell culture techniques in adenoid cystic carcinoma (ACC) to create cell lines and short-term cultures for study. Gene expression profiling and examination of primary ACC has revealed a neural signaling pattern that includes the Trk neurotrophin receptors and markers that are reminiscent of stem cells (Sox10, NOTCH). Although we have only recently started exploring salivary cancers in our lab, we have made good progress with recent finding of a neural crest stem like population that depends on NOTCH1, SOX10, and FABP7 expression. We are now focusing on the role of MYB in maintenance of this stem cell population.

a. Panaccione, A, Yi, Z, Ryan, M, Moskaluk, CA, Anderson, KS, **Yarbrough, WG**, Ivanov, SV. MYB fusions and CD markers as tools for authentication and purification of cancer stem cells from salivary adenoid cystic carcinoma, *Stem Cell Research*, 21:160-166, 2017. PMCID: PMC5518784.
b. Panaccione, A, Guo, Y, **Yarbrough, WG**, Ivanov, SV, Expression Profiling of Clinical Specimens Supports the Existence of Neural Progenitor-like Stem Cells in Basal Breast Cancers, *Clinical Breast Cancer*, 2017. PMCID: PMC5482752.
c. Panaccione, A, Zhang, Y, Mi, Y, Yoshitsuqu, M, Guo, Y, Prasad, M, McDonald, WH, El-Naggar, AK, **Yarbrough, WG,** Ivanov, SV, Chromosomal abnormalities and molecular landscape of metastasizing mucinous salivary adenocarcinomas, *Oral Oncology*, 66 (38-45), March 2017. PMCID: PMC5335866.
d. Panaccione A, Chang MT, Carbone BE, Guo Y, Moskaluk CA, Virk RK, Chiriboga L, Prasad MJudson B, Mehra S, **Yarbrough WG**, Ivanov SV. NOTCH1 and SOX10 are Essential for Proliferation and Radiation Resistance of Cancer Stem–Like Cells in Adenoid Cystic Carcinoma, *Clinical Cancer Research*, 22(8):2083-2095, 2016. PMCID: PMC4834904.

3. **Cell cycle, p16, ARF, p53, NF-kB** – Our studies of HNSCC revealed a familial cancer syndrome whose family members carried a defective and non-functional copy of the cell cycle inhibitor p16INK4a. These studies led us to examine function of mutant p16 proteins described in cancer. Since there was an additional transcript that hybridized with a p16 probe, we cloned the transcript and discovered that it encoded a protein translated in a different reading frame from p16 that was an activator of p53. We found that loss of this alternate reading frame protein ($p14^{ARF}$) resulted in inhibition of p53 and that expression of ARF caused p53 activation and cell cycle arrest. Using a yeast 2-hybrid screen, we found that ARF bound and inhibited MDM2, resulting in p53 activation. Publication of these findings resulted in the 13th most referenced article of 1998. Relying once again on a yeast 2-hybrid assay, we found a protein that we named LZAP, which bound and regulated ARF. Remarkably, we found that LZAP had much wider activities including inhibition of p38MAPK and regulation of the PP2C phosphatases including the wild-type p53-

induced phosphatase-1 (Wip1). One of the more interesting findings of this line of research revealed that LZAP inhibited NF-kB, bound to RelA, was lost in a portion of HNSCC, and that loss of LZAP resulted in NF-kB activation, cell transformation, and selective transcription of NF-kB responsive genes. We continue to explore LZAP regulation of phosphatases and additional activities that may relate to the remarkable and early embryonic lethality that we observed in zebrafish following loss of LZAP.

a. Wamsley JJ, Gary C, Biktasova A, Hajek M, Bellinger G, Virk R, Issaeva N, **Yarbrough WG**. Loss of LZAP inactivates p53 and regulates sensitivity of cells to DNA damage in a p53-dependent manner. *Oncogenesis*, April 2017, 6(4):e314. PMCID: PMC5520489.
b. Wamsley J, Issaeva N, An H, Lu X, Donehower L, **Yarbrough WG**. LZAP is a novel Wip1 binding partner and positive regulator of its phosphatase activity in vitro, *Cell Cycle*, 2017 Jan 17; 16(2):213-223. PMCID: PMC5283812.
c. Liu D, Wang W-D, Melville DB, Cha YI, Yin Z, Issaeva N, Knapik EW, **Yarbrough WG**. Tumor suppressor Lzap regulates cell cycle progression, doming and zebrafish epiboly, *Developmental Dynamics,* 2011 240(6):1613-25. PMCID: PMC3287344.
d. Wang J, An H, Mayo MW, Baldwin AS, **Yarbrough WG**. LZAP, a putative tumor suppressor selectively inhibits NF-kB. *Cancer Cell*, 2007, 12(3):239-51. PMID: 17785205.

Complete List of Published Work in MyBibliography:
https://www.ncbi.nlm.nih.gov/sites/myncbi/wendell.yarbrough.1/bibliography/40375352/public/?sort=date&direction=ascending

D. Additional Information: Research Support and/or Scholastic Performance

Ongoing Research Support

DE028005-01A1 Yarbrough (PI) 07/01/2019-06/30/2024
1-R01 Grant
NIH
Significance of TRAF3 and CYLD Mutations in HPV-Associated Head and Neck Cancer
The major goal of this project is to explore our hypothesis, in Specific Aim 1. We will use next generation sequencing to determine molecular characteristics and validate prognostic significance of NF-?B activation and HPV genome integration in HPV-positive HNSCC.
Role: PI

DE027942-01A1 Yarbrough (PI) 04/01/2019 – 03/31/2024
R01 Grant
NIDCR
Exploring Mechanisms of Therapeutic Demethylation Effects in HPV-Associated Head and Neck Cancer
Role: PI

Completed Research Support (past 3 years)

P30 CA016359 Fuchs (PI) 8/01/2018-07/30/2020
NIH/NCI
Genetic Landscape of Head and Neck Cancer Among HIV-infected Patients
The major goal of this project is to study genetics of tumors using whole exome sequencing from HIV-infected patients at Yale New Haven Hospital with Head and Neck cancers.
Role: CO-PI

5R01DE013173-13 (Yarbrough) 12/01/2011 – 11/30/2018
NIH/NIDCR: Tumor suppressor qualities and mechanisms of LZAP activity
Goals: Determine LZAP tumor suppressor qualities and describe interactions with the p53-induced phosphatase, Wip1.
Role: PI

WITHHELD (Emu and Yarbrough) 9/1/2016 – 8/31/2018
PRIVATE SUPPORT
Molecular and Immunologic Profile of Head and Neck Squamous Cell Cancers Among HIV-Infected Individuals.
Goals: The major goals of this project are to characterize gene expression and mutation profiles from HIV-infected individuals with HNSCC and better understand the impact of co-infection on molecular pathogenesis of tumor growth.
Role: Co- Principal Investigator

5P30 CA016359-34 (Fuchs) 08/09/2007 – 09/2018
NIH/NCI
Cancer Center Support Grant
Goals: To support research infrastructure in the basic, clinical and population sciences, promote education and outreach to better facilitate the prevention, treatment and care of Cancer patients
Role: Co-leader of the Molecular Virology program (starting 8/1/2012)

PRIVATE SUPPORT (Yarbrough) 1/02/2017 – 09/2018
Research Project: A new mechanism of HPV carcinogenesis HNSCC
Goals: Determine the carcinogenic properties, physical and biological characterization of HDTA.
Role: PI

OMB No. 0925-0001 and 0925-0002 (Rev. 03/2020 Approved Through 02/28/2023)

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: **Zakharkin, Stanislav**

eRA COMMONS USER NAME (credential, e.g., agency login):

POSITION TITLE: **Research Scientist**

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE	Completion Date	FIELD OF STUDY
Novosibirsk State University, Novosibirsk, Russia	MS	1993	Genetics
University of Arkansas for Medical Sciences, Little Rock, AR	PhD	2002	Biochemistry and Molecular Biology
University of Alabama at Birmingham, Birmingham, AL	Postdoc	2006	Statistical Genetics

A. Personal Statement

I am a senior research statistician with 13+ years of professional experience, including design, analysis, and interpretation of clinical trials and data mining of complex surveys. I have expert knowledge of a wide variety of statistical methods, machine learning, and data mining tools as applied in research environments. I have contributed extensively to the scholarly biomedical research literature with co-authorship of over 30 peer reviewed publications covering applied and methodological research. At WebMD, I support design, execution, and analysis of quantitative studies as well as consulting on statistical methodology and general research and development. I previously held positions with PepsiCo, Mondelez International, and Solae for whom I provided statistical analysis and methodology development. I was a Postdoctoral Fellow in Statistical Genetics at the University of Alabama at Birmingham and holds a Ph.D. in Biochemistry and Molecular Biology from the University of Arkansas for Medical Sciences and an M.S. in Genetics from Novosibirsk State University (Russia). I am an accredited professional statistician (PStat) by the American Statistical Association. My scholarly output includes 30 publications and 3 book chapters.

Relevant publications

1. **Zakharkin SO**, Kim K, Mehta T, Chen L, Barnes S, Scheirer KE, Parrish RS, Allison DB, Page GP. Sources of variation in Affymetrix microarray experiments. *BMC Bioinformatics.* 2005 Aug 29;6:214. PMID: 16124883. PMCID: PMC1232851.

2. Kim K, Aronov P, **Zakharkin SO**, Anderson D, Perroud B, Thompson IM, Weiss RH. Urine metabolomics analysis for kidney cancer detection and biomarker discovery. *Mol Cell Proteomics.* 2009 Mar;8(3):558-70. PMID: 19008263. PMCID: PMC2649817.

3. Szalai AJ, Wu J, Lange EM, McCrory MA, Langefeld CD, Williams A, **Zakharkin SO**, George V, Allison DB, Cooper GS, Xie F, Fan Z, Edberg JC, Kimberly RP. Single-nucleotide polymorphisms in the C-reactive protein (CRP) gene promoter that affect transcription factor binding, alter transcriptional activity, and associate with differences in baseline serum CRP level. *J Mol Med.* 2005 Jun;83(6):440-7. PMID: 15778807.

4. Kokorina NA, Lewis JS Jr, **Zakharkin SO**, Krebsbach PH, Nussenbaum B. rhBMP-2 has adverse effects on human oral carcinoma cell lines in vivo. *Laryngoscope*. 2012 Jan;122(1):95-102. PMID: 21997819. PMCID: PMC3895340.

B. Positions and Honors

Positions and Employment

2018-	Associate Director, Marketing Science, WebMD, LLC
2016-2018	Senior Principal Scientist, Statistics, Computational Intelligence and Analytics, PepsiCo
2009-2016	Senior Associate Principal Scientist, Global Statistics, Mondelez International
2006-2009	Senior Research Scientist, Research, Development and Quality, Solae (now part of DuPont Nutrition & Health)

C. Contributions to Science

1. I provide advanced statistical methodology to complex research studies. Selected technical skills include: analysis of complex surveys, statistical modeling, multivariate methods, design of experiments, clinical statistics (sample size calculations and analysis of clinical nutrition trials), chemometrics and high-dimensional data analysis, statistical programming (R, SAS), machine learning, data mining tools, and collaborative projects with academia scientists.

    a. Li N, Hansen BJ, Ignozzi AJ, Sul LV, Csepe TA, Zhao J, **Zakharkin SO**, Kalyanasundaram A, Davis JP, Besiadecki BJ, Kilic A, Janssen PML, Mohler PJ, Weiss R, Hummel JD, Fedorov VV. Redundant and Diverse Intranodal Pacemakers and Conduction Pathways Protect the Human Sinoatrial Node From Failure. *Sci Transl Med*. 2017 Jul 26;9(400). PMID: 28747516. PMCID: PMC5775890.

    b. Kokorina NA, **Zakharkin SO**, Krebsbach PH, Nussenbaum B. Treatment effects of rhBMP-2 on invasiveness of oral carcinoma cell lines. *Laryngoscope*. 2011 Sep;121(9):1876-1880. PMID: 22024838. PMCID: PMC3205421.

    c. Kim K, **Zakharkin SO**, Allison DB. Expectations, validity, and reality in gene expression profiling. *J Clin Epidemiol.* 2010 Sep;63(9):950-959. PMID: 20579843. PMCID: PMC2910173.

    d. Sand JP, Kokorina NA, **Zakharkin SO**, Lewis JS J, Nussenbaum B. BMP-2 expression correlates with local failure in head and neck squamous cell carcinoma. *Otolaryngol Head Neck Surg*. 2014 Feb;150(2):245-250. PMID: 24247005.

D. Additional Information: Research Support

None.

OMB Number: 4040-0010
Expiration Date: 12/31/2022

Project/Performance Site Location(s)

Project/Performance Site Primary Location

❍ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name:	The University of North Carolina at Chapel Hill
Duns Number:	608195277
Street1*:	104 Airport Drive, Suite 2200
Street2:	Campus Box 1350
City*:	Chapel Hill
County:	NC
State*:	NC: North Carolina
Province:	
Country*:	USA: UNITED STATES
Zip / Postal Code*:	27599-1350
Project/Performance Site Congressional District*:	NC-004

Additional Location(s) File Name:

Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED Other Project Information

1. Are Human Subjects Involved?* ● **Yes** ○ **No**

1.a. If YES to Human Subjects

Is the Project Exempt from Federal regulations? ○ Yes ● No

If YES, check appropriate exemption number: _ 1 _ 2 _ 3 _ 4 _ 5 _ 6 _ 7 _ 8

If NO, is the IRB review Pending? ● **Yes** ○ **No**

IRB Approval Date:

Human Subject Assurance Number 00004801

2. Are Vertebrate Animals Used?* ○ **Yes** ● **No**

2.a. If YES to Vertebrate Animals

Is the IACUC review Pending? ○ Yes ○ No

IACUC Approval Date:

Animal Welfare Assurance Number

3. Is proprietary/privileged information included in the application?* ○ **Yes** ● **No**

4.a. Does this project have an actual or potential impact - positive or negative - on the environment?* ○ **Yes** ● **No**

4.b. If yes, please explain:

4.c. If this project has an actual or potential impact on the environment, has an exemption been authorized or an environmental assessment (EA) or environmental impact statement (EIS) been performed? ○ Yes ○ No

4.d. If yes, please explain:

5. Is the research performance site designated, or eligible to be designated, as a historic place?* ○ **Yes** ● **No**

5.a. If yes, please explain:

6. Does this project involve activities outside the United States or partnership with international collaborators?* ● **Yes** ○ **No**

6.a. If yes, identify countries: Germany

6.b. Optional Explanation:

	Filename
7. Project Summary/Abstract*	AbstractOverallrV21045663934.pdf
8. Project Narrative*	NarrativeOverallr1045594785.pdf
9. Bibliography & References Cited	ReferencesOverallr1045594786.pdf
10.Facilities & Other Resources	FacilitiesOverallrV21045663936.pdf
11.Equipment	EquipmentOverallr1045594788.pdf
12. Other Attachments	AcronymsOverallr1045594791.pdf Foreign Justification.pdf

Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

ABSTRACT – Overall

Widespread HPV vaccination in the US could prevent 32,100 cancers every year. Despite this tremendous potential, HPV vaccination coverage is far short of the nation's goal of 80%. Provider recommendations are uniquely powerful in increasing HPV vaccine uptake. However, primary care teams and healthcare systems face barriers to effective HPV vaccine communication, and many questions remain unanswered about how to increase the potency of provider recommendations. We propose the P01 Program Project, "Improving Provider Announcement Communication Training (IMPACT)." The goal of IMPACT is to improve HPV vaccine communication and uptake among adolescents. IMPACT's specific aims are to 1) Identify opportunities to improve HPV vaccine communication; 2) Evaluate the impact and cost of HPV vaccine communication interventions in cluster randomized clinical trials; and 3) Support implementation of HPV vaccine communication interventions in healthcare systems. **The IMPACT Program Project's shared theme is amplifying the impact of a Research-Tested Intervention Program to improve HPV vaccine communication in healthcare systems.** The projects will work together to enhance the impact of the Announcement Approach Training (AAT), an HPV vaccine communication training for primary care professionals, which received designation as a Research-Tested Intervention Program (RTIP) from the National Cancer Institute. Project 1 will establish **how** to involve the whole primary care team in HPV vaccine recommendations. The project will examine whether optimizing the use of standing orders support increases HPV vaccine uptake in clinics receiving the AAT. Project 2 will examine **what** motivates providers to recommend HPV vaccination. The project will establish whether clinic-level financial incentives increase vaccine uptake in clinics receiving the AAT. Project 3 will examine **who** should facilitate the trainings. The project will establish whether engaging clinical champions in healthcare systems to implement the AAT within their own systems increases vaccine uptake. Project 4 will examine **which** interventions fit systems' resources. The project will examine the budget impact, cost-effectiveness, and population health impact of HPV vaccine interventions in rural and nonrural communities and aid decision makers with a decision support tool to facilitate the adoption of promising interventions. The research projects will receive support from 3 cores: Administrative, Data, and Intervention. **IMPACT's activities will culminate with the creation of the AAT Intervention Package to support improving HPV vaccine uptake in healthcare systems.** Throughout the proposed Program Project, the shared theme and AAT focus will create synergies among the projects and cores that generates significant and novel scientific insights into how to improve HPV vaccine communication and uptake. Our approach will also accelerate the evolution of communication trainings for primary care professionals, accomplishing in 5 years what might otherwise take two decades.

NARRATIVE – Overall

The Program Project's goal is to improve HPV vaccine communication and coverage in healthcare systems, a critically important opportunity for cancer prevention. We will create a package of intervention modules to accelerate improvements in HPV vaccine communication and uptake in healthcare systems.

FACILITIES AND OTHER RESOURCES – Overall

University of North Carolina (used by Overall Program)

Facilities

The **Gillings School of Global Public Health** is one of the leading schools in the United States. It is one of 67 schools of public health in the United States, Puerto Rico, and Mexico accredited by the Council on Education for Public Health as of 2020. The School consistently ranks among the top three Schools of Public Health in the nation. The School's 233 full-time faculty members are nationally and internationally recognized for their research, publications, and public health service. With over $193 million in annual grant funding, the pursuit of excellence is the byword for the School, as it strives to fulfill its mission: improve public health, promote individual well-being, and eliminate health disparities across North Carolina and around the world. The School has over 1,700 students enrolled from over 50 countries.

The School is part of the **University of North Carolina (UNC) at Chapel Hill**. Founded in 1792, the University of North Carolina is the oldest public university in the United States. The University of North Carolina at Chapel Hill is the flagship campus for the 16-campus UNC system. With more than 30,000 students, some 37% are enrolled in the University's six professional schools and five health affairs schools. These include Business, Law, Education, Journalism, Social Work, Information and Library Sciences, and the Schools of Dentistry, Medicine, Nursing, Pharmacy and Public Health. Seven research centers span all five schools and serve the entire faculty of the University.

The UNC **Department of Health Behavior** is one of seven departments in the UNC Gillings School of Global Public Health. Founded in 1942, the Department develops and disseminates knowledge and interventions that promote the health of individuals and communities. The Department's 30 faculty members, including Drs. Brewer, Gilkey, and Gottfredson, have backgrounds in behavioral science, health education, social and cognitive psychology, public policy, international health, medicine, medical sociology, and communications, and are united by their commitment to the disciplines of public health together with the social and behavioral sciences. The departmental faculty are supported by eight staff members, including a business manager, two additional staff focused on grants management, an accounting manager, and a departmental secretary.

The Gillings School's **Department of Health Policy and Management (HPM)** is the home department of Drs. Trogdon and Wheeler. The department's 30 full-time faculty represent all of the major disciplines relevant to health services research, including accounting, business, dentistry, economics, finance, health and hospital administration, law, medical care organization, medicine, operations research, organizational behavior, and policy analysis. In addition to 30 full-time faculty, the department is comprised of approximately 400 students, 11 staff members, and approximately 100 adjunct faculty. HPM provides sufficient office space, meeting space, telecommunications capabilities, and computing resources for Drs. Trogdon and Wheeler to perform research tasks, analyze results, and prepare manuscripts. HPM program graduates are making significant contributions to the health care field. The vision is to train the best and brightest health leaders of tomorrow in order to help make this world a better place to live. The HPM research program takes a multidisciplinary approach to studying important and complex issues in health policy and service delivery. By applying innovative quantitative and qualitative methodological approaches, researchers aim to improve the availability, quality, efficiency, and effectiveness of health care services and reduce health disparities at the local, national, and international levels.

The Gillings School's **Department of Maternal and Child Health** was founded in 1950 and is one of the world's leading academic departments for research, teaching, and practice. The department is dedicated to improving the health of women, children, and families — domestically and globally. Research strengths include: Developing a strong evidence base to improve health policies, programs and practices for women and children — locally and globally; Working in interdisciplinary teams to develop innovative solutions for addressing health disparities among women and children; Using implementation science to support the success of proven women's and children's interventions at scale; and Using quantitative and qualitative methods to improve the health of women, children, and families across North Carolina, the nation and the world. Dr. Ozawa is adjunct faculty to this department.

The Gillings School's **Department of Biostatistics** was founded in 1949 and is internationally recognized as a leader in biostatistics research and training. The department is the statistical home for many studies in the UNC schools of medicine and nursing, and provides statistical support for UNC Lineberger Comprehensive Cancer Center and the NC Translational and Clinical Sciences Institute (NC TraCS). The Department of

Biostatistics provides expertise in biostatistics, clinical trial design and conduct, computer programming, and advanced research data processing services. The 43 faculty in the Department, including Dr. Ibrahim, conduct methodological research in survival analysis, sequential analyses, clinical trial design, categorical data analysis, analyses with missing data, assurement/misclassification errors, multivariate/longitudinal analysis, resampling techniques, robust regression, meta-analysis, psychometrics, regression diagnostics, quantitative epidemiology, genetics methods, and health service methods. This department will advise the Data Core.

The **UNC Lineberger Comprehensive Cancer Center (UNC Lineberger)** at the University of North Carolina at Chapel Hill is the public comprehensive cancer center for the people and state of North Carolina. The UNC Lineberger mission is to reduce cancer incidence, morbidity, and mortality in North Carolina and the nation through research, treatment, training, and outreach. In pursuit of that mission, the Center's objectives include fostering interdisciplinary basic and translational cancer research through the organization of multidisciplinary care and population science programs. The center has been rated "exceptional" during the past two Cancer Center Support Grant reviews, with impact scores of 18 in 2010 and 11 in 2015. UNC Lineberger members hold more than $70 million in NCI funding. All UNC investigators are full members of the cancer center.

First established in 1879 and expanded to a four-year program in 1952, the **UNC School of Medicine** is a fully accredited institution consisting of 1,700 faculty members in 20 academic departments, four curricula, and 17 specialized centers and programs. The School of Medicine enrolls about 1,500 students per year, including ~700 medical students. In addition, there are ~600 residents and 500 fellows in the Department. Members of the School of Medicine are drawn from a wide range of departments including Biochemistry and Nutrition, Cell Biology and Anatomy, Dermatology, Family Medicine, Internal Medicine, Microbiology & Immunology, Obstetrics/Gynecology, Pathology, Pediatrics, Pharmacology, Physiology, Psychiatry, Radiation Oncology, Radiology, and Surgery. Clinical specialties represented include GYN, head and neck, medical, neuro, pediatric, radiation, surgical, and urologic oncology. The School's administrative offices are in the MacNider Building and classrooms are in Berryhill Hall, both in close proximity to UNC Hospitals, the Gillings School of Global Public Health, and the Lineberger Cancer Center.

The **UNC Eshelman School of Pharmacy** is an internationally recognized leader in pharmacy practice, education, and research. The school was founded in 1897 and is the only public school of pharmacy in the state of North Carolina and one of the oldest in the nation. The school consists of 122 faculty and enrolls about 580 professional students and 100 graduate students. The school develops leaders in pharmacy education, pharmacy practice, and pharmaceutical sciences who make a difference on human health worldwide. The School offers opportunities in pharmacy and the pharmaceutical sciences that are simply not available anywhere else. In 2014, the School expanded its opportunities for collaboration by joining forces with the pharmacy schools at Monash University in Melbourne, Australia, and University College London. The three institutions formed the PharmAlliance, an international partnership among the leading institutions of their kind on three continents. The alliance will take on challenges that no one school could overcome alone to advance and transform research, education, and practice in pharmacy and the pharmaceutical sciences worldwide. Dr. Ozawa is in the Division of Practice Advancement and Clinical Education, one of the 5 divisions in the School. Dr. Ozawa leads the Global Health Economics for Pharmacy (GHEP) team, whose mission is to develop economic evidence for vaccines, medicines and pharmacy practice to save lives, improve quality of care, and reduce poverty globally. Demonstrating the economic value of vaccines, an area of strength of GHEP, is important for countries to continue their investments in immunization programs and allocate further funding in health.

The North Carolina Institute for Public Health (NCIPH) at the UNC Gillings School of Global Public Health serves as a bridge between academia and public health practice. NCIPH's mission is to facilitate collaborative solutions to population health challenges in North Carolina and beyond by utilizing staff expertise, and that of Gillings faculty and students, to train, coach, convene, facilitate and consult in order to develop leaders, transform organizations, translate data to impact and to strengthen the capacity of public health partners to support thriving, healthy communities. This past year NCIPH completed 60 different training programs and trained 4,405 people. Evaluation data across all NCIPH courses showed participants were satisfied (98%) and that courses were relevant to daily professional activities (98%). Project 3 and the Intervention Core will be utilizing services from NCIPH.

The **North Carolina Translational and Clinical Sciences Institute (NC TraCS)** is the central translational and clinical research resource for UNC and the state of North Carolina. NC TraCS was established in 2008, with renewed funding from the NIH National Center for Advancing Translational Sciences for a third award cycle (2018-2023) in 2017. NC TraCS maintains seamless research support and administrative connections

among its 13 components and programs, most of which are methodologically focused and each providing special expertise, unique research facilities, and the tools necessary to support research from basic science discovery to practice and health policy translation. In addition, as a member of the national Clinical and Translational Science Award (CTSA) network, NC TraCS strives to partner with fellow CTSAs to develop, test, and disseminate clinical and translational research resources and best practices that will accelerate the translation of biomedical discovery into benefits for human health. These partnerships have resulted in numerous cross-CTSA research projects to improve research infrastructure and introduce best practices in informatics and data science, education, and regulatory science. NC TraCS includes research partners RTI International, North Carolina A&T State University, and North Carolina State University. Project 2 will use services from NC TraCS.

The **UNC Connected Health for Applications & Interventions Core (CHAI Core)**, a NIH-funded core facility, has been collaborating with researchers since 2000 to develop and conduct behavioral intervention research, qualitative research, and eHealth and mHealth intervention development. The mission of CHAI Core is to apply state-of-the-art resources and techniques to the development of high quality and rigorously evaluated behavioral science interventions aimed at promoting health and preventing disease in populations at risk. CHAI Core fills a critical gap in existing resources for researchers by facilitating access to and translation of science-based research relevant to communication, health behavior theory, intervention design, and evaluation into strategies and tools that can produce more effective interventions. CHAI Core has developed a highly collaborative team which is available to provide consultation and assistance with grant submissions, methodology, and intervention development. Specifically, CHAI Core offers consulting and services in behavior change interventions and applications; logos and brochures, recruitment and presentation materials; user experience; tailored messaging and feedback; both native and responsive design for mobile technology; and qualitative research methods such as interview guide development, qualitative interviews and focus groups, qualitative coding and analysis, in-depth reports, and manuscript support. CHAI Core's infrastructure and personnel are funded through the Gillings School of Global Public Health Nutrition Obesity Research Center (NIDDK funded; P30 DK56350) and the Lineberger Comprehensive Cancer Center (NCI funded; P30-CA16086). Projects 2 and 4 will use services from CHAI Core.

Computing Resources

UNC Gillings School of Global Public Health and University of North Carolina computing systems will be used in the conduct of this study. Desktop computers operate Windows 10 and include word processing, database, and statistical software packages. Desktop computers connect to Windows and UNIX servers for large storage capacity, software updates, and access controls. The server environment is backed up regularly, kept current with software updates, and is monitored for performance and security issues. Data security is enforced with a password protected file and directory structure. In addition, UNC offers extensive computing capabilities through the integration of diverse and multi-platform environments linked through local and wide area networks. Campus computer resources are made available through this distributed server environment including: additional file shares, distributed task management, database access, and web services. These networks and services are maintained by UNC Information and Technology Services (ITS) and School of Public Health Instructional and Information Systems. ITS also manages a complex network of servers, routers, and gateways that link the campus to the remainder of the academic, governmental, and corporate Internet communities. In addition to hardware access, ITS provides many software applications on its centralized systems, including interactive file editors, system utilities, and compilers. The well-known and widely used statistical packages of SAS, SPSS, STATA, BMDP, SUDAAN, and LIMDEP are available on the network.

Office

The primary offices for all personnel are in Rosenau Hall in the Department of Health Behavior and McGavran-Greenberg Hall in the Department of Health Policy and Management at UNC Gillings School of Global Public Health, and Beard Hall in the UNC Eshelman School of Pharmacy in Chapel Hill, NC. Most personnel offices are near each other, and near the department's main office and administrative support staff.

The Ohio State University (Project 1 subcontract)

The **Ohio State University (OSU)** provides a rich environment for achieving the objectives outlined in this application. OSU was founded in 1870 as the major land grant institution in the state of Ohio. During the past 146 years, the University has grown to be among the country's leading research universities. Its mission is the

attainment of international distinction in education, scholarship, and public service. OSU is composed of 15 colleges offering more than 200 undergraduate programs and 285 master's, doctoral, and professional degree programs. With approximately 45,289 undergraduates and a total enrollment of 58,663, it is one of the largest single-campus universities in the country. Currently the University employs 2,724 regular full-time faculty, 1,311 regular clinical and research faculty, and approximately 2,083 other instructional staff. The University has been accredited by the North Central Association of Colleges and Schools since 1913. The Health Sciences at OSU includes the Colleges of Dentistry, Medicine, Nursing, Optometry, Pharmacy, Public Health, and Veterinary Medicine. The Health Sciences colleges are geographically connected within a one-mile radius in a cluster of buildings surrounding the Health Sciences Library and adjacent to the OSU Wexner Medical Center, the Ross Heart Hospital and the James Cancer Hospital.

The College of Public Health (CPH) works to protect and improve the health of the people of Ohio, the nation, and the world through interdisciplinary research, teaching, and service. The College benefits from being part of one of the most comprehensive health science centers in the nation and enjoys the advantages of close proximity to faculty and students in an exceptional breadth of academic disciplines. The College was the first fully accredited college of public health in Ohio and has the largest and most comprehensive public health offerings in the state. The College is organized internally into five divisions: Biostatistics, Environmental Health Sciences, Epidemiology, Health Behavior and Health Promotion, and Health Services Management and Policy. The College offers both undergraduate and graduate level degree programs. The Master of Public Health (MPH) and Master of Health Administration (MHA) degree programs are oriented toward professional practice, and the MS and PhD in public health are the traditional research/academic degrees. The interdisciplinary nature of public health is evidenced by the many popular dual and combined degree programs offered including MPH/MD, MHA/MD, MPH/JD, MHA/JD, MHA/MBA, MPH/MS, MPH/PharmD, and MPH/DVM. The college offers an undergraduate major leading to a BSPH and an undergraduate minor as well. In addition to the academic divisions, the College contains the Center for Health Outcomes, Policy, and Evaluation Studies (HOPES) and the Center for Public Health Practice.

Office

Cunz Hall includes over eighty private offices for faculty and staff as well as open office areas for graduate research assistants and additional staff members. Office support areas are located on each of the four floors with two thirty-seat student computer labs on floors two and three. Conference rooms, break areas, and student areas are located on each floor. Outside there is a plaza area with seating and tables, a rain garden, and a green roof above the south entry. Many energy saving, light filtering, and sustainable practices have been engineered into the building, resulting in it being the first LEED certified renovated building on The Ohio State University's campus.

Computer

The College of Public Health has one full-time Director, one full-time Systems Manager, one full-time Systems Specialist, one full-time Web Development Specialist, and one student staff member in the information systems office. Over the past 9 years, the College has been actively upgrading all aspects of the information systems facilities. The College currently maintains its own email system, web servers/website, database servers, file servers, tape backup system, Cisco firewalling/networking, desktop management system (LANDesk), and video streaming services. All machines are connected to a windows domain and have access to secure file sharing, personal network storage, Microsoft Exchange email, backup services, and automated updates. All faculty and staff are permitted to use either a PC or a Mac. The standard PC configuration is typically a Dell Optiplex desktop or Latitude laptop. Mac users are typically using Mac Pro desktops or Mac Book Pro laptops. All machines are protected by Cisco firewalling and have restricted access to ensure security compliance. All mail and files are backed up nightly via tape and rotated off campus in accordance with the disaster recovery/business continuity plan established by the College.

AMGA Analytics (Project 1 subcontract)

AMGA Analytics is a subsidiary of AMGA (American Medical Group Association), the 501(c)(6) trade association that represents multi-specialty medical groups, integrated delivery systems, and other organized systems of care. More than 175,000 physicians practice in AMGA's 440-plus member organizations. Its members care for one in three Americans.

AMGA supports members in using data to drive greater efficiencies in clinical and operational processes that improve population health. Its methods include shared learning collaboratives (e.g., adolescent vaccinations, type 2 diabetes bundle measure, adult immunization, obesity, heart failure, rheumatoid arthritis, chronic obstructive pulmonary disease, hypertension). More than 100 medical groups and integrated health systems have participated in AMGA learning collaboratives. AMGA publishes peer-reviewed manuscripts, best practices compendiums, and white papers with innovative and replicable programs that provide AMGA members and the broader health community with a quality improvement rubric that can be replicated in their own organizations.

AMGA's national disease awareness and management campaigns include the Together 2 Goal® diabetes campaign (150 participating organizations) which has exceeded its aim to improve the health of 1 million patients with diabetes by 2020 and has been extended for two years. AMGA's Measure Up Pressure Down® hypertension campaign improved hypertension detection and control for ~540,000 patients.

Data Access

Through a collaboration with Optum®, AMGA has access to identified longitudinal clinical patient records from 22 U.S. health care organizations, providing care for ~20 million patients. Data in the Common Data Repository (CDR) span 1/1/2014—3/31/2020 and is refreshed quarterly. The CDR includes ambulatory care data for all systems and hospital data for 12 of the 22 organizations. Adjudicated claims data are available for 12 organizations. The available data include clinical encounters, procedures, ED visits and hospital admissions (from integrated systems), clinical observations, medication prescriptions, laboratory results, diagnoses on claims, diagnoses on patient problem lists, patient medication lists, patient demographics and NLP-derived variables from clinical notes and reports. Optum also provides AMGA with access to data from the OptumLabs Data Warehouse with administrative claims data for 133 million patients and 79 million de-identified clinical EHR records.

AMGA is a business associate with AMGA member organizations using an Optum data analytics platform and has access to patient- and provider-identified data for the purposes of the Collaborative for Performance Excellence (CPX). This collaborative offers insights by benchmarking across other high-performing organizations, providing ways to identify and replicate best practices in the domains of high-risk patients, practice efficiency, total cost of care, and clinical quality and safety.

AMGA's strong research and advanced analytics experience allows the group to conduct rigorous mixed methods studies to understand which care processes work best and translate these findings to its members. Recent research partnerships include the following: Centers for Disease Control and testing of a hypertension prevalence tool, Tufts and implementation of a diabetes predictive model (funded by PCORI); measure development in obesity, adult immunization, palliative care, homebound patient care; and Johns Hopkins University and chronic kidney disease detection.

Data Integrity and Security

AMGA computing facilities are fully protected by an industry standard firewall with comprehensive malware protection monitoring deployed computing devices. All systems are password protected, users are required to change password quarterly, passwords must meet a minimum complexity standard.
Remote access into AMGA systems requires use of a virtual private networks (VPN). Internal network architecture is segmented into virtual local area networks (VLANS), with restricted access between VLANS. All data are encrypted at rest and in transit. Access to the Optum data is restricted to a small group of authorized users within the Analytics subsidiary. AMGA has policies in place addressing use of all AMGA facilities and resources:

1. Acceptable Use Policy: Addresses the acceptable and unacceptable use of internet/intranet/extranet-related systems including computer equipment, operating systems, storage media, and network accounts providing electronic mail and internet access.
2. Device and Media Control Policy: Governs provisioning, accountability, disposal and reuse of electronic media, as well as the processes used during relocation of these items.
3. Security Policy: Governs the physical and logical security procedures safeguarding Analytics systems and assets, in addition to the policies applicable to all AMGA resources.
4. Access Control Policy: Addresses maintenance and control over role-based access to the systems that contain Protected Health Information (PHI).

Office Space and Computer Support

All staff have excellent office space and advanced computer hardware and software, local access to servers via gigabit Ethernet and remote access via VPN, advanced database software, encrypted storage, and automated backup. All PHI remains on Optum severs, but data about provider organizations and individual providers can also be sensitive, so all staff who work with sensitive data can only access that data on dedicated remote servers where access is controlled and monitored. SQL is used for database programming. Tableau and SAS are used for data visualization, Stata, SAS and R for statistical analysis. WebEx and Zoom are used for on-line interaction with collaborators and member medical groups, as well as remote staff.

AMGA Vehicles for Dissemination and Translation

In addition to traditional dissemination channels through peer reviewed publications and scientific conferences, AMGA has substantial resources dedicated to informing and educating health care providers about innovative approaches to enhancing value in population health. AMGA has two national conferences each year, a series of webinars and regional meetings, and leadership councils for people in similar roles (CEO, COO, CMO, CQO, CIO/CMIO, etc.) across the membership. AMGA also publishes *Group Practice Journal*, which includes practical articles written by members that focus primarily on improving quality and reducing the cost of care. Circulation is over 70,000, among the leaders of both member and non-member organizations. The CPX collaborative is another important channel for dissemination and translation.

AMGA Members

AMGA has long-established, well-developed relationships with its member organizations allowing it to collect qualitative data and gain real-world insights into care at the organizational, provider, and patient levels. Its organization members have access to physicians and a broad range of other health professionals who choose to be part of multi-specialty practices and integrated health systems.

North Carolina Network Consortium (Project 2)

North Carolina Network Consortium (NCnet) is a practice-based research network (PBRN) centered at UNC in partnership with TraCS and Sheps Center. NCnet had its beginnings in the North Carolina Family Medicine Research Network (NC-FM-RN) and has grown to include the Robeson County Primary Care Research Network (RCPCrN) which has a focus on serving the non-reservation American Indian population in NC, the North Carolina Child Health Research Network (NCCHRN), and North Carolina Multisite Adolescent Research Consortium for Health (NC MARCH) which work to improve the health of children and adolescents in NC. NC-net collaborates with practice networks as well as individual practices. Its practices are located across the state of North Carolina and include primary care practices, pediatric practices, and school-based clinics. NCnet members include clinics in the UNC healthcare system, such as the UNC Physician's Network with over 90 clinics across the state. NCnet is also a member of the larger practice-based research network North Carolina Network Consortium. The North Carolina Network Consortium includes 67 additional clinics in North Carolina affiliated with other large healthcare systems using Epic. NCnet staff have extensive experience in working with investigators and community-based clinics to conduct pragmatic trials, which will be critical to enhance feasibility and recruitment of clinics.

University of Wisconsin-Madison (Project 3 subcontract)

The **University of Wisconsin-Madison School of Medicine and Public Health** (UW-SMPH) has the largest research commitment of any school or college on the UW-Madison campus, receiving over $355 million in extramural support in FY 2016. More than 1,200 faculty members work in 27 departments and 21 centers and institutes, and have active research programs covering virtually every aspect of basic, clinical, and public health research. Existing internationally recognized centers include the Wisconsin Alzheimer's Disease Research Center, the UW Paul P. Carbone Comprehensive Cancer Center, the UW Institute for Clinical and Translational Research (a CTSA program), and the Waisman Center. New facilities, such as the Wisconsin Institutes for Medical Research and the UW Cardiovascular Research Center, ensure that UW-Madison will remain at the forefront of basic, clinical, and translational research, ultimately improving the health of the residents of Wisconsin and beyond.

In the University of Wisconsin School of Medicine and Public Health (UW-SMPH), the **Department of Pediatrics** has the health of children and adolescents as its focus. The Department maintains a balanced program that seeks new knowledge through research, provides outstanding educational opportunities, delivers high quality comprehensive clinical care and service, advocates vigorously for children and adolescents, and is responsive to the changing needs of community and society. A vital corollary of this effort is the education of medical students, residents, fellows, and clinical/translational researchers. The Department of Pediatrics received over $25 million in research grants in the 2016 financial year, of which nearly $16 million was federally funded. The research facilities at the UW Department of Pediatrics currently occupy approximately 39,000 square feet. Department faculty members have research space in the Clinical Science Center (CSC), (where Dr. Cox's research group has office space adjacent to other faculty researchers), Waisman Center, Medical Sciences Center, and Unity-Point Health-Meriter Hospital. Additionally, several members of the Department of Pediatrics have joint appointments and additional office space in other departments on the campus, facilitating interdisciplinary research.

In January of 2006, the University of Wisconsin School of Medicine and Public Health and community healthcare partners launched the **Health Innovation Program (HIP)**, under the direction of Dr. Maureen Smith. The creation of the Health Innovation Program was driven by the six aims for improvement delineated in the Institute of Medicine's report "Crossing the Quality Chasm: A New Health Systems for the 21st Century"—to create a local and statewide healthcare system that is effective, efficient, equitable, patient-centered, safe, and timely. A major goal of the Health Innovation Program is to integrate federally-funded research with healthcare practice improvement, particularly through increasing the availability of data on populations and providing resources for dissemination of effective evidence-based programs. By linking data on patients across multiple systems of care, the Health Innovation Program creates an exceptional tool for patient-centered research to improve healthcare delivery and for the development, testing, and dissemination of new interventions. Site PI Elizabeth Cox, MD, PhD, is a long-standing member of HIP. For this proposal, HIP will be providing the infrastructure and expertise to securely process electronic health record data from the Wisconsin Collaborative for Health Quality to provide a dataset for evaluating the intervention. HIP will also be in charge of regulatory compliance for this data at UW.

Office

Office space is provided for all personnel on this project. The Department of Pediatrics provides office space, meeting space, local telephones, and administrative support for this project in the CSC. Adjacent to Dr. Cox's locked, private office, all members of Dr. Cox's research team have assigned office space in the CSC. This space is lockable, as is critical for maintenance of human subjects' protections within this protocol. Currently, Dr. Cox's group occupies 1360 square feet of CSC space.

Computer

Department personnel have personally assigned desktop computer systems with 100MB connections to the Internet. All members of Dr. Cox's research team use network-connected Windows 10 computers. The Computer Services Division serves UW-SMPH Pediatrics faculty, support staff, and researchers at a dozen locations in the Madison area. They manage 350 networked Macintosh and Windows client machines, 60 networked laser printers and 25 servers. All machines communicate over a switched Ethernet connected to the campus network. Client machine user data is continually backed up to servers, and the servers are backed up nightly to disk and weekly to tape. The Department of Pediatrics has a variety of computer services available, including file sharing, print services, backup/restore, web/application development, and in-house hardware and software purchasing, maintenance and support. The Department maintains a user-friendly and comprehensive computer support staff of six IT-trained individuals. A computer graphic design service is also available for departmental researchers. Faculty, staff or students may use both desktop and laptop computers with client-server network access in their offices, as well as laptops with wireless virtual private network access when traveling. Network access is available for biomedical and health sciences databases through the UW-Madison Health Sciences Library.

Data Systems

A key strength of the Health Innovation Program is its ability to provide health services researchers and health system partners with robust access to multiple years of linked data from healthcare organizations across the state of Wisconsin. The Health Innovation Program has special expertise in working with large datasets of healthcare claims and/or electronic health records data and has developed a library of algorithms and analytic

code to define chronic conditions, co-morbidities and complications, and health care utilization variables. Dedicated data support staff help design research databases and develop analysis datasets. Experienced SAS programmers and statisticians have broad methodological experience.

The Health Innovation Program stores and analyzes multiple national and local datasets, including claims and enrollment data for all Medicare beneficiaries in the state of Wisconsin and Illinois. The program also regularly receives electronic health record data from >20 health systems across the state that submit to a central repository at the Wisconsin Collaborative for Healthcare Quality, and claims data for >30 insurers that submit to the Wisconsin all-payer claims database. Additionally, the Health Innovation Program has direct access to electronic health record data from UW Health, a network of primary and specialty care clinics throughout south-central Wisconsin, and to commercial and Medicaid claims for Unity Health Insurance. Combined, these data sources represent a tremendous resource for studying the effectiveness of interventions in clinical practice, and tracking the dissemination and implementation of effective interventions. The Health Innovation Program has established legal agreements governing data use (including preparatory-to-research and preliminary data for grant applications).

Regulatory Compliance

The Health Innovation Program has a regulatory infrastructure with dedicated Compliance and Security Coordinators who oversee data and systems security and regulatory compliance. Our compliance, security, and professional IT staff manage all issues related to HIPAA and IRB compliance including transfer of data and/or secure transfer setup, setup of security and privacy controls including HIPAA-compliant access and audit controls, transmission security, designation of security responsibility, and security awareness and training; assurance of regulatory compliance including review of IRB applications and data use agreements, coordination of access to project folders and files, review of training certifications, and onboarding of users; and setup of remote access to IT resources including training of individual users and support for updating non-HIP computers to meet security requirements.

Our users have access to our application servers for statistical processing; data storage for datasets with personal health information (PHI); backup and recovery; technical, physical, and management security and privacy controls; ongoing review of regulatory agreements and access compliance; remote access to IT resources; and IT helpdesk support.

Computing Resources

The Health Innovation Program provides access for 250 internal and remote users to the latest statistical software and clinical research tools, including SAS, Stata, R, Mplus, EpiData, and PASS on a secure, HIPAA-compliant, highly available, fault tolerant, scalable network infrastructure which is located across three data centers. The infrastructure resources are administered by a full-time staff of IT professionals and include redundant systems, multiple application servers with 184 CPU cores (2.7-3.1 GHz), 1384 GB of RAM, internal PCIe SSD cards, over 350 terabytes of storage, and 10-16 GB network connections.

Two on-campus data centers are managed and monitored by University of Wisconsin School of Medicine and Public Health's Information Technology and the University of Wisconsin-Division of Information Technology to provide managed networking, firewall and security services. The University of Wisconsin School of Medicine and Public Health also provides a managed, public, wireless access point for guest access to the Internet.

Wisconsin Collaborative for Healthcare Quality (Project 3)

The **Wisconsin Collaborative for Healthcare Quality (WCHQ)**, a voluntary statewide consortium of healthcare organizations in Wisconsin, has led the nation in measuring and reporting quality of care in physician groups. The Collaborative's national leadership is evidenced by grants from Centers for Medicare & Medicaid Services, Robert Wood Johnson Foundation, and the Commonwealth Foundation. Founded in 2003, UWMF (now UW Health) was a charter member of the Collaborative along with five other Wisconsin health systems. The Collaborative's current membership includes 38 organizations, including 22 large health systems, and represents approximately 50% of Wisconsin primary care physicians and 60% of all Wisconsin physicians. Collaborative members agree to common measures of healthcare quality and publicly report the performance of their healthcare organizations against the measures. The Collaborative Performance & Progress Report is a broad collection of 42 outpatient and inpatient performance measures, independently audited. Examples of performance measures include vaccination rates, including HPV vaccination rates from

24 participating health systems. Several of these measures compiled by WCHQ are reported by physician groups, while the rest are reported by hospitals and health plans. For HPV vaccination coverage, the Collaborative will provide the UW Health Innovation Program (see below) extensive patient-level electronic health record data from participating health systems meeting this proposal's eligibility criteria. The Collaborative will also work with the investigators to recruit health systems for the RCT.

West Virginia Practice Based Research Network (Project 3)

The **West Virginia Practice Based Research Network (WVPBRN)** is part of the Community Engagement and Outreach Core of the West Virginia Clinical and Translational Science Institute. WVPBRN's mission is to improve the health of West Virginians by connecting primary care practices and researchers to conduct translational practice-based research. Their network includes 95 clinical sites, 13 educational and organizational partners, and 54 ongoing or completed research projects. Their clinical partners are located in almost every county across the state of West Virginia, assuring that they have a wide reach to primary care providers and patients across the state. The network's partners have access to the resources and services of the West Virginia Clinical and Translation Science Institute, including help with project design, data collection, and writing support. WVPBRN aims to facilitate research projects that will make a difference in West Virginia communities.

WebMD (Data Core subcontract)

WebMD Market Research has been providing online health care professionals to the market research industry for over 10 years. This project will be managed out of WebMD's New York offices. The New York offices are the home for staff responsible for implementing web surveys, including questionnaire programming and design, engineering tasks (i.e., database management), and project management.

Each year WebMD delivers over 100,000 completes to online market research studies. WedMD has ongoing relationships with Health Care professionals across a wide array of areas including Physicians, Dentists, Nurse Practitioners, Physician Assistants, Medical Directors, and Pharmacists. The healthcare professionals are used for both on-line quantitative and qualitative research.

WebMD Market Research sources for the online sample is a proprietary network of practicing healthcare professionals who joined Medscape to access clinical content (news, condition and drug information, journal articles), CME activities, and clinical tools (pill identifier, drug interaction tool, clinical calculators). WebMD Market Research sample is a subset of the Medscape network of health care professionals who visit the Medscape sites and apps for clinical content and tools. All healthcare professionals are targeted via online recruitment tactics (i.e. email, onsite).

Health care professionals may be invited to a survey via email or through the Medscape website. Invitations inform the survey participant of project details, such as the length of survey, the study topic, honoraria that will be earned, and any special instructions or requirements for completing the survey. Respondents are paid competitive rates based on the length of survey and the specialty of the health care professional. The honorarium is paid in the form of an Amazon.com gift card.

WebMD Market Research provides sample to both client hosted surveys and Medscape hosted surveys. When a survey is client hosted, WebMD relies on the client to perform data quality checks. If the client identifies a speeder/cheater, WebMD does not charge for that respondent and requests that the client provide information on the specific respondent so that the respondent can be removed from its panel. When Medscape is programming and hosting the surveys, WebMD checks the data for speeders and cheaters. Standard practice is to disqualify respondents who complete the survey in 25% or shorter than the median time. For example, if the expected LOI was 10 minutes, anyone who tries to complete in 2.5 minutes or less would be disqualified. WebMD also keeps a detailed workflow process from receipt of the RFP through the payment of honoraria to the Health Care Professional.

Physician panelists are matched against the AMA. WebMD restricts recruitment to AMA matched physicians. Each panelist is assigned a unique Medscape ID, which WebMD uses to confirm that the person it invites to complete the survey is the same person who completes the survey. When speeders/cheaters are identified, WebMD marks their profile and excludes them from its panel. In addition, in early 2018 WebMD started working with Lexis Nexis to provide additional fraud detection. Physicians must go through a series of vetting questions (address where they grew up, property they owned, etc.) before they can qualify for their first

survey. This is a one-time vetting process and the physician does not have to go through it again once validated. Additional validation such as history of content consumption on Medscape is also used as needed.

WebMD uses MARSC as the panel management tool. The MARSC digital interface makes it easy to manage quotas of the extraction of samples for market research projects. The sampling software selects representative and statistically relevant samples from our Medscape database. Based on a target matrix it can define the type of sample it is looking for and set quotas. Surveys are programmed in either Decipher or Confirmit based upon the client needs.

WebMD employs a “defense in depth” approach to data security through a comprehensive information security program inclusive of dedicated information security staff and strong technical controls. Traffic to WebMD’s Consumer and Professional portals are filtered through the use of traditional and web application firewalls. Information is secured within WebMD’s telco grade SOC1 compliant and geographically dispersed internet data centers through the use of physical controls including man traps, 24x7 guard protection, and closed-circuit security camera coverage. Access to sensitive data is further restricted to a subset of personnel based on the principle of least privilege. WebMD Market Research follows CASRO/Insights Association guidelines.

Wake Forest University Health Sciences (Intervention Core subcontract)

Wake Forest University is a private, non-sectarian university founded in 1834. In addition to the School of Medicine and the College of Arts and Sciences, it is home to the Babcock School of Management, the Divinity School, and the Law School. **Wake Forest School of Medicine** (WFSM - academic entity) and **Wake Forest Baptist Health** (WFBH - clinical entity) together have over 1,350 faculty members (clinicians, educators and researchers), over 550 adjunct faculty members, 250 network physicians, and over 230 community physicians. WFSM was recognized in *US News and World Report’s* “2017 Best Medical Schools” list, placing 53rd in the nation among research programs and 74th in primary care. In addition to its MD, PhD, and master’s degree programs, the School of Medicine offers five joint-degree programs and is also the clinical site for several outside universities’ programs, including Forsyth Technical Community College, the University of North Carolina at Greensboro, and Winston-Salem State University. WFSM is currently the fourth-most selective medical school in the U.S., with an acceptance rate of 2.8 percent.

WFSM has 726 residents and fellows, 546 medical students, 174 Physician Assistant students, 48 Nurse Anesthesia (CRNA) students, 23 Doctorate of Nursing Practitioner (DNP) students and 318 graduate students. The WFSM Physician Assistant program, which features an innovative MS/PA track incorporating research into clinical training, is ranked 7th in the nation for 2020 by U.S. News & World Report’s Graduate School Rankings, up from 9th the previous year. WFSM provides continuing medical education and advanced training for health care professionals through the Northwest Area Health Education Center (AHEC), as well as leadership and organizational development, education and research in continuing medical education. In the summer of 2016, WFSM opened the $60 million Bowman Gray Center for Medical Education in the Wake Forest Innovation Quarter.

WFSM has a diverse faculty body: 344 faculty are devoted to basic research; 955 are clinical faculty (MD and MD/PhD faculty); 534 are women and 319 faculty are underrepresented minorities. WFSM is also a leading research center in the fields of regenerative medicine, cancer, cardiovascular sciences, neurosciences and addiction, aging and cognition, diabetes, obesity, and metabolism. WFSM ranks in the top third of all U.S. medical schools in NIH funding. WFSM received $223.4 million in total research costs from extramural grants in FY 2019, of which 77% are federally funded.

The Division of Public Health Sciences. The Department of Public Health Sciences was formed in 1989 from the Center for Prevention Research and Biometry, which had been founded in 1986 as evidence of the school's commitment to programs in prevention research. Thanks to the success and growth of the Department of Public Health Sciences, the Dean approved the creation of a Division of Public Health Sciences with three departments in January 2006: Biostatistics and Data Science, Epidemiology & Prevention, and Social Sciences & Health Policy. A fourth department was added in 2017, Implementation Science.

The Division, currently led by Lynne E. Wagenknecht, DrPH, Professor and Director, received more than $30 million in FY19 in extramural research funding from 163 collaborative research projects headed by Division faculty. Historically, the Division has been ranked among the top two of similar groups nationally in NIH funding. The Division's overall goals are to further research programs in the areas of biostatistics, epidemiology, nutrition, and health promotion/disease prevention, and to strengthen research at the school by providing consultation in the development of research proposals, study design, analysis, and other

methodological issues. The Division, together with the CTSI, offers a Master of Science degree in Clinical and Population Translational Science. This program is especially targeted to the training of physicians and post-doctoral fellows.

In 2017, the **Department of Implementation Science** was created to serve as a catalyst for the adoption, integration, and sustainability of evidence-based practices into real word settings to improve population health. The Department will focus on three core areas of inquiry and translation:

- the use of health services research to identify opportunities for improved care delivery—prioritizing organizational, health systems, and policy gaps and solutions
- identifying efficacious, cost-effective, and time-neutral solutions to implementing the best and most promising health care and public health practices
- testing implementation and dissemination strategies to more efficiently and effectively translate evidence-based strategies into real world clinical and population health settings.

Faculty and staff in this Department reflect the diversity of academics and stakeholders who are critical to achieving the mission of improved population health through science-to-practice translation.

Office

Faculty and staff of the Division of Public Health Sciences are located primarily at 525@Vine, a 232,000-square-foot, state-of-the-art research and lab facility in Winston-Salem's downtown Innovation Quarter. The Division also maintains the Public Health Research Center (PHRC) in Piedmont Plaza I and an additional clinical research suite in Piedmont Plaza II, both on the nearby Wake Forest Baptist Medical Center campus. The Division maintains a library of software from all of its studies that enables it to provide timely materials. Its programmers convene regular meetings to discuss methods for improving its performance and for keeping up-to-date with all current technologies.

Computer

RISU provides a variety of computational platforms for faculty and staff to perform their research activities. Ranging from interactive Linux systems used for primary statistical and genetic analysis to high performance compute clusters used for distributed parallel processing to Windows-based servers used for database and statistical processing, DPHS provides a host of resources to accomplish the research goals of its investigators.

The Wake Forest Data Lake, an EMC solution for private cloud storage and computing, is currently composed of 36TB of Greenplum massive parallel computing storage (cloud database for parallel computing) and 856TB Hadoop storage, 384 E5-2660 computing cores at 2.20GHz, and 768GB memory. The Hadoop storage is implemented through (2) 20TB XIO Bricks of SSD storage and (6) Isilon X410-136TB Hybrid SED Nodes. This private cloud is fast growing both in size and functionalities. Such cloud resources allow it to address the challenges of hosting very large data warehouses and performing massive parallel processing on data warehouses. Each of the systems listed above connects to the centralized storage system, providing over 130 TB of storage for researchers. Storage platforms include Isilon, EMC, and Compellent. The Wake Forest Data Lake, an EMC solution for private cloud storage, provides 856TB Hadoop storage implemented through (2) 20TB XIO Bricks of SSD storage and (6) Isilon X410-136TB Hybrid SED Nodes. This private cloud is fast growing both in size and functionalities. PHS utilizes many specialized applications to perform statistical genetics research. The Division also manages over 40 Windows-based servers for uses including application servers, database servers and file servers. The Division has created its own clinical trials web platforms encompassing database servers, web hosting servers, and SAS servers for providing real-time access to clinical trial data to study staff.

All servers that are available to the Internet are secured in a DMZ zone, with two hardware firewalls. Local software firewalls are also used on each public server. The Division also monitors public servers, at the server software location, to help guarantee security. Operating system patches and hotfixes are implemented in a timely fashion, and can be managed remotely in an emergency. All servers are physically located in one state-of-the-art 5,500 square foot data center in a new building designed for security and reliability. It is located at the new downtown campus of WFSM and provides a central presence for high-end computing (e.g., computing clusters), data storage facilities, centralized backup, and disaster recovery. The entire building's electrical needs are backed by a one Megawatt on-site generator. The data center provides a fully monitored environment for data processing equipment for the undergraduate campus of Wake Forest University (WFU), as well as a collocation facility for commercial and public service providers for the Innovation Quarter (downtown research park), ensuring multiple high-bandwidth Internet paths and diverse state-of-the-art services. The networking environment is a fully converged, high speed, multi-use network supporting video

streaming, VoIP, video teleconferencing and high-bandwidth display signage in addition to the typical data traffic along with a fully integrated wireless environment across all campuses. WFU is one of the founding members of Internet II and utilizes the research and education network daily with our shared Virginia Tech-Wake Forest School of Biomedical Engineering. WFU also provides the Piedmont region of North Carolina with a Regional Point of Presence (RPoP) called WinstonNet. This robust connection to Internet II and to the North Carolina Research and Education network (NCREN) is capable of 10 Gbps and is positioned to move to the Lambda Rail.

Biohazard Statement (Overall Program)

No procedures in the proposal are potentially hazardous to research personnel or the environment.

EQUIPMENT – Overall

None.

LIST OF ACRONYMS – Overall

AAT	Announcement Approach Training
CDC	Centers for Disease Control and Prevention
Covid-19	Coronavirus disease 2019
FDA	Food and Drug Administration
HPV	Human papillomavirus
IMPACT	Improving Provider Announcement Communication Training
IQIP	Immunization Quality Improvement for Providers
IRB	Institutional review board
MA	Medical assistant
NCI	National Cancer Institute
NIH	National Institutes of Health
NIS-Teen	National Immunization Survey- Teen
QI	Quality improvement
RCT	Randomized clinical trial
RN	Registered nurse
RTIP	Research Tested Intervention Program
TCORS	Tobacco Center of Regulatory Science
UNC	University of North Carolina
WHO	World Health Organization

FOREIGN JUSTIFICATION – Overall

This proposal includes one foreign external advisor whose expertise is integral to the success of the proposed Research Project 4. Ms. Colleen Higgins, MSPH, is a mathematical modeler skilled at coding and building computer simulations on public health topics. Ms. Higgins is an American citizen living in Germany. Ms. Higgins has worked with Dr. Ozawa for over a year to build an agent-based model that assesses the impact of substandard and falsified antimalarials (SAFARI model) in five different countries. Ms. Higgins holds a Masters of Science in Public Health from the Department of Health Policy and Management at UNC Gillings School of Global Public Health and has programming expertise in Java Script, AnyLogic, Python, and NetLogo. Ms. Higgins is uniquely suited to advise this project due to her extensive experience coding and building computer simulations for agent-based models. She will work with the project team on Project 4's Aim 2 to build an agent-based model to assess the cost-effectiveness of HPV provider communication intervention strategies. She will help to conceptualize the structure of the model, write and audit code, perform sensitivity analyses, interpret and present output data, and conduct searches and/or data analyses to gather relevant data inputs. The US does not have scholars with Ms. Higgins's unique combination of skills and expertise that perfectly apply to this proposal.

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED Senior/Key Person Profile (Expanded)

PROFILE - Project Director/Principal Investigator

Prefix: First Name*: Noel Middle Name T. Last Name*: Brewer Suffix:

Position/Title*: Professor
Organization Name*: The University of North Carolina at Chapel Hill
Department: Health Behavior
Division: Gillings Sch. of Public Hlth
Street1*: 325 Rosenau Hall
Street2: CB 7440
City*: Chapel Hill
County: Orange
State*: NC: North Carolina
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 27599-7440

Phone Number*: (919) 966-3282 Fax Number: (919) 966-2921

E-Mail*: ntb@unc.edu

Credential, e.g., agency login: eRA COMMONS USER NAME

Project Role*: PD/PI Other Project Role Category:

Degree Type: PhD Degree Year: 2002

Attach Biographical Sketch*: File Name: BioBrewerOverallrV21045663935.pdf

Attach Current & Pending Support: File Name:

Tracking Number: GRANT13205496 Funding Opportunity Number: PAR-20-077 . Received Date: 2020-09-18T11:41:16.000-04:00

PHS 398 Cover Page Supplement

OMB Number: 0925-0001

Expiration Date: 02/28/2023

1. Vertebrate Animals Section

Are vertebrate animals euthanized? ○ Yes ○ No

If "Yes" to euthanasia

Is the method consistent with American Veterinary Medical Association (AVMA) guidelines?

○ Yes ○ No

If "No" to AVMA guidelines, describe method and provide scientific justification

2. *Program Income Section

*Is program income anticipated during the periods for which the grant support is requested?

○ Yes ● No

PHS 398 Cover Page Supplement

3. Human Embryonic Stem Cells Section

*Does the proposed project involve human embryonic stem cells? ○ Yes ● No

4. Human Fetal Tissue Section

*Does the proposed project involve human fetal tissue obtained from elective abortions? ○ Yes ● No

If "yes" then provide the HFT Compliance Assurance

If "yes" then provide the HFT Sample IRB Consent Form

5. Inventions and Patents Section (Renewal applications)

*Inventions and Patents: ○ Yes ● No

If the answer is "Yes" then please answer the following:

*Previously Reported: ○ Yes ○ No

6. Change of Investigator/Change of Institution Section

❑ Change of Project Director/Principal Investigator

Name of former Project Director/Principal Investigator

Prefix:

*First Name:

Middle Name:

*Last Name:

Suffix:

❑ Change of Grantee Institution

*Name of former institution:

PHS 398 Research Plan

OMB Number: 0925-0001
Expiration Date: 02/28/2023

Introduction	
1. Introduction to Application (for Resubmission and Revision applications)	IntroApplicationOverallrV21045663937.pdf
Research Plan Section	
2. Specific Aims	SpecificAimsOverallrV21045663938.pdf
3. Research Strategy*	ResearchStrategyOverallrV21045663939.pdf
4. Progress Report Publication List	
Other Research Plan Section	
5. Vertebrate Animals	
6. Select Agent Research	
7. Multiple PD/PI Leadership Plan	
8. Consortium/Contractual Arrangements	
9. Letters of Support	LOSOverallCombinedr1045594797.pdf
10. Resource Sharing Plan(s)	ResourceSharingOverallr1045594798.pdf
11. Authentication of Key Biological and/or Chemical Resources	
Appendix	
12. Appendix	

Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

INTRODUCTION TO APPLICATION – Overall

CRITIQUE, RESPONSE TO CRITIQUE

SPECIFIC AIMS – Overall

Widespread HPV vaccination could prevent 32,100 cancers every year in the US. HPV vaccination coverage is far short of the nation's goal of 80%, especially in rural areas, a problem that improving provider recommendations could address. Many questions remain unanswered about how to increase the potency of provider recommendations, especially in healthcare systems where most providers now work. To address these research gaps, we propose a P01 Program Project, "Improving Provider Announcement Communication Training (IMPACT)." The IMPACT Program Project's goal is to improve primary care teams' communication and HPV vaccination uptake among adolescents. Our research projects will build on the Announcement Approach Training (AAT), which the National Cancer Institute (NCI) designated a Research-Tested Intervention Program (RTIP) for cancer control. AAT motivates providers to effectively recommend HPV vaccination and appropriately address parents' questions and concerns.

The Program Project's theme is amplifying the impact of this RTIP to improve HPV vaccine communication in healthcare systems. Project 1 will establish **how** to involve the whole primary care team in HPV vaccine recommendations. The project will examine whether support for implementation of existing standing orders increases HPV vaccine uptake in clinics receiving the AAT. Project 2 will examine **what** motivates providers to recommend HPV vaccination. The project will establish whether clinic-level financial incentives increase HPV vaccine uptake in clinics receiving the AAT. Project 3 will examine **who** should facilitate the trainings. The project will establish whether engaging clinical champions in healthcare systems to implement the AAT in their systems increases HPV vaccine uptake. Project 4 will examine **which** interventions fit systems' resources. The project will examine the budget impact, cost-effectiveness, and population health impact of our HPV vaccine communication interventions in rural and nonrural communities and aid health care system leaders with a decision support tool to facilitate the adoption of promising interventions. The research projects will rely on a shared national primary care team survey managed by the Data Core, implementation data collection facilitated by the Intervention Core, and regular communication and coordination by the Administrative Core. **These research activities will culminate with our AAT Intervention Package for healthcare systems.** The following integrated aims guide the Program Project.

Aim 1. Identify opportunities to improve HPV vaccine communication. *To meet this aim, projects will:*

Project 1 (P1). Characterize roles of nurses, medical assistants and standing orders in HPV vaccination.
P2. Characterize providers' perceptions of financial incentives and behavioral nudges for HPV vaccination.
P3. Characterize clinical champions and the strategies they use for improving HPV vaccination.
P4. Identify differences in contextual factors in rural and nonrural areas that may influence implementation and effectiveness of HPV vaccine communication interventions.

Aim 2. Evaluate the impact and cost of HPV vaccine communication interventions in cluster RCTs.

P1. Evaluate the impact of standing orders support on HPV vaccine communication and uptake in a cluster randomized clinical trial (RCT).
P2. Evaluate the impact of financial incentives on HPV vaccine communication and uptake in a cluster RCT.
P3. Evaluate the impact of clinical champions on HPV vaccine communication and uptake in a cluster RCT.
P4. Develop dynamic HPV microsimulation models to evaluate the budget impact, cost-effectiveness, and population health impact of HPV vaccine communication interventions, including ones developed by P1-3.

Aim 3. Support implementation of HPV vaccine communication interventions in healthcare systems.

P1-3. Calculate the cost of implementing interventions (AAT, standing orders, financial incentives, and clinical champions intervention).
P4. Develop a web-based interactive decision support tool to support stakeholder implementation planning.
P1-4. Contribute modules to the AAT Intervention Package to support healthcare systems in choosing and implementing interventions to improve HPV vaccine communication and uptake.

The IMPACT Program Project will make a **significant contribution to cancer prevention** by developing new evidence on effective interventions to improve HPV vaccine communication and uptake in healthcare systems. The proposed research addresses NCI's priority to "broaden the prevention of HPV cancers" including by increasing HPV vaccine uptake.

RESEARCH STRATEGY – Overall

PROGRAM PROJECT THEME

HPV vaccination can prevent cancer but is underused. Every year, HPV infections cause an estimated 34,800 anal, cervical, oropharyngeal, penile, vaginal, and vulvar cancers in the US.[1-3] HPV vaccination could eliminate 32,100 cancers annually, which represents over 80% of cervical and anal cancers and the majority of the other HPV cancers as well.[4] Several trials have found that HPV vaccine is effective in preventing precancers, and recent studies have reported promising data that the vaccine is already leading to a reduction in cervical cancers.[5-7] National recommendations call for routine administration of HPV vaccine to adolescents ages 11 and 12 and catch-up doses at older ages.[8] The US has made substantial progress in increasing HPV vaccination uptake. However, only 54% of adolescents have received the recommended number of HPV vaccine doses,[9] far short of the Healthy People 2020 goal of 80%. No state has yet reached this goal. A major cause of low uptake is infrequent and inadequate HPV vaccine recommendations.

We propose to establish the Improving Provider Announcement Communication Training (IMPACT) Program Project at the University of North Carolina (UNC). The goal of the IMPACT Program is to improve primary care teams' HPV vaccination communication and uptake among adolescents served by healthcare systems. We will meet this goal by building scientific evidence for the effectiveness and cost of communication interventions – and expanding healthcare systems' capacity to implement these interventions. Our research projects will build on the Announcement Approach Training (AAT). AAT motivates providers to effectively recommend HPV vaccination and appropriately address parents' questions and concerns and increase vaccination uptake. The National Cancer Institute (NCI) has designated the AAT an evidence-based cancer control strategy via their Research-Tested Intervention Programs.

The Program Project theme is amplifying the impact of this Research-Tested Intervention Program to improve HPV vaccine communication in healthcare systems. Four projects will address the theme in the context of healthcare systems that serve rural and nonrural areas. Project 1 will establish **how** to involve the whole primary care team in HPV vaccine recommendations **(Figure 1)**. The project will examine whether standing orders support, which promotes inclusion of the whole primary care team, increases HPV vaccine uptake. Project 2 will examine **what** motivates primary care team members to recommend HPV vaccination. The project will establish whether clinic-level financial incentives increase vaccine uptake in clinics receiving the AAT. Project 3 will examine **who** should facilitate the trainings. The project will establish whether engaging clinical champions to implement the AAT increases vaccine uptake. Project 4 will examine **which** of our interventions fit systems' resources based on budget impact, cost-effectiveness, and population health impact in rural and nonrural communities. The project will aid healthcare system leaders with a decision support tool to facilitate the implementation of promising interventions based on evidence generated from Projects 1-3. The research projects will receive support from 3 cores: Administrative, Data, and Intervention.

Figure 1. Contribution of projects to the IMPACT Program Project theme

SIGNIFICANCE

Provider recommendations are powerful. Observational studies show a large impact of provider recommendation on HPV vaccine uptake.[10-14] The nationally representative National Immunization Survey-Teen found that adolescents whose parents had not received a recommendation from a provider had a low HPV vaccine initiation rate of 47%.[15] With a provider recommendation, uptake was 28 percentage points higher (**Figure 2**). Across 59 studies, the odds ratio is 10.1 (95% CI: 7.6-13.4) for the association of a provider recommendation and HPV vaccine initiation.[16,17]

Infrequent and poor-quality recommendations are a key barrier to HPV vaccination.[18] Up to half of parents of adolescents in some studies have not received a recommendation for HPV vaccine.[17] Over a quarter of providers routinely give ambiguous recommendations, and ~40% give recommendations that are inconsistent (focus only on perceived high-risk groups) or encourage delay,[19] which can undermine HPV vaccine uptake.[10] **An effective recommendation approach is using a presumptive recommendation**

where the provider announces the vaccines for which the child is due, assuming the family is ready to vaccinate.[20,21] Presumptive provider communication about adolescent vaccination is increasingly common but not yet universal.[22-25] Many providers do not reliably use presumptive announcements, and even those who do may have room to improve their communication with patients. Importantly, HPV vaccination uptake is much higher for adolescents seen by providers who use presumptive announcements.[26]

Figure 2. Impact of provider recommendation on HPV vaccine uptake

Providers face many barriers that limit their ability to provide effective recommendations. Parents value HPV vaccine and other vaccines,[25] but they have more questions about HPV vaccine than any other adolescent vaccine. This leads to the impression among providers that recommending HPV vaccine will take too long. Providers misunderstand the questions and believe that parents place low importance on HPV vaccination.[25] HPV is a sexually transmitted infection, and discussion of sex and related topics can be uncomfortable for some families and providers.[27] A third of providers expect discussions about HPV vaccination to be uncomfortable because of the topic of sex.[27] To address all of these issues, we developed the Announcement Approach, a brief method for recommending HPV vaccine as cancer prevention at the same time as recommending other adolescent vaccines, and we embedded the method into the AAT.

The Announcement Approach Training for providers is effective in increasing HPV vaccination. In a randomized clinical trial (RCT), Brewer, Gilkey and colleagues evaluated the AAT. They recruited 30 clinics where they delivered training to vaccine providers in presumptive announcements (along with strategies for helping hesitant parents), training in participatory communication, or no training.[28] Immunization records for the over 17,000 11-12 year old adolescents served by the clinics showed a 5.4 percentage point increase in HPV vaccine initiation among the announcement training arm above the control arm ($p<.05$). In contrast, participatory communication training did not improve HPV vaccination. The AAT also shortened the time required to make HPV vaccine recommendations by ~40% and was well received by providers.[28] NCI has designated the AAT as a Research-Tested Intervention Program. The CDC and American Academy of Pediatrics also now endorse presumptive announcements as a best practice for recommending HPV vaccine.

Healthcare systems are critically important settings for HPV vaccine interventions like AAT. The nation's healthcare systems continue to centralize, creating more and larger integrated healthcare systems. The proportion of newly trained pediatricians working in small private practices dropped from 41% to 15% in a decade.[29-31] Most pediatricians and family physicians now start their careers in clinics that are part of healthcare systems. These systems offer high-reach for implementing best practices to increase HPV vaccine recommendations such as AAT, yet little is known about best practices for engaging system leadership; partnering to identify capacity, needs and solutions; and planning, implementing, and evaluating interventions in these complex multi-level settings (i.e., system, clinic, provider, family). Systems are also highly responsive to quality metrics, such as Healthcare Effectiveness Data and Information Set measures, which now include a measure for HPV vaccination. Understanding how to intervene in healthcare systems was also a priority identified by the National HPV Vaccination Roundtable.[32] We have established partnerships with healthcare systems in Mississippi, Missouri, North Carolina, Texas, and Wisconsin as sites for the randomized clinical trials in this Program Project (See **Letters of Support** for Projects 1-3). These states all have substantial rural populations and HPV prevention needs typical of the US overall (**Table 1**).

Systems may struggle to locate and implement effective interventions to improve provider communication about HPV vaccine. Several resources exist for engaging systems, including the National HPV Vaccination Roundtable's Steps Guide and an approach developed by the Vaccine Adolescents against Cancers Project.[33-35] These resources have many strengths including being flexible, open-ended frameworks that allow systems to choose among a wide array of approaches that suit their interests. However, these existing resources have not been built based on a systematic consideration of existing evidence, and they have not been evaluated using strong research methods including RCTs. Most interventions in these resources also do not focus on HPV vaccine communication. Cost and cost-effectiveness are largely unknown for these interventions overall and for many of their recommended components.

Table 1. Characteristics of states for RCTs

	Population in rural areas[36]	HPV vaccine initiation[9]	Cervical cancer deaths*
US Overall	19%	72%	2.0
Mississippi	51%	50%	3.6
Missouri	30%	69%	2.4
North Carolina	34%	71%	1.8
Texas	15%	65%	3.0
Wisconsin	30%	72%	1.3

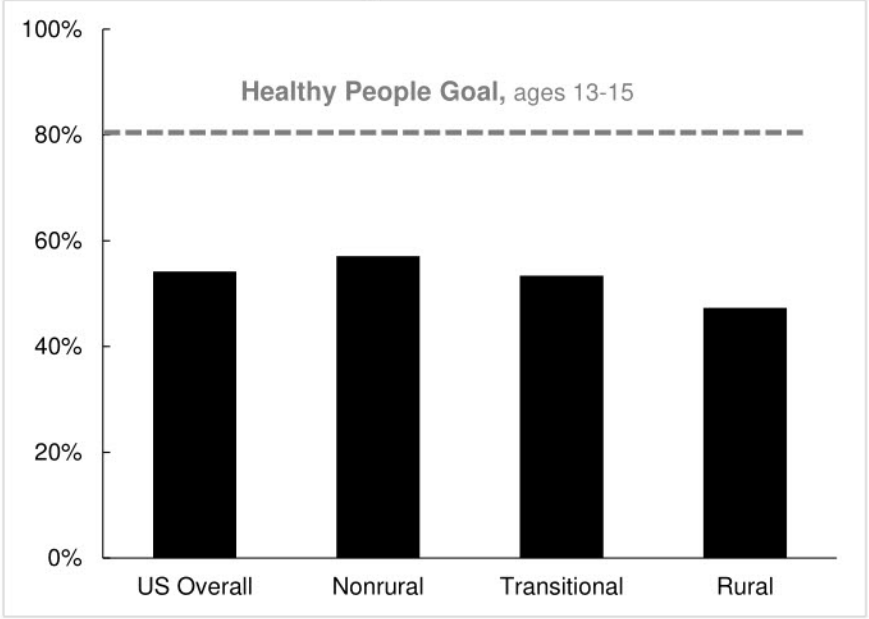
*per 100,000 women annually in 2017[37]

Healthcare systems need evidence-based interventions and strategies for implementing them. Systems manage healthcare to meet many performance standards and so must prioritize efficient use of resources across these efforts. Using the whole primary care team to make strong HPV vaccine recommendations aligns with systems' priority on efficiency. Systems value cost and cost-effectiveness data for making decisions, even as such data are in short supply. They also already incentivize providers, but little data are available to support using or not using financial incentives to increase HPV vaccination. Systems may be able to leverage internal clinical champions—providers who are committed to improving a clinical practice—to increase the impact of their interventions,[38-43] yet the best way to identify and train these champions remains unknown.[44-46] Finally, healthcare systems are reaching increasingly into rural areas, making it important to understand how HPV vaccine communication interventions may be applied to these settings.

Longstanding rural-nonrural differences characterize HPV vaccine coverage. HPV vaccine coverage is persistently lower in rural areas (**Figure 3**). Up-to-date HPV vaccine coverage is 47% in rural areas, as compared to 53% in suburban or transitional areas and 57% in urban areas (defined as principal cities).[9] HPV cancer rates in rural areas now surpass those of nonrural areas, adding new urgency to interventions.[47] Understanding how to intervene in rural areas is a research priority identified by the National HPV Vaccination Roundtable at a recent national meeting on best practices and research gaps.[32]

All geographic areas are far below the Healthy People 2020 goal. While rural areas are a priority, intervention in nonrural areas is also important for achieving national goals since most people (~80%) live in nonrural areas as defined by NIS–Teen.[48] The result is that even the most highly effective interventions delivered solely in rural areas will have little impact on the nation's overall vaccination coverage. We believe that the most valuable interventions are those that can be broadly applied to raise HPV vaccination coverage nationally, while also simultaneously reducing rural-nonrural disparities. Thus, we propose that a quarter of all intervention sites in our main trials will serve rural areas. A significant contribution of the Program will be to expand the field's understanding of how to partner with healthcare systems and intervene to increase HPV vaccination in rural and nonrural areas.

Figure 3. HPV Vaccination coverage in rural and nonrural areas of the US, for adolescents ages 13-17. NIS–Teen 2019[9]



We see an urgent need to build capacity for implementing promising interventions to improve primary care teams' HPV vaccine communication in healthcare systems.[6] Many questions remain unanswered about how to increase the potency of HPV vaccine communication: how the whole primary care team can support HPV vaccine communication, what motivates providers to recommend the vaccine, how best to find and train clinical champions, and what interventions are most cost-effective and whether they are likely to have impact in rural settings. We seek to increase the impact of the AAT, a research-tested HPV vaccine communication intervention, by enhancing it for RNs and MAs and pairing it with related interventions to further expand its benefits, and ensure it can be used in rural and nonrural settings. Given the large gaps in research on HPV vaccine communication, these topics are especially promising research opportunities that require building on the capacity of multiple integrated research projects.

INNOVATION

The proposed Program offers three key innovations. **First, we will develop new evidence on how to better support the whole primary care team in recommending HPV vaccination.** Provider recommendations are among the most potent motivators of vaccination, but we know little about how to improve recommendation frequency and quality, and most studies have focused on physicians. The proposed set of integrated studies will expand the field's understanding of how to greatly increase the impact of HPV vaccine communication by enhancing the AAT and leveraging its impact by using the whole primary care team, incentives, and champions.

Second, the Program will bring novel insights about improving HPV vaccination communication in healthcare systems. Most existing HPV vaccine interventions lack a clearly defined audience and do not provide explicit implementation support. In contrast, our interventions are designed specifically for meeting the needs of healthcare systems, including those that provide care to rural populations. Through formative work,

Table 2. IMPACT Team Members

Team Member	Discipline	IMPACT Component	Role
Noel Brewer, PhD	Health Psychology, Psychology of Decision Making, Economics	**Overall Program Research Project 1 Administrative Core**	**Principal Investigator Project Lead Core Lead**
Paul Reiter, PhD	Epidemiology	Research Project 1	Co-Investigator
Lisa Mansfield, PhD	Nursing	Research Project 1	Advisor
Paul Darden, MD	Pediatrics	Research Project 1	Advisor
Litjen (LJ) Tan, PhD	Immunology, Vaccine Policy	Research Project 1	Advisor
Justin Trogdon, PhD	Economics	**Research Project 2 Data Core**	**Project Lead Core Co-Lead**
Michelle Hernandez, MD	Pediatrics	Research Project 2	Co-Investigator
Harsha Thirumurthy, PhD	Economics	Research Project 2	Advisor
Melissa Gilkey, PhD	Health Behavior	**Research Project 3 Intervention Core**	**Project Lead Core Co-Lead**
Elizabeth Cox, MD, PhD	Pediatrics, Health Services Research	Research Project 3	Co-Investigator
Jason Terk, MD	Pediatrician	Research Project 3	Advisor
Stephanie Wheeler, PhD	Health Policy and Management, Decision Sciences	**Research Project 4**	**Project Co-Lead**
Sachiko Ozawa, PhD	Health Systems, Health Economics	**Research Project 4**	**Project Co-Lead**
Kristen Hassmiller Lich, PhD	Health Policy and Management	Research Project 4	Co-Investigator
Sarah Mills, PhD	Health Behavior	Research Project 4	Co-Investigator
Evan Myers, MD	Obstetrics and Gynecology, Public Health	Research Project 4	Advisor
Jane Kim, PhD	Health Policy, Decision Sciences	Research Project 4	Advisor
Colleen Higgins, MSPH	Health Policy and Management	Research Project 4	Advisor
Lisa Spees, PhD	Health Policy and Management	Research Project 4	Co-Investigator
Jennifer Spencer, PhD	Decision Sciences	Research Project 4	Advisor
Lynn Fiscus, MD	Pediatrics, Internal Medicine	Administrative Core Intervention Core	External Advisory Board Clinical Advisory Board
Kristin Oliver, MD	Pediatrics	Administrative Core	External Advisory Board
Margot Savoy, MD	Family Medicine	Administrative Core	External Advisory Board
Peter Szilagyi, MD	Medicine	Administrative Core	External Advisory Board
Tami Thomas, PhD, RN	Nursing Science	Administrative Core Intervention Core	External Advisory Board Clinical Advisory Board
Wendell Yarbrough, MD	Internal Medicine	Administrative Core	External Advisory Board
Nisha Gottfredson, PhD	Quantitative Psychology, Health Behavior	**Data Core**	**Core Co-Lead**
Joseph Ibrahim, PhD	Biostatistics	Data Core	Co-Investigator
Sarah Birken, PhD	Health Policy and Management, Implementation Science	**Intervention Core** Research Project 1-4	**Core Co-Lead** Co-Investigator
Bryan Weiner, PhD	Implementation Science	Intervention Core	Advisor
Chris Barry, PA-C	Physician Assistant	Intervention Core	Clinical Advisory Board
Tim McCoy, DO	Family Medicine	Intervention Core	Clinical Advisory Board
Karen Ernst	Patient and Family Advocacy	Intervention Core	Clinical Advisory Board
Brittany Thompson, LPN	Nursing	Intervention Core	Clinical Advisory Board
Sandra Weaver, CMA III	Medical assistant	Intervention Core	Clinical Advisory Board
Susan Whitely, MD	Family Medicine	Intervention Core	Clinical Advisory Board

RCTs, cost-effectiveness analysis, and population outcomes, we will generate new insights that can inform healthcare systems' work on improving HPV vaccination uptake.

Third, we will help decision makers within and outside of healthcare systems prioritize these interventions. Decision makers in healthcare systems lack the information they need to choose among HPV vaccine communication interventions. Using simulation modeling of budget impact, cost-effectiveness and population health impact in rural and nonrural communities and evidence of interventions' implementation determinants and outcomes (e.g., acceptability)—summarized in a web-based interactive decision support tool and the AAT Intervention Package—we will facilitate the adoption of promising cancer prevention interventions to increase HPV vaccination across settings. Rural areas have clear needs that few studies have addressed. We will help decision makers understand how best to meet the needs of rural clinics and providers.

APPROACH

Program Project Team

Our multidisciplinary research projects and support cores build on many disciplines, as shown in **Table 2**. IMPACT includes 13 UNC researchers and clinicians and 23 from other institutions. Our team includes faculty with training in Health Behavior, Pediatrics, Nursing, Implementation Science, Health Systems, Health Policy, Economics, Decision Sciences, and several disciplines within Psychology. IMPACT investigators have substantial expertise and proven records of conducting interdisciplinary HPV vaccination research and in disseminating study findings to vaccination programs who translate them to practice.

The IMPACT leadership team has an extensive record of highly productive collaboration on previous research studies. Drs. Brewer and Gilkey have collaborated to develop measures of provider recommendation quality and parental vaccination confidence, evaluate the AAT and other interventions in RCTs, and conduct observational studies to identify individual, interpersonal, and organizational barriers to HPV vaccination.[10,19,22-24,28,49] Drs. Brewer and Trogdon have collaborated previously on geospatial analysis of needs for HPV vaccine providers in Texas.[50,51] Drs. Wheeler and Trogdon have collaborated previously with Dr. Brewer on cost-effectiveness modeling of interventions to increase HPV vaccination; using market scan data to estimate HPV vaccination; and a systematic review of the cost-effectiveness of breast cancer treatment appoaches.[52] Brewer and Gottfredson collaborated on studies of the psychometric properties of perceived message effectiveness scales.[53] Drs. Wheeler and Trogdon have collaborated on research on risk stratification. Overall, our team has published over 50 papers together, mostly on HPV vaccination.

Announcement Approach Training

To contextualize the AAT, which is central to all activities of IMPACT, this section describes presumptive announcements, how they are included in the Announcement Approach to recommending adolescent vaccination, and finally how the approach is included in the AAT (**Table 3**).

Table 3. Sections of the Announcement Approach Training (AAT)

Review Evidence	1. Promote positive **attitudes** toward recommending HPV vaccine	▪ HPV vaccine as cancer prevention ▪ 1-minute video of woman with cervical cancer ▪ Recommendations for routine provision, safety ▪ Coverage for adolescent vaccines ▪ Impact of presumptive announcements
Build Skills	2. Build **perceived behavioral control** for HPV vaccine recommendations	▪ Making an effective announcement (Announce) ▪ Talking with hesitant parents (Connect and Counsel) ▪ Research-tested messages for hesitant parents ▪ Managing parents who still decline
Practice		▪ 1-minute video demonstrating the approach ▪ Tips from other vaccine communication experts ▪ Practice using the approach with partner ▪ Partners evaluate each other's recommendations
Implement in Your Clinic	3. Make recommending HPV vaccine a **norm** 4. Increase **intentions** to recommend HPV vaccine	▪ Embed the approach into clinic flow ▪ Identify roles for RNs and MAs ▪ Apply the approach with the next 5 patients ▪ Next steps

Announcements should indicate that HPV vaccination is part of routine care, like other vaccines previously received. We recommend that announcements: 1) note the child's age to establish that what follows is part of routine care; 2) say the child is due for several vaccines (noting the diseases prevented not the vaccine names); and 3) say that the child will receive the vaccines today. An example of a presumptive announcement is, "Now that Sophia is 12, she is due for 3 vaccines. Today, she'll get vaccines to prevent meningitis, HPV cancers, and whooping cough."

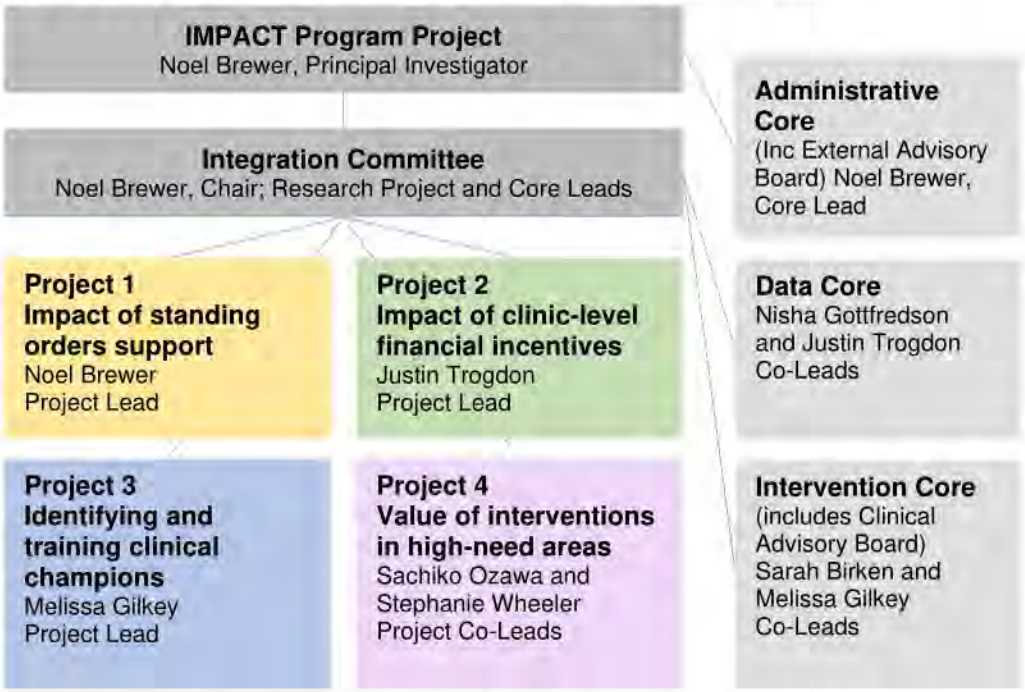
The Announcement Approach pairs the presumptive announcement with techniques to meet the needs of hesitant parents. In the **first part of the Announcement Approach**, the primary care team member uses an announcement and can move on with the visit. If parents have questions or concerns, providers should use the **second part of the Announcement Approach**: "Connect and Counsel." To do this, the team member 1) connects with the parent by showing empathy and confirming the parent's main question without reinforcing misinformation; and 2), counsels the parent using a research-tested message and encourages them to vaccinate today. Messages in the Counsel step increase parents' intentions to vaccinate in our prior randomized experiments (e.g., "This vaccine is one of the most studied medications on the market. The HPV vaccine is safe, just like the other vaccines given at this age").[54] If parents decline same-day vaccination, the team member makes a note in the patient's chart and addresses HPV vaccination at the next visit.

We have embedded this communication approach into a standardized, interactive intervention known as Announcement Approach Training (AAT). AAT sections and training objectives are shown in **Table 3**. The AAT is an in-clinic, 1-hour training with CME, led by a primary care professional.

Overview of Program Project

The Program's overall goal is to improve HPV vaccine communication and uptake by adapting the AAT for healthcare systems. To achieve this goal, the IMPACT Program Project (**Figure 4**), led by Dr. Noel Brewer as Principal Investigator, will build on an exceptional team of scientists working together on 4 research projects, 3 cores, a Clinical Advisory Board, and an External Advisory Board.

Figure 4. Organizational chart for the IMPACT Program Project



<u>Project 1. The impact of standing orders support on HPV vaccine communication and uptake.</u>

Led by Dr. Noel Brewer, **Project 1** will conduct research to expand the role of RNs and MAs in HPV vaccine recommendations and optimize standing orders. Nurses are among the most highly trusted medical professionals, and the US has more than three times as many nurses as physicians.[55] Most importantly, the expertise and skills of RNs and MAs are vastly underused in HPV vaccine communication. Up to 75% of attendees at our AAT sessions are RNs and MAs. We will work with systems and clinics to optimize the use of standing orders so that they specify roles for primary care team members to recommend and deliver HPV vaccine, modify clinic flow to economize time for patients and staff, and address barriers to make standing orders part of everyday practice. Research has examined the impact of creating *new* standing orders for vaccination,[56-58] including as one part of multi-component trials to increase HPV vaccine uptake. No randomized trials we are aware of have examined the impact of support for implementing existing HPV vaccination standing orders. Thus, we propose to develop intervention materials and support systems for clinics to optimize *existing* standing orders and evaluate this intervention in a cluster RCT.

Project 2. The impact of clinic-level financial incentives on HPV vaccine communication and uptake.

Led by Dr. Justin Trogdon, **Project 2** will examine the impact of financial incentives on HPV vaccination coverage in clinics that receive the AAT. Financial incentives can be a potent external motivator and are an increasingly central part of payment reform efforts that align financial incentives in healthcare systems with quality of care.[59-61] Behavioral nudges create choice environments that make desired choices easier to adopt.[62] Nudges, such as use of financial incentives, combined with peer comparison feedback to leverage loss aversion, may provide further motivation for providers to provide high-value preventive care.[63-65] No studies have clearly established whether financial incentives motivate providers to recommend HPV vaccination. We propose to conduct a cluster RCT to examine whether clinic-level financial incentives for providers, supported by behavioral nudges and AAT training, can improve HPV vaccine communication and uptake.

Project 3. Engaging clinical champions to improve HPV vaccine communication and uptake in healthcare systems.

Led by Dr. Melissa Gilkey, **Project 3** will examine the impact of leveraging clinical champions from within healthcare systems. AAT is effective for raising HPV vaccination uptake, but strategies are needed for bringing the intervention to scale efficiently in healthcare systems. To address this gap, we propose to develop and evaluate an innovative “train-the-trainer” strategy for delivering AAT. This strategy involves identifying clinical champions for HPV vaccination and training them to deliver AAT to other primary care professionals within their own system. In a 2-arm cluster randomized non-inferiority trial, we will compare the effectiveness of AAT delivered by champions to traditional AAT delivered by external facilitators. We hypothesize that Champion AAT is non-inferior to Traditional AAT for improving HPV vaccine communication and uptake, thereby expands the options that systems have available for implementing AAT. If successful, this project will advance cancer prevention science by quantifying the impact that clinical champions can have on HPV vaccine uptake, while also yielding practical tools to scale up AAT in healthcare systems.

Project 4. Budget impact, cost-effectiveness, and population outcomes of interventions to improve HPV vaccine communication and uptake in rural and nonrural communities.

Co-led by Drs. Stephanie Wheeler and Sachiko Ozawa, **Project 4** will 1) identify differences in contextual factors across clinics and health systems in rural and nonrural areas that may influence the implementation and effectiveness of the AAT, 2) model the budget impact, cost-effectiveness and population health impact of HPV vaccine communication interventions including those evaluated in Projects 1-3, and 3) develop a decision support tool to help healthcare systems facilitate the adoption of promising interventions. Project 4’s overall goal is to accelerate the uptake of promising interventions by integrating the new evidence generated from Projects 1-3 and existing literature with a web-based interactive decision support tool that can aid stakeholders’ use of simulation model results and inform implementation planning. We also acknowledge that HPV vaccine communication interventions that are effective (and cost-effective) in general populations may need to be tailored to be successful in rural areas or other medically underserved settings. Therefore, Project 4 will generate evidence to inform HPV vaccination implementation planning in healthcare systems in both rural and nonrural settings.

Cores

The **Administrative Core**, led by Dr. Noel Brewer, will provide overall guidance, administrative support, and fiscal management for the P01 Program Project. The Administrative Core will have a central function in establishing linkages and integration between all program elements, ensuring regular communication both within the program and with external organizations, and overseeing the Program Project as a whole. Linking all the projects and cores is an Integration Committee whose regular meetings, hosted by the Administrative Core, will ensure communication and harmonization of research approaches. The core will manage operations, including budgets and reporting, and ensure progress toward milestones through regular monitoring of project and core progress, evaluation and planning at an annual retreat and feedback from our External Advisory Board. Finally, the Administrative Core will administer the Rapid Response Pilot Grant Program which will support pilot studies on new and emerging issues in provider communication about HPV vaccine.

The **Data Core,** co-led by Drs. Nisha Gottfredson and Justin Trogdon, will support vaccine outcomes data acquisition, data management, and data analysis needs. The Data Core will support integration and create efficiencies and cost-savings across research projects by centralizing data-related services. To support formative research, the core will manage the national primary care team survey to give research projects access to a higher-quality sample of a more diverse group of providers than would be possible if each project

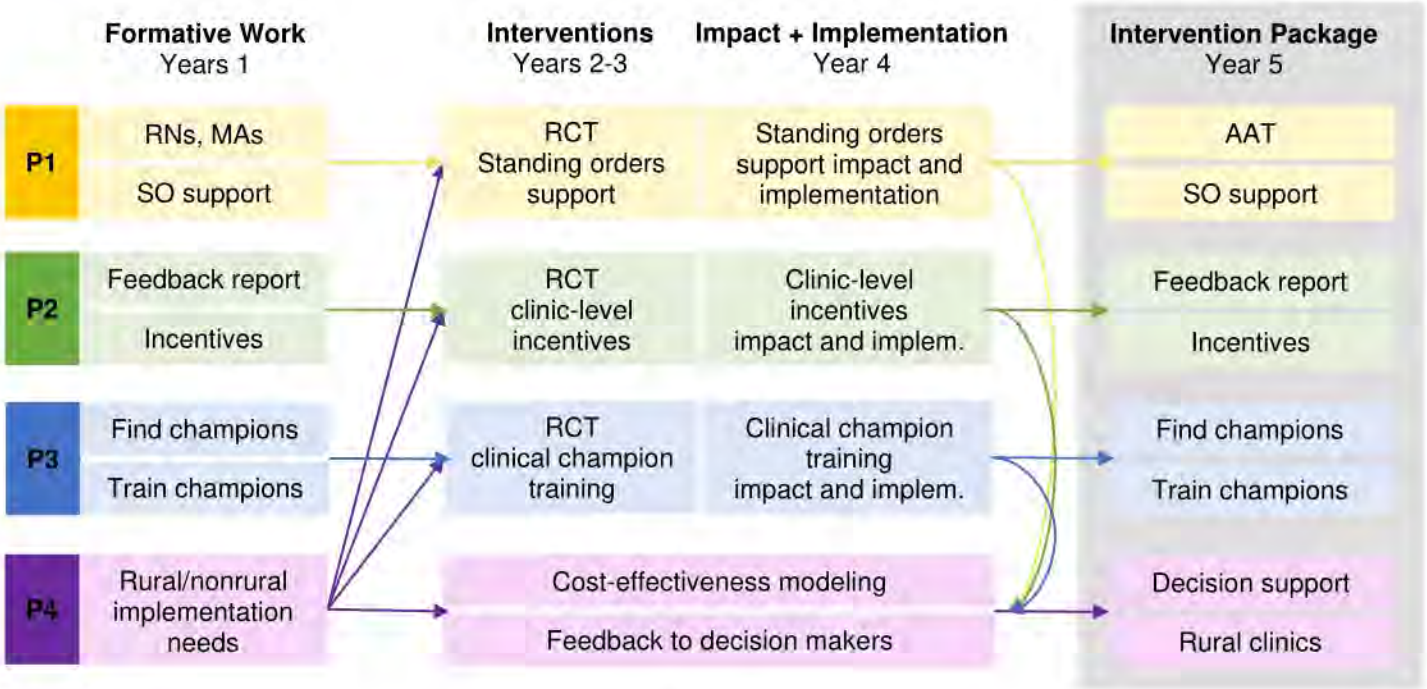
conducted a provider survey independently. To support the planned trials and subsequent cost-effectiveness analysis, the Data Core will provide centralized, and therefore more integrated and efficient, services that include acquisition and standardization of large administrative datasets, data analysis, and consulting.

The **Intervention Core**, co-led by Drs. Sarah Birken and Melissa Gilkey**,** will support conduct of the enhanced AAT interventions and implementation data acquisition, management, and analysis. First, the Intervention Core will facilitate connections to clinical experts across multiple disciplines by maintaining a standing Clinical Advisory Board with quarterly meetings to which research projects and cores can bring issues for which they need advice. Such issues may include identifying optimal ways to recruit and retain participating clinical sites and solving implementation problems as they arise in clinical environments. Second, the core will keep intervention materials up-to-date and consistently used across the multi-year intervention period to offer providers the most comprehensive evidence on improving HPV vaccination. Third, the core will facilitate projects' use of common implementation measures and data collection procedures, an important service given IMPACT's activities related to cross-project comparisons of cost. Finally, the core will coordinate development of the AAT Intervention Package and disseminate our research findings and intervention materials to academic, practice, and policy audiences in a timely manner to speed the translation of evidence into clinical practice improvements.

Integration and Coordination

The Program will pursue three aims that integrate the activities of the research projects and cores to promote synergy and coordination (**Figure 5**). In the Program's Aim 1, we will identify opportunities to improve providers' HPV vaccine communication. In Aim 2, we will conduct RCTs to evaluate interventions and build the cost-effectiveness simulation model. We will also evaluate the impact and cost of the interventions and feed these data into cost-effectiveness analysis. In Aim 3, we will create the package of intervention modules for healthcare systems. Project 4 will identify differences in contextual factors across rural and nonrural areas that may influence AAT implementation and effectiveness and share their insights with Projects 1-3 to support their interventions. Projects will contribute intervention modules to the AAT Intervention Package for healthcare systems to use in their decisions to adopt and efforts to implement AAT and P1-3 interventions. The cores will add research capacity, ensure methodological excellence, and facilitate dissemination of the study findings. Our External Advisory Board and Clinical Advisory Board will further build synergy across the projects and cores. Successful integration is central to the Program, advancing public health research and practice in a way that individual research projects could not achieve on their own. **Our approach will also accelerate the evolution of provider communication trainings, accomplishing in 5 years what might otherwise take 2 decades** if our studies were conducted sequentially. We describe this integration in detail in the sections that follow on the Program Project Aims.

Figure 5. Timeline and activities of proposed research projects



Aim 1. Identify opportunities to improve providers' HPV vaccine communication.

In this first phase, the research projects will generate new insights on opportunities to improve provider communication and develop or refine tools that will guide our later intervention work. Project 1 will understand the role of RNs, MAs, and standing orders in HPV vaccine communication. Project 2 will characterize providers' perceptions of financial incentives and behavioral nudges tied to HPV vaccination. Project 3 will characterize clinical champions and strategies they use to improve HPV vaccination. Project 4 will identify opportunities for and barriers to engaging rural and nonrural providers in HPV vaccine communication training.

National survey (Year 1)

An integration activity in the first year is the research projects' collaboration on the national primary care team survey, which will gather data from a national sample of 2,500 primary care providers with a role in providing HPV vaccine. Participants will include 500 US pediatricians, 500 family physicians, 500 physician assistants and nurse practitioners, 500 nurses, and 500 medical assistants working in pediatric primary care.

Research Projects 1, 2, and 4 will each add survey questions addressing research questions in **Table 4**. (Formative work for Project 3 focuses specifically on clinical champions, who may not be well represented in the national survey. For this reason, Project 3 will collect data qualitatively through champion interviews instead of participating in the national survey.) The ~20-minute survey will allow each project to have at least 15 survey questions on the survey, with an additional set of questions assessing demographics (e.g., medical training, role in HPV vaccine provision, rurality) available to all projects. The projects will develop their own survey items, cognitively test them with providers, and update the items. The Data Core will work with projects to merge the items into an integrated survey with consistent terminology, section transitions, and response scales. The Data Core will manage the survey, including contracting with WebMD to conduct the survey. WebMD will recruit the providers from a standing panel they maintain, program the survey, pilot test it, collect the survey data, and provide a working dataset. The Data Core will clean the data, establish standard demographic variables, and provide working datasets to the research projects. With support from the Data Core, research projects will analyze the survey data relevant to their projects.

Table 4. Research questions for national primary care team survey

Project	Research Questions	Providers	RNs/MAs
1	What role should RNs and MAs have in HPV vaccine communication?	•	•
	What do RNs and MAs want in HPV vaccine communication training?		•
	How are standing orders for HPV vaccines implemented in primary care?	•	•
2	How do providers receive information on their vaccination performance?	•	
	How willing are providers to share data on their HPV vaccination performance with other providers in their clinic?	•	
	How does the primary care team perceive "pay-for-performance" initiatives for HPV vaccination or other care?	•	•
4	How might AAT implementation opportunities differ between rural and nonrural areas?	•	•
	How might AAT implementation challenges differ between rural and nonrural areas?	•	•
Shared	Zip-code, Rurality (Rural urban continuum codes), Clinic size, Practice setting	•	•

Intervention development (Years 1-2)

Finishing in the first half of Year 2, the research projects will use their findings to develop and refine intervention materials for the RCTs. Project 1 will refine text related to RNs and MAs in HPV vaccination in the AAT and refine intervention materials for standing orders support for the RCT. Project 2 will refine a feedback report to report HPV vaccination coverage paired with improvement targets to providers and clinics and establish the level of incentives. Project 3 will develop a protocol for identifying clinical champions and update an existing train-the-trainer curriculum to engage champions in the delivery of AAT in healthcare systems. Project 4 will identify rural-nonrural contextual differences that may influence the implementation and effectiveness of HPV communication interventions. At the Annual Scientific Retreat at the end of Year 1, research projects will share their survey and intervention development findings and discuss the modules they will contribute to the AAT Intervention Package.

Aim 1 Deliverables

The formative research conducted in Years 1 and 2 will establish the empirical basis for the planned interventions. Project 4 will share their findings on rural-nonrural differences with the other projects to inform the interventions. In preparation for the AAT Intervention Package for healthcare systems, Project 1 will draft a module on expanding the role of RNs and MAs in HPV vaccine recommendations through AAT and standing orders support. Project 2 will draft a module on motivating physicians with incentives and an HPV vaccine coverage feedback report to help providers follow their progress toward vaccination goals. Project 3 will draft a module on identifying and engaging clinical champions. Project 4 will draft a module on engaging providers in rural and nonrural areas.

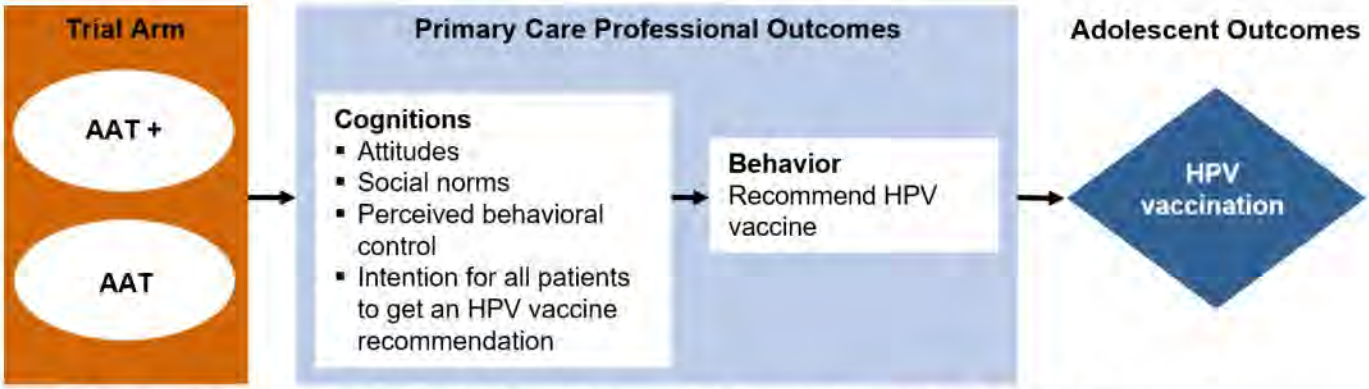
Aim 2. Evaluate the impact and cost of HPV vaccine communication interventions in healthcare systems.

In this next phase, research projects will pilot and deliver their interventions. Project 1 will conduct a cluster RCT on the impact of AAT enhanced with standing orders support. Project 2 will conduct a cluster RCT on the impact of financial incentives in clinics receiving AAT. Project 3 will conduct a cluster RCT on the impact of training clinical champions to facilitate AAT trainings. During this time, Project 4 will build their HPV microsimulation model and develop the decision support tool for stakeholders.

Conceptual model

Our RCTs rely on the shared conceptual model shown in **Figure 6** that is based on the Theory of Planned Behavior (TPB).[66] The model suggests that our interventions to improve healthcare professionals' communication will increase positive attitudes toward recommending HPV vaccination, social norms, perceived behavioral control (i.e., confidence that one can recommend the vaccine effectively), and intentions to make sure all patients get a recommendation for the vaccine. This will lead to an increase in HPV vaccine recommendations and higher uptake of HPV vaccine. We have used TPB successfully in a prior trial to guide the development and evaluation of an intervention to improve HPV vaccination.[67]

Figure 6. Conceptual model for IMPACT intervention projects



AAT + is AAT enhanced with standing orders support (P1), incentives (P2), or clinical champions (P3)

For our evaluation framework, we rely on Proctor et al.'s Implementation Outcomes Framework.[68] The framework suggests that our interventions to improve provider communication will have the greatest impact if they are well received (e.g., acceptable, appropriate) and integrated into practice (e.g., feasible, sustainable). Furthermore, the intervention should be delivered with fidelity, reach most patients with provider recommendations, and be made at a reasonable cost to sustain impact over time. The Consolidated Framework for Implementation Research informs our evaluation framework's conceptualization of determinants of AAT and enhanced intervention implementation.[69] Such determinants may include clinics' structural characteristics and rurality of the patient population served.

Piloting interventions (Year 2)

In Year 2, projects will pilot their interventions. The focus of the pilot testing will be to ensure that the planned procedures for data collection work in practice and to gather data on administrative processes. The Data Core will work with the healthcare systems to ensure that outcomes data on HPV vaccine uptake is consistently measured across projects. During this time, Project 4 will begin building their HPV microsimulation model. Projects will share the findings of the pilots at the annual retreat and discuss changes to the AAT, trial

procedures, and measures necessary to make the trials successful and data comparable across trials. We will also discuss the inputs from intervention projects into the simulation model and any early challenges faced in building it.

Intervention and modeling (Years 2-4)

The intervention projects will conduct RCTs in Years 2-3, with data collection continuing thorough Year 4. The Intervention Core will ensure timely and standardized training of providers who will facilitate AAT sessions, ensure their consistent use of AAT materials, and their periodic retraining. The Intervention Core will harmonize the collection of cost data is harmonized and meets the needs of the planned cost-effectiveness analyses.

All trials will report HPV vaccination uptake among adolescents age 11-12, verified through electronic health records. The Data Core will manage the large vaccination databases, conducting regular data quality checks. All intervention projects will analyze their vaccination data during this period, with support from biostatisticians in the Data Core.

Project 1's RCT will evaluate the impact of standing orders support. They will randomly assign 40 clinics from healthcare systems to 1 of 2 trial arms: AAT or AAT enhanced with standing orders support. Project 2's RCT will evaluate the impact of financial incentives with behavioral nudges. They will randomly assign 34 clinics to the intervention arm with clinic-level financial incentives or the control arm. Both trial arms will receive AAT. Project 3's RCT will compare the impact of Champion AAT to Traditional AAT on HPV vaccination uptake in a non-inferiority trial. Project 3 will randomize 40 clinics in healthcare systems to the Champion AAT arm or the Traditional AAT arm.

While the trials are going on, Project 4 will develop a national county-level HPV microsimulation model parameterized using data from existing literature. They will estimate rural-nonrural HPV-related cancers based on HPV vaccination levels and simulate existing HPV communication interventions in rural-nonrural settings. At the annual retreat at the end of each year, projects will share updates on their trials and papers from the national survey. The projects will continue to share strategies around recruitment, the AAT, and data quality.

Aim 2 Deliverables

Based on the RCT findings, projects will each contribute an intervention module to the package of interventions to inform healthcare system leaders' adoption decisions and efforts to implement AAT and P1-3 interventions. The intervention projects (Projects 1-3) will rely on findings from their respective RCTs. These modules will address implementing standing orders support (Project 1), implementing clinic-level incentives (Project 2), and training clinical champions (Project 3), informed by findings from their RCTs. Project 4 will develop their model of HPV communication interventions. Projects will also assess whether the interventions are equally effective and have equal value in rural and nonrural areas.

Aim 3. Support implementation of HPV vaccine communication interventions in healthcare systems.

Projects will move into the final phase of data analysis and writing up findings for publications. They will also refine their modules for the package of interventions for healthcare systems. **Table 5** summarizes the main sections and contents of the planned package.

Cost of interventions (Years 4-5)

Projects 1-3 will analyze the cost data from their trials. The Intervention Core will facilitate collection of these data across the projects. Using these cost data and the impact data from Aim 2, Project 4 will finalize their budget impact, cost-effectiveness, and population health impact analyses.

Decision support tool (Years 4-5)

Project 4 will develop and pilot a tool to help decision makers select modules from the planned package of interventions for healthcare systems. The decision support tool will incorporate modeled estimates of budget impact, cost-effectiveness, and population health impact of HPV vaccine interventions, built using cost and impact data collected by each intervention in Projects 1-3, as well as a summary of the implementation outcomes from Projects 1-3. Project 4 will finalize the decision support tool for inclusion in the package.

Aim 3 Deliverables

A main deliverable of the Program Project is the AAT Intervention Package that will support healthcare system leaders choosing and implementing high-quality HPV vaccine communication interventions. Existing

intervention approaches for healthcare systems rely on brief checklists or are not publicly available or manualized; furthermore, existing interventions do not provide data on cost or tools to support implementation.[33,35] In contrast, our Intervention Package will guide healthcare system leaders through the resources developed, evaluated and refined over the five years of the Program Project, to help them build an evidence-based initiative to improve HPV vaccine communication and uptake.

As shown in **Table 5**, the Intervention Package will include an executive summary to quickly orient users. **Section 1** will motivate the need for interventions to increase uptake of HPV vaccine, including in clinics serving rural populations. **Section 2** will include a decision support tool for *choosing* interventions. The tool will provide a high-level summary of the empirical evidence for the effectiveness of the interventions and information on budget impact, cost-effectiveness, and population impact. It will also summarize implementation findings including, for example, intervention acceptability and potential sustainability. **Section 3** will provide detailed instructions for *implementing* the interventions. These sections will include intervention protocols and materials, including slides, scripts, workshop materials and meeting agendas. Each module will also describe budgetary requirements, as well as key facilitators and barriers to successful implementation. The Intervention Core will coordinate the creation of an online manual to present the package, building on adult learning principles and working with graphic designers. We will revise the package based on the Clinical Advisory Board's feedback. We will also plan to study the combinations of interventions in future research.

Table 5. AAT Intervention Package for healthcare systems

Content	Developed by
Executive summary	Intervention Core
Section 1. Overview	
Benefits to healthcare systems of increasing HPV vaccine coverage	Admin Core + Data Core
Needs of rural and nonrural clinics	Project 4
Section 2. Decision support tool for choosing interventions	Project 4
Section 3. Modules for implementing interventions	
Announcement Approach Training	Project 1
Including RNs and MAs through standing orders support	Project 1
Motivating physicians with incentives	Project 2
Engaging clinical champions	Project 3

What if Covid-19 precludes in-person delivery of AAT workshops and other research activities? We have substantial experience planning and delivering AAT workshops by remote webinar, should the pandemic prevent in-person delivery of the interventions. All other research activities can be done remotely including formative interviews, the national survey, primary care team surveys, and key informant interviews.

What will go into the Intervention Package if a trial is ineffective? It is important to share information on what is and is not effective. The intervention package will focus on AAT and other effective interventions, including findings related to cost and other implementation outcomes and determinants. For ineffective interventions, we will focus on the main effectiveness findings and some process data on likely explanations.

Dissemination

The IMPACT Program Project will work to disseminate our research findings and the AAT Intervention Package to academic, practice, and policy audiences in a timely manner to speed the translation of evidence into clinical practice improvements. The Intervention Core, along with the Administrative Core and projects, will facilitate national dissemination. We will reach academic and practice-based audiences through peer-reviewed publications, presentations, and social media content, and via our leadership roles in organizations including the National HPV vaccination Roundtable, the Cancer Prevention and Control Research Network, Lineberger Comprehensive Cancer Center, and others. We will also actively disseminate our final AAT Intervention Package to healthcare systems. Working with our Clinical Advisory Board, we will identify and present our package to leaders in healthcare systems, as well as professional organizations such as the American Academy of Pediatrics and the American Academy of Family Physicians. The Principal Investigator and Project Leads will meet with interested systems, explore opportunities for implementation, and work with teams to develop action plans. In this way, we aim to expand our efforts, which currently extend to 15 states, to improve primary care providers' communication and delivery systems. We will make all study products, including the final AAT Intervention Package, freely available via hpvIQ.org, our existing website for disseminating tools for improving HPV vaccine communication and uptake in primary care.

PHS Human Subjects and Clinical Trials Information

OMB Number: 0925-0001

Expiration Date: 02/28/2023

Use of Human Specimens and/or Data

Does any of the proposed research in the application involve human specimens and/or data *	❍ Yes ● No
Provide an explanation for any use of human specimens and/or data not considered to be human subjects research.	
Are Human Subjects Involved	● Yes ❍ No
Is the Project Exempt from Federal regulations?	❍ Yes ● No
Exemption Number	❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑ 6 ❑ 7 ❑ 8
Other Requested Information	

Human Subject Studies

Study#	Study Title	Clinical Trial?
The form does not have any study records		

Delayed Onset Studies

Delayed Onset Study#	Study Title	Anticipated Clinical Trial?	Justification
The form does not have any delayed onset studies			

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August 7, 2020

Noel T. Brewer, PhD
Department of Health Behavior
Gillings School of Global Public Health
The University of North Carolina at Chapel Hill
325 Rosenau Hall
Chapel Hill, NC 27599

Dear Noel:

It has been thrilling to watch you build your program of Cancer Prevention and Control work over these years, demonstrating that fundamental behavioral research is clearly translatable into public health advances. Your individual accomplishments have positioned you to lead larger teams of colleagues culminating in this P01 submission. Therefore, it is with admiration and pleasure that I, as the Director of the UNC Lineberger Comprehensive Cancer Center (UNC Lineberger), write in support of this Program Project, "Improving Provider Announcement Communication Training" (IMPACT), a P01 proposal in response to the National Cancer Institute PAR-20-077.

This large team effort is based upon your and your colleagues' substantial completed and published work. We now know that the time is right for a multi-pronged approach to accelerating the uptake of this crucial prevention modality to the larger health care arena. IMPACT's overall goal is to improve provider communication and HPV vaccine coverage among adolescents by developing and supporting interventions to improve HPV vaccine uptake in large healthcare systems. Your Program Project has input from a host of faculty recruited by UNC Lineberger over the past 15 years many whom you have worked with as colleagues. The team is simply superb with a range of skills perfect for this ambitious approach to dramatically enhance the uptake of HPV vaccination in this country.

The impact on North Carolina and the US is the target of this proposal. That objective fits perfectly with a major goal of our UNC Lineberger 2020-2025 Strategic Plan to drastically reduce HPV cancers throughout the world, including our large efforts in sub Saharan Africa. To approach this overall goal with a mix of theoretical behavioral, implementation, and health services science is a hallmark of our UNC Lineberger prevention and early detection efforts. In your P01, an important assessment of cost-effectiveness is an appropriate nod to practicality as health care providers everywhere will need to work together toward a world without HPV cancers.

As stated above, the proposed research team has been assembled over the years by co-recruitment by UNC Lineberger and departments, in this case particularly the Gillings School of Global Public Health. As Principal Investigator of the P01, you will oversee the grant activities and multidisciplinary team including project and core leads (Drs. Justin Trogdon, Melissa Gilkey, Stephanie Wheeler, and Nisha Gottfredson). These are active Cancer Center members with whom you have a great relationship.

Dr. Stephanie Wheeler is also Associate Director of the Cancer Center's Office of Community Outreach and Engagement. One of your clinical external advisors, Dr. Wendell Yarbrough, was just recruited back to UNC as Chair of our Department of Head and Neck Surgery; he has both a longstanding clinical interest in the HPV head and neck cancer epidemic as well as a lab studying the biology and therapy of HPV oral cancer.

You and your collaborators are national leaders doing groundbreaking work in cancer prevention and control. Your data leading to the FDA's potential inclusion of graphic warnings on cigarette packages is just one recent example of policy changing research from our population science efforts. These are undergirded by UNC Lineberger investment in recruiting and then supporting public health and cancer outcomes faculty with pilot project, computational database infrastructure, and start-up funds.

Our support for this program's genesis included $100,000 over this last 18 months to finalize preliminary data and spearhead grant preparation. In order to assure the success of the P01 and the team:

a. We will continue to support the cancer control infrastructure staff and the office space rent where so many of these efforts are housed;
b. UNC Lineberger's Office of Community Outreach and Engagement will support the dissemination of your Intervention Core's HPV vaccine communication intervention package for large healthcare systems, including the filming of video materials;
c. UNC Lineberger will fund the expenses for the P01's Annual Scientific Retreat in Chapel Hill, NC; and
d. We will continue the program's developmental support by providing $40,000 yearly to the PI to be used for a research assistant or other expenses to expand the program in new directions.

Noel, I believe that your efforts have already changed the national landscape for increasing HPV vaccination. You would be the first to say you have not done it alone as you have drawn on colleagues and trainees over the years from a rich group of cancer control and behavioral researchers. Looking toward the future, the evidence generated in this proposed Program Project will provide effective strategies to accelerate implementation of HPV vaccine communication interventions in large healthcare systems, an objective sorely needed if we are to take the next steps towards elimination of HPV related cancers.

I am proud of you and your team and am hopeful that this important proposal will find favorable endorsement.

Sincerely,

H. Shelton Earp, III, MD
Director, UNC Lineberger Comprehensive Cancer Center
Director, UNC Cancer Care
Lineberger Professor of Cancer Research
Professor of Medicine & Pharmacology

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August 7, 2020

Noel T. Brewer, PhD
Professor, Health Behavior
Gillings School of Global Public Health
University of North Carolina at Chapel Hill
ntb@unc

Re: National Cancer Institute, PAR-20-077

Dear Dr. Brewer:

On behalf of the UNC Gillings School of Global Public Health, I enthusiastically offer my strong support for your proposal to the National Cancer Institute (PAR-20-077) for the P01 Program Project, "Improving Provider Announcement Communication Training (IMPACT)." I understand that the overall goal of the IMPACT Program Project is to improve provider communication and HPV vaccine coverage among adolescents by evaluating and supporting implementation of interventions in large healthcare systems. As Principal Investigator for the program project, you will direct and oversee grant activities and the interdisciplinary team for the proposed P01 Program Project.

Your IMPACT Program clearly aligns with the mission and goals of the Gillings School. Preventing diseases and delivering proven solutions faster are two of our strategic themes. For many years, the School has supported research in cancer prevention and implementation science, two areas that the proposed research will inform.

To demonstrate our support for your research, the Gillings School will provide $10,000 yearly to your P01, for the five-year period. In Years 1 and 4, the funds will support a Senior Biostatistician in the Data Core. In other years, you may use the resources flexibly as needed to support the other core functions of the P01.

During your work for the President's Cancer Panel, which I chaired from 2011 - January 2019, you helped us understand the importance of provider communication to address low HPV-vaccine coverage in the U.S. I am particularly proud of your intervention work to improve HPV vaccine uptake through strategic provider communication. Evidence generated in this proposed Program Project will provide effective strategies to further accelerate implementation of HPV-vaccine communication interventions in large healthcare systems, representing a critically important opportunity for cancer prevention. I'm excited by the promise of your approach to accelerate the evolution of provider communication trainings -- accomplishing in 5 years what might otherwise take two decades.

Your stature as a leading researcher in communication interventions for health promotion and disease prevention, stellar global track record, and reputation as one of the leading scholars in the field of HPV vaccination bode well for the success of this important work. Your work and the proposed project can deliver impact now and in the years to come. I look forward to hearing about the accomplishments of your IMPACT Program Project. Please feel free to contact me for additional information.

Warm regards,

Barbara K. Rimer

BKR/lw

cc: Penny Gordon-Larsen, PhD. Associate Dean for Research
Katie Thornsvard, MAC, Associate Dean for Finance and Business

RESOURCE SHARING PLAN – Overall

We agree with the NIH principle that data sharing is essential for expedited translation of research results into knowledge, products, and procedures to improve human health. All projects and cores will follow the same procedures. We will make data collection instruments available online for public use after data collection and analyses are complete. Leads of the research projects and the Data Core will oversee sharing of de-identified data produced by the Program Project. Dr. Brewer will oversee this process.

Research team use

Each Project Lead and the Data Core Lead will be responsible for storing their respective databases on UNC's secure server during the study period. To the extent that each project or core will collect human subjects data, data sharing processes will be included in the protocol submitted for IRB approval to ensure all practices are appropriately integrated into consent forms and that subjects are fully informed about how their data will be used.

External use

The research projects and Data Core will produce de-identified datasets and codebooks for sharing with external investigators, making use of the UNC Dataverse digital data repository (dataverse.unc.edu) hosted by the Odum Institute Data Archive. The availability of the data will be announced in the publications resulting from the study, and as part of any conference presentation. To obtain a copy of a dataset and codebook, a researcher will have to submit a request in writing, identifying themselves and their affiliated institution, indicating what they plan to do with the data, and including assurances that they will not share the data with others without the written permission of the PI. Requestors will sign a data use agreement through UNC's Office of Industry Contracting (OIC@unc.edu) to receive the dataset and codebook and agree to acknowledge NIH and the study investigators in any publications resulting from the data. Available resources include de-identified data from the Program's national primary care team survey, Projects' 1-3 trial data, and Project 4's cost-effectiveness model inputs and outputs. The dataset will be provided on a CD or through a password-protected download from the UNC Dataverse website. The documentation of the data will clearly describe each variable in the dataset, which data collection instrument supplied that variable, and what each code for each variable represents. Copies of the instruments will be included in a pdf format. The documentation also will include explanatory notes regarding the collection of the data and any special codes used for missing data. It also will include contact information for questions and all relevant references to publications that are based on the data. Interview data will not be shared because it would be difficult to protect participants' identities even if we were to remove all identifiers. We do not expect any limitations on the secondary research uses of the data. We will also monitor recommendations on best practices to prevent deductive disclosure.

Some of the data proposed for analysis are already publicly accessible for free, or for a fee (e.g., state immunization records). To the extent allowable by data use agreements and IRB protocols, we will share these data with other researchers. For transparency and to ensure reproducibility, all of these data will be appropriately described and cited, along with details of any manipulation performed on raw data, in publications and other products from the research.

Additional information about data sharing for project-specific data is available in the Resource Sharing Plans for the individual projects.

OMB Number: 4040-0010
Expiration Date: 12/31/2022

APPLICATION FOR FEDERAL ASSISTANCE
SF 424 (R&R)

5. APPLICANT INFORMATION **Organizational DUNS*:** 608195277

Legal Name*:	The University of North Carolina at Chapel Hill
Department:	Office of Sponsored Research
Division:	Research
Street1*:	104 Airport Drive
Street2:	Campus Box 1350
City*:	Chapel Hill
County:	Orange
State*:	NC: North Carolina
Province:	
Country*:	USA: UNITED STATES
ZIP / Postal Code*:	27599-1350

Person to be contacted on matters involving this application

Prefix:	First Name*:	Middle Name:	Last Name*:	Suffix:
	Andrea		Cogdill	

Position/Title:	Grants Analyst
Street1*:	130 Mason Farm Road
Street2:	CB 9525, Bioinformatics Bldg.
City*:	Chapel Hill
County:	Orange
State*:	NC: North Carolina
Province:	
Country*:	USA: UNITED STATES
ZIP / Postal Code*:	27599-9525

Phone Number*: (919) 9623950 Fax Number: (919) 843-7094 Email: grants@unc.edu

7. TYPE OF APPLICANT* H: Public/State Controlled Institution of Higher Education

Other (Specify):

Small Business Organization Type ❍ Women Owned ❍ Socially and Economically Disadvantaged

11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT*
Administrative Core – Improving Provider Announcement Communication Training (IMPACT)

12. PROPOSED PROJECT

Start Date*	Ending Date*
07/01/2021	06/30/2026

OMB Number: 4040-0010
Expiration Date: 12/31/2022

Project/Performance Site Location(s)

Project/Performance Site Primary Location

❍ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name:	The University of North Carolina at Chapel Hill
Duns Number:	608195277
Street1*:	104 Airport Drive
Street2:	Campus Box 1350
City*:	Chapel Hill
County:	Orange
State*:	NC: North Carolina
Province:	
Country*:	USA: UNITED STATES
Zip / Postal Code*:	27599-1350
Project/Performance Site Congressional District*:	NC-004

Additional Location(s) File Name:

Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED Other Project Information

1. Are Human Subjects Involved?* ○ **Yes** ● **No**

1.a. If YES to Human Subjects

Is the Project Exempt from Federal regulations? ○ Yes ○ No

If YES, check appropriate exemption number: _ 1 _ 2 _ 3 _ 4 _ 5 _ 6 _ 7 _ 8

If NO, is the IRB review Pending? ○ **Yes** ○ **No**

IRB Approval Date:

Human Subject Assurance Number

2. Are Vertebrate Animals Used?* ○ **Yes** ● **No**

2.a. If YES to Vertebrate Animals

Is the IACUC review Pending? ○ Yes ○ No

IACUC Approval Date:

Animal Welfare Assurance Number

3. Is proprietary/privileged information included in the application?* ○ **Yes** ● **No**

4.a. Does this project have an actual or potential impact - positive or negative - on the environment?* ○ **Yes** ● **No**

4.b. If yes, please explain:

4.c. If this project has an actual or potential impact on the environment, has an exemption been authorized or an environmental assessment (EA) or environmental impact statement (EIS) been performed? ○ Yes ○ No

4.d. If yes, please explain:

5. Is the research performance site designated, or eligible to be designated, as a historic place?* ○ **Yes** ● **No**

5.a. If yes, please explain:

6. Does this project involve activities outside the United States or partnership with international collaborators?* ○ **Yes** ● **No**

6.a. If yes, identify countries:

6.b. Optional Explanation:

	Filename
7. Project Summary/Abstract*	AbstractACr1045594937.pdf
8. Project Narrative*	NarrativeACr1045594938.pdf
9. Bibliography & References Cited	ReferencesACr1045594939.pdf
10.Facilities & Other Resources	FacilitiesACr1045594940.pdf
11.Equipment	EquipmentACr1045594941.pdf
12. Other Attachments	AcronymsACr1045594942.pdf

Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

ABSTRACT – Administrative Core

The Administrative Core will provide overall guidance, administrative support, and fiscal management for the P01 Program Project, “Improving Provider Announcement Communication Training (IMPACT).” Dr. Noel Brewer will be the Administrative Core Lead as well as the Principal Investigator for the Overall Program Project. The Administrative Core will have a central function in establishing linkages and integration between all program elements, ensuring regular communication both within the program and with external organizations, and overseeing the Program Project as a whole and the pilot grant program. The three specific aims of the Administrative Core are as follows. **Aim 1. Foster effective collaboration across IMPACT’s research projects and cores to achieve integration of their research activities and products.** The Administrative Core will establish an Integration Committee comprised of project and core leads; annually convene the External Advisory Board comprised of stakeholders including vaccination providers and healthcare system leaders; and coordinate our Annual Scientific Retreat. **Aim 2. Manage IMPACT’s operations and progress toward milestones.** The Administrative Core will provide organizational leadership and infrastructure necessary for overseeing research projects and shared core resources; provide administrative support to ensure regulatory compliance of research; oversee fiscal management and reporting; and monitor projects’ and cores’ progress toward milestones across all phases of research. **Aim 3. Administer the Rapid Response Pilot Grant Program.** The Pilot Grant Program will fund new and timely pilot studies to address emerging ideas and the evolving needs of the field. Using a comprehensive approach, the Administrative Core will leverage our integrated research projects and cores, collaborative relationships, shared resources, and investigators’ expertise to establish capacity that individual research projects could not achieve on their own. The Administrative Core addresses the **IMPACT Program Project theme** by helping our research projects to build capacity for HPV vaccine communication interventions among primary care teams in healthcare systems.

NARRATIVE – Administrative Core

Not applicable.

FACILITIES AND OTHER RESOURCES – Administrative Core

Refer to Overall Component for Administrative Core Facilities and Other Resources.

EQUIPMENT – Administrative Core

None.

LIST OF ACRONYMS – Administrative Core

AAT	Announcement Approach Training
CDC	Centers for Disease Control and Prevention
Covid-19	Coronavirus disease 2019
FDA	Food and Drug Administration
HPV	Human papillomavirus
IMPACT	Improving Provider Announcement Communication Training
IRB	Institutional review board
NCI	National Cancer Institute
NIH	National Institutes of Health
QI	Quality improvement
RCT	Randomized clinical trial
RTIP	Research Tested Intervention Program
TCORS	Tobacco Center of Regulatory Science
UNC	University of North Carolina
WHO	World Health Organization

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED Senior/Key Person Profile (Expanded)

PROFILE - Project Director/Principal Investigator

Prefix: First Name*: Noel Middle Name T. Last Name*: Brewer Suffix:

Position/Title*: Professor
Organization Name*: The University of North Carolina at Chapel Hill
Department: Health Behavior
Division: Gillings Sch. of Public Hlth
Street1*: 325 Rosenau Hall
Street2: CB 7440
City*: Chapel Hill
County: Orange
State*: NC: North Carolina
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 27599-7440

Phone Number*: (919) 966-3282 Fax Number: (919) 966-2921

E-Mail*: ntb@unc.edu

Credential, e.g., agency login: eRA COMMONS USER NAME

Project Role*: Other (Specify) Other Project Role Category: Core Lead

Degree Type: PhD Degree Year: 2002

Attach Biographical Sketch*: File Name:

Attach Current & Pending Support: File Name:

Tracking Number: GRANT13205496 Funding Opportunity Number: PAR-20-077 . Received Date: 2020-09-18T11:41:16.000-04:00

PROFILE - Senior/Key Person

Prefix: First Name*: Melissa Middle Name Last Name*: Gilkey Suffix:

Position/Title*: Associate Professor
Organization Name*: The University of North Carolina at Chapel Hill
Department: Health Behavior
Division: Gillings Sch. of Public Hlth
Street1*: 317 Rosenau Hall
Street2: CB 7440
City*: Chapel Hill
County: Orange
State*: NC: North Carolina
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 27599-7440

Phone Number*: (919) 966-8650 Fax Number:

E-Mail*: gilkey@email.unc.edu

Credential, e.g., agency login: eRA COMMONS USER NAME

Project Role*: Co-Investigator Other Project Role Category:

Degree Type: PhD Degree Year: 2011

Attach Biographical Sketch*: File Name:

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Justin Middle Name G. Last Name*: Trogdon Suffix:

Position/Title*: Professor
Organization Name*: The University of North Carolina at Chapel Hill
Department: Health Policy and Management
Division: Gillings Sch. of Public Hlth
Street1*: 1101-B McGavran-Greenberg
Street2: 135 Dauer Drive, CB 7411
City*: Chapel Hill
County: Orange
State*: NC: North Carolina
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 27599-7411

Phone Number*: (919) 962-2433 Fax Number: (919) 843-6380

E-Mail*: justintrogdon@unc.edu

Credential, e.g., agency login: eRA COMMONS USER NAME

Project Role*: Co-Investigator Other Project Role Category:

Degree Type: PhD Degree Year: 2004

Attach Biographical Sketch*: File Name:

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Stephanie Middle Name B. Last Name*: Wheeler Suffix:

Position/Title*: Professor
Organization Name*: The University of North Carolina at Chapel Hill
Department: Health Policy and Management
Division: Gillings Sch. of Public Hlth
Street1*: 1104E McGavran-Greenberg
Street2: CB 7411
City*: Chapel Hill
County: Orange
State*: NC: North Carolina
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 27599-7411

Phone Number*: (919) 966-7374 Fax Number:

E-Mail*: stephanie_wheeler@unc.edu

Credential, e.g., agency login: eRA COMMONS USER NAME

Project Role*: Co-Investigator Other Project Role Category:

Degree Type: PhD Degree Year: 2010

Attach Biographical Sketch*: File Name:

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Nisha Middle Name Claire Last Name*: Gottfredson Suffix:

Position/Title*: Assistant Professor
Organization Name*: The University of North Carolina at Chapel Hill
Department: Health Behavior
Division: Gillings Sch. of Public Hlth
Street1*: 319C Rosenau Hall
Street2: CB 7440
City*: Chapel Hill
County: Orange
State*: NC: North Carolina
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 27599-7440

Phone Number*: 919-445-9385 Fax Number: 919-966-4520

E-Mail*: gottfredson@unc.edu

Credential, e.g., agency login: eRA COMMONS USER NAME

Project Role*: Co-Investigator Other Project Role Category:

Degree Type: PhD Degree Year: 2011

Attach Biographical Sketch*: File Name:

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Sachiko Middle Name Last Name*: Ozawa Suffix:

Position/Title*: Associate Professor
Organization Name*: The University of North Carolina at Chapel Hill
Department: SOP - Practice Advancement
Division: UNC Eshelman School of Pharmac
Street1*: Beard Hall 115H
Street2: CB 7574
City*: Chapel Hill
County: Orange
State*: NC: North Carolina
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 27599-7574

Phone Number*: (919) 966-2626 Fax Number:

E-Mail*: ozawa@unc.edu

Credential, e.g., agency login: eRA COMMONS USER NAME

Project Role*: Co-Investigator Other Project Role Category:

Degree Type: PhD Degree Year: 2010

Attach Biographical Sketch*: File Name:

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Sarah Middle Name Last Name*: Birken Suffix:

Position/Title*: Associate Professor
Organization Name*: Wake Forest University Health Sciences
Department: Implementation Science
Division: School of Medicine
Street1*: Medical Center Boulevard
Street2:
City*: Winston-Salem
County: Forsyth
State*: NC: North Carolina
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 27157-0000

Phone Number*: (336) 713-4231 Fax Number:

E-Mail*: sbirken@wakehealth.edu

Credential, e.g., agency login: eRA COMMONS USER NAME

Project Role*: Co-Investigator Other Project Role Category:

Degree Type: PhD Degree Year: 2011

Attach Biographical Sketch*: File Name:

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Kristin Middle Name Last Name*: Oliver Suffix:

Position/Title*: Assistant Professor
Organization Name*: Icahn School of Medicine at Mount Sinai
Department: Department of Pediatrics
Division:
Street1*: 1 Gustave Levy Place
Street2: Box 1057
City*: New York
County: Manhattan
State*: NY: New York
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 10028-0000

Phone Number*: (212) 824-7348 Fax Number:

E-Mail*: kristin.oliver@mssm.edu

Credential, e.g., agency login:

Project Role*: Other (Specify) Other Project Role Category: External Advisory Board

Degree Type: MD Degree Year: 2008

Attach Biographical Sketch*: File Name: BioOliverACr1045595384.pdf

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Margot Middle Name L. Last Name*: Savoy Suffix:

Position/Title*: Associate Professor and Department Chair
Organization Name*: Temple University Health System
Department: Family & Community Medicine
Division: Lewis Katz School of Medicine
Street1*: 1316 West Ontario Street
Street2:
City*: Philadelphia
County:
State*: PA: Pennsylvania
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 19140-0000

Phone Number*: (215) 707-8961 Fax Number:

E-Mail*: Margot.Savoy@tuhs.temple.edu

Credential, e.g., agency login:

Project Role*: Other (Specify) Other Project Role Category: External Advisory Board

Degree Type: MD Degree Year: 2002

Attach Biographical Sketch*: File Name: BioSavoyACr1045594944.pdf

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Peter Middle Name Last Name*: Szilagyi Suffix:

Position/Title*: Professor
Organization Name*: University of California Los Angeles
Department: Department of Pediatrics
Division: School of Medicine
Street1*: 10833 Le Conte Avenue
Street2: #12-311 MDCC
City*: Los Angeles
County: Los Angeles
State*: CA: California
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 90095-1752

Phone Number*: (310) 206-6328 Fax Number:

E-Mail*: pszilagyi@mednet.ucla.edu

Credential, e.g., agency login: eRA COMMONS USER NAME

Project Role*: Other (Specify) Other Project Role Category: External Advisory Board

Degree Type: MD Degree Year: 1981

Attach Biographical Sketch*: File Name: BioSzilagyiACr1045594945.pdf

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Tami Middle Name L. Last Name*: Thomas Suffix:

Position/Title*: Professor
Organization Name*: Florida International University
Department: Nursing and Health Sciences
Division:
Street1*: 11200 S.W. 8th Street
Street2: AHC-3 534-A
City*: Miami
County:
State*: FL: Florida
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 33199-0001

Phone Number*: (305) 348-7743 Fax Number:

E-Mail*: tthomas@fiu.edu

Credential, e.g., agency login: eRA COMMONS USER NAME

Project Role*: Other (Specify) Other Project Role Category: External Advisory Board

Degree Type: PhD Degree Year: 2006

Attach Biographical Sketch*: File Name: BioThomasACr1045595385.pdf

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Wendell Middle Name Last Name*: Yarbrough Suffix:

Position/Title*: Professor
Organization Name*: The University of North Carolina at Chapel Hill
Department: ENT - Head and Neck
Division:
Street1*: 170 Manning Drive
Street2: CB 7070
City*: Chapel Hill
County: Orange
State*: NC: North Carolina
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 27599-7070

Phone Number*: 919-843-7091 Fax Number:

E-Mail*: dell@med.unc.edu

Credential, e.g., agency login: eRA COMMONS USER NAME

Project Role*: Other (Specify) Other Project Role Category: Other Significant Contributor

Degree Type: MD Degree Year: 1989

Attach Biographical Sketch*: File Name: BioYarbroughACrV21045663940.pdf

Attach Current & Pending Support: File Name:

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 1

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2021 **End Date*:** 06-30-2022 **Budget Period: 1**

A. Senior/Key Person

Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.	Noel	T.	Brewer		Core Lead	CAL. MONTHS, INST. BASE SALARY				46,808.00	13,746.00	60,554.00
2.	Melissa		Gilkey		Co-Investigator					2,396.00	751.00	3,147.00
3.	Justin	G.	Trogdon		Co-Investigator					3,309.00	987.00	4,296.00
4.	Stephanie	B	Wheeler		Co-Investigator					3,859.00	1,129.00	4,988.00
5.	Nisha	Claire	Gottfredson		Co-Investigator					2,169.00	692.00	2,861.00
6.	Sachiko		Ozawa		Co-Investigator					2,812.00	858.00	3,670.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **79,516.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
1	Program Manager	12			87,550.00	29,178.00	116,728.00
1	Administrative Assistant	0.61			1,642.00	758.00	2,400.00
2	**Total Number Other Personnel**					**Total Other Personnel**	**119,128.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**198,644.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 1

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2021 **End Date*:** 06-30-2022 **Budget Period: 1**

C. Equipment Description	
List items and dollar amount for each item exceeding $5,000	
Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	
Additional Equipment: File Name:	

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	6,000.00
2. Foreign Travel Costs	
Total Travel Cost	**6,000.00**

E. Participant/Trainee Support Costs	**Funds Requested ($)***
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant Trainee Support Costs**	

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 1

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2021 **End Date*:** 06-30-2022 **Budget Period: 1**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	4,000.00
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8. Other Costs	44,000.00
Total Other Direct Costs	**48,000.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**252,644.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. Organized Research_On Campus	55.5	252,644.00	140,217.00
		Total Indirect Costs	**140,217.00**

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number): DHHS, Darryl Mayes, 202-401-2808

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**392,861.00**

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	392,861.00

L. Budget Justification* File Name: BudgetJustificationACr1045595412.pdf

(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 2

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2022 **End Date*:** 06-30-2023 **Budget Period: 2**

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.		Noel	T.	Brewer		Core Lead	CAL. MONTHS, INST. BASE SALARY				46,808.00	13,746.00	60,554.00
2.		Melissa		Gilkey		Co-Investigator					2,396.00	751.00	3,147.00
3.		Justin	G.	Trogdon		Co-Investigator					3,309.00	987.00	4,296.00
4.		Stephanie	B	Wheeler		Co-Investigator					3,859.00	1,129.00	4,988.00
5.		Nisha	Claire	Gottfredson		Co-Investigator					2,169.00	692.00	2,861.00
6.		Sachiko		Ozawa		Co-Investigator					2,812.00	858.00	3,670.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **79,516.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
1	Program Manager	10.8			78,795.00	26,260.00	105,055.00
1	Administrative Assistant	0.61			1,642.00	758.00	2,400.00
2	**Total Number Other Personnel**					**Total Other Personnel**	**107,455.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**186,971.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 2

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2022 **End Date*:** 06-30-2023 **Budget Period: 2**

C. Equipment Description	
List items and dollar amount for each item exceeding $5,000	
Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	
Additional Equipment: File Name:	

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	6,000.00
2. Foreign Travel Costs	
Total Travel Cost	**6,000.00**

E. Participant/Trainee Support Costs	**Funds Requested ($)***
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant Trainee Support Costs**	

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 2

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2022 **End Date*:** 06-30-2023 **Budget Period: 2**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	1,000.00
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8. Other Costs	44,000.00
Total Other Direct Costs	**45,000.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**237,971.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. Organized Research_On Campus	55.5	237,970.00	132,073.00
		Total Indirect Costs	**132,073.00**

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number): DHHS, Darryl Mayes, 202-401-2808

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**370,044.00**

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	370,044.00

L. Budget Justification* File Name: BudgetJustificationACr1045595412.pdf (Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 3

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2023 **End Date*:** 06-30-2024 **Budget Period: 3**

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.		Noel	T.	Brewer		Core Lead	CAL. MONTHS, INST. BASE SALARY				46,808.00	13,746.00	60,554.00
2.		Melissa		Gilkey		Co-Investigator					2,396.00	751.00	3,147.00
3.	Dr.	Justin	G.	Trogdon		Co-Investigator					3,309.00	987.00	4,296.00
4.		Stephanie	B	Wheeler		Co-Investigator					3,859.00	1,129.00	4,988.00
5.		Nisha	Claire	Gottfredson		Co-Investigator					2,169.00	692.00	2,861.00
6.		Sachiko		Ozawa		Co-Investigator					2,812.00	858.00	3,670.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **79,516.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
1	Program Manager	10.2			74,418.00	24,801.00	99,219.00
1	Administrative Assistant	0.61			1,642.00	758.00	2,400.00
2	**Total Number Other Personnel**					**Total Other Personnel**	**101,619.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**181,135.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 3

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2023 **End Date*:** 06-30-2024 **Budget Period: 3**

C. Equipment Description	
List items and dollar amount for each item exceeding $5,000	
Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	

Additional Equipment: File Name:

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	6,000.00
2. Foreign Travel Costs	
Total Travel Cost	**6,000.00**

E. Participant/Trainee Support Costs		**Funds Requested ($)***
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other:		
Number of Participants/Trainees	**Total Participant Trainee Support Costs**	

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 3

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2023 **End Date*:** 06-30-2024 **Budget Period: 3**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	1,000.00
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8. Other Costs	4,000.00
Total Other Direct Costs	**5,000.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**192,135.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. Organized Research_On Campus	55.5	192,134.00	106,634.00
		Total Indirect Costs	**106,634.00**

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number): DHHS, Darryl Mayes, 202-401-2808

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**298,769.00**

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	298,769.00

L. Budget Justification* File Name: BudgetJustificationACr1045595412.pdf (Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 4

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2024 **End Date*:** 06-30-2025 **Budget Period: 4**

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.		Noel	T.	Brewer		Core Lead	CAL. MONTHS, INST. BASE SALARY				46,808.00	13,746.00	60,554.00
2.		Melissa		Gilkey		Co-Investigator					2,396.00	751.00	3,147.00
3.	Dr.	Justin	G.	Trogdon		Co-Investigator					3,309.00	987.00	4,296.00
4.		Stephanie	B	Wheeler		Co-Investigator					3,859.00	1,129.00	4,988.00
5.		Nisha	Claire	Gottfredson		Co-Investigator					2,169.00	692.00	2,861.00
6.		Sachiko		Ozawa		Co-Investigator					2,812.00	858.00	3,670.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **79,516.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
1	Program Manager	12			87,550.00	29,178.00	116,728.00
1	Administrative Assistant	0.61			1,642.00	758.00	2,400.00
2	**Total Number Other Personnel**					**Total Other Personnel**	**119,128.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**198,644.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 4

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2024 **End Date*:** 06-30-2025 **Budget Period: 4**

C. Equipment Description	
List items and dollar amount for each item exceeding $5,000	
Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	
Additional Equipment: File Name:	

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	6,000.00
2. Foreign Travel Costs	
Total Travel Cost	**6,000.00**

E. Participant/Trainee Support Costs	**Funds Requested ($)***
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant Trainee Support Costs**	

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 4

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2024 **End Date*:** 06-30-2025 **Budget Period: 4**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	4,000.00
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8. Other Costs	44,000.00
Total Other Direct Costs	**48,000.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**252,644.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. Organized Research_On Campus	55.5	252,643.00	140,217.00
		Total Indirect Costs	**140,217.00**

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number): DHHS, Darryl Mayes, 202-401-2808

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**392,861.00**

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	392,861.00

L. Budget Justification* File Name: BudgetJustificationACr1045595412.pdf

(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 5

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2025 **End Date*:** 06-30-2026 **Budget Period: 5**

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.		Noel	T.	Brewer		Core Lead	CAL. MONTHS, INST. BASE SALARY				46,808.00	13,746.00	60,554.00
2.		Melissa		Gilkey		Co-Investigator					2,396.00	751.00	3,147.00
3.	Dr.	Justin	G.	Trogdon		Co-Investigator					3,309.00	987.00	4,296.00
4.		Stephanie	B	Wheeler		Co-Investigator					3,859.00	1,129.00	4,988.00
5.		Nisha	Claire	Gottfredson		Co-Investigator					2,169.00	692.00	2,861.00
6.		Sachiko		Ozawa		Co-Investigator					2,812.00	858.00	3,670.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **79,516.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
1	Program Manager	12			87,550.00	29,178.00	116,728.00
1	Administrative Assistant	1.01			2,703.00	1,247.00	3,950.00
2	**Total Number Other Personnel**					**Total Other Personnel**	**120,678.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**200,194.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 5

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2025 **End Date*:** 06-30-2026 **Budget Period: 5**

C. Equipment Description	
List items and dollar amount for each item exceeding $5,000	
Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	
Additional Equipment: File Name:	

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	6,000.00
2. Foreign Travel Costs	
Total Travel Cost	**6,000.00**

E. Participant/Trainee Support Costs	**Funds Requested ($)***
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant Trainee Support Costs**	

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 5

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2025 **End Date*:** 06-30-2026 **Budget Period: 5**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	1,000.00
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8. Other Costs	44,000.00
Total Other Direct Costs	**45,000.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**251,194.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. Organized Research_On Campus	55.5	251,194.00	139,413.00
		Total Indirect Costs	**139,413.00**

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number): DHHS, Darryl Mayes, 202-401-2808

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**390,607.00**

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	390,607.00

L. Budget Justification* File Name: BudgetJustificationACr1045595412.pdf

(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

BUDGET JUSTIFICATION – Administrative Core

Key Personnel

Noel T. Brewer, PhD, Core Lead

Year 1	Year 2	Year 3	Year 4	Year 5
CAL. MONTHS				

Dr. Brewer is Professor of Health Behavior at the UNC Gillings School of Global Public Health. He is the Principal Investigator for the proposed Program Project and will lead the Administrative Core. Dr. Brewer is an accomplished leader in HPV vaccine communication and an experienced administrator, well-suited to oversee the complex work of the Program Project. He presently chairs the National HPV Vaccination Roundtable and regularly advises WHO, CDC, and other organizations on vaccine communication. Dr. Brewer will take overall responsibility for all activities in the Administrative Core, for ensuring that the research goals are met in a timely manner with scientific integrity, and that the work is done within budget amounts and is in compliance with UNC and NIH requirements. Dr. Brewer will organize and lead the Integration Committee in regular meetings and convene the External Advisory Board that will make decisions regarding the strategic direction for the Program. He will have overall budgetary, administrative, and scientific responsibility for the research project and cores and will coordinate and implement activities essential to carrying out the research aims and achieving the Program Project's goals. Dr. Brewer will supervise the Program Manager and Administrative Assistant to facilitate the Core.

Melissa B. Gilkey, PhD, Co-Investigator

Year 1	Year 2	Year 3	Year 4	Year 5
CAL. MONTHS				

Dr. Gilkey is Associate Professor of Health Behavior and will lead Project 3 and co-lead the Intervention Core. She will serve as a member of the Administrative Core's Integration Committee to enhance communication and synergy and discuss strategic directions for the Program's research projects and cores. Dr. Gilkey will attend the biweekly Integration Committee meetings and the Annual Scientific Retreat in Chapel Hill, NC. She will also advise on funding decisions for the Program's Pilot Grant Program.

Nisha C. Gottfredson, PhD, Co-Investigator

Year 1	Year 2	Year 3	Year 4	Year 5
CAL. MONTHS				

Dr. Gottfredson is Assistant Professor of Health Behavior at the UNC Gillings School of Global Public Health and will co-lead the Data Core. She will serve as a member of the Administrative Core's Integration Committee to enhance communication and synergy and discuss strategic directions for the Program's research projects and cores. Dr. Gottfredson will attend the biweekly Integration Committee meetings and the Annual Scientific Retreat in Chapel Hill, NC. She will also advise on funding decisions for the Program's Pilot Grant Program.

Sachiko Ozawa, PhD, Co-Investigator

Year 1	Year 2	Year 3	Year 4	Year 5
CAL. MONTHS				

Dr. Ozawa is Associate Professor at the UNC Eshelman School of Pharmacy in the Division of Practice Advancement and Clinical Education and adjunct faculty of Maternal and Child Health in the Gillings School of Global Public Health and will co-lead Project 4. She will serve as a member of the Administrative Core's Integration Committee to enhance communication and synergy and discuss strategic directions for the Program's research projects and cores. Dr. Ozawa will attend the biweekly Integration Committee meetings and the Annual Scientific Retreat in Chapel Hill, NC. She will also advise on funding decisions for the Program's Pilot Grant Program.

Justin G. Trogdon, PhD, Co-Investigator

Year 1	Year 2	Year 3	Year 4	Year 5
CAL. MONTHS				

Dr. Trogdon is Professor of Health Policy and Management at the UNC Gillings School of Global Public Health and will lead Project 2 and co-lead the Data Core. He will serve as a member of the Administrative Core's Integration Committee to enhance communication and synergy and discuss strategic directions for the Program's research projects and cores. Dr. Trogdon will attend the biweekly Integration Committee meetings and the Annual Scientific Retreat in Chapel Hill, NC. He will also advise on funding decisions for the Program's Pilot Grant Program.

Stephanie B. Wheeler, PhD, Co-Investigator

Year 1	Year 2	Year 3	Year 4	Year 5
CAL. MONTHS				

Dr. Wheeler is Professor of Health Policy and Management at the UNC Gillings School of Global Public Health and will co-lead Project 4. She will serve as a member of the Administrative Core's Integration Committee to enhance communication and synergy and discuss strategic directions for the Program's research projects and core. Dr. Wheeler will attend the biweekly Integration Committee meetings and the Annual Scientific Retreat in Chapel Hill, NC. She will also advise on funding decisions for the Program's Pilot Grant Program.

Sarah A. Birken, PhD, Co-Investigator (☐ CM, Years 1-5 charged to Intervention Core)
Dr. Birken is Associate Professor in the Department of Implementation Science in the Division of Public Health Sciences at Wake Forest University Health Sciences and will Co-Lead the Intervention Core. She will serve as a member of the Administrative Core's Integration Committee to enhance communication and synergy and discuss strategic directions for the Program's research projects and cores. Dr. Birken will attend the biweekly Integration Committee meetings and the Annual Scientific Retreat in Chapel Hill, NC. She will also advise on funding decisions for the Program's Pilot Grant Program. The cost for her effort is kept administratively in the Intervention Core to simplify subcontracts to her home institution.

Wendell G. Yarbrough, MD, Other Significant Collaborator (In-kind)
Dr. Yarbrough is Chair of Otolaryngology at UNC's School of Medicine and a head and neck cancer surgeon at UNC Healthcare. He will advise Dr. Brewer and colleagues in collaboration with our External Advisory Board (described in Other Costs) providing input on the strategic direction of the IMPACT Program. He will contribute in-kind hours in Years 1-5. (See Letter of Support).

Other Personnel

TBD, Program Manager

Year 1	Year 2	Year 3	Year 4	Year 5
12 CM	10.8 CM	10.2 CM	12 CM	12 CM

The Program Manager will be responsible for managing the Administrative Core's day-to-day activities, including facilitating Program communication, coordinating research projects and shared core resources, overseeing fiscal management and grant reporting, and monitoring projects' and cores' progress toward milestones. The Program Manager will ensure regulatory compliance of research including ethics approval, trial registration, and data safety monitoring. The Program manager will also coordinate the Program's Rapid Response Pilot Program (described in Other Costs) and support dissemination of Program findings.

TBD, Administrative Assistant

Year 1	Year 2	Year 3	Year 4	Year 5
0.61 CM	0.61 CM	0.61 CM	0.61 CM	1.01 CM

The Administrative Assistant will provide administrative support for the Administrative Core, including logistical support for meetings, events, and processing travel. The Administrative Assistant will also provide support to the Program Manager and Dr. Brewer with other Program logistical duties.

Lynn Fiscus, MD, Other Collaborator (In-kind)
Dr. Lynn Fiscus is the Medical Director of UNC Physicians Network and a primary care physician. She will advise Dr. Brewer and colleagues in collaboration with our External Advisory Board (described in Other Costs) providing input on the strategic direction of the IMPACT Program. She will contribute in-kind hours in Years 1-5. (See Letter of Support).

Total Expenses for Personnel=$965,588

Fringe Benefits
Fringe benefits associated with the salary request for this budget has been calculated in accordance with our Institution's DHHS Rate Agreement. The University of North Carolina at Chapel Hill applies appropriate fringe benefit rates to the personnel on this proposal: Basic permanent employee benefits are **25.889%** of annual salary plus **$6,512/FTE/YR** for fixed health insurance.

Travel

Travel for Conferences

Year 1	Year 2	Year 3	Year 4	Year 5	Total
$1,500	$1,500	$1,500	$1,500	$1,500	$7,500

Dr. Brewer will attend 1 national conference each year to disseminate findings from the IMPACT Program ($1,500 per year). Attending national conferences will allow Dr. Brewer and colleagues to disseminate the Program's findings to a broad audience including public health practitioners, researchers, and policymakers. Additionally, attending conferences will expose Dr. Brewer to the latest research in the field which will inform the Program's research activities.

Travel for Annual Scientific Retreat

Year 1	Year 2	Year 3	Year 4	Year 5	Total
$4,500	$4,500	$4,500	$4,500	$4,500	$22,500

For the Program's Annual Scientific Retreat (described in Other Expenses), we will invite key speakers and members from our External Advisory Board to attend in person. Travel is budgeted for 3 scholars ($1,500 per person) to attend the Annual Scientific Retreat each year.

Total Expenses for Travel=$30,000

Supplies

Data Storage

Year 1	Year 2	Year 3	Year 4	Year 5	Total
$3,000	-	-	$3,000	-	$6,000

Two computers for staff will be purchased in Year 1 ($1,500 X 2 computers = $3,000 in Year 1). After their warranties expire, two additional computers will be purchased in Year 4 ($1,500 X 2 computers = $3,000 in Year 4).

Project Supplies

Year 1	Year 2	Year 3	Year 4	Year 5	Total
$1,000	$1,000	$1,000	$1,000	$1,000	$5,000

Each year, $1,000 will be used for supplies needed to carry out Core meetings and activities including office supplies and printing of meeting materials and other documents as necessary in Years 1-5.

Total Expenses for Supplies=$11,000

Other Expenses

Rapid Response Pilot Grant Program

Year 1	Year 2	Year 3	Year 4	Year 5	Total
$40,000	$40,000	-	$40,000	$40,000	$160,000

The Administrative Core will administer the Program's Rapid Response Pilot Grant Program to support novel research on provider communication about HPV vaccination. The pilot grant program will support 1-2 small 6-12 month internal pilot studies annually. The program will skip Year 3 to accommodate work on trials.

External Advisory Board (EAB)

Year 1	Year 2	Year 3	Year 4	Year 5	Total
$4,000	$4,000	$4,000	$4,000	$4,000	$20,000

We will establish an External Advisory Board (EAB) comprised of a distinguished group of HPV vaccine stakeholders from multiple areas including HPV vaccination in primary care, healthcare systems leadership, and quality improvement. The EAB will consist of Dr. Kristin Oliver (MD, Mount Sinai and American Academy of Pediatrics, pediatrician and researcher in preventive medicine and vaccination), Dr. Peter Szilagyi (MD, UCLA School of Medicine, pediatrician and researcher in pediatric health services including vaccination), Dr. Tami Thomas (PhD, Florida International University and Academy of Nurse Practitioners, pediatric nurse practitioner and researcher in nursing and rural health disparities), and Dr. Margot Savoy (MD, Temple University, family physician and researcher in medical quality improvement). We also plan to recruit an HPV vaccine expert from CDC to join the advisors; CDC experts are not permitted to be identified or receive funding in research proposals. These stakeholders, along with Dr. Wendell Yarbrough (MD, UNC School of Medicine, head and neck cancer surgeon and Chair of Otolaryngology) and Dr. Lynn Fiscus (MD, UNC Healthcare, medical director of UNC Physicians Network and primary care physician) will provide input on overall direction to the Program (see Letters of Support). The EAB will attend our Annual Scientific Retreat to evaluate progress to date and advise on plans for future work. If needed, the Board will also attend key Integration Committee meetings via teleconference. ($1,000 per advisor who can receive funding X 4 = $4,000 per Year).

Annual Scientific Retreat (In-kind)
The Administrative Core will host a one-day, in-person Annual Scientific Retreat in Chapel Hill, NC in Years 1-5. UNC Lineberger will fund the expenses for the retreat (see Dr. Earp's Letter of Support).

Total Expenses for Other Expenses=$191,000

Indirect Costs
At UNC-Chapel Hill, F&A costs are calculated on a Modified Total Direct Costs (MTDC) base. This base consists of all direct salaries and wages, applicable fringe benefits, materials and supplies, services, travel and up to the first $25,000 of each subaward (regardless of the period of performance of the subawards under the award). Modified total direct costs shall exclude equipment, capital expenditures, charges for patient care, rental costs, tuition remission, scholarships and fellowships, participant support costs and the portion of each subaward in excess of $25,000.

Per UNC-Chapel Hill's current federally negotiated rate agreement (dated 11/23/2016), F&A costs associated with the proposed research project are calculated at the approved on-campus research rate of 55.5% of MTDC in all years. The cognizant agency for UNC-Chapel Hill is the U.S. Department of Health and Human Services. The cognizant agency point of contact is Darryl Mayes, (202) 401-2808.

RESEARCH & RELATED BUDGET - Cumulative Budget

	Totals ($)	
Section A, Senior/Key Person		397,580.00
Section B, Other Personnel		568,008.00
Total Number Other Personnel	10	
Total Salary, Wages and Fringe Benefits (A+B)		965,588.00
Section C, Equipment		
Section D, Travel		30,000.00
1. Domestic	30,000.00	
2. Foreign		
Section E, Participant/Trainee Support Costs		
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other		
6. Number of Participants/Trainees		
Section F, Other Direct Costs		191,000.00
1. Materials and Supplies	11,000.00	
2. Publication Costs		
3. Consultant Services		
4. ADP/Computer Services		
5. Subawards/Consortium/Contractual Costs		
6. Equipment or Facility Rental/User Fees		
7. Alterations and Renovations		
8. Other 1	180,000.00	
9. Other 2		
10. Other 3		
Section G, Direct Costs (A thru F)		1,186,588.00
Section H, Indirect Costs		658,554.00
Section I, Total Direct and Indirect Costs (G + H)		1,845,142.00
Section J, Fee		
Section K, Total Direct and Fee (I + J)		1,845,142.00

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OMB Number: 0925-0001

Expiration Date: 02/28/2023

1. Vertebrate Animals Section

Are vertebrate animals euthanized? ○ Yes ○ No

If "Yes" to euthanasia

Is the method consistent with American Veterinary Medical Association (AVMA) guidelines?

○ Yes ○ No

If "No" to AVMA guidelines, describe method and provide scientific justification

2. *Program Income Section

*Is program income anticipated during the periods for which the grant support is requested?

○ Yes ● No

If you checked "yes" above (indicating that program income is anticipated), then use the format below to reflect the amount and source(s). Otherwise, leave this section blank.

*Budget Period *Anticipated Amount ($) *Source(s)

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3. Human Embryonic Stem Cells Section

*Does the proposed project involve human embryonic stem cells? ○ Yes ● No

If the proposed project involves human embryonic stem cells, list below the registration number of the specific cell line(s) from the following list: http://grants.nih.gov/stem_cells/registry/current.htm. Or, if a specific stem cell line cannot be referenced at this time, check the box indicating that one from the registry will be used:

Specific stem cell line cannot be referenced at this time. One from the registry will be used.

Cell Line(s) (Example: 0004):

4. Human Fetal Tissue Section

*Does the proposed project involve human fetal tissue obtained from elective abortions? ○ Yes ● No

If "yes" then provide the HFT Compliance Assurance

If "yes" then provide the HFT Sample IRB Consent Form

5. Inventions and Patents Section (Renewal applications)

*Inventions and Patents: ○ Yes ○ No

If the answer is "Yes" then please answer the following:

*Previously Reported: ○ Yes ○ No

6. Change of Investigator/Change of Institution Section

❑ Change of Project Director/Principal Investigator

Name of former Project Director/Principal Investigator

Prefix:

*First Name:

Middle Name:

*Last Name:

Suffix:

❑ Change of Grantee Institution

*Name of former institution:

PHS 398 Research Plan

OMB Number: 0925-0001
Expiration Date: 02/28/2023

Introduction	
1. Introduction to Application (for Resubmission and Revision applications)	IntroApplicationACr1045594949.pdf
Research Plan Section	
2. Specific Aims	SpecificAimsACr1045594950.pdf
3. Research Strategy*	ResearchStrategyACr1045594951.pdf
4. Progress Report Publication List	
Other Research Plan Section	
5. Vertebrate Animals	
6. Select Agent Research	
7. Multiple PD/PI Leadership Plan	
8. Consortium/Contractual Arrangements	
9. Letters of Support	LOSACCombinedr1045594952.pdf
10. Resource Sharing Plan(s)	ResourceSharingACr1045594953.pdf
11. Authentication of Key Biological and/or Chemical Resources	
Appendix	
12. Appendix	

INTRODUCTION TO APPLICATION – Administrative Core

CRITIQUE, RESPONSE TO CRITIQUE

SPECIFIC AIMS – Administrative Core

The overall goal of the proposed P01 Program Project, "Improving Provider Announcement Communication Training (IMPACT)," is to improve primary care teams' HPV vaccine communication and increase HPV vaccination uptake, a critically important goal in cancer prevention. We will achieve this goal through integrated research projects on the Program Project's theme of amplifying the impact of a Research-Tested Intervention Program to improve HPV vaccine communication in healthcare systems. **The Administrative Core will provide the leadership, infrastructure, and management necessary** for coordinating the day-to-day operations of our Program Project. The Core will facilitate communication and promote effective integration across IMPACT to ensure the research projects and cores maximize collaboration and promote synergy across all phases of the research and dissemination. The Administrative Core will support the activities of the Program's diverse team of interdisciplinary scientists, primary care professionals and support staff and ensure that the scientific goals of the overall Program Project are met.

Dr. Noel Brewer will lead the core and provide leadership and oversight to ensure that the Program's complex set of research projects and cores function efficiently and integrate effectively to meet all aims and objectives. Dr. Brewer has extensive expertise, including overseeing large center projects, leading multidisciplinary teams with cross-institution collaborations, and conducting complex research studies. The Administrative Core will establish and oversee an **Integration Committee** comprised of IMPACT's project and core leads to enhance program communication and synergy. The Core will also establish and convene an **External Advisory Board** of vaccination stakeholders to offer strategic advice for the Program. In addition to integrating the work of the research projects and cores, the Administrative Core will also facilitate an internal **Rapid Response Pilot Grant Program** to provide funding for new and timely pilot work to address the evolving needs of the field. The specific aims of the Administrative Core are as follows.

Aim 1. Foster effective collaboration across IMPACT's research projects and cores to achieve integration of their research activities and products. *Activities to achieve aim:*

a. Facilitate communication and coordination across research projects and cores, including through biweekly Integration Committee meetings.
b. Convene the External Advisory Board of vaccination stakeholders annually to provide strategic input on the Program's accomplishments and planned activities and to establish stakeholder investment in IMPACT's research products as they are developed to build support for dissemination and implementation.
c. Coordinate the Program's Annual Scientific Retreat on strategic themes. Attendees will be scientists and trainees associated with IMPACT including the External Advisory Board.

Aim 2. Manage IMPACT's operations and progress toward milestones.

a. Oversee fiscal management and reporting and monitor projects' and cores' progress toward milestones.
b. Oversee regulatory compliance of research project and cores including ethics approval, trial registration, and data safety monitoring.
c. Support efforts to disseminate Program findings to scientists, clinicians and healthcare system leaders.

Aim 3. Administer the Rapid Response Pilot Grant Program.

a. Facilitate development of ideas for pilot studies of innovations in HPV vaccination communication. Solicit applications for pilot projects.
b. Manage the review and funding process for pilot studies and monitor the progress of funded studies.

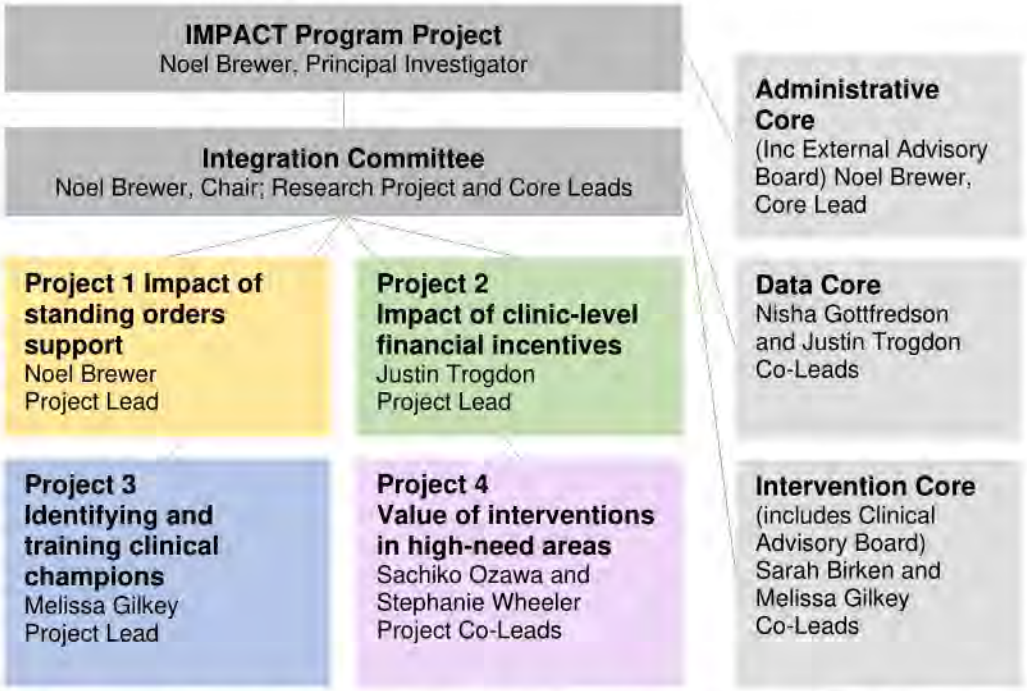
The Administrative Core will implement these specific aims throughout the IMPACT Program (Years 1-5) to support its goal of improving HPV vaccine communication quality and uptake. The Core will provide the foundation and coordination needed to support the activities of IMPACT's diverse team of interdisciplinary researchers, promote synergy across the projects and cores, and support capacity. Using a comprehensive approach, we will leverage our shared resource cores, collaborative relationships, and investigators' expertise to establish capacity and advance public health research in a way that individual research projects could not achieve on their own. The proposed Program Project makes a **significant contribution to cancer prevention** by developing new evidence on effective strategies to accelerate implementation of HPV vaccine communication interventions in healthcare systems.

RESEARCH STRATEGY – Administrative Core

OVERVIEW

"Improving Provider Announcement Communication Training (IMPACT)" is an integrated P01 Program Project with an overall goal to improve provider communication and HPV vaccine uptake. The integrated research projects and cores will conduct scientific research with the **shared theme** of amplifying the impact of a Research-Tested Intervention Program to improve HPV vaccine communication in healthcare systems. The Administrative Core will provide the leadership and management necessary to support the activities of IMPACT's diverse team of interdisciplinary researchers, promote synergy across the projects and cores, and coordinate day-to-day operations. Using a comprehensive approach, we will leverage our shared resource cores, collaborative relationships, and investigators' expertise to achieve the proposed integration of research projects in creating the Announcement Approach Training (AAT) Intervention Package for healthcare systems. IMPACT's organizational chart appears in **Figure 1**. The intervention package builds on the AAT, delivered in 12 states and recognized by NCI as a Research Tested Intervention Program (RTIP).

Figure 1. Organizational chart for the IMPACT Program Project



IMPACT PI and Administrative Core Lead

The Program Project team will be led by Dr. Brewer, an accomplished leader in HPV vaccine communication and an experienced administrator who is well-suited to oversee the complex work of the Program Project as Principal Investigator. He presently chairs the National HPV Vaccination Roundtable and regularly advises WHO, CDC and other organizations on vaccine communication. Dr. Brewer has served in a leadership capacity as a member of the National Vaccine Advisory Committee working group on HPV vaccine, co-chair of a workshop for the President's Cancer Panel, and special advisor to the Chair of the Panel. He has successfully advocated for federal panels to make recommendations in 3 key areas that hold promise for addressing low HPV coverage: communication trainings for providers, quality improvement visits to clinics, and establishing viable alternative vaccination settings such as schools and pharmacies.

Dr. Brewer has extensive expertise leading multidisciplinary teams with cross-institution collaborations, including overseeing large center projects, and conducting complex research studies, as described below. Dr. Brewer leads a current CDC-funded research project on HPV communication trainings for clinicians and HPV vaccine quality improvement. Dr. Brewer led the Developmental and Pilot Funding Program and a research project for UNC's $20 million FDA Tobacco Center of Regulatory Science (TCORS) grant (P50CA180907) that focused on using communication science to guide FDA's messaging about cigarettes and other tobacco products. Furthermore, Dr. Brewer has extensive management experience gained while running his Health Cognition and Behavior Lab overseeing over 20 project managers, postdoctoral research associates, and graduate research assistants; directing Cervical Cancer-Free North Carolina; and serving as collaborative scientific lead for UNC's Research Center for Excellence in Clinical Preventive Services.

Dr. Brewer will also serve as Administrative Core Lead. The Core will coordinate the Program's **Integration Committee**, which will be comprised of the Project and Core Leads to strategically enhance the Program's collaboration and synergy (see Aim 1 below). To promote organizational efficiency, Co-Investigators, senior

project trainees, and key staff will also attend these meetings as needed. Administrative Core staff will provide logistical support and management assistance to the Integration Committee and overall Core. The Core will also establish and direct an **External Advisory Board** comprised of key leaders and HPV vaccination stakeholders to provide input on the strategic direction of the Program (see Aim 1 below and **Letters of Support**) and to create stakeholder investment in the Program's research products and to build stakeholder interest for later supporting our dissemination and implementation to expand our reach. In addition to integrating the work of our projects and cores, the Administrative Core will also facilitate an internal **Rapid Response Pilot Grant Program** to provide funding for new and timely pilot work to address the evolving needs of the field.

The Administrative Core will implement Aims 1-3 throughout the life of the Program (Years 1-5). The Core will be housed at UNC Lineberger Comprehensive Cancer Center, an NCI-designated center with more than 300 members, which is the largest research organization on the UNC campus. Lineberger's administrative team has extensive experience directing large, interdisciplinary grants (handling more than $125 million per year in funding), which helps enable our Program to accomplish its aims (See Dr. Earp's **Letter of Support**).

Project and core leaders

IMPACT has 4 research projects and 3 cores, as shown in **Figure 1**. The Project and Core Leads have effectively collaborated conducting research projects together, including over 50 joint publications. The Leads bring together established expertise across departments at UNC including Lineberger Comprehensive Cancer Center (Cancer Prevention and Control Program, Biostatistics Core, Communication for Health Applications and Interventions Core, and Cancer Prevention and Control Research Network), Gillings School of Global Public Health (Departments of Health Behavior; Health Policy and Management; Biostatistics; and Maternal and Child Health); Eshelman School of Pharmacy; and School of Medicine. The Program is committed to integrating ideas across disciplines and providing a strong platform for the proposed activities. All research Project and Core Leads have served as principal investigators on federal research grants.

Dr. Noel Brewer, Professor of Health Behavior in the UNC Gillings School of Global Public Health, studies how people make risky health decisions. His research focuses on ways to increase HPV vaccination uptake, effectively communicate the harms of tobacco use, and appropriate use of medical screening tests. Dr. Brewer developed the Announcement Approach Training on vaccine provider communication. He has 280 peer-reviewed papers, including over 125 papers on vaccination. Dr. Brewer served as associate editor of *Health Psychology Review* and co-edited FDA's book, *Communicating Risks and Benefits: An Evidence-Based User's Guide*. In addition to his other duties, he will lead **Project 1**.

Dr. Justin Trogdon is Professor of Health Policy and Management in the UNC Gillings School of Global Public Health. He is a health economist with over 80 publications focused primarily on the economics of cancer and cancer prevention, including HPV vaccination. He has studied HPV vaccination and related cancers from economic and geospatial perspectives. He has used Medicaid claims data to estimate the economic burden of cervical cancer among Medicaid in the adoption of 9-valent HPV vaccine. He is also conducting an economic evaluation for a pragmatic trial of an intervention to improve provider and family communication about HPV vaccination and sex. Dr. Trogdon will lead **Project 2** and co-lead the **Data Core**.

Dr. Melissa Gilkey is Associate Professor of Health Behavior in the UNC Gillings School of Global Public Health and studies interventions to improve the delivery of HPV vaccine in clinics and healthcare systems. With expertise in adolescent health and cancer prevention, she has evaluated the implementation of evidence-based interventions to improve HPV vaccination and developed measurement tools to facilitate this work. She has published over 40 peer-reviewed papers on adolescent immunization, and currently chairs the National HPV Vaccination Roundtable's Best Practices Task Group. She is co-editor of the book, *Patient Advocacy for Health Care Quality*. Dr. Gilkey will lead **Project 3** and co-lead the **Intervention Core**.

Dr. Sachiko Ozawa is Associate Professor at the UNC Eshelman School of Pharmacy in the Division of Practice Advancement and Clinical Education. Her research focuses on examining the value of vaccines, assessing the economic burden of diseases and examining the demand and utilization of health care. Dr. Ozawa has over 45 publications including key papers on the economic benefits of vaccination and serves on the WHO Strategic Advisory Group of Experts Global Vaccine Action Plan Working Group on the demand for immunization. She is also a member of the Scientific Committee Review Panel for the International Health Economics Association. Dr. Ozawa will co-lead **Project 4**.

Dr. Stephanie Wheeler is Professor of Health Policy and Management in the UNC Gillings School of Global Public Health and a decision scientist with expertise in mathematical modeling and economic evaluation to inform implementation planning in cancer prevention and control. She is PI of the NCI- and CDC-funded

Cancer Prevention and Control Research Network Coordinating Center. She is also an expert in cancer equity research, with prior work focused on rural and geographic disparities in cancer care delivery and is Associate Director for Community Outreach and Engagement at Lineberger. Dr. Wheeler has over 125 publications, the majority focused on cancer care delivery and economic evaluation. Dr. Wheeler will co-lead **Project 4**.

Dr. Nisha Gottfredson is Assistant Professor of Health Behavior at the UNC Gillings School of Global Public Health. Her main applied research interest is adolescent health, including familial influences on adolescent health and behaviors. Dr. Gottfredson is also a quantitative methodologist with expertise in psychometrics and analysis of nested data structures. She has published over 70 publications in these areas. Dr. Gottfredson will collaborate with project investigators as the lead statistician on study design, developing strong and integrated survey measures, data management, and advanced statistical analyses. Dr. Gottfredson will co-lead the **Data Core**.

Dr. Sarah Birken is Associate Professor in the Department of Implementation Science at the Wake Forest School of Medicine. She has more than 50 publications relating to the implementation of evidence-based practices in healthcare. Specifically, Dr. Birken's research seeks to understand the role of context in facilitating evidence-based practice implementation. She has served as co-investigator or principal investigator on more than 20 studies of evidence-based practice implementation, most related to cancer prevention, control, and survivorship. Dr. Birken will co-lead the **Intervention Core**.

Aim 1. Foster effective collaboration across IMPACT's research projects and cores to achieve integration of their activities and research products

1a. Facilitate communication and coordination across research projects and cores.

The Core will leverage our shared resource cores, collaborative relationships, and investigators' expertise to establish capacity and achieve outcomes in a way that individual research projects could not achieve on their own. IMPACT Program leadership and most collaborators are on UNC Chapel Hill's main campus, allowing for regular in-person meetings to optimize collaboration. Our regular meeting schedule will include 1) weekly Administrative Core staff meetings; 2) biweekly Integration Committee meetings; 3) ad hoc meetings with projects and cores as needed for collaborative topics; 4) annual meetings of the External Advisory Board (see Activity 1b); and 5) the Annual Scientific Retreat (see Activity 1c).

Weekly meetings between Dr. Brewer and the Administrative Core's staff will serve as a venue for developing agendas and materials for Integration Committee meetings and planning other work of the Core. The Administrative Core will coordinate input from research project and core leaders and facilitate communication among projects and cores. We will establish an internal Integration Committee to ensure that research projects and cores effectively communicate and collaborate on research activities through the life of the Program. To enhance integration, the committee will include the Leads of the four research projects, the Data Core, and the Intervention Core. We will also invite Co-Investigators, senior project trainees, and key staff to attend. Dr. Brewer will chair the Integration Committee.

The main responsibilities of the Integration Committee will be to facilitate collaboration and sharing information across research projects and cores. The Integration Committee will accomplish this through biweekly meetings and establishing protocols for sharing project data and results. The Integration Committee will also ensure progress of the Program, including research projects and cores, in meeting specific aims in accordance with timelines. Finally, the Integration Committee will review membership on the External Advisory Board and plan agendas for its meetings. The Integration Committee will review progress updates on each research project and core, develop plans for data sharing, identify solutions to issues raised in the research process, plan communications with the External Advisory Board, and discuss cross-cutting Program logistics and financial management. A major role of the Integration Committee will be to ensure that projects align with the Program's aims and overall goal (to improve HPV vaccine communication and uptake) and that projects and cores are effectively integrated. Integration Committee members will routinely share "work in progress" so that findings in one research project or core are available in real time to inform ongoing work by other teams.

1b. Convene the External Advisory Board.

The Administrative Core will establish an External Advisory Board to provide strategic input on IMPACT Program research activities and products. In addition, exposing the Board to our research across the five years will establish investment in our products and build enthusiasm for later supporting our dissemination and implementation efforts, thus expanding our potential reach. The External Advisory Board will include a

distinguished group of HPV vaccine stakeholders from multiple areas including HPV vaccination in primary care, healthcare systems leadership, and quality improvement (see **Letters of Support**). Board members appear in **Table 1**. External Advisory Board members will attend our Annual Scientific Retreat to evaluate progress to date and advise on plans for future work. If needed, the Board will also attend key Integration Committee meetings via teleconference.

Table 1. External Advisory Board members

Board member	Expertise
Lynn Fiscus, MD, UNC Healthcare	Primary care physician, medical director of UNC Physicians Network
Kristin Oliver, MD, Mount Sinai and American Academy of Pediatrics	Pediatrician, researcher in preventive medicine
Margot Savoy, MD, MPH, FAAFP Temple University	Family physician, researcher in medical quality improvement
Peter Szilagyi, MD, UCLA School of Medicine	Pediatrician, health services researcher
Tami Thomas, PhD in Nursing, CPNP, National Academy of Nurse Practitioners	Pediatric nurse practitioner, researcher in pediatric nursing and rural health disparities
Wendell Yarbrough, MD, UNC School of Medicine	Head and neck cancer surgeon, Chair of Otolaryngology
TBN, Centers for Disease Control and Prevention	HPV vaccination QI. CDC experts cannot be identified in proposals

1c. Coordinate the Program's Annual Scientific Retreat.

The Administrative Core will coordinate the Annual Scientific Retreat to collaboratively review the Program's accomplishments and priorities and successfully integrate upcoming research activities. The one-day, in-person retreat will include all investigators, co-investigators, consultants, postdocs, graduate students, staff, and the External Advisory Board. Organized by the PI and Administrative Core staff with input from the Integration Committee and External Advisory Board, the retreat will take place in Chapel Hill, NC where we have successfully held retreats for other UNC centers.

Each retreat will have a theme linked to major milestones (**Table 2**). The first activity of each retreat will be presentations of the previous year's work, with an emphasis on findings related to the retreat's theme. The second activity will be a presentation by an invited guest keynote speaker on the retreat's theme. The third activity of the retreat will be to collaboratively review alignment of IMPACT Program accomplishments with our planned milestones, aims, and overall goal. Attendees will proactively identify areas of success and potential improvement related to collaboration and related forms of synergistic engagement. The review will help the team overcome challenges from the previous year and will inform plans for the coming year. The final activity will be an executive session with the Integration Committee and the External Advisory Board to review priorities, accomplishments and successful integration of projects and cores for maximum impact. Attendees will draft a set of suggested actions to strengthen the Program in the coming year. The Program will address these in the coming year and the PI will report on how we acted on these suggestions at the next retreat.

Aim 2. Manage IMPACT's operations and monitor progress toward milestones

The Administrative Core will manage operations of the Program, including overseeing research projects and shared core resources, providing administrative support to ensure regulatory compliance of research, overseeing fiscal management and grant reporting, and monitoring projects' and cores' progress toward milestones. These Administrative Core program topics will routinely be on Integration Committee meeting agendas. Administrative Core staff will manage the proposed Program's day-to-day activities, facilitate program communication, and provide logistical support for meetings and travel. Staff will provide administrative support to ensure regulatory compliance of research including ethics approval, trial registration, and data safety monitoring. Staff will oversee fiscal management and submitting progress reports to NCI and help monitor projects' and cores' progress toward milestones. The Administrative Core will also

Table 2. Program milestones and retreat themes

Yr	Program Milestones	Retreat Theme
1	▪ National Primary Care Team Survey ▪ RCT intervention materials	Innovations in partnering with clinics in healthcare systems
2	▪ Projects 1-3 RCTs begin	Innovations in retention of participants and clinics
3	▪ Projects 1-3 RCTs continue ▪ Cost-effectiveness model development	Innovations in analysis of behavioral trials
4	▪ Interventions' impact on HPV vacc. ▪ Intervention cost analyses	Innovations in using cost-eff. findings to inform practice
5	▪ Cost effectiveness findings ▪ AAT Intervention Package	Dissemination of Intervention Package

support the Program's dissemination efforts in collaboration with projects and cores. Dr. Brewer will oversee all Administrative Core staff to manage the operations of our Program.

2a. Oversee fiscal management and monitor projects' and cores' progress toward milestone.

Dr. Brewer will work closely with Administrative Core staff and the Director of the Business Office of the Lineberger Comprehensive Cancer Center to manage all fiscal aspects of the grant, including subcontracts. Dr. Brewer will review any major budget changes with the Integration Committee. Dr. Brewer and the Administrative Core staff will also be responsible for submission of progress and budget reports required by the funders. As UNC ranks among the nation's top 20 universities in National Institutes of Health funding, UNC's Office of Sponsored Research has the substantial experience and infrastructure necessary to help the administrative staff with fiscal management and reporting. The Administrative Core will oversee the Program's progress and ensure timeliness of key milestones and that the Program achieves all aims (**Table 2**).

2b. Oversee regulatory compliance of project and cores.

Our Program will ensure that all research projects receive institutional review board (IRB) approval and meet other regulatory obligations. The Administrative Core staff will support the four research projects to produce, process, and track their IRB applications, modifications, and approvals. We will ensure appropriate Data Safety Monitoring Plans and conflict of interest disclosures are in place. Administrative Core staff will work closely with the Projects 1-3 to ensure RCT studies are registered on clinicaltrials.gov prior to study enrollment and that summary updates are submitted as needed.

2c. Support efforts to disseminate Program findings.

The Administrative Core will support efforts to disseminate our research findings and intervention materials to scientists, clinicians, and healthcare system leaders to speed the translation of evidence into real-world use. We will proactively identify unique opportunities for cross-Program dissemination such as joint symposia at conferences, special issues of journals (e.g., for the national survey findings), and webinars. We will also produce press releases and other communications to document and share information on IMPACT's research. The Administrative Core will write the overview for the AAT Intervention Package, describing the health system benefits of improving HPV vaccination. The Intervention Core will oversee the AAT Intervention Package for healthcare systems and facilitate disseminating it to academic and practice communities, including by activating our External Advisory Board. See the Intervention Core's dissemination plan for more details. Finally, the Administrative Core will track papers and scientific presentations to monitor these activities to ensure timely dissemination of research findings.

Aim 3. Administer the Rapid Response Pilot Grant Program

We propose a Rapid Response Pilot Grant Program to **support novel research on provider communication about HPV vaccination**. We expect time-sensitive ideas and novel opportunities to arise in the planned research studies, especially the trials. For example, the AAT started as a small collaboration between the NC Immunization Branch and UNC. We propose to formalize a mechanism for funding emergent opportunities for research partnerships across IMPACT and with external programs and practitioners.

With an annual budget of $40,000, the pilot grant program will support 1-2 small, internal pilot studies each year. The program will skip Year 3 to accommodate work on trials. Dr. Brewer previously led a similar pilot grant program for the UNC TCORS that funded three dissertation studies and two pilot studies that were used in K Award applications by postdocs, and led to funded R03 (CA206487), R21 (CA234968), and six R01 (CA223600, DA04890, DA049155, CA239192, CA241420, CA240732) grants. We are eager to support a similar internal pilot grant program that can support early career researchers and expand research on HPV vaccine communication.

Our proposed process for soliciting applications, reviewing them, and then monitoring and evaluating progress of funded studies appears in **Figure 2**. The Administrative Core will form a 5-person Pilot Program committee, chaired by a Project or Core Lead and including a senior faculty member, a junior faculty member, a trainee, and a vaccine provider, all affiliated with IMPACT, to oversee the pilot grant program each year and gain grant review experience. The Data Core will provide advice on statistical analyses of research studies funded by the Pilot Program to help trainees and junior faculty readily access biostatistical expertise necessary to facilitate using more complicated research methods and analyses.

Figure 2. Overview of Pilot Program review process

3a. Facilitate idea development and solicit applications.

A key activity of the Pilot Program is to encourage new collaborations across projects and cores that **build new scientific insights about provider HPV vaccine communication**. We will advertise the program through our collaborators and department listservs. For the two months before the application deadline, pilot funding will be a standing agenda item at the biweekly Integration Committee meetings. We will invite researchers interested in applying to join those meetings to discuss their ideas and potential for collaboration. Pilot studies must include researchers from one research project plus an additional research project or core. Program leadership has experience facilitating these collaborations within and across centers.

Applications will need to focus on HPV vaccine communication, preferably building on areas of strength within the Program (standing orders, incentives, champions, rural populations, and cost-effectiveness). The Administrative Core will solicit applications for pilot studies annually that are 6-12 months in length with budgets up to $40,000. In the beginning years, we will prioritize applications about novel add-on studies to already planned Program data collection (e.g., national primary care team survey and trials) with later years focusing on secondary analyses of Program Project datasets and exploring new directions. To support trainees' career development and grant writing skills, students can propose to use these funds for their dissertation research. When funds permit, we may also fund "rapid response" studies that can be submitted year-round to address emerging issues.

3b. Manage application review and monitor progress of funded pilot studies.

The Administrative Core will coordinate the application, review, and selection process. The Pilot Program committee will use rigorous criteria for selection (significance, investigators, innovation, approach, environment, and Program integration), conduct peer review processes, and advise Administrative Core staff on the implementation of systematic monitoring processes. Two Pilot Program committee members will review each application using a standardized process and score using the standard NIH review criteria. Each reviewer will provide a brief anonymous written critique of the application to encourage improvements in current and future applications, focused on constructive, study-appropriate feedback. If the subcommittee lacks the knowledge to evaluate a proposed study, Administrative Core staff will solicit the help of relevant experts. We will give special consideration to applications from trainees and junior faculty and will provide them with NIH-formatted review to support their subsequent funding proposals. We will encourage applications from trainees and faculty from under-represented racial and ethnic minority groups, and we will flag applications to ensure they receive adequate review and careful consideration for funding.

The Integration Committee will review application recommendations by the Pilot Program committee and make funding decisions, prioritizing innovative, time-sensitive research that promotes Program integration by informing HPV vaccine communication. Funded pilot studies will submit semiannual reports to the Administrative Core addressing success in achieving the specific aims. The standard report will include narrative responses to challenges, narrative discussions of collaboration and integration, publications and grant applications in preparation, and plans for full-scale studies. The Pilot Program committee will review the reports to identify pilot studies that have research challenges. Such cases will be brought to the attention of the Administrative Core, and a member of the Core will follow up with the pilot study researchers and report back to the Integration Committee. The pilot projects will likely involve data collection that involves interacting with human subjects. When the Core issues notices of award to pilot grantees, this letter will include a statement that we will not award until a copy of an approval memo from UNC's Institutional Review Board has been provided to the Administrative Core Lead. The Administrative Core does not plan to conduct research.

Other considerations and solutions

What if Covid-19 makes travel and meeting in person infeasible? If needed, we will conduct the annual meeting, advisory meetings, and working meetings remotely, adjusting format and content as needed. We will also monitor pilot study applications to ensure that their proposed methods are feasible in the current context.

What if an IMPACT leader is incapacitated? Once funded, the PI and Leads will establish continuity plans.

PHS Human Subjects and Clinical Trials Information

OMB Number: 0925-0001

Expiration Date: 02/28/2023

Use of Human Specimens and/or Data

Does any of the proposed research in the application involve human specimens and/or data *	❍ Yes ● No
Provide an explanation for any use of human specimens and/or data not considered to be human subjects research.	
Are Human Subjects Involved	❍ Yes ● No
Is the Project Exempt from Federal regulations?	❍ Yes ❍ No
Exemption Number	❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑ 6 ❑ 7 ❑ 8
Other Requested Information	

REFERENCES – Administrative Core

None.

August 7, 2020

Noel T. Brewer, PhD Department of Health Behavior
Gillings School of Global Public Health University of North Carolina
325 Rosenau Hall CB7440 Chapel Hill, NC 27599

Dear Dr. Brewer:

I look forward to collaborating with you and your research team on the proposed NCI Program Project "Improving Provider Announcement Communication Training" (IMPACT). I am pleased to accept your invitation to participate as a member of your Program's External Advisory Board, which will be comprised of key leaders and HPV vaccination stakeholders to provide input on the strategic direction of the IMPACT Program.

Based on my expert knowledge and leadership experience as the Chief Value Officer for the University of North Carolina Physicians Network and Chair of the Primary Care collaborative of UNC Healthcare, I am well suited to advise your Program's overall direction and provide input on the innovative research and major milestones. As part of the External Advisory Board, I understand I am invited to attend your Program's Annual Scientific Retreat in Years 1-5 in-person or via teleconference. In Year 1, I will also be available for an initial teleconference to advise on your Program's strategic plans. If needed, I can also provide feedback at other key meetings via teleconference or by e-mail.

I am very excited to be supporting such an innovative Program Project that can improve HPV vaccine coverage and contribute to cancer prevention.

Best wishes,

Lynne C Fiscus MD, MPH, FAAP, FACP

UNC Physicians Network
2000 Perimeter Park Drive, Suite 200
Morrisville, NC 27560
(984) 215-4000

uncpn.com

August 13, 2020

Noel T. Brewer, PhD
Department of Health Behavior
Gillings School of Global Public Health
University of North Carolina
325 Rosenau Hall CB7440
Chapel Hill, NC 27599

Dear Dr. Brewer:

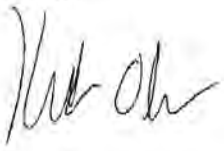
I am writing to express my strong support for your P01 Program Project "Improving Provider Announcement Communication Training" (IMPACT). I am very excited to be supporting such an innovative Program Project that can improve HPV vaccine coverage and contribute to cancer prevention. I look forward to collaborating with you and your research team.

I gladly accept your invitation to participate on your External Advisory Board (EAB), which will be comprised of key leaders and HPV vaccination stakeholders to provide input on the strategic direction of the IMPACT Program. As a practicing pediatrician with public health and quality improvement experience, and through my work in HPV vaccination with the American Academy of Pediatrics and the National HPV Vaccination Roundtable, I am well suited to advise your Program's overall direction and provide input on the innovative research and major milestones. I understand I am invited to attend your Program's Annual Scientific Retreat in Years 1-5 in-person or via teleconference. In Year 1, I will also be available for an initial teleconference to advise on your Program's strategic plans. If needed, I can also provide feedback at other key meetings via teleconference or by e-mail.

I understand that travel/lodging expenses have been budgeted for me to attend your Annual Scientific Retreat in Chapel Hill, NC. I agree to be paid $\$$ ____ each year for serving on the External Advisory Board.

I very much look forward to working with you and other team members on this important research endeavor.

Sincerely,



Kristin Oliver, MD, MHS
Assistant Professor
Icahn School of Medicine at Mount Sinai
Department of Environmental Medicine and Public Health
Department of Pediatrics
Deputy Director, Preventive Medicine Residency

July 29, 2020

Noel T. Brewer, PhD
Department of Health Behavior
Gillings School of Global Public Health
University of North Carolina
325 Rosenau Hall CB7440
Chapel Hill, NC 27599

Dear Dr. Brewer:

I am writing to express my strong support for your P01 Program Project "Improving Provider Announcement Communication Training" (IMPACT). I look forward to collaborating with you and your research team on this important research endeavor to increase HPV vaccination coverage.

I gladly accept your invitation to participate on your External Advisory Board (EAB), which will be comprised of key leaders and HPV vaccination stakeholders to provide input on the strategic direction of the IMPACT Program. As a practicing family physician, chair of the Department of Family and Community medicine at the Lewis Katz School of Medicine at Temple University, and chief quality officer for Temple Faculty Physicians, I am well suited to advise your Program's overall direction and provide input on the innovative research and major milestones.

As a nationally recognized leader in adolescent immunization including HPV vaccination, I have served as the AAFP representative on the National HPV Vaccination Roundtable steering committee. As NHPVRT Provider Education task group chair, I led the group to successfully launching a series of action guides to assist practices and health systems use team-based care to improve HPV rates. As a member and chair of the AAFP Commission on Health of the Public and Science, I've developed preventive care policy for family physicians. I assisted and mentored family practices across the country increase their vaccination rates using quality improvement to implement best practices as AAFP Adolescent Vaccine Champions project advisor. I have also served as a member of the ACIP HPV and ACIP Evidence-based Medicine working groups and as the former AAFP liaison to the ACIP. Locally, I remain an active member of the Immunization Coalition of Delaware and collaborate with partners across the state to bring a joint HPV vaccine provider education event to Delaware. I have published numerous articles and speak regularly both locally and nationally about the importance of vaccinations in preventive care including the value of HPV vaccine in the adolescent platform to adolescent groups, parents and the medical community. I also leverage my social media presence to promote immunizations and the value of primary care.

I understand as part of the External Advisory Board I am invited to attend your Program's Annual Scientific Retreat in Years 1-5 in-person or via teleconference, with travel/lodging expenses budgeted for me to attend your Annual Scientific Retreat in Chapel Hill, NC. In Year 1, I will also be available for an initial teleconference to advise on your Program's

strategic plans. If needed, I can also provide feedback at other key meetings via teleconference or by e-mail. I agree to be paid [$] each year for serving on the External Advisory Board.

I very much look forward to supporting the Program's innovative efforts to improve HPV vaccine coverage and contribute to cancer prevention.

Sincerely,

Margot L. Savoy, MD, MPH, FAAFP, FABC, CPE, CMQ, FAAPL
Chair & Associate Professor of Family & Community Medicine
Lewis Katz School of Medicine at Temple University and Temple University Hospital
Chief Quality Officer
Temple Faculty Physicians, Inc

August 13, 2020

Noel T. Brewer, PhD
Department of Health Behavior
Gillings School of Global Public Health
University of North Carolina
325 Rosenau Hall CB7440
Chapel Hill, NC 27599

Dear Dr. Brewer:

I am pleased to accept your invitation to participate as an external advisor on your P01 Program Project "Improving Provider Announcement Communication Training" (IMPACT). I look forward to supporting the innovative work of your research team to improve HPV vaccine coverage and contribute to cancer prevention.

I look forward to serving on your External Advisory Board (EAB), which will be comprised of key leaders and HPV vaccination stakeholders to provide input on the strategic direction of the IMPACT Program. Based on my 20+ years of experience as a pediatrician and health services and clinical researcher with a focus on raising immunization rates in primary care, I am well suited to advise your research team on the Program's overall direction and provide input on the innovative research and major milestones. As part of the EAB, I understand I am invited to attend your Program's Annual Scientific Retreat in Years 1-5 in-person or via teleconference. In Year 1, I will also be available for an initial teleconference to advise on your Program's strategic plans. If needed, I can also provide feedback at other key meetings via teleconference or by e-mail.

I agree to be paid $\boxed{\$\quad}$ each year for serving on the External Advisory Board and understand that travel/lodging expenses have been budgeted for me to attend your Annual Scientific Retreat in Chapel Hill, NC.

I look forward to collaborating with your research team on this timely Program Project.

Sincerely,

Peter S Szilagyi

Peter Szilagyi, MD MPH
Professor of Pediatrics
Executive Vice-Chair and Vice-Chair for Research, Department of Pediatrics
University of California, Los Angeles
pszilagyi@mednet.ucla.edu
310-206-6328

August 13, 2020

Noel T. Brewer, PhD Department of Health Behavior
Gillings School of Global Public Health University of North Carolina
325 Rosenau Hall CB7440 Chapel Hill, NC 27599

Dear Dr. Brewer:

I look forward to collaborating with you and your research team on the proposed NCI P01 Program Project "Improving Provider Announcement Communication Training" (IMPACT). I am very excited to be supporting such an innovative Program Project that can improve HPV vaccine coverage and contribute to cancer prevention.

I am pleased to accept your invitation to participate on your External Advisory Board (EAB), which will be comprised of key leaders and HPV vaccination stakeholders to provide input on the strategic direction of the IMPACT Program. Given my expertise as a pediatric nurse practitioner, NIH Funded researcher in the area of HPV in Rural Areas and multi-disciplinary collaborations, I am well suited to advise your Program's overall direction and provide input on the innovative research and major milestones. I understand I am invited to attend your Program's Annual Scientific Retreat in Years 1-5 in-person or via teleconference. In Year 1, I will also be available for an initial teleconference to advise on your Program's strategic plans. If needed, I can also provide feedback at other key meetings via teleconference or by e-mail.

The Program will provide travel and lodging expenses for me to attend your Annual Scientific Retreat in Chapel Hill, NC. I agree to be paid $\$$ ____ each year for my work with your External Advisory Board.

I am eagerly looking forward to working with your group on this valuable Program Project.

Sincerely,

Tami L. Thomas

Tami L. Thomas, PhD, RN, APRN-CPNP, FAANP, FAAN
Professor and Associate Dean Research and PhD Program Director

August 16, 2020

Noel T. Brewer, PhD
Department of Health Behavior
Gillings School of Global Public Health
University of North Carolina
325 Rosenau Hall CB7440
Chapel Hill, NC 27599

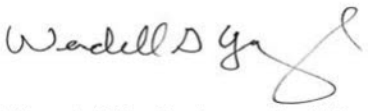
Dear Dr. Brewer:

I am pleased to express my strong support for your NCI P01 Program Project proposal "Improving Provider Announcement Communication Training" (IMPACT). I look forward to working with you and your colleagues as a member of your External Advisory Board, which will be comprised of key leaders and HPV vaccination stakeholders to provide input on the strategic direction of the IMPACT Program.

Based on my expertise as a head and neck cancer surgeon and Chair of UNC School of Medicine's Otolaryngology department, I am well suited to advise your research team on the Program's overall direction and provide input on the innovative research and major milestones. As part of the EAB, I understand I am invited to attend your Program's Annual Scientific Retreat in Years 1-5 in-person or via teleconference. In Year 1, I will also be available for an initial teleconference to advise on your Program's strategic plans. If needed, I can also provide feedback at other key meetings via teleconference or by e-mail.

I very much look forward to advising you and your research team on this innovative and important Program Project.

Sincerely,



Wendell G. Yarbrough, MD, MMHC, FACS
Thomas J. Dark Distinguished Professor of
Otolaryngology/Head and Neck Surgery
Professor and Chair, Dept. of Otolaryngology/Head and Neck Surgery
University of North Carolina

RESOURCE SHARING PLAN – Administrative Core

We agree with the NIH principle that data sharing is essential for expedited translation of research results into knowledge, products, and procedures to improve human health. All projects and cores will follow the same procedures. We will make data collection instruments available online for public use after data collection and analyses are complete. Leads of the research projects and the Data Core will oversee sharing of de-identified data produced by the Program Project. Dr. Brewer will oversee this process. See the Program's Overall Resource Sharing Plan for more details.

The Administrative Core does not currently have specific plans to be the primary home of any data generated by this Program Project. It is likely that some of the pilot projects this Core will fund will involve data collection. When the Core issues notices of awards to pilot grantees, we will require that funded pilot grants adopt the same resource sharing procedures as the Overall Program. The Administrative Core will facilitate communication between research projects and the Data Core to develop consistent systems for data protection, archiving and sharing. Finally, the Administrative Core will ensure that projects and cores follow the resource sharing plan for the Program Project. Administrative Core staff will work with the projects and cores to ensure that data sources and analytic methods are presented publicly and clearly to scientific and practice audiences.

OMB Number: 4040-0010
Expiration Date: 12/31/2022

APPLICATION FOR FEDERAL ASSISTANCE
SF 424 (R&R)

5. APPLICANT INFORMATION **Organizational DUNS*:** 608195277

Legal Name*:	The University of North Carolina at Chapel Hill
Department:	Office of Sponsored Research
Division:	Research
Street1*:	104 Airport Drive
Street2:	Campus Box 1350
City*:	Chapel Hill
County:	Orange
State*:	NC: North Carolina
Province:	
Country*:	USA: UNITED STATES
ZIP / Postal Code*:	27599-1350

Person to be contacted on matters involving this application

Prefix:	First Name*:	Middle Name:	Last Name*:	Suffix:
	Andrea		Cogdill	

Position/Title:	Grants Analyst
Street1*:	130 Mason Farm Road
Street2:	CB 9525, Bioinformatics Bldg.
City*:	Chapel Hill
County:	Orange
State*:	NC: North Carolina
Province:	
Country*:	USA: UNITED STATES
ZIP / Postal Code*:	27599-9525

Phone Number*: (919) 962-3950 Fax Number: (919) 843-7094 Email: grants@unc.edu

7. TYPE OF APPLICANT* H: Public/State Controlled Institution of Higher Education

Other (Specify):

Small Business Organization Type ❍ Women Owned ❍ Socially and Economically Disadvantaged

11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT*
Intervention Core - Improving Provider Announcement Communication Training (IMPACT)

12. PROPOSED PROJECT

Start Date*	Ending Date*
07/01/2021	06/30/2026

OMB Number: 4040-0010
Expiration Date: 12/31/2022

Project/Performance Site Location(s)

Project/Performance Site Primary Location

❍ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name:	The University of North Carolina at Chapel Hill
Duns Number:	608195277
Street1*:	104 Airport Drive
Street2:	Campus Box 1350
City*:	Chapel Hill
County:	Orange
State*:	NC: North Carolina
Province:	
Country*:	USA: UNITED STATES
Zip / Postal Code*:	27599-1350
Project/Performance Site Congressional District*:	NC-004

Project/Performance Site Location 1

❍ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name:	Wake Forest University Health Sciences
DUNS Number:	937727907
Street1*:	Medical Center Boulevard
Street2:	
City*:	Winston-Salem
County:	Forsyth
State*:	NC: North Carolina
Province:	
Country*:	USA: UNITED STATES
Zip / Postal Code*:	27157-0000
Project/Performance Site Congressional District*:	NC-005

Additional Location(s) File Name:

Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED Other Project Information

1. Are Human Subjects Involved?* ○ **Yes** ● **No**

1.a. If YES to Human Subjects

Is the Project Exempt from Federal regulations? ○ Yes ○ No

If YES, check appropriate exemption number: _ 1 _ 2 _ 3 _ 4 _ 5 _ 6 _ 7 _ 8

If NO, is the IRB review Pending? ○ **Yes** ○ **No**

IRB Approval Date:

Human Subject Assurance Number

2. Are Vertebrate Animals Used?* ○ **Yes** ● **No**

2.a. If YES to Vertebrate Animals

Is the IACUC review Pending? ○ Yes ○ No

IACUC Approval Date:

Animal Welfare Assurance Number

3. Is proprietary/privileged information included in the application?* ○ **Yes** ● **No**

4.a. Does this project have an actual or potential impact - positive or negative - on the environment?* ○ **Yes** ● **No**

4.b. If yes, please explain:

4.c. If this project has an actual or potential impact on the environment, has an exemption been authorized or an environmental assessment (EA) or environmental impact statement (EIS) been performed? ○ Yes ○ No

4.d. If yes, please explain:

5. Is the research performance site designated, or eligible to be designated, as a historic place?* ○ **Yes** ● **No**

5.a. If yes, please explain:

6. Does this project involve activities outside the United States or partnership with international collaborators?* ○ **Yes** ● **No**

6.a. If yes, identify countries:

6.b. Optional Explanation:

	Filename
7. Project Summary/Abstract*	AbstractICr1045594954.pdf
8. Project Narrative*	NarrativeICr1045594955.pdf
9. Bibliography & References Cited	ReferencesICr1045594956.pdf
10.Facilities & Other Resources	FacilitiesICr1045594957.pdf
11.Equipment	EquipmentICr1045594958.pdf
12. Other Attachments	AcronymsICr1045594959.pdf

Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

ABSTRACT – Intervention Core

The Intervention Core will support the proposed Program Project, “Improving Provider Announcement Communication Training (IMPACT)” with the goal of improving HPV vaccination in healthcare systems. The Intervention Core will synthesize project-specific findings regarding the implementation and effectiveness of standing orders support (Project 1), financial incentives (Project 2), and clinical champions (Project 3) into the Announcement Approach Training (AAT) Intervention Package. AAT is a brief communication workshop that helps primary care teams improve the way they recommend HPV vaccine and address parents’ concerns. In a prior randomized clinical trial, AAT increased HPV vaccine coverage by 5 percentage points over the control within just 3 months. The proposed Program Project seeks to amplify AAT’s impact by combining it with the interventions to be tested in Projects 1-3. The Program Project will then compare the population impact and cost-effectiveness of these interventions, including in rural areas (Project 4). The Intervention Core will support the four research projects in the P01 to maximize the quality and comparability of AAT interventions delivered and evaluated over the 5-year study period. **Aim 1 is to convene a Clinical Advisory Board to provide projects with multi-disciplinary implementation support.** Our board includes leaders in pediatrics, family medicine, nursing, quality improvement, and patient and family advocacy. Through quarterly meetings, the board will support the development of intervention materials, the recruitment and retention of clinical sites, and the interpretation and dissemination of study findings. **Aim 2 is to prepare AAT facilitators and training materials for intervention delivery.** To achieve the highest-quality interventions, we will centralize (1) the training of the facilitators who will deliver our AAT workshops to primary care teams and (2) the preparation of intervention materials. **Aim 3 is to harmonize assessment of implementation measures, including cost.** The Intervention Core will monitor the quality of implementation data collected in Projects 1-3 to ensure timeliness, completeness, and accuracy. This quality monitoring will support the successful completion of Project 4’s cost-effectiveness analyses and other information for the AAT Intervention Package. **Aim 4 is to facilitate the national dissemination of study findings and intervention materials.** Collaborating with Projects 1-4, the Intervention Core will disseminate study deliverables to audiences in academia, clinical practice, and public health. Most notably, the **Core will lead the production of the AAT Intervention Package for improving HPV vaccination in healthcare systems**. In sum, the Intervention Core will be instrumental to the Program Project’s goals of improving primary care teams’ communication, increasing HPV vaccine uptake, and ensuring that today’s youth have the highest level of protection against future HPV cancers. The Intervention Core addresses the **IMPACT Program Project theme** by building capacity for HPV vaccine communication interventions among primary care teams in healthcare systems.

NARRATIVE – Intervention Core

The Intervention Core will support the efforts of 4 research projects to conduct high-quality evaluations of Announcement Approach Training interventions. We will accomplish this goal by coordinating clinical expertise, preparing training materials and facilitators, harmonizing key measures, and sharing study products.

FACILITIES AND OTHER RESOURCES – Intervention Core

Refer to Overall Component for both Intervention Core and Wake Forest University School of Medicine Facilities and Other Resources.

EQUIPMENT – Intervention Core

None.

LIST OF ACRONYMS – Intervention Core

AA	Announcement Approach
AAT	Announcement Approach Training
CDC	Centers for Disease Control and Prevention
CFIR	Consolidated Framework for Implementation Research
Covid-19	Coronavirus disease 2019
HPV	Human papillomavirus
IMPACT	Improving Provider Announcement Communication Training
NCI	National Cancer Institute
NCIPH	North Carolina Institute for Public Health
P01	Program Project
PCP	Primary care professionals
RCT	Randomized clinical trial
TPB	Theory of Planned Behavior
UNC	University of North Carolina

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED Senior/Key Person Profile (Expanded)

PROFILE - Project Director/Principal Investigator

Prefix: First Name*: Melissa Middle Name Last Name*: Gilkey Suffix:

Position/Title*: Associate Professor
Organization Name*: The University of North Carolina at Chapel Hill
Department: Health Behavior
Division: Gillings Sch. of Public Hlth
Street1*: 317 Rosenau Hall
Street2: CB 7440
City*: Chapel Hill
County: Orange
State*: NC: North Carolina
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 27599-7440

Phone Number*: (919) 966-8650 Fax Number:

E-Mail*: gilkey@email.unc.edu

Credential, e.g., agency login: eRA COMMONS USER NAME

Project Role*: Co-Investigator Other Project Role Category:

Degree Type: PhD Degree Year: 2011

Attach Biographical Sketch*: File Name:

Attach Current & Pending Support: File Name:

Tracking Number: GRANT13205496 Funding Opportunity Number: PAR-20-077 . Received Date: 2020-09-18T11:41:16.000-04:00

PROFILE - Senior/Key Person

Prefix: First Name*: Sarah Middle Name A. Last Name*: Birken Suffix:

Position/Title*: Associate Professor
Organization Name*: Wake Forest University Health Sciences
Department: Implementation Science
Division: School of Medicine
Street1*: Medical Center Boulevard
Street2:
City*: Winston-Salem
County: Forsyth
State*: NC: North Carolina
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 27157-0000

Phone Number*: (336) 713-4231 Fax Number:

E-Mail*: sbirken@wakehealth.edu

Credential, e.g., agency login: eRA COMMONS USER NAME

Project Role*: Other (Specify) Other Project Role Category: Core Lead

Degree Type: PhD Degree Year: 2011

Attach Biographical Sketch*: File Name: BioBirkenICr1045594968.pdf

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Bryan Middle Name J Last Name*: Weiner Suffix:

Position/Title*: Professor
Organization Name*: University of Washington
Department: Department of Health Services
Division: School of Public Health
Street1*: Box 357965
Street2:
City*: Seattle
County:
State*: WA: Washington
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 98195-7230

Phone Number*: (206) 221-7882 Fax Number:

E-Mail*: bjweiner@uw.edu

Credential, e.g., agency login: eRA COMMONS USER NAME

Project Role*: Other (Specify) Other Project Role Category: Advisor

Degree Type: PhD Degree Year: 1994

Attach Biographical Sketch*: File Name: BioWeinerICr1045594969.pdf

Attach Current & Pending Support: File Name:

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 1

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2021 **End Date*:** 06-30-2022 **Budget Period: 1**

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.		Melissa		Gilkey		Co-Investigator	CAL. MONTHS, INST. BASE SALARY				9,583.00	3,002.00	12,585.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **12,585.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
1	Project Manager	6			33,475.00	11,922.00	45,397.00
1	Orientation Leader	1.2			15,273.00	5,569.00	20,842.00
1	Data Analyst	0.96			5,739.00	2,007.00	7,746.00
1	Research Assistant	1.2			4,686.00	1,864.00	6,550.00
4	**Total Number Other Personnel**					**Total Other Personnel**	**80,535.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**93,120.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 1

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2021 **End Date*:** 06-30-2022 **Budget Period: 1**

C. Equipment Description	
List items and dollar amount for each item exceeding $5,000	
Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	
Additional Equipment: File Name:	

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	8,800.00
2. Foreign Travel Costs	
Total Travel Cost	**8,800.00**

E. Participant/Trainee Support Costs		**Funds Requested ($)***
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other:		
Number of Participants/Trainees	**Total Participant Trainee Support Costs**	

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 1

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2021 **End Date*:** 06-30-2022 **Budget Period: 1**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	500.00
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	62,699.00
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8. Other Costs	42,848.00
Total Other Direct Costs	**106,047.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**207,967.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. Organized Research_On Campus	55.5	170,268.00	94,499.00
		Total Indirect Costs	**94,499.00**

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number): DHHS, Darryl Mayes, 202-401-2808

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**302,466.00**

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	302,466.00

L. Budget Justification* File Name: BudgetJustificationICrV21045711762.pdf

(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 2

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2022 **End Date*:** 06-30-2023 **Budget Period: 2**

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.		Melissa		Gilkey		Co-Investigator	CAL. MONTHS, INST. BASE SALARY				9,583.00	3,002.00	12,585.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **12,585.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
1	Project Manager	6			33,475.00	11,922.00	45,397.00
1	Orientation Leader	1.2			15,273.00	5,569.00	20,842.00
1	Data Analyst	1.2			7,174.00	2,508.00	9,682.00
1	Research Assistant	1.2			4,686.00	1,864.00	6,550.00
4	**Total Number Other Personnel**					**Total Other Personnel**	**82,471.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**95,056.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 2

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2022 **End Date*:** 06-30-2023 **Budget Period: 2**

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	

Additional Equipment: File Name:

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	
2. Foreign Travel Costs	
Total Travel Cost	

E. Participant/Trainee Support Costs	**Funds Requested ($)***
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant Trainee Support Costs**	

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 2

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2022 **End Date*:** 06-30-2023 **Budget Period: 2**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	500.00
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	62,711.00
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8. Other Costs	37,092.00
Total Other Direct Costs	**100,303.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**195,359.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. Organized Research_On Campus	55.5	132,648.00	73,620.00
		Total Indirect Costs	**73,620.00**

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number): DHHS, Darryl Mayes, 202-401-2808

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**268,979.00**

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	268,979.00

L. Budget Justification* File Name: BudgetJustificationICrV21045711762.pdf

(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 3

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2023 **End Date*:** 06-30-2024 **Budget Period: 3**

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.		Melissa		Gilkey		Co-Investigator	CAL. MONTHS, INST. BASE SALARY				9,583.00	3,002.00	12,585.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **12,585.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
1	Project Manager	6			33,475.00	11,922.00	45,397.00
1	Orientation Leader	1.2			15,273.00	5,569.00	20,842.00
1	Data Analyst	1.2			7,174.00	2,508.00	9,682.00
1	Research Assistant	1.2			4,686.00	1,864.00	6,550.00
4	**Total Number Other Personnel**					**Total Other Personnel**	**82,471.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**95,056.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 3

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2023 **End Date*:** 06-30-2024 **Budget Period: 3**

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	

Additional Equipment: File Name:

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	
2. Foreign Travel Costs	
Total Travel Cost	

E. Participant/Trainee Support Costs	**Funds Requested ($)***
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant Trainee Support Costs**	

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 3

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2023 **End Date*:** 06-30-2024 **Budget Period: 3**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	500.00
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	62,724.00
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8. Other Costs	28,469.00
Total Other Direct Costs	**91,693.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**186,749.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. Organized Research_On Campus	55.5	124,025.00	68,834.00
		Total Indirect Costs	**68,834.00**

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number): DHHS, Darryl Mayes, 202-401-2808

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**255,583.00**

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	255,583.00

L. Budget Justification* File Name: BudgetJustificationICrV21045711762.pdf (Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 4

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2024 **End Date*:** 06-30-2025 **Budget Period: 4**

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.		Melissa		Gilkey		Co-Investigator	CAL. MONTHS, INST. BASE SALARY				9,583.00	3,002.00	12,585.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **12,585.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
1	Project Manager	6			33,475.00	11,922.00	45,397.00
1	Orientation Leader	0.6			7,637.00	2,785.00	10,422.00
1	Data Analyst	1.2			7,174.00	2,508.00	9,682.00
1	Research Assistant	1.2			4,686.00	1,864.00	6,550.00
4	**Total Number Other Personnel**					**Total Other Personnel**	**72,051.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**84,636.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 4

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2024 **End Date*:** 06-30-2025 **Budget Period: 4**

C. Equipment Description	
List items and dollar amount for each item exceeding $5,000	
Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	
Additional Equipment: File Name:	

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	
2. Foreign Travel Costs	
Total Travel Cost	

E. Participant/Trainee Support Costs		**Funds Requested ($)***
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other:		
Number of Participants/Trainees	**Total Participant Trainee Support Costs**	

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 4

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2024 **End Date*:** 06-30-2025 **Budget Period: 4**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	500.00
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	62,736.00
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8. Other Costs	28,461.00
Total Other Direct Costs	**91,697.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**176,333.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. Organized Research_On Campus	55.5	113,597.00	63,046.00
		Total Indirect Costs	**63,046.00**

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number): DHHS, Darryl Mayes, 202-401-2808

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**239,379.00**

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	239,379.00

L. Budget Justification* File Name: BudgetJustificationICrV21045711762.pdf

(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 5

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2025 **End Date*:** 06-30-2026 **Budget Period: 5**

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.		Melissa		Gilkey		Co-Investigator	CAL. MONTHS, INST. BASE SALARY				9,583.00	3,002.00	12,585.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **12,585.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
1	Project Manager	6			33,475.00	11,922.00	45,397.00
1	Research Assistant	1.2			4,686.00	1,864.00	6,550.00
2	**Total Number Other Personnel**					**Total Other Personnel**	**51,947.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**64,532.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 5

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2025 **End Date*:** 06-30-2026 **Budget Period: 5**

C. Equipment Description	
List items and dollar amount for each item exceeding $5,000	
Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	
Additional Equipment: File Name:	

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	11,800.00
2. Foreign Travel Costs	
Total Travel Cost	**11,800.00**

E. Participant/Trainee Support Costs	**Funds Requested ($)***
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant Trainee Support Costs**	

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 5

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2025 **End Date*:** 06-30-2026 **Budget Period: 5**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	500.00
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	62,749.00
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8. Other Costs	44,102.00
Total Other Direct Costs	**107,351.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**183,683.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. Organized Research_On Campus	55.5	120,934.00	67,118.00
		Total Indirect Costs	**67,118.00**

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number): DHHS, Darryl Mayes, 202-401-2808

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**250,801.00**

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	250,801.00

L. Budget Justification* File Name: BudgetJustificationICrV21045711762.pdf

(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

BUDGET JUSTIFICATION – Intervention Core

Key Personnel

Melissa Gilkey, PhD, Core Co-Lead

Year 1	Year 2	Year 3	Year 4	Year 5
CAL. MONTHS				

Dr. Gilkey is Associate Professor in the Department of Health Behavior in the University of North Carolina (UNC) Gillings School of Global Public Health. Dr. Gilkey studies individual, interpersonal, and organizational approaches to improving the delivery of HPV vaccine in primary care. She has extensive experience using quantitative and qualitative methods to study the implementation of cancer prevention interventions, with a focus on conducting surveys and interviews with healthcare providers. As Co-Lead of the Intervention Core (in partnership with Dr. Sarah Birken), she will draw on her expertise conducting large-scale randomized clinical trials (RCTs) to implement and evaluate interventions to improve HPV vaccination. This experience includes: 1) leading an RCT within 25 clinics that successfully engaged clinical champions to deliver HPV vaccine-related training; 2) implementing an RCT with 91 clinics that used assessment and feedback to improve HPV vaccination coverage; and 3) leading an ongoing RCT that has successfully recruited and intervened with >250 clinics to evaluate the impact of physician communication training and assessment and feedback on HPV vaccination. Dr. Gilkey will share responsibility with Dr. Birken for completing Intervention Core aims. Specifically, she will lead the preparation of Announcement Approach Training (AAT) materials and facilitators (Aim 2) and the packaging of intervention modules into the AAT Intervention Package (Aim 4). Dr. Gilkey's leadership role will entail maintaining scientific integrity throughout the project, developing materials and curricula, meeting with co-investigators, and supervising project staff.

Sarah A. Birken, PhD, Core Co-Lead
See Wake Forest University Health Sciences Consortium/Contractual Costs.

Other Personnel

TBN, Project Manager

Year 1	Year 2	Year 3	Year 4	Year 5
6.0 CM	6.0 CM	6.0 CM	6.0 CM	6.0 CM

The TBN Project Manager will be responsible for managing daily project operations for the Intervention Core, and will serve as the liaison between the Co-Leads, core team, and study contractors. The Project Manager will oversee training and advisory board event logistics, travel coordination for the clinical advisory board, and will manage timelines for the development of training curricula and dissemination materials. The Project Manager will coordinate preparation of progress reports and will manage the Intervention Core budget.

TBN, Announcement Approach Training (AAT) Orientation Leader, MD

Year 1	Year 2	Year 3	Year 4	Year 5
1.2 CM	1.2 CM	1.2 CM	0.6 CM	-

The Orientation Leader will be a practicing primary care physician, specializing in either Pediatrics or Family Medicine. The Orientation Leader will be responsible for the training of other AAT facilitators who will deliver communication workshops as part of Projects 1-3. In this capacity, the Orientation Leader will work with the Intervention Core team and the North Carolina Institute for Public Health (NCIPH) to enhance the train-the-trainer curriculum in Years 1-2, and will deliver training, performance feedback, and ongoing technical assistance to AAT facilitators in Years 1-4. By centralizing the training of facilitators in this way, our goal is to maximize the quality and comparability of interventions delivered in Projects 1-3.

TBN, Data Analyst

Year 1	Year 2	Year 3	Year 4	Year 5
0.96 CM	1.2 CM	1.2 CM	1.2 CM	-

The TBN Data Analyst will be a Masters-level Principal Statistician in the Biostatistics and Survey Methods Core at the UNC Lineberger Comprehensive Cancer Center. (S)he will support the Intervention Core by collecting data from Projects 1-3 on AAT intervention implementation to inform the Intervention Core's data harmonization efforts, writing algorithms to run continuous data quality checks, and executing those checks on a regular, on-going basis throughout the course of the study. Additionally, the Data Analyst will support analyses of implementation outcomes data from Projects 1-3 in Year 4 of the Program to support the development of the Intervention Package. The statistician will work closely with the Data Core, as well as Projects 1-4, which each will provide other statistical support.

TBN, Research Assistant

Year 1	Year 2	Year 3	Year 4	Year 5
1.2 CM	1.2 CM	1.2 CM	1.2 CM	1.2 CM

The TBN Research Assistant will support the Intervention Core team by assisting with the development and harmonization of measures for use across projects. (S)he will also assist the Project Manager with coordination of Advisory Board meeting logistics each year.

Total Expenses for Personnel=$432,400

Fringe Benefits

Fringe benefits associated with the salary request for this budget has been calculated in accordance with our Institution's DHHS Rate Agreement. The University of North Carolina at Chapel Hill applies appropriate fringe benefit rates to the personnel on this proposal: Basic permanent employee benefits are **25.889%** of annual salary plus **$6,512/FTE/YR** for fixed health insurance. P&A Practice Plan member benefits calculate at **30.796%** of annual salary plus **$8,652.80/FTE/YR** for fixed health insurance.

Travel

Travel for In-Person Clinical Advisory Board Meeting

Year 1	Year 2	Year 3	Year 4	Year 5	Total
$8,800	-	-	-	$8,800	$17,600

The Clinical Advisory Board will convene for two in-person meetings in Chapel Hill over the course of the 5-year Program – one in Year 1 and one in Year 5. We have budgeted for roundtrip travel and housing for the 8 advisory board members to travel to Chapel Hill for each meeting. ($1,100 per Member X 8 Members = $8,800 per meeting).

Conference Travel

Year 1	Year 2	Year 3	Year 4	Year 5	Total
-	-	-	-	$3,000	$3,000

In Year 5, two investigators will attend the *AcademyHealth Annual Conference on the Science of Dissemination and Implementation*. The purpose of the trip will be to present methods from our implementation data harmonization efforts. The cost for each trip is budgeted at $1,500 (2 X $1,500 = $3,000).

Total Expenses for Travel=$20,600

Supplies

Train the Trainer Materials

Year 1	Year 2	Year 3	Year 4	Year 5	Total
$500	$500	$500	$500	$500	$2,500

In Years 1-5, $500 will be used for project supplies needed to develop and carry out the train-the-trainer AAT curriculum across Projects 1-3 of the Program, including office supplies and printing of handouts, pamphlets, and meeting materials. These funds will also support the creation and dissemination of the Intervention Package developed in Years 4-5 that consolidates findings from all projects (Projects 1-4). While the Intervention Package will be available and predominately disseminated online, select materials and posters will be printed and shared during presentations and meetings with policymakers, decision makers, and conferences.

Total Expenses for Supplies=$2,500

Other Expenses

Honorarium, Bryan Weiner, PhD

Year 1	Year 2	Year 3	Year 4	Year 5	Total
$8,000	$8,000	$8,000	$8,000	$8,000	$40,000

Dr. Weiner is Professor in the Department of Global Health and the Department of Health Services at the University of Washington. Dr. Weiner's work focuses on the adoption, implementation, and sustainability of evidence-based interventions in healthcare delivery. Dr. Weiner has extensive experience in studying improvement practices, service delivery models, cancer prevention and control and evidence-based prevention practices. He is a leader in the field of Implementation Science and has led studies that have advanced the knowledge of effective implementation strategies and has developed new theories and measures in his field. Dr. Weiner will consult on the Program as a senior scientist about organizational change theory. He will be paid an honorarium of $8,000 per year.

Clinical Advisory Board (CAB)

Year 1	Year 2	Year 3	Year 4	Year 5	Total
$8,000	$8,000	$8,000	$8,000	$8,000	$40,000

We have identified a Clinical Advisory Board to consult the Program team on implementation of the AAT across Projects 1-3 of the grant. The Clinical Advisory Board is comprised of a multidisciplinary team of national clinical leaders in primary care. Members will include physicians with extensive experience in pediatrics and family medicine (Tim McCoy, DO, Susan Whitely, MD) and quality improvement in large healthcare systems (Lynne Fiscus, MD, MPH). Additional members will be leaders in pediatric nursing (Brittany Thompson, LPN, Tami Thomas, PhD, APRN), physician assisting (Chris Barry, PA-C), and medical assisting (Sandra Weaver, CMAIII). Finally, Karen Ernst will serve as the board's patient and family advocate. The advisory board will meet quarterly in Years 1-5 and will provide input on the implementation of the AAT intervention in Projects 1-3, as well as the dissemination of findings in Years 4-5 of the Program (see Letters of Support). Advisory board members will receive $1,000 annually for their participation. ($1,000 per advisor X 8 = $8,000 per year).

North Carolina Institute for Public Health

Year 1	Year 2	Year 3	Year 4	Year 5	Total
$11,848	$9,492	$7,276	$3,035	$8,716	$40,367

The North Carolina Institute for Public Health (NCIPH) is housed within the UNC Gillings School of Global Public Health and offers workforce training and education to public health practitioners as a part of its mission to serve as a bridge between academia and public health practice partners. NCIPH will work with the Intervention Core team by supporting the delivery of AAT across Projects 1, 2, and 3 in the grant (Years 1-3). This work will include: making updates to the AAT intervention curriculum as needed to incorporate Program pilot findings and emerging data on HPV vaccination coverage, and working with projects to ensure AAT intervention updates are implemented consistently and in a timely manner. NCIPH will design and deliver the train-the-trainer curriculum for the physicians and other healthcare providers who will be responsible for delivering the AAT workshops to clinics in Projects 1-3. Along with the AAT Orientation Leader, NCIPH will deliver 2 train-the-trainer workshops in Year 1, 4 trainings in Year 2, and 4 trainings in Year 3. In Years 4-5 of

the Program, NCIPH will work with the study team to synthesize intervention materials and procedures from Projects 1-4 into a comprehensive Intervention Package for dissemination to healthcare systems. Additionally, NCIPH will assist the research team in developing "research-to-practice" briefs and social media content to disseminate findings in practice and policy settings via established networks, including the Cancer Prevention and Control Research Network. The proposed budget reflects NCIPH's own cost estimates for their work in Years 1-5 of the grant.

Clinical Advisory Board Meeting

Year 1	Year 2	Year 3	Year 4	Year 5	Total
$6,000	-	-	-	$6,000	$12,000

The Clinical Advisory Board will convene for an in-person meeting in Chapel Hill in Years 1 and 5 of the Program. We have budgeted $6,000 to fund each in-person meeting, which includes the cost for conference room reservations at the Kenan Flagler School of Business' Rizzo Center in Chapel Hill ($2,370), breakfast, lunch and refreshments for the Clinical Advisory Board and Program team ($1,280), and dinner for the Clinical Advisory Board and members of the Program team ($2,350). The in-person meetings will allow members of the Clinical Advisory Board to meet each other at the beginning of the grant, and to facilitate networking between the Board and Program team.

New Media Campaigns

Year 1	Year 2	Year 3	Year 4	Year 5	Total
$9,000	$9,000	$4,593	$8,826	$13,386	$44,805

New Media Campaigns is a full-service digital agency that works with clients to launch and manage their websites and digital properties. New Media Campaigns will maintain an existing public-facing study website (hpvIQ.org) and work with the Intervention Core team to format and design materials over the course of the project. In Years 1-3, New Media Campaigns will provide graphic design services for the AAT PowerPoint that will be posted on the hpvIQ.org study website, in addition to updating HPV communication training tools offered to providers on the website. In Years 3-5, New Media Campaigns will regularly refresh the study website to update intervention materials and videos as Program findings are analyzed and made ready for dissemination. In Years 4-5, New Media Campaigns will format the comprehensive Intervention Package that includes materials and procedures for dissemination to healthcare systems (Years 4-5). They will also provide graphic design services to the Core team for the "research-to-practice" policy briefs and social media content for dissemination to healthcare practices and policy makers. New Media Campaign's projected cost for this work is included in this budget.

Continuing Medical Education (CME) costs

Year 1	Year 2	Year 3	Year 4	Year 5	Total
-	$600	$600	$600	-	$1,800

Continuing medical education (CME) for physicians attending the AAT workshops will be funded by the Intervention Core as it will be used by Projects 1, 2, and 3. We have budgeted $600 per year (Years 2-4) for CME certification through the American Association of Family Physicians (AAFP).

Continuing Education (CE) costs

Year 1	Year 2	Year 3	Year 4	Year 5	Total
-	$2,000	-	-	-	$2,000

In addition to CME certification costs, we have budgeted for continuing education (CE) certification for nurses attending AAT workshops. This one-time, multi-year certification costs $2,000 through the National Association of Pediatric Nurse Practitioners (NAPNAP). The NAPNAP continuing education certification will be used by Projects 1, 2, and 3.

AAT Dissemination (In-kind)

UNC Lineberger's Office of Community Outreach and Engagement will provide additional in-kind support in the dissemination of the AAT Intervention Package (see Dr. Earp's Letter of Support).

Total Expenses for Other Expenses=$180,972

Indirect Costs

At UNC-Chapel Hill, F&A costs are calculated on a Modified Total Direct Costs (MTDC) base. This base consists of all direct salaries and wages, applicable fringe benefits, materials and supplies, services, travel and up to the first $25,000 of each subaward (regardless of the period of performance of the subawards under the award). Modified total direct costs shall exclude equipment, capital expenditures, charges for patient care, rental costs, tuition remission, scholarships and fellowships, participant support costs and the portion of each subaward in excess of $25,000.

Per UNC-Chapel Hill's current federally negotiated rate agreement (dated 11/23/2016), F&A costs associated with the proposed research project are calculated at the approved on-campus research rate of 55.5% of MTDC in all years. The cognizant agency for UNC-Chapel Hill is the U.S. Department of Health and Human Services. The cognizant agency point of contact is Darryl Mayes, (202) 401-2808.

Consortium/Contractual Costs

Wake Forest University Health Sciences

Year 1	Year 2	Year 3	Year 4	Year 5	Total
$62,699	$62,711	$62,724	$62,736	$62,749	$313,619

The budget includes one domestic subcontract with Wake Forest University School of Medicine. This subcontract includes support for Dr. Sarah Birken across all years of the Program Project and computer fees at Wake Forest University. Dr. Birken is Associate Professor of Implementation Science in the Division of Health Sciences at Wake Forest University School of Medicine. Dr. Birken is an implementation scientist and health services researcher with over fifteen years of experience in quality improvement, innovations in cancer care, and translating evidence-based interventions into practice. She has been Principal Investigator or Co-Investigator on numerous grants that have examined the optimization of cancer care and preventive health services, especially for rural patients. Dr. Birken will collaborate closely with the IMPACT Principal Investigator, Noel T. Brewer, at the University of North Carolina-Chapel Hill and colleagues in the Intervention Core, Administrative Core, and Projects 1-4 of the proposed Program project. In Years 1-4 of the Program Project, Dr. Birken will consult on developing and carrying out strategies for effective implementation of intervention components and enhancing the Announcement Approach Training. Additionally, in all five years of the Program Project, Dr. Birken will coordinate the Clinical Advisory Board and will consult on harmonization of implementation measures across projects. Finally, in Years 4-5 of the Program Project, she will advise the team on how to meaningfully translate evidence from the research projects into tools that can be disseminated and implemented in a variety of settings. In Year 5, Dr. Birken will also contribute to manuscript preparation. Dr. Birken will dedicate 3.0 calendar months to the Program Project in years 1-5. The cost for Dr. Birken's effort across the Program Project is kept administratively in the Intervention Core to simplify subcontracts to her home institution. A detailed budget and a budget justification for the proposed subcontract is included in this application.

Total Expenses for Consortium/Contractual Costs=$313,619

RESEARCH & RELATED BUDGET - Cumulative Budget

	Totals ($)	
Section A, Senior/Key Person		62,925.00
Section B, Other Personnel		369,475.00
Total Number Other Personnel	18	
Total Salary, Wages and Fringe Benefits (A+B)		432,400.00
Section C, Equipment		
Section D, Travel		20,600.00
1. Domestic	20,600.00	
2. Foreign		
Section E, Participant/Trainee Support Costs		
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other		
6. Number of Participants/Trainees		
Section F, Other Direct Costs		497,091.00
1. Materials and Supplies	2,500.00	
2. Publication Costs		
3. Consultant Services		
4. ADP/Computer Services		
5. Subawards/Consortium/Contractual Costs	313,619.00	
6. Equipment or Facility Rental/User Fees		
7. Alterations and Renovations		
8. Other 1	180,972.00	
9. Other 2		
10. Other 3		
Section G, Direct Costs (A thru F)		950,091.00
Section H, Indirect Costs		367,117.00
Section I, Total Direct and Indirect Costs (G + H)		1,317,208.00
Section J, Fee		
Section K, Total Direct and Fee (I + J)		1,317,208.00

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 1

ORGANIZATIONAL DUNS*: 9377279070000

Budget Type*: ○ Project ● Subaward/Consortium

Enter name of Organization: Wake Forest University Health Sciences

Start Date*: 07-01-2021 **End Date*:** 06-30-2022 **Budget Period: 1**

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.		Sarah	A.	Birken	PhD	Core Lead	CAL. MONTHS, INST. BASE SALARY				34,993.00	5,074.00	40,067.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **40,067.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*

Total Number Other Personnel **Total Other Personnel**

Total Salary, Wages and Fringe Benefits (A+B) **40,067.00**

RESEARCH & RELATED Budget (A-B) (Funds Requested)

Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 1

ORGANIZATIONAL DUNS*: 9377279070000

Budget Type*: ❍ Project ● Subaward/Consortium

Enter name of Organization: Wake Forest University Health Sciences

Start Date*: 07-01-2021 **End Date*:** 06-30-2022 **Budget Period: 1**

C. Equipment Description	
List items and dollar amount for each item exceeding $5,000	
Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	
Additional Equipment: File Name:	

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	
2. Foreign Travel Costs	
Total Travel Cost	

E. Participant/Trainee Support Costs		**Funds Requested ($)***
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other:		
Number of Participants/Trainees	**Total Participant Trainee Support Costs**	

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 1

ORGANIZATIONAL DUNS*: 9377279070000

Budget Type*: ❍ Project ● Subaward/Consortium

Enter name of Organization: Wake Forest University Health Sciences

Start Date*: 07-01-2021 **End Date*:** 06-30-2022 **Budget Period: 1**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	384.00
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
Total Other Direct Costs	**384.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**40,451.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. Modified Total Direct Costs	55	40,451.00	22,248.00
		Total Indirect Costs	**22,248.00**

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number): DHHS, Steven Zuraf, 202-401-2808

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**62,699.00**

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	62,699.00

L. Budget Justification* File Name: BudJustWakeForestICr1045594966.pdf

(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 2

ORGANIZATIONAL DUNS*: 9377279070000

Budget Type*: ○ Project ● Subaward/Consortium

Enter name of Organization: Wake Forest University Health Sciences

Start Date*: 07-01-2022 **End Date*:** 06-30-2023 **Budget Period: 2**

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.		Sarah	A.	Birken	PhD	Core Lead	CAL. MONTHS, INST. BASE SALARY				34,993.00	5,074.00	40,067.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **40,067.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*

Total Number Other Personnel **Total Other Personnel**

Total Salary, Wages and Fringe Benefits (A+B) **40,067.00**

RESEARCH & RELATED Budget (A-B) (Funds Requested)

Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 2

ORGANIZATIONAL DUNS*: 9377279070000

Budget Type*: ❍ Project ● Subaward/Consortium

Enter name of Organization: Wake Forest University Health Sciences

Start Date*: 07-01-2022 **End Date*:** 06-30-2023 **Budget Period: 2**

C. Equipment Description	
List items and dollar amount for each item exceeding $5,000	
Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	
Additional Equipment: File Name:	

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	
2. Foreign Travel Costs	
Total Travel Cost	

E. Participant/Trainee Support Costs		**Funds Requested ($)***
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other:		
Number of Participants/Trainees	**Total Participant Trainee Support Costs**	

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 2

ORGANIZATIONAL DUNS*: 9377279070000

Budget Type*: ❍ Project ● Subaward/Consortium

Enter name of Organization: Wake Forest University Health Sciences

Start Date*: 07-01-2022 **End Date*:** 06-30-2023 **Budget Period: 2**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	392.00
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
Total Other Direct Costs	**392.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**40,459.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. Modified Total Direct Costs	55	40,459.00	22,252.00
		Total Indirect Costs	**22,252.00**

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number): DHHS, Steven Zuraf, 202-401-2808

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**62,711.00**

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	62,711.00

L. Budget Justification* File Name: BudJustWakeForestICr1045594966.pdf

(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 3

ORGANIZATIONAL DUNS*: 9377279070000

Budget Type*: ○ Project ● Subaward/Consortium

Enter name of Organization: Wake Forest University Health Sciences

Start Date*: 07-01-2023 **End Date*:** 06-30-2024 **Budget Period: 3**

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.		Sarah	A.	Birken	PhD	Core Lead	CAL. MONTHS, INST. BASE SALARY				34,993.00	5,074.00	40,067.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **40,067.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*

Total Number Other Personnel **Total Other Personnel**

Total Salary, Wages and Fringe Benefits (A+B) **40,067.00**

RESEARCH & RELATED Budget (A-B) (Funds Requested)

Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 3

ORGANIZATIONAL DUNS*: 9377279070000

Budget Type*: ❍ Project ● Subaward/Consortium

Enter name of Organization: Wake Forest University Health Sciences

Start Date*: 07-01-2023 **End Date*:** 06-30-2024 **Budget Period: 3**

C. Equipment Description	
List items and dollar amount for each item exceeding $5,000	
Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	
Additional Equipment: File Name:	

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	
2. Foreign Travel Costs	
Total Travel Cost	

E. Participant/Trainee Support Costs		**Funds Requested ($)***
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other:		
Number of Participants/Trainees	**Total Participant Trainee Support Costs**	

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 3

ORGANIZATIONAL DUNS*: 9377279070000

Budget Type*: ❍ Project ● Subaward/Consortium

Enter name of Organization: Wake Forest University Health Sciences

Start Date*: 07-01-2023 **End Date*:** 06-30-2024 **Budget Period: 3**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	400.00
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
Total Other Direct Costs	**400.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**40,467.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. Modified Total Direct Costs	55	40,467.00	22,257.00
		Total Indirect Costs	**22,257.00**

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number): DHHS, Steven Zuraf, 202-401-2808

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**62,724.00**

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	62,724.00

L. Budget Justification* File Name: BudJustWakeForestICr1045594966.pdf

(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 4

ORGANIZATIONAL DUNS*: 9377279070000

Budget Type*: ○ Project ● Subaward/Consortium

Enter name of Organization: Wake Forest University Health Sciences

Start Date*: 07-01-2024 **End Date*:** 06-30-2025 **Budget Period: 4**

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.		Sarah	A.	Birken	PhD	Core Lead	CAL. MONTHS, INST. BASE SALARY				34,993.00	5,074.00	40,067.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **40,067.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*

Total Number Other Personnel **Total Other Personnel**

Total Salary, Wages and Fringe Benefits (A+B) **40,067.00**

RESEARCH & RELATED Budget (A-B) (Funds Requested)

Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 4

ORGANIZATIONAL DUNS*: 9377279070000

Budget Type*: ❍ Project ● Subaward/Consortium

Enter name of Organization: Wake Forest University Health Sciences

Start Date*: 07-01-2024 **End Date*:** 06-30-2025 **Budget Period: 4**

C. Equipment Description	
List items and dollar amount for each item exceeding $5,000	
Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	
Additional Equipment: File Name:	

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	
2. Foreign Travel Costs	
Total Travel Cost	

E. Participant/Trainee Support Costs		**Funds Requested ($)***
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other:		
Number of Participants/Trainees	**Total Participant Trainee Support Costs**	

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 4

ORGANIZATIONAL DUNS*: 9377279070000

Budget Type*: ❍ Project ● Subaward/Consortium

Enter name of Organization: Wake Forest University Health Sciences

Start Date*: 07-01-2024 **End Date*:** 06-30-2025 **Budget Period: 4**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	408.00
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
Total Other Direct Costs	**408.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**40,475.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. Modified Total Direct Costs	55	40,475.00	22,261.00
		Total Indirect Costs	**22,261.00**

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number): DHHS, Steven Zuraf, 202-401-2808

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**62,736.00**

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	62,736.00

L. Budget Justification* File Name: BudJustWakeForestICr1045594966.pdf

(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 5

ORGANIZATIONAL DUNS*: 9377279070000

Budget Type*: ○ Project ● Subaward/Consortium

Enter name of Organization: Wake Forest University Health Sciences

Start Date*: 07-01-2025 **End Date*:** 06-30-2026 **Budget Period: 5**

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.		Sarah	A.	Birken	PhD	Core Lead	CAL. MONTHS, INST. BASE SALARY				34,993.00	5,074.00	40,067.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **40,067.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*

Total Number Other Personnel **Total Other Personnel**

Total Salary, Wages and Fringe Benefits (A+B) **40,067.00**

RESEARCH & RELATED Budget (A-B) (Funds Requested)

Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 5

ORGANIZATIONAL DUNS*: 9377279070000

Budget Type*: ❍ Project ● Subaward/Consortium

Enter name of Organization: Wake Forest University Health Sciences

Start Date*: 07-01-2025 **End Date*:** 06-30-2026 **Budget Period: 5**

C. Equipment Description	
List items and dollar amount for each item exceeding $5,000	
Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	
Additional Equipment: File Name:	

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	
2. Foreign Travel Costs	
Total Travel Cost	

E. Participant/Trainee Support Costs		**Funds Requested ($)***
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other:		
Number of Participants/Trainees	**Total Participant Trainee Support Costs**	

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 5

ORGANIZATIONAL DUNS*: 9377279070000

Budget Type*: ❍ Project ● Subaward/Consortium

Enter name of Organization: Wake Forest University Health Sciences

Start Date*: 07-01-2025 **End Date*:** 06-30-2026 **Budget Period: 5**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	416.00
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
Total Other Direct Costs	**416.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**40,483.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. Modified Total Direct Costs	55	40,483.00	22,266.00
		Total Indirect Costs	**22,266.00**

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number): DHHS, Steven Zuraf, 202-401-2808

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**62,749.00**

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	62,749.00

L. Budget Justification* File Name: BudJustWakeForestICr1045594966.pdf

(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

BUDGET JUSTIFICATION - Wake Forest University School of Medicine

Key Personnel

Sarah A. Birken, PhD, Core Co-Lead

Year 1	Year 2	Year 3	Year 4	Year 5
CAL. MONTHS				

Dr. Birken is Associate Professor in the Department of Implementation Science in the Division of Health Sciences at Wake Forest University School of Medicine. Dr. Birken is an implementation scientist and health services researcher with over fifteen years of experience in quality improvement, innovations in cancer care, and translating evidence-based interventions into practice. She has been the Principal Investigator or Co-Investigator on numerous grants that have examined the optimization of cancer care and preventive health services, especially for rural patients. Dr. Birken will collaborate closely with the IMPACT Principal Investigator, Noel T. Brewer, at the University of North Carolina-Chapel Hill and colleagues in the Intervention Core, Administrative Core, and Projects 1-4 of the proposed Program project. In Years 1-4 of the Program Project, Dr. Birken will consult on developing and carrying out strategies for effective implementation of intervention components and enhancing the Announcement Approach Training. Additionally, in all five years of the Program Project, Dr. Birken will coordinate the Clinical Advisory Board and will consult on harmonization of implementation measures across projects. Finally, in Years 4-5 of the Program Project, she will advise the team on how to meaningfully translate evidence from the research projects into tools that can be disseminated and implemented in a variety of settings. In Year 5, Dr. Birken will also contribute to manuscript preparation.

Fringe Benefits
The fringe rate for Wake Forest University School of Medicine is budgeted at 14.5% for faculty salaries.

Total Expenses for Personnel=$200,335

Other Expenses

Computer fees

Year 1	Year 2	Year 3	Year 4	Year 5	Total
$384	$392	$400	$408	$416	$2,000

Network computer charges cover CPU and disk storage charges for data analysis and for support services for computer hardware and software. More specifically, this charge will provide unlimited server use, regular system back-up, internet access, site licensing of software, and user support for software. The current rate is $128/FTE per month for project faculty activities (Birken). All PHS faculty have PCs connected to LAN and have access to PHS servers for research and HIPAA compliance purposes. Research computing costs are budgeted based on effort commitment in each year of the project for a total cost of $2,000.

Total Expenses for Other Expenses=$2,000

INDIRECT COSTS
Facilities & Administration costs have been applied to this project budget, in accordance with our federally negotiated rate of 55%.

RESEARCH & RELATED BUDGET - Cumulative Budget

	Totals ($)	
Section A, Senior/Key Person		200,335.00
Section B, Other Personnel		
Total Number Other Personnel		
Total Salary, Wages and Fringe Benefits (A+B)		200,335.00
Section C, Equipment		
Section D, Travel		
1. Domestic		
2. Foreign		
Section E, Participant/Trainee Support Costs		
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other		
6. Number of Participants/Trainees		
Section F, Other Direct Costs		2,000.00
1. Materials and Supplies		
2. Publication Costs		
3. Consultant Services		
4. ADP/Computer Services	2,000.00	
5. Subawards/Consortium/Contractual Costs		
6. Equipment or Facility Rental/User Fees		
7. Alterations and Renovations		
8. Other 1		
9. Other 2		
10. Other 3		
Section G, Direct Costs (A thru F)		202,335.00
Section H, Indirect Costs		111,284.00
Section I, Total Direct and Indirect Costs (G + H)		313,619.00
Section J, Fee		
Section K, Total Direct and Fee (I + J)		313,619.00

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OMB Number: 0925-0001

Expiration Date: 02/28/2023

1. Vertebrate Animals Section

Are vertebrate animals euthanized? ○ Yes ○ No

If "Yes" to euthanasia

Is the method consistent with American Veterinary Medical Association (AVMA) guidelines?

○ Yes ○ No

If "No" to AVMA guidelines, describe method and provide scientific justification

2. *Program Income Section

*Is program income anticipated during the periods for which the grant support is requested?

○ Yes ● No

If you checked "yes" above (indicating that program income is anticipated), then use the format below to reflect the amount and source(s). Otherwise, leave this section blank.

*Budget Period *Anticipated Amount ($) *Source(s)

Tracking Number: GRANT13205496

Funding Opportunity Number: PAR-20-077 . Received Date: 2020-09-18T11:41:16.000-04:00

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3. Human Embryonic Stem Cells Section

*Does the proposed project involve human embryonic stem cells? ○ Yes ● No

If the proposed project involves human embryonic stem cells, list below the registration number of the specific cell line(s) from the following list: http://grants.nih.gov/stem_cells/registry/current.htm. Or, if a specific stem cell line cannot be referenced at this time, check the box indicating that one from the registry will be used:

Specific stem cell line cannot be referenced at this time. One from the registry will be used.

Cell Line(s) (Example: 0004):

4. Human Fetal Tissue Section

*Does the proposed project involve human fetal tissue obtained from elective abortions? ○ Yes ● No

If "yes" then provide the HFT Compliance Assurance

If "yes" then provide the HFT Sample IRB Consent Form

5. Inventions and Patents Section (Renewal applications)

*Inventions and Patents: ○ Yes ○ No

If the answer is "Yes" then please answer the following:

*Previously Reported: ○ Yes ○ No

6. Change of Investigator/Change of Institution Section

❑ Change of Project Director/Principal Investigator

Name of former Project Director/Principal Investigator

Prefix:

*First Name:

Middle Name:

*Last Name:

Suffix:

❑ Change of Grantee Institution

*Name of former institution:

PHS 398 Research Plan

OMB Number: 0925-0001
Expiration Date: 02/28/2023

Introduction	
1. Introduction to Application (for Resubmission and Revision applications)	IntroApplicationICrV21045663941.pdf
Research Plan Section	
2. Specific Aims	SpecificAimsICr1045594971.pdf
3. Research Strategy*	ResearchStrategyICr1045594973.pdf
4. Progress Report Publication List	
Other Research Plan Section	
5. Vertebrate Animals	
6. Select Agent Research	
7. Multiple PD/PI Leadership Plan	MultipleP1PlanICr1045594979.pdf
8. Consortium/Contractual Arrangements	ConsortWakeForestICr1045594977.pdf
9. Letters of Support	LOSICCombinedr1045594976.pdf
10. Resource Sharing Plan(s)	ResourceSharingICr1045594978.pdf
11. Authentication of Key Biological and/or Chemical Resources	
Appendix	
12. Appendix	

INTRODUCTION TO APPLICATION – Intervention Core

CRITIQUE, RESPONSE TO CRITIQUE

SPECIFIC AIMS – Intervention Core

Raising HPV vaccine coverage nationally will require a concerted effort to implement evidence-based interventions in healthcare systems that provide primary care to adolescents. The first step is training primary care teams to improve their communication so that every adolescent receives a high-quality recommendation for HPV vaccination. Our Announcement Approach Training (AAT) is an evidence-based intervention that accomplishes this goal via a one-hour, in-clinic workshop; AAT raises HPV vaccine coverage 5 percentage points over secular trends. The next step involves amplifying AAT's impact by combining it with other promising interventions, such as standing orders support, financial incentives, and the engagement of clinical champions. Testing the impact of these interventions with randomized clinical trials (RCTs) and understanding their implementation, including their cost, could greatly facilitate healthcare systems' ability to use them. However, conducting multiple RCTs in real-world clinical settings requires careful coordination.

The Intervention Core is designed to provide this coordination for the proposed Program Project (P01), "Improving Provider Announcement Communication Training (IMPACT)," while also ensuring that Projects 1-4 have support to overcome common challenges to evaluating evidence-based interventions such as AAT. These challenges include recruiting and retaining clinical sites and solving implementation problems as they arise in diverse and dynamic clinical environments. Projects must also keep intervention materials up-to-date across the multi-year intervention period to offer primary care teams the best available evidence on improving HPV vaccination. Similarly, cross-project comparisons will require shared measures and data collection procedures. Finally, we must disseminate research products rapidly to speed the translation of evidence into clinical practice improvements. To address these challenges, the Intervention Core has 4 aims.

Aim 1. Convene a Clinical Advisory Board for multi-disciplinary implementation support. Projects 1-4.

a. Recruit a Clinical Advisory Board of primary care professionals (physicians, nurse practitioners, physician assistants, nurses, medical assistants), quality improvement leaders, and patient and family advocates with expertise in delivering preventive care to adolescents.
b. Hold quarterly meetings of the Clinical Advisory Board to advise the study team on developing the trials, recruiting and retaining clinical sites, implementation challenges, and dissemination of findings.

Aim 2. Prepare AAT facilitators and training materials for intervention delivery. Projects 1-3.

a. Coordinate updates to intervention materials as needed to incorporate emerging evidence, including pilot findings and data on HPV vaccine coverage, effectiveness, and safety. Work with Projects 1-3 to ensure that updates are implemented consistently and in a timely manner.
b. Coordinate across Projects 1-3 to prepare the AAT facilitators. Using our train-the-trainer curriculum, we will train facilitators through didactic instruction, opportunities to practice workshop delivery before fielding, and ongoing performance review and feedback.

Aim 3. Harmonize assessment of key implementation measures, including cost. Projects 1-4.

a. Establish shared tools and procedures to assess implementation measures in Projects 1-3.
b. Monitor the timeliness, completeness, and accuracy of data collected in Projects 1-3.
c. Facilitate implementation outcomes data sharing for decision tool development in Project 4.

Aim 4. Facilitate national dissemination of study findings and intervention materials. Projects 1-4.

a. Synthesize projects' intervention materials into a package for dissemination to healthcare systems.
b. Refresh the study team's existing website to make intervention materials and findings publicly available.
c. Support dissemination of projects' scientific findings across diverse academic audiences, including the fields of social and behavioral sciences, health economics, health policy, and academic medicine.
d. Develop "research-to-practice" briefs and social media content to disseminate findings in pediatric primary care practice and policy settings via established vaccination and cancer prevention networks.

The Intervention Core will support all projects in the P01 to maximize the timeliness, quality, and impact of AAT interventions to be delivered and evaluated in the 5-year study period. By bringing project-specific findings and materials together into a comprehensive intervention package, the Core's work will produce a valuable resource for healthcare systems. In these ways, the Core is instrumental to the **IMPACT Program Project theme** by building capacity for HPV vaccine communication interventions among primary care teams in healthcare systems, ensuring that today's adolescents are protected against future HPV-attributable cancers.

RESEARCH STRATEGY – Intervention Core

OVERVIEW

The proposed Program Project seeks to develop and evaluate a comprehensive intervention package to improve HPV vaccination in healthcare systems. Supporting healthcare systems, in which a parent organization operates multiple clinics, is critical because these systems provide care for an increasingly large majority of US adolescents.[1,2] An important first step for systems will be to implement evidence-based interventions, such as Announcement Approach Training (AAT), that improve primary care teams' HPV vaccine communication.[3] AAT is a 1-hour, in-clinic communication workshop proven to raise HPV vaccine coverage.[4,5] In addition, systems need guidance for amplifying AAT's impact with 3 other promising interventions to improve HPV vaccine delivery: (1) **standing orders support** for nurses and other primary care team members to administer HPV vaccinations (Project 1); (2) **financial incentives** for clinics that meet goals for improving HPV vaccine coverage (Project 2); and (3) training for **clinical champions** to deliver and promote AAT communication workshops in their own healthcare systems (Project 3).[3] Through 4 coordinated projects, our P01 will test these interventions to compare their effectiveness and cost in real-world settings. Together, these projects will build the evidence base on interventions for changing primary care teams' behavior and yield practical tools that systems can use to translate research into improved HPV vaccination.

The Intervention Core will support research projects' capacity to: deliver high-fidelity interventions; collect high-quality data on implementation determinants and outcomes, including cost; and examine budget impact, cost-effectiveness, and population health outcomes. The Program Project will model these outcomes for healthcare systems overall and for clinics serving patients in **rural areas** who less often receive HPV vaccine.[6] The Intervention Core's support will include convening a Clinical Advisory Board to provide interdisciplinary implementation support (Aim 1), preparing materials and facilitators to deliver AAT communication workshops (Aim 2), and harmonizing data collection for implementation measures (Aim 3). The Intervention Core will also support the dissemination of study findings and interventions, including developing the AAT Intervention Package, to be disseminated to healthcare systems to help them prioritize and implement interventions to improve HPV vaccine communication and adolescents' HPV vaccine uptake (Aim 4). In these ways, the Intervention Core is **integral to the timeliness, quality, and impact** of all projects in the Program Project.

APPROACH

Intervention Core Team

Core Leads. The Intervention Core will be led jointly by two investigators with complementary expertise in implementation science and cancer prevention research. **Sarah Birken**, PhD, Associate Professor of Implementation Science at Wake Forest University School of Medicine, is an implementation scientist and health services researcher who seeks to understand the role of context in facilitating evidence-based practice implementation. She has served as principal or co-investigator investigator on over 20 studies of evidence-based practice implementation, most related to cancer prevention, control, and survivorship. She also co-edited the recently published *Handbook on Implementation Science.*[7] Dr. Birken will coordinate the **Clinical Advisory Board** in Aim 1 and **harmonize data collection on implementation measures** in Aim 3. She will also draw on her extensive network, including established relationships with cancer prevention and control policymakers (e.g., Commission on Cancer) to **facilitate study findings' dissemination** in Aim 4.

Melissa Gilkey, PhD, Associate Professor of Health Behavior at the University of North Carolina, is a social and behavioral scientist with extensive experience developing and evaluating interventions to improve HPV vaccine communication. She has recruited providers and clinics across multiple studies, including interventions that used provider training to improve HPV vaccination.[4, 8-10] Dr. Gilkey has received training in implementation science through NCI's Training Institute for Dissemination and Implementation Research in Health and offers methodological expertise in surveying and interviewing healthcare providers. Dr. Gilkey will **prepare AAT materials and facilitators** in Aim 2 and **develop the AAT Intervention Package** (Aim 4).

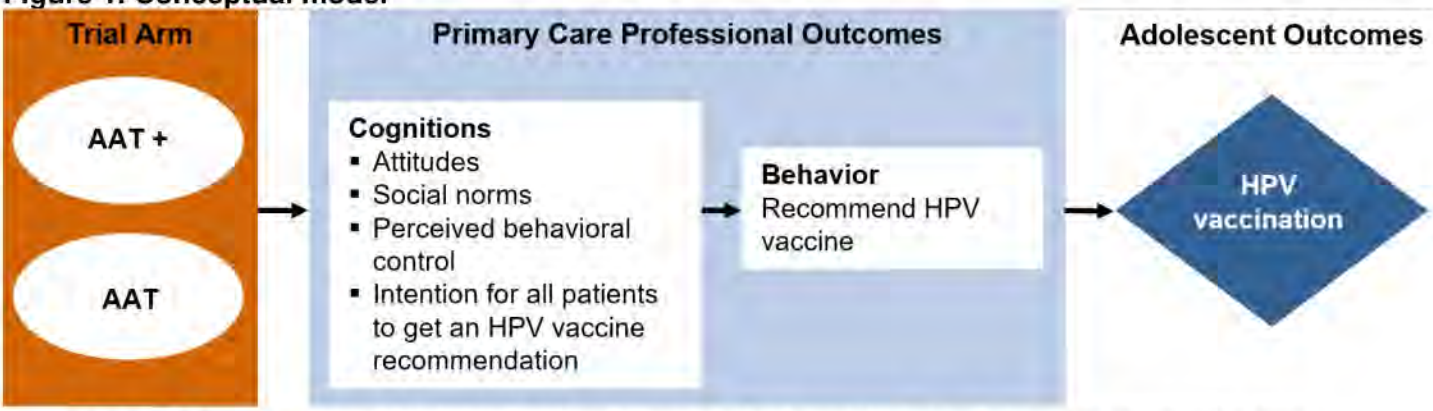
Other key collaborators. **Bryan Weiner**, PhD, Professor of Global Health at the University of Washington, researches the adoption, implementation, and sustainability of innovations and evidence-based practices in health care. Dr. Weiner will lend additional expertise in organizational change theory. The **North Carolina Institute for Public Health**[11] (NCIPH) specializes in professional development and capacity building for health professionals. NCIPH will support developing and packaging intervention materials and training facilitators to deliver AAT workshops in Projects 1-3. **New Media Campaigns**[12] will provide graphic and web design services.

Core structure. Drs. Birken and Gilkey will use a collaborative, team-centric decision-making style to lead the Core. Meeting twice per month, they will discuss and jointly agree on strategic planning, staffing, and budgetary matters. Dr. Birken will be the contact lead, responsible for the Intervention Core's administration, reports to the funding agency, and interface with other IMPACT research projects and cores. In terms of day-to-day management, each Core Lead will take primary responsibility for a subset of key activities outlined in the Specific Aims. Dr. Birken will lead Aim 1, Aim 3, and Aim 4 (Activities 4c and 4d). Dr. Gilkey will lead Aim 2 and Aim 4 (Activities 4a and 4b). Drs. Birken and Gilkey will also participate in P01-wide Integration Committee meetings to coordinate their activities across the projects and cores. In the event of conflicting views that cannot be resolved, they will consult with the P01's PI, Dr. Noel Brewer, for a third view. The Administrative Core research strategy provides more detail on P01-wide collaboration.

Conceptual Model and Evaluation Framework

Conceptual model. Our P01's shared conceptual model (**Figure 1**) is designed to promote understanding of the AAT and related interventions across projects. Guided by the **Theory of Planned Behavior (TPB)**,[13,14] the conceptual model suggests that interventions must change providers' cognitions, including recommendation intentions, to encourage recommendation behaviors. In turn, improvements in these constructs will increase our primary outcome of *HPV vaccination* among adolescents. We have used TPB successfully in prior trials to design and evaluate interventions to improve HPV vaccine communication.[5]

Figure 1. Conceptual model



AAT + is AAT enhanced with standing orders support (P1), incentives (P2), or clinical champions (P3)

Evaluation framework. In deciding whether to adopt interventions, healthcare system leaders need information on their effectiveness and implementation outcomes (i.e., cost, acceptability, adoption, appropriateness, feasibility, fidelity, and reach; **Table 1**).[16-17] Implementation outcomes are important antecedents to intermediate outcomes, such as recommending HPV vaccine.[15] Guided by **Proctor and colleagues' framework**, projects will assess implementation outcomes for their interventions (e.g., standing orders support intervention) and the behaviors the interventions encourage (e.g., use of standing orders).[15]

Facilitating healthcare systems' implementation of interventions requires understanding determinants of interventions' implementation (i.e., implementation barriers and facilitators). Projects' evaluation of implementation determinants will be guided by the **Consolidated Framework for Implementation Research** (CFIR), which organizes 37 constructs conceptualized as determinants of implementation into five domains (e.g., outer and inner setting; process).[18]

Aim 1. Convene a Clinical Advisory Board for multi-disciplinary implementation support.

Overview. The Clinical Advisory Board will provide Projects 1-4 with the diverse clinical expertise needed to successfully engage primary care teams to improve HPV vaccine communication and uptake. The board will guide the study team to: (1) develop materials and procedures for the trials conducted in Projects 1-3; (2) recruit and retain clinical sites; (3) address implementation challenges that arise during intervention delivery; (4) interpret and disseminate research findings; and (5) revise and disseminate the AAT Intervention Package to healthcare systems. Convened quarterly, the board is integral to the P01's goal of creating practical tools for improving HPV vaccine communication and coverage.

1a. Recruit the Clinical Advisory Board.

Clinical Advisory Board members will be a multidisciplinary team of clinical leaders in primary care (see letters of support). Members will include physicians with expertise in pediatrics, family medicine, and quality improvement in healthcare systems (**Lynne Fiscus**, MD; **Tim McCoy**, DO; and **Susan Whitely**, MD). Additional members will represent nurses (**Tami Thomas**, APRN; and **Brittany Thompson**, LPN), physician assistants (**Chris Barry**, PA-C), and medical assistants (**Sandra Weaver**, CMA III). **Karen Ernst** will serve as a patient and family advocate. Board members will receive $1,000 per year for their participation.

1b. Hold quarterly Clinical Advisory Board meetings.

We will host 2 in-person, full-day meetings in Chapel Hill, NC to allow for the more extensive planning needed to initiate the trials in Year 1 and disseminate findings in Year 5. Other meetings will be 90 minutes in length, conducted using video conferencing software. Facilitation duties will rotate among the P01 principal investigator and project and core leads.

Dr. Birken will develop meeting agendas to address predetermined topics, with at least 30 minutes reserved for emergent issues. Year 1 will focus on orientation, procedures, and findings from Project 1 and 2 pilot projects; Years 2 and 3 will address recruitment and procedures for the randomized clinical trials (RCTs); Year 4 will focus on preliminary RCT findings; and Year 5 will focus on developing and disseminating the AAT Intervention Package. We will distribute meeting materials at least 1 week before meetings to allow adequate time for review. To ensure that all members may fully participate, we will use facilitation strategies (e.g., online voting; iterative discussion). We will record meetings and save materials in a shared folder. We will conduct brief online annual surveys to assess and improve members' experiences.

Table 1. Implementation construct definitions

Construct	Operational definition
Outcomes[15]	
Acceptability	PCPs like AAT/like using AA.
Adoption	PCPs attend AAT/try using AA.
Appropriateness	PCPs believe that attending AAT/using AA fits their clinic's needs.
Cost	Delivery cost of AAT and AA from the perspective of healthcare systems
Feasibility	PCPs believe that attending AAT/using AA is doable.
Fidelity	PCPs receive key sections of AAT/use recommended components of AA.
Reach	% of PCPs who attend AAT/use AA for all patients.
Sustainability	PCPs believe that the clinic can continue to offer AAT/they can continue to use AA.
Determinants[18]	Implementation barriers and facilitators (e.g., leadership buy in; implementation climate; patient needs and resources)

Note. PCPs = Primary Care Professionals; AA = Announcement Approach; AAT = Announcement Approach Training

Aim 2. Prepare AAT facilitators and training materials for intervention delivery.

Overview. In Aim 2, we will coordinate across Projects 1-3 to ensure that AAT interventions are delivered with fidelity. First, we will coordinate updates to the AAT Intervention Package so that all projects consistently use the most current materials and procedures. Second, we will prepare facilitators to deliver AAT workshops using our train-the-trainer curriculum and ongoing technical assistance.

2a. Coordinate updates to the AAT Intervention Package.

Dr. Gilkey will coordinate updates to the AAT Intervention Package with Dr. Brewer, who developed and maintains the AAT. Dr. Gilkey will request proposed revisions from Projects 1-3 during P01-wide meetings and retreats and solicit feedback from the Clinical Advisory Board. Updates will primarily occur after pilot studies in preparation for the Project 1-3 RCTs. However, regular updates will also be needed to ensure that AAT interventions incorporate: (1) any changes to national recommendations for HPV vaccine administration that occur during the study period and (2) the latest evidence on HPV vaccine effectiveness, safety, and communication. Project leads and the Clinical Advisory Board will review updates before implementation to ensure that AAT workshops offer the highest quality training possible.

To ensure updates are consistently used across projects, we will maintain an online repository of the most current intervention materials. We will train Project 1-3 project managers and AAT facilitators on any updates to intervention materials and monitor the use of updated materials through fidelity assessments described in Aim 3.

2b. Train facilitators to deliver AAT workshops.

In partnership with NCIPH, Dr. Gilkey will lead the training of physicians and other healthcare professionals to facilitate AAT communication workshops across Projects 1-3. A recent evaluation found that our curriculum is highly acceptable to facilitators-in-training and effective for increasing their AAT delivery knowledge, skills, and confidence.[19] Guided by the AAT train-the-trainer curriculum, facilitator training is a 3-step process:

1. **Participant observation.** Facilitators-in-training participate in an AAT workshop led by an experienced facilitator so that they experience a training firsthand.
2. **Orientation.** Facilitators-in-training attend a 1-hour orientation that includes didactic instruction on the objectives of the AAT, coaching on group facilitation and adult learning, addressing participant questions, and how to use the standardized intervention materials. Orientations use an existing agenda, slide set, and talking points and provide a facilitator resource binder with the materials.
3. **Practice.** Facilitators-in-training practice delivering the training on three occasions: twice on their own and once with study staff who evaluate their performance and provide feedback using a structured evaluation form. Additional practice sessions may be scheduled to further strengthen workshops.

After completing the curriculum, facilitators will receive technical assistance and performance feedback. First, we will hold monthly conference calls with all AAT facilitators to share updates and provide "booster" training on intervention materials, solicit feedback on barriers and facilitators to workshop delivery, and address questions or concerns as a group. Second, we will review fidelity assessments conducted as part of the Project 1-3 implementation outcomes evaluation with each facilitator monthly by phone. These calls will provide the opportunity for study staff to give facilitators one-on-one feedback to improve their performance and address any barriers to delivering the AAT workshop with fidelity.

Aim 3. Harmonize assessment of implementation measures, including cost.

Overview. We will work to ensure the comparability of key implementation measures. Dr. Birken will consult with Dr. Weiner to support Projects 1-3 in using shared implementation measures and data collection procedures. During the intervention delivery period, we will continually monitor implementation measure quality, with a focus on timeliness, completeness, and accuracy. Maximizing implementation data quality is critical to developing the AAT Intervention Package and delivering cost data needed in Project 4.

3a. Assess a defined set of shared implementation measures.

To promote cross-project comparisons, Projects 1-3 will adopt a defined set of shared measures to assess implementation determinants and outcomes (**Table 2**). We will use a shared data dictionary to define measures, including response options and data collection procedures.

Table 2. Implementation data sources and quality assurance measures

Data source	Quality Assurance
Intervention expense records **Tracking logs of participants** **Checklists of content**	• Projects use standardized instruments across projects • Projects submit data regularly to the Core for quality checks • Projects check for outliers, data completeness • Projects use double data entry
Surveys of AAT participants	• Projects use standardized instruments across projects • Projects check for data completeness • Projects use valid and reliable items (e.g., acceptability, appropriateness, feasibility[21]) • Projects conduct cognitive tests and piloting with Clinical Advisory Board before fielding
Key informant interviews	• Projects use standardized instruments across projects • Projects conduct cognitive tests and piloting before fielding with Clinical Advisory Board

3b. Assure implementation data quality.

We will assure data quality using the methods in **Table 2**. During the intervention period, Projects 1-3 will submit implementation measures twice-per-month for quality checking in consultation with Dr. Weiner, who developed selected survey items.[21] Project 1-3 project managers will send data to the Intervention Core's data analyst, who will monitor data collection timeliness and evaluate data accuracy and completeness by checking for outliers, unexpected patterns, and missing values. The analyst will work with project managers to identify and correct errors as needed. If data quality problems arise that cannot be resolved within the Intervention Core, we will

raise these issues with the Integration Committee. The analyst will work closely with Project 4 to verify data quality, ensuring valid model inputs.

3c. Support cost-effectiveness modeling.

We will prioritize the quality-checking of cost data to ensure that datasets from Projects 1-3 are accurate, complete, and delivered on time for cost-effectiveness modeling in Project 4. The data analyst's quality reports will keep Project 4 investigators apprised of any issues that arise. Dr. Birken's roles as co-Lead of the Intervention Core and co-Investigator on Project 4 will also facilitate communication between the two teams.

Aim 4. Facilitate national dissemination of study findings and intervention materials.

Overview. The Intervention Core will work with Projects 1-4 to ensure broad dissemination of study products. Activities will include synthesizing the AAT Intervention Package and disseminating research findings to scientific, clinical practice, and policy audiences.

4a. Synthesize the AAT Intervention Package.

Beginning in Year 4, Dr. Gilkey will work with NCIPH and New Media Campaigns to create the online AAT Intervention Package to include materials such as slides and scripts for healthcare system leaders' use. Projects and cores will all contribute content (**Table 3)**. Package modules will include an overview of the need for interventions to increase HPV vaccine uptake including in rural areas (**Section 1**); a decision tool to support healthcare system leaders' choices among the interventions, including implementation outcomes (e.g., interventions' acceptability) and cost-effectiveness (**Section 2**); and modules on each intervention, including their effectiveness and budget impact and potential facilitators and barriers to their implementation (**Section 3**). For Section 2, Dr. Birken will report implementation outcomes identified in Projects 1-3 to inform leaders' adoption decisions. For example, she will note any concerns about interventions' potential sustainability reported in stakeholder interviews. For Section 3, Dr. Birken will translate implementation determinants into a checklist for each intervention so that primary care professionals tasked with AAT implementation may consider whether they face similar barriers or facilitators. NCIPH will provide guidance on professional training and principles of adult learning, and New Media Campaigns will provide graphic design services to ensure materials' accessibility and attractiveness. We will revise the package based on the Clinical Advisory Board's feedback.

Table 3. AAT Intervention Package for healthcare systems

Content	Developed by
Executive summary	Intervention Core
Section 1. Overview	
Benefits to healthcare systems of increasing HPV vaccine coverage	Admin Core + Data Core
Needs of rural and nonrural clinics	Project 4
Section 2. Decision support tool for choosing interventions	Project 4
Section 3. Modules for implementing interventions	
Announcement Approach Training	Project 1
Including RNs and MAs through standing orders support	Project 1
Motivating physicians with incentives	Project 2
Engaging clinical champions	Project 3

4b. Refresh the study website.

Dr. Gilkey will lead efforts to regularly update our study team's existing website, hpvIQ.org, to make study products freely available to healthcare system leaders seeking to improve HPV vaccination. Designed by New Media Campaigns, hpvIQ.org is a well-established online resource for clinical interventions to promote HPV vaccination that we have developed across multiple prior studies.[22] The site is included in HPV vaccine-related clearinghouses, including those hosted by CDC and the National HPV Vaccination Roundtable.

Every quarter throughout the 5-year study period, we will solicit website content from projects and work with New Media Campaigns to implement updates. Early in the study, we will primarily post discrete tools from the Projects along with instructions for use. In later years, we will post peer-reviewed papers (as allowed by publishers' policies), research summaries, and the full AAT Intervention Package. We will monitor website analytics (e.g., unique visitors) to evaluate demand for our content.

4c. Disseminate research findings.

Dr. Birken will lead the Core's work to support and track research findings' dissemination to diverse stakeholders. Project leads will share research findings with **academic audiences** via peer-reviewed

manuscripts and professional societies' meetings on cancer prevention and control (e.g., American Society of Preventive Oncology), pediatrics (Pediatric Academic Societies), health services research and implementation science (AcademyHealth), and the social and behavioral sciences (Society of Behavioral Medicine). We will actively distribute findings via the Cancer Prevention and Control Research Network (of which Dr. Birken is a workgroup lead and Dr. Wheeler [Project 4 co-Lead] is Coordinating Center PI) and attend the National HPV Vaccination Roundtable and the NCI-funded Cancer Center Collaborative's **HPV vaccine meetings**.

4d. Disseminate practice and policy findings.

Dr. Birken will also lead the Intervention Core's work to support and track study products' dissemination to practice and policy audiences. We will reach additional **public health practitioners and policymakers** by presenting at meetings of the Association of Immunization Managers, CDC's National Immunization Conference, and CDC's Preteen VaxScene webinar series. We will develop research-to-practice briefs and social media content to support these presentations and to share key research findings and intervention materials. We have used these channels in past studies to make presentations to audiences of over 500 public health practitioners, suggesting that these venues are a highly effective dissemination tool.[23]

We will disseminate the AAT Intervention Package to support healthcare systems in adopting and implementing AAT. Working with our advisory boards, we will present our package to leaders of healthcare systems and professional organizations (e.g., the American Academy of Pediatrics). P01 leaders will also meet with interested systems to develop action plans. In this way, we aim to expand our efforts, which currently extend to 15 states, to improve HPV vaccine communication and uptake. UNC Lineberger Comprehensive Cancer Center's Office of Community Outreach and Engagement (directed by Project 4 co-Lead Dr. Wheeler) will provide additional in-kind support for disseminating the package (see Dr. Earp's Letter of Support).

Potential Challenges and Solutions

What if Covid-19 precludes in-person Intervention Core meetings? We have substantial experience conducting stakeholder meetings by remote webinar, should the pandemic prevent in-person meetings. The Intervention Core can accomplish other activities (e.g., train-the-trainer) remotely.

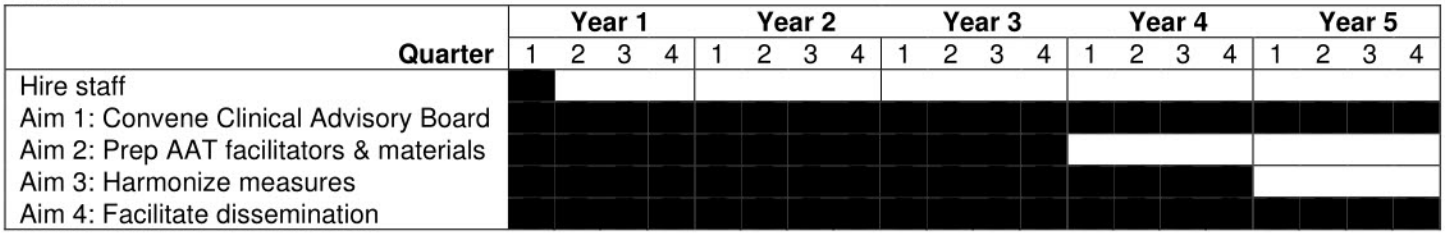
What will go into the AAT Intervention Package if a trial is ineffective? The AAT Intervention Package will focus on AAT, which has already been found to be effective, as well as interventions that the trials establish as effective.[4] For any ineffective interventions, we will include process data on likely explanations.

Relevance to Program Project Theme

The **IMPACT Program Project theme** is to build capacity for HPV vaccine communication interventions among primary care teams in healthcare systems. The Intervention Core supports this theme by coordinating clinical expertise; preparing intervention materials and trainers; harmonizing assessment of implementation determinants and outcomes, including cost data for Project 4's budget impact and cost-effectiveness modeling; and facilitating the dissemination of study findings in our comprehensive AAT Intervention Package. Together, the IMPACT Program Project's research projects and cores can help reduce the incidence of HPV cancers by increasing adoption of HPV communication interventions and uptake of HPV vaccination in healthcare systems, especially those serving rural populations.

The Intervention Core will support all P01 projects to maximize interventions' quality and impact. By integrating project-specific findings and materials into the AAT Intervention Package, the Intervention Core will produce a valuable resource for healthcare systems. The Intervention Core is instrumental to the P01's goals of improving primary care teams' communication, increasing HPV vaccine coverage, and ensuring that today's adolescents have the highest level of protection against future HPV cancers.

Timeline



PHS Human Subjects and Clinical Trials Information

OMB Number: 0925-0001

Expiration Date: 02/28/2023

Use of Human Specimens and/or Data

Does any of the proposed research in the application involve human specimens and/or data *

❍ Yes ● No

Provide an explanation for any use of human specimens and/or data not considered to be human subjects research.

Are Human Subjects Involved

❍ Yes ● No

Is the Project Exempt from Federal regulations?

❍ Yes ❍ No

Exemption Number

❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑ 6 ❑ 7 ❑ 8

Other Requested Information

MULTIPLE PD/PI LEADERSHIP PLAN – Intervention Core

Rationale

Dr. Melissa Gilkey (UNC-Health Behavior) and Dr. Sarah Birken (Wake Forest University School of Medicine), have chosen to co-lead the proposed Intervention Core because their complementary training and expertise provide a strong foundation for the Core's success. The Intervention Core will support all 4 Projects in the IMPACT Program Project (P01). Specifically, the Core will: 1) convene a multidisciplinary Clinical Advisory Board to provide timely implementation support; 2) prepare Announcement Approach Training (AAT) facilitators to deliver interventions with fidelity across Projects 1-3; 3) harmonize assessment of key implementation outcomes, including cost; and 4) facilitate the synthesis of Project 1-4 findings to create an AAT Intervention Manual for dissemination to healthcare systems. Thus, the Core requires bringing together expertise in randomized clinical trials, health services research, as well as implementation and dissemination to achieve its role in the Program.

Dr. Gilkey is an expert in health behavior who contributes her extensive experience in implementation of cancer prevention interventions, particularly focused on conducting surveys and interviews with healthcare providers. In addition, she has extensive experience conducting large-scale randomized clinical trials (RCTs) to implement and evaluate interventions. She has successfully led an RCT within 25 clinics that engaged clinical champions to deliver HPV vaccine-related training, an RCT with 91 clinics using assessment and feedback to increase HPV coverage, and an RCT that has recruited >250 clinics to evaluate the impact of physician communication training on HPV. Finally, Dr. Gilkey has received training in implementation science through NCI's Training Institute for Dissemination and Implementation Research in Health. Thus, Dr. Gilkey brings expertise in implementation of interventions related to HPV vaccination to the Intervention Core.

Dr. Birken contributes health services research and implementation science expertise, with specific skills in the translation of evidence into practice, quality improvement, and innovations in cancer care. She has led multiple studies to evaluate preventive health services and optimization of cancer care, particularly in rural communities. Further, she has led several studies on the application of implementation theories to deliver patient-centered care. Dr. Birken therefore brings her experience in quality improvement and dissemination of cancer prevention interventions to the Core's activities of harmonizing measures and dissemination of the Program's research findings.

Together, Drs. Gilkey and Birken have considerable experience participating in large multi-center research projects, often in positions of leadership. They both have the management skills necessary to successfully conduct the proposed research.

Governance/Organizational Structure

Drs. Gilkey and Birken will work together across all aims of the proposed Core, with each investigator taking primary responsibility for a subset of aims. Dr. Gilkey will lead the preparation of AAT materials and faculty (**Aim 2**) and development of the AAT intervention package (**Aim 4**). For her role in leading the preparation of the AAT materials and faculty, Dr. Gilkey will coordinate updates to the AAT intervention package (**Activity 2a**) by requesting proposed revisions from Projects 1-3 of the Program. She will oversee the maintenance of an online, shared archive of current intervention materials and coordinate with the North Carolina Institute for Public Health (NCIPH) to train physicians and other healthcare providers to deliver AAT communication workshops across Projects 1-3 (**Activity 2b**). Finally, Dr. Gilkey will work with the NCIPH and New Media Campaigns to package the AAT intervention manual for dissemination purposes (**Activity 4a**) while also leading efforts to renew the study team's existing website, hpvIQ.org, to make available discrete tools and their instructions for others seeking to improve HPV vaccination in primary care settings (**Activity 4b**).

Dr. Birken's primary responsibilities in this project include leading coordination of the Clinical Advisory Board (**Aim 1**) and harmonization of data collection on implementation measures (**Aim 3**). For her role in coordinating the Clinical Advisory Board (**Aim 1**), Dr. Birken will develop meeting agendas, distribute meeting materials approximately 1 week prior to meetings, and oversee that meetings are recorded and materials, including meeting notes, are archived in a shared folder. Dr. Birken will ensure comparability of key implementation measures by coordinating with Projects 1-3 (**Aim 3**). She will facilitate communication between the Core and the reseach projects so that implementation determinants and outcomes data are accurate, complete, and collected in a timely manner with the goal of supporting cost effectiveness modeling in Project 4. In addition, Dr. Birken will lead the Intervention Core's work to support and track the dissemination of study products to various audiences, including academic, practice, and policy audiences (**Activities 4c, 4d**).

Alongside project leaders, Drs. Gilkey and Birken will work towards disseminating the Program's findings through (1) publishing in peer-review journals; (2) presenting at professional meetings, including those in cancer prevention and control, health services research, pediatrics, and social and behavioral sciences; and (3) presenting at meetings of the Cancer Prevention and Control Research Network, Association of Immunization Managers, CDC's National Immunization Conference, and CDC's Preteen VaxScene webinars. Additionally, they will ensure that the AAT intervention package is presented to leaders in large healthcare systems as well as medical professional organizations.

Communication

Dr. Birken will be the contact Core Lead and maintain responsibility for overall administrative and fiscal management of the Core, including the central budget as well as preparation of progress reports, which will be prepared in collaboration with Dr. Gilkey. In general, consensus between Core Leads will be obtained prior to fiscal and administrative changes and annual report submission.

Drs. Gilkey and Birken will meet at least biweekly, either in person or by phone, with more frequent meetings scheduled depending on project needs. These meetings will be used to develop Core priorities, coordinate the activities, and review progress. Operational matters of progress as well as potential problems, anticipated upcoming issues, and general program oversight will also be discussed at these meetings.

Conflict Resolution

If any conflict arises as to scientific direction, Drs. Gilkey and Birken will meet to try and resolve the disagreement. If they fail to reach a resolution, they will consult with the P01's Pricinpal Investigator, Noel Brewer, for additional support.

Change in Core Lead location

No relocation for either Core Co-Lead is anticipated. However, in the highly unlikely event that a Core Lead moves to a different institution, attempts will be made to transfer the relevant portions of the grant to the new institution. In the event that transfer is not possible, an appropriate replacement for Core Lead will be recruited as necessary from UNC.

REFERENCES – Intervention Core

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CONSORTIUM/CONTRACTUAL ARRANGEMENTS – Intervention Core

The Intervention Core proposal includes a collaborative effort between UNC and the Wake Forest University School of Medicine (WFSM). UNC will serve as the prime institution for the Intervention Core, and WFSM will serve as the subrecipient. The proposed activities include a subcontract with WFSM to involve Dr. Sarah Birken in all proposed specific aims as a Core Co-Lead. The appropriate programmatic and administrative personnel of each organization involved in this grant application are aware of the NIH consortium agreement policy and are prepared to establish the necessary inter-organizational agreement(s) consistent with that policy.

Dr. Melissa Gilkey is the Core Lead responsible for ensuring proper conduct of the activities in the core at the consortium site of UNC. Dr. Sarah Birken is the Core Lead responsible for ensuring proper conduct of the project at WFSM. UNC will manage the programmatic, fiscal, and administrative tasks necessary to ensure the overall success of the subcontract. Drs. Gilkey and Birken will share responsibility for leading weekly meetings in all years of the Core. Dr. Birken will attend these meetings by phone. Dr. Birken, along with the other relevant Program Project staff, will attend quarterly meetings of the Program Project's Clinical Advisory Board each year of the study.

As Co-Lead on this core, Dr. Birken will be responsible for coordinating and convening all meetings of the Clinical Advisory Board. She will also ensure timely completion of data collection materials by leading the harmonization of implementation data collection measures. Dr. Birken will also collaborate and contribute to dissemination activities, including development of dissemination modules, as well as reports, papers, and publications.

The grantee and subrecipient organizations are prepared to make a formal consortium agreement with terms and conditions stipulating ownership of all data, reports, materials, inventions and if applicable, future use. This agreement will be developed in accordance with NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards Subpart B: Terms and Conditions for Specific Types of Grants, Grantees, and Activities (15 Consortium Agreements).

UNC RESEARCH

University of North Carolina at Chapel Hill
Subrecipient Letter of Intent

To be completed by Subrecipient

SUBRECIPIENT	SPONSOR
Legal Name: Wake Forest University Health Sciences	Legal Name: The University of North Carolina at Chapel Hill
DUNS: 937727907	DUNS: 608195277
Lead PI: Sarah A. Birken, PhD	Lead PI: Noel T. Brewer

Subrecipient Administrative Contact:	*Sponsor Administrative Contact:*
Name/Title: Angela Horton, OSP Administrator IV	Name/Title: David Paul/Assistant Vice Chancellor
Address: Office of Sponsored Programs Medical Center Boulevard, Winston-Salem, NC 27103	Address: 104 Airport Drive, Suite 2200 Chapel Hill, NC, 27599
Phone: 336-716-1433	Phone: 919-966-3411
Email: ahorton@wakehealth.edu	Email: ResAdminOSR@unc.edu

GENERAL INFORMATION

Project Title: Program Project- Improving Provider Announcement Communication Training (IMPACT)

Prime Awarding Agency: National Cancer Institute

RFA/RFP: PAR-20-077

Project Period: Start 8/01/2021 End 7/31/2026

UNC-CH Proposal Number: (Enter UNC IPF Number)

BUDGET INFORMATION

Choose as appropriate below:

(•) Federal Rate ( ) Sponsor Rate ( ) Other

Applicable F&A Rate: 55 %

Direct Costs: $202,335.00

Indirect Costs: $111,284.00

Total Request: $313,619.00

COMPLIANCE INFORMATION

Human Subjects: ( ) Yes (•) No

Animal Subjects: ( ) Yes (•) No

Is your institution a participant of Federal Demonstration Partnership (FDP) Clearing House? (•) Yes ( ) No

This LETTER OF INTENT confirms the appropriate program and administrative personnel have reviewed and approve the above referenced Solicitation/ RFP/RFA. Further, the institution and its Principal Investigator certify that:

Information submitted within this application is true, complete, and accurate to the best of the institution's and PI's knowledge; any false, fictitious, or fraudulent statements or claims may subject the institution and PI to criminal, civil, or administrative penalties; PI agrees to accept responsibility for the scientific conduct of the project and to provide the required progress reports if an award is made, and a mutually agreeable subcontract is executed as a result thereof.

Included: • Statement of Work • Budget • Budget Justification Other:

Subrecipient Principal Investigator: [signature]

Date: 07/21/20

Subrecipient Authorized Official: Angela Horton-Acting for Sara Stanley

Digitally signed by Angela Horton-Acting for Sara Stanley
Date: 2020.07.22 11:12:42 -04'00'

Date: Stanley

Form Approved Through 02/28/2023 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Application

Do not exceed character length restrictions indicated.

LEAVE BLANK—FOR PHS USE ONLY.

Type	Activity	Number
Review Group		Formerly
Council/Board (Month, Year)		Date Received

1. TITLE OF PROJECT *(Do not exceed 81 characters, including spaces and punctuation.)*
Program Project- Improving Provider Announcement Communication Training (IMPACT)

2. RESPONSE TO SPECIFIC REQUEST FOR APPLICATIONS OR PROGRAM ANNOUNCEMENT OR SOLICITATION ☐ NO ☒ YES
(If "Yes," state number and title)
Number: PAR-20-077 Title: National Cancer Institute Program Project Applications

3. PROGRAM DIRECTOR/PRINCIPAL INVESTIGATOR

3a. NAME (Last, first, middle)	3b. DEGREE(S)	3h. eRA Commons User Name
Birken, Sarah A.	PhD	eRA COMMONS USER NAME

3c. POSITION TITLE
Associate Professor

3d. MAILING ADDRESS *(Street, city, state, zip code)*
Medical Center Boulevard
Winston-Salem, NC 27157

3e. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Implementation Science-PHS

3f. MAJOR SUBDIVISION
School of Medicine

3g. TELEPHONE AND FAX *(Area code, number and extension)*
TEL: 336-713-3358 FAX:

E-MAIL ADDRESS:
sbirken@wakehealth.edu

4. HUMAN SUBJECTS RESEARCH	4a. Research Exempt	If "Yes," Exemption No.
☐ No ☒ Yes	☒ No ☐ Yes	

4b. Federal-Wide Assurance No.	4c. Clinical Trial	4d. NIH-defined Phase III Clinical Trial
FWA00001435	☒ No ☐ Yes	☒ No ☐ Yes

5. VERTEBRATE ANIMALS ☒ No ☐ Yes — 5a. Animal Welfare Assurance No. A3391-01

6. DATES OF PROPOSED PERIOD OF SUPPORT *(month, day, year—MM/DD/YY)*		7. COSTS REQUESTED FOR INITIAL BUDGET PERIOD		8. COSTS REQUESTED FOR PROPOSED PERIOD OF SUPPORT	
From	Through	7a. Direct Costs ($)	7b. Total Costs ($)	8a. Direct Costs ($)	8b. Total Costs ($)
08/01/2021	07/31/2026	40,451	62,699	202,335	313,619

9. APPLICANT ORGANIZATION
Name: Wake Forest University Health Sciences
Address: Medical Center Boulevard
Winston-Salem, NC 27157

10. TYPE OF ORGANIZATION
Public: → ☐ Federal ☐ State ☐ Local
Private: → ☒ Private Nonprofit
For-profit: → ☐ General ☐ Small Business
☐ Woman-owned ☐ Socially and Economically Disadvantaged

11. ENTITY IDENTIFICATION NUMBER
223849199
DUNS NO. 937727907 Cong. District NC-005

12. ADMINISTRATIVE OFFICIAL TO BE NOTIFIED IF AWARD IS MADE
Name: Sara Stanley
Title: Director, Office of Sponsored Programs
Address: Wake Forest University Health Sciences
Medical Center Boulevard
Winston-Salem, NC 27157
Tel: 336-716-2382 FAX: 336-716-4480
E-Mail: awards@wakehealth.edu

13. OFFICIAL SIGNING FOR APPLICANT ORGANIZATION
Name: Sara Stanley
Title: Director, Office of Sponsored Programs
Address: Wake Forest University Health Sciences
Medical Center Boulevard
Winston-Salem, NC 27157
Tel: 336-716-2382 FAX: 336-716-4480
E-Mail: awards@wakehealth.edu

14. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

SIGNATURE OF OFFICIAL NAMED IN 13. *(In ink. "Per" signature not acceptable.)*
Angela Horton-Acting for Sara Stanley
Digitally signed by Angela Horton-Acting for Sara Stanley
Date: 2020.07.20 10:08:41 -04'00'

DATE

Program Director/Principal Investigator (Last, First, Middle): Birken, Sarah A.

SCOPE OF WORK

This Statement of Work is for Dr. Sarah Birken to collaborate with Dr. Noel Brewer at the University of North Carolina at Chapel Hill on the proposed study titled Improving Provider Announcement Communication Training (IMPACT): Program Project - Intervention Core to complete the following:

1. Work with Dr. Brewer and colleagues to finalize details of study design and protocol.
2. Advise on the theoretical approach from an implementation science perspective.
3. Lead the intervention core to understand relationships among implementation determinants, implementation outcomes, intermediate outcomes, and HPV vaccination as they relate to the interventions of interest.
4. Communicate with Dr. Brewer and colleagues on an ongoing basis with regard to study implementation, progress, and ongoing study needs.
5. Engage with group teleconferences on approximately a monthly basis, and travel to group face-to-face meetings on approximately an annual basis.
6. Engage with study team to address any unforeseen study needs.
7. Work with Dr. Brewer and colleagues on fine-tuning and interpreting analysis, and writeup of study findings, including collaboratively finalizing study results and their interpretation, and drafting manuscripts for publication in support of the study Specific Aims.

Collaborate and assist in all study publications and presentations.

RELEVANCE (See instructions):

PROJECT/PERFORMANCE SITE(S) (if additional space is needed, use Project/Performance Site Format Page)

Project/Performance Site Primary Location			
Organizational Name: Wake Forest University Department of Health Sciences School of Medicine			
DUNS: 937727907			
Street 1: Medical Center Boulevard		Street 2:	
City: Winston-Salem	County: Forsyth		State: NC
Province:	Country: USA		Zip/Postal Code: 27157
Project/Performance Site Congressional Districts: NC-005			

Additional Project/Performance Site Location			
Organizational Name:			
DUNS:			
Street 1:		Street 2:	
City:	County:		State:
Province:	Country:		Zip/Postal Code:
Project/Performance Site Congressional Districts:			

June 17, 2020

Noel T. Brewer, PhD
Professor of Health Behavior
Gillings School of Global Public Health
University of North Carolina
Campus Box 7440
Chapel Hill, NC 27599

Dear Dr. Brewer:

I am writing to express my enthusiastic support to be a consultant and a Clinical Advisory Board member for your proposed NCI P01 grant, "Improving Provider Announcement Communication Training (IMPACT)" Program Project. I believe the Program and its proposed research studies are essential steps in increasing HPV vaccination uptake in the community.

In the event of funding, I will join the Program as a Clinical Advisory Board member to the Program's research projects and supporting cores. In addition, I will help recruit and retain providers for the proposed studies, review intervention materials and procedures, review data collection procedures and instruments, and advise on the dissemination of research findings and tools. I understand that my responsibilities require quarterly meetings for the 5-year project period that will occur via webinar, except for two in-person meetings that will occur in Year 1 and Year 5. For my efforts, I will be compensated [$] annually for 5 years, including travel costs for any in-person meetings.

My qualifications for this role include my 20+ years as a Family Medicine physician and my leadership positions. I have served as the Central Iowa Clinically Integrated Network Medical Director, the Accountable Care Organization Medical Director for Catholic Health Initiatives, and as the Department Chair of Family Medicine. I have been a member of the Iowa Medical Society and served on its Committee on Legislation, working to support legislation in the interest of public health and medicine. I also serve as the Mercy One Central Iowa Medical Group Quality chair where we have been awarded 2 separate grants (one where you were our key note speaker) working to improve our HPV vaccination rates across our Central Iowa Primary Care clinics.

Moreover, I am committed to HPV vaccination efforts. I have worked with the National Area Health Education Centers (AHEC) Organization to present my experience as a physician leader in preventing HPV cancers in health systems.

I would be pleased to contribute my perspective as a primary care provider and my expertise in mobilizing health systems for better vaccination uptake. I have been committed to efforts that promote public health, and specifically to improving HPV vaccination rates. I believe that the proposed studies in the Program are critical to protect the public from HPV-attributable cancers. I am enthusiastic to be a contributing member to these efforts and look forward to our future collaboration.

Sincerely,

Tim McCoy, D.O.
Department Chair, Family Medicine
Central Iowa CIN Medical Director
MercyOne Medical Group - Central Iowa

June 4, 2020

Noel T. Brewer, PhD
Professor of Health Behavior
Gillings School of Global Public Health
University of North Carolina
Campus Box 7440
Chapel Hill, NC 27599

Dear Dr. Brewer:

I am writing to express my enthusiastic support to be a consultant and a Clinical Advisory Board member for your proposed Program Project, "Improving Provider Announcement Communication Training (IMPACT)" Program Project. As a physician assistant specializing in pediatrics, I believe in the importance of vaccination to prevent vaccination-preventable disease, including HPV-related cancers. It is my great pleasure to be part of a concerted effort to increase HPV vaccination within the community.

In the event of funding, I would join the Program Project as a Clinical Advisory Board member and consultant for the Program's research projects and supporting cores. My primary contribution will be to provide the perspective of the physician assistant. In addition, I will advise on provider recruitment and retention for the Program's research projects while also reviewing intervention materials, intervention procedures, and data collection protocols. Finally, I will provide insight on how to best disseminate research findings to the larger population of providers. I understand that my responsibilities require quarterly meetings for the 5-year project period that will occur via webinar, except for two in-person meetings that will occur in Year 1 and Year 5. For my efforts, I will be compensated $ annually for 5 years.

My qualifications for the role are as follows. For the past 15+ years, I have worked as a physician assistant specializing in pediatric care. Through my clinical practice, I have gained experience in working with parents who have hesitated or declined immunizations for preventable diseases. Moreover, I have engaged with the larger physician assistant community through my professional memberships in the American Academy of Physician Assistants and American Academy of Pediatrics. I have served as the former American Academy of Physician Assistants Medical Liaison to the American Academy of Pediatrics and as the president of the Society for Physician Assistants in Pediatrics. Currently, I serve on the Board of Directors in the North Carolina Academy of Physician Assistants.

I would be pleased to contribute my expertise in advocating for immunization uptake and insight into patient-provider relationships, especially in regards to immunization efforts. I look forward to supporting the Program's efforts to increase HPV vaccination uptake in the community.

Sincerely,

CBarry PA-C

Chris Barry, PA-C, MMSc, DFAAPA

August 8, 2020

Noel T. Brewer, PhD
Professor of Health Behavior
Gillings School of Global Public Health
University of North Carolina
Campus Box 7440
Chapel Hill, NC 27599

Dear Dr. Brewer:

I am writing to state my enthusiastic support to be a Clinical Advisory Board member for your proposed NCI P01 grant, "Improving Provider Announcement Communication Training (IMPACT)" Program Project. HPV vaccination constitutes a critical part of protecting adolescents and young adults from future HPV-attributable cancers. I believe that the proposed studies under the Program Project are critical in achieving this important public health goal. I would be pleased to contribute my expertise in pediatric care, HPV vaccine dissemination, and strengthening healthcare delivery and systems.

In the event of funding, I would support and join the Program Project as a Clinical Advisory Board member including consultation on the research projects and supporting cores. As part of my role, I will review intervention materials, data collection procedures and advise on the dissemination of research findings. I understand that my responsibilities require quarterly meetings for the 5-year Program Project that will occur via webinar, except for two in-person meetings that will occur in Year 1 and Year 5. For my efforts, I will be compensated [$] annually for 5 years including travel costs for any in-person meetings.

My qualifications for this role include my practice as a board-certified pediatric nurse practitioner that includes advanced nursing practice and primary care for adolescents and school-age children for over 20 years. In addition, I have extensive expertise in conducting research with national and international interventions that disseminate healthcare innovations, such as the HPV vaccine, to adolescent and pediatric populations who experience health disparities in rural areas. My research has been credited in reducing health disparities and improving adolescent health regionally, nationally, and internationally. Moreover, I have developed HPV survey instruments for parents and students for use in primary care and research.

If I can be of further support, please feel free to contact me at the information provided below.

Kind Regards,

Tami L. Thomas

Tami L. Thomas, PhD, RN, APRN-CPNP, FAANP, FAAN
Professor and Associate Dean
Research, Faculty Development and PhD Program Director
Nicole Wertheim College of Nursing & Health Sciences
Florida International University

June 12, 2020

Noel T. Brewer, PhD
Professor of Health Behavior
Gillings School of Global Public Health
University of North Carolina
Campus Box 7440
Chapel Hill, NC 27599

Dear Dr. Brewer:

I am writing to express my enthusiastic support to be a consultant and a Clinical Advisory Board member for your proposed Program Project grant, "Improving Provider Announcement Communication Training (IMPACT)" Program Project. HPV vaccination is critical to protecting adolescents from future HPV-attributable cancers. I believe that the research studies proposed under the Program will be critical to achieving this protection through increasing uptake of HPV vaccination in the community.

In the event of funding, I would be interested in joining the Program Project as a Clinical Advisory Board member who consults on the research projects and overall organization of the Program, including the cores that support research efforts. My primary contribution will be providing the perspective of the physician. My other responsibilities will involve helping recruit and retain providers for the proposed studies, reviewing intervention materials and procedures, reviewing data collection procedures and instruments, and advising on the dissemination of research findings and tools. I understand that my responsibilities require quarterly meetings for the 5-year project period that will occur via webinar, except for two in-person meetings that will occur in Year 1 and Year 5. For my efforts, I will be compensated $ annually for 5 years, including travel costs for any in-person meetings.

My qualifications for this role include my practice as a family medicine doctor for more than 20 years, during which I have engaged with the community to present important public health topics. Moreover, I have been involved extensively in physician organizations, including the American Academy of Family Physicians and the American Medical Association. I have been a member of the Arizona Medical Association since 1997 and currently serve as the organization's 128th president.

I would be pleased to contribute my expertise in primary care, community engagement in public health, and mobilization of physicians through physician organizations. I support the efforts of the research team to increase HPV vaccination in the community and firmly believe that the proposed studies will contribute towards this goal. I look forward to our future collaboration.

Sincerely,
Susan M. Whitely md

Susan M. Whitely, MD
Family Medicine, Health Outlook Family Medicine PC
President, Arizona Medical Association

UNC PHYSICIANS NETWORK
UNC HEALTH CARE

June 4, 2020

Noel T. Brewer, PhD
Professor of Health Behavior
Gillings School of Global Public Health
University of North Carolina
Campus Box 7440
Chapel Hill, NC 27599

Dear Dr. Brewer:

I am writing to express my eager support to be a Clinical Advisory Board member for your proposed Program Project, "Improving Provider Announcement Communication Training (IMPACT)" Program Project. As an Internal Medicine-Pediatrics physician who practices primary care, I believe in the importance of HPV vaccination, as it offers protection to adolescents and young adults from future HPV-related cancers. In turn, I support the efforts of the Program Project and its proposed research studies, which prove essential in achieving the goal of increased HPV vaccination uptake.

In the event of funding, I plan to join the Program Project as a Clinical Advisory Board member who provides guidance to the Program's research projects and its supporting cores. My primary contribution will to be provide expertise on quality improvement initiatives. In addition, I will help review intervention materials and procedures, review data collection procedures, advise on the dissemination of research findings and tools, and recruit and retain providers for the proposed studies. I understand that my responsibilities require quarterly meetings for the 5-year project period that will occur via webinar, except for two in-person meetings that will occur in Year 1 and Year 5. For my efforts, I will be compensated $ annually for 5 years.

My qualifications for this role include my years of practice as a primary care physician and my time as an executive medical director in various health practices. I served as the Executive Medical Director for the University of Minnesota Ambulatory Clinics and the Executive Regional Medical Director for Fairview Medical Group in Minnesota. I have served as a practice transformation consultant for the American Medical Association, working on the development and implementation of solutions for preventing physician burnout. Currently, I am the President and Chief Executive Officer of the University of North Carolina Physicians Network. Moreover, I am the Chair of the Primary Care Collaborative of UNC Health. In turn, I have vast experience in developing physician and administrative dyad teams to improve the quality of healthcare services. I have cultivated partnerships with operations leaders to implement systems and processes that sustain efforts for quality improvement.

UNC Physicians Network
2000 Perimeter Park Drive, Suite 200
Morrisville, NC 27560
(984) 215-4000

uncpn.com

UNC PHYSICIANS NETWORK
UNC HEALTH CARE

I would be pleased to contribute my expertise in developing clinical and administrative teams and my expertise in community-based and ambulatory care. I support the efforts of the research team to increase HPV vaccination and look forward to contributing to the research projects to achieve such an important goal.

Sincerely,

Lynne Fiscus, MD, MPH
President and Chief Executive Officer
University of North Carolina Physicians Network

UNC Physicians Network
2000 Perimeter Park Drive, Suite 200
Morrisville, NC 27560
(984) 215-4000

uncpn.com

June 25, 2020

Noel T. Brewer, PhD
Professor of Health Behavior
Gillings School of Global Public Health
University of North Carolina
Campus Box7440
Chapel Hill, NC 27599

Dear Dr. Brewer:

I am writing to express my enthusiastic support to be a consultant and a Clinical Advisory Board member for your proposed NCI P01 grant, "Improving Provider Announcement Communication Training (IMPACT)" Program Project. I am committed to efforts to increase HPV vaccination coverage, as I have spent a significant part of my career both recommending and administering HPV vaccine to adolescent and young adult patients. Therefore, I am very excited to be a part of the Program and its proposed research studies. I believe it will be critical in achieving greater HPV vaccination uptake and consequently, protection against HPV-related cancers.

In the event of funding, I will join the Program as a Clinical Advisory Board member who consults on the Program's research projects and supporting cores. My primary contribution to the board will be providing the perspective of the licensed practical nurse (LPN). In addition, I will help recruit and retain providers for the proposed studies, review intervention materials and procedures, review data collection procedures and instruments, and advise on the dissemination of research findings and tools. I understand that my responsibilities require quarterly meetings for the 5-year project period that will occur via webinar, except for two in-person meetings that will occur in Year 1 and Year 5. For my efforts, I will be compensated $ annually for 5 years including travel costs for any in-person meetings.

My seven years of experience as an LPN working in Family Medicine, Pediatrics, Internal Medicine and student health makes me qualified for this position. I have ample experience communicating with adolescent and young adult patients and their families about HPV infection, HPV vaccination and the prevention of cervical cancer. This includes providing education to families about how HPV is transmitted as well as the importance of the vaccine as a preventive tool against HPV-related cancers. In my current role as a clinical nurse I administer and order vaccines and provide patient education. I would be pleased to contribute my experience and expertise to the proposed Program Project and believe that the proposed studies in the Program are essential in achieving better HPV vaccination uptake. I am enthusiastic to be a contributing member to these efforts and look forward to our future collaboration.

Sincerely,

Brittany Thompson, LPN

Brittany Thompson, LPN

UNC Health Panther Creek

June 22, 2020

Noel T. Brewer, PhD
Professor of Health Behavior
Gillings School of Global Public Health
University of North Carolina
Campus Box 7 440
Chapel Hill, NC 27599

Dear Dr. Brewer:

I am writing to express my enthusiastic support to be a consultant and a Clinical Advisory Board member for your proposed NCI P01 grant, "Improving Provider Announcement Communication Training (IMPACT)" Program Project. I believe that HPV vaccination is important for protecting against HPV-related cancers and the Program as well as its proposed studies are critical in increasing HPV immunization uptake in primary care.

In the event of funding, I would be interested in joining the Program as a Clinical Advisory Board member who consults on the Program's research projects and overall organization of the Program, including the cores that support research efforts. My primary contribution will be providing the perspective of the medical assistant. My other responsibilities will involve helping recruit and retain providers for the proposed studies, reviewing intervention materials and procedures, reviewing data collection procedures and instruments, and advising on the dissemination of research findings and tools. I understand that my responsibilities require quarterly meetings for the 5-year project period that will occur via webinar, except for two in-person meetings that will occur in Year 1 and Year 5. For my efforts, I will be compensated $ annually for 5 years.

My qualifications for this role include my experience as a certified medical assistant. I have spent the last 15 years working as a certified medical assistant in children's primary care, allowing me to gain insight into engaging with pediatric patients as well as parents for health care. Moreover, I have been a vaccination "champion" in seven different pediatric practices. In that capacity, I have served as the vaccine "go to" person for both families and providers in those practices. Additionally, I have attended several national vaccination conferences to increase my knowledge about pediatric vaccine administration and my effectiveness at communicating with families about vaccination. Altogether, my experience as a medical assistant and vaccine champion qualifies me to provide insight to clinic work flows, engagement with pediatric patients and parents and working with an interdisciplinary team to achieve set goals.

I would be pleased to contribute my expertise in medical assisting. I look forward to supporting the Program's efforts to increase HPV vaccination uptake and prevent future HPV-related cancers.

Sincerely,

Sandra Weaver CMAIII

Sandra Weaver, CMAIII
UNC Family Medicine and Pediatrics

July 6, 2020

Noel T. Brewer, PhD
Professor of Health Behavior
Gillings School of Global Public Health
University of North Carolina
Campus Box 7440
Chapel Hill, NC 27599

Dear Dr. Brewer:

I am writing to express my enthusiastic support to be a consultant and Clinical Advisory Board member for your proposed NCI P01 grant, "Improving Provider Announcement Communication Training (IMPACT)" Program Project. I believe that HPV vaccination is a critical component to protecting adolescents from HPV-related cancer. It is my great pleasure to be part of the Program and its proposed research to increase HPV vaccination uptake in primary care.

In the event of funding, I would join the Program Project as a Clinical Advisory Board member and consultant for the Program's research projects and supporting cores. My primary contribution will be to provide the perspective of parents and patient advocates. Specifically, I will advise on intervention materials, intervention procedures, and data collection protocols. Finally, I will provide insight on how to best disseminate research findings to the larger population of providers. I understand that my responsibilities require quarterly meetings for the 5-year project period. For my efforts, I will be compensated $ annually for 5 years, including travel costs for any in-person meetings.

I have been actively involved in parent advocacy in regards to immunization efforts, making me qualified for my role as Clinical Advisory Board member. I have continued to express my passion for vaccination through my role as Executive Director for Voices for Vaccines, a parent-led organization that supports and advocates for on-time vaccination and reduction of vaccine-preventable diseases, such as HPV-related cancers. I have served in this role for the past 6 years and consequently, have worked closely with the organization's scientific advisory board to ensure that the organization reflects current and accurate science-based information on vaccines. In addition to this current role, I work as a co-founder of the Minnesota Childhood Immunization Coalition, which is a coalition of parents, healthcare workers, public health workers, and health organizations dedicated to supporting legistation that improves immunization policies and engaging in parent-to-parent educational conversations.

My goal across these activities is to provide evidence-based information that is accessible, relevant, and parent-centered so that families have the tools they need to make the best possible decisions for their children.

I would be pleased to contribute my expertise in parent advocacy. I look forward to supporting the Program's efforts to increase HPV vaccination uptake and prevent future HPV-related cancers.

Karen Ernst

Karen Ernst, MA
Executive Director, Voices for Vaccines
Co-Founder, Minnesota Childhood Immunization Coalition

UNC | GILLINGS SCHOOL OF GLOBAL PUBLIC HEALTH

THE UNIVERSITY OF NORTH CAROLINA AT CHAPEL HILL
GILLINGS SCHOOL OF GLOBAL PUBLIC HEALTH
North Carolina Institute for Public Health

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O 919-966-7613 | F 919-962-0268

Rosenau Hall | Room 221 | Campus Box 8165
135 Dauer Drive | Chapel Hill, NC 27599-8165
sph.unc.edu/nciph

June 1, 2020

Noel T. Brewer, PhD
Professor of Health Behavior
Gillings School of Global Public Health
University of North Carolina at Chapel Hill
Campus Box 7440
Chapel Hill, NC 27599

Dear Dr. Brewer:

I am writing to offer our services and support for your NCI P01 proposal "Improving Provider Announcement Communication Training (IMPACT)" Program Project. For the Intervention Core, the North Carolina Institute for Public Health (NCIPH) will provide technical support for the development and implementation of the project's HPV vaccine-focused Announcement Approach Training (AAT) Intervention Package.

We look forward to working with the Intervention Core team to support the delivery of the AAT Intervention Package across Projects 1-3 in the proposed Program. Our work will include: making updates to the AAT Intervention Package to incorporate pilot findings and emerging data and ensuring package updates are implemented consistently and efficiently. In Years 1-3 we will also design and deliver the proposed "Train the Trainer" curriculum to those physicians and health care providers who will then further disseminate the trainings. In Years 4-5, we will work with the Intervention Core team to synthesize intervention materials and procedures from all Projects into a comprehensive package for dissemination to healthcare systems. Additionally, NCIPH will assist in developing "research-to-practice" briefs and social media content to disseminate findings in practice and policy settings. To support us in this work NCIPH will engage Dr. Jennifer Leeman, an implementation scientist and Principal Investigator of UNC's CDC/NCI-funded Cancer Prevention and Control Research Network center. Dr. Leeman has prior experience as a co-investigator on implementation interventions to increase HPV vaccination in primary care.

NCIPH has expertise in providing technical assistance to public health research projects and in developing and delivering trainings to public health and health care professionals. We are housed within the UNC Gillings School of Global Public Health and it is part of our mission to serve as a bridge between academia and public health practice partners. We have a wealth of experience in a range of public health topic areas, improvement planning, and population health and have prepared train the trainer programs for many organizations, including The Centers for Disease Control and Prevention, The Pan American Health Organization, and the World Health Organization as well as U.S. state and local public health associations and agencies.

As part of the UNC Gillings School of Global Public Health, we are committed to improving the health and well-being of people in North Carolina, across the U.S., and around the world. We look forward to working with your team on the critical work to promote HPV vaccine uptake and prevent HPV-related cancers.

We enthusiastically support your proposal and wish you the best of luck.

Sincerely,

Douglas W. Urland, MPA
Director
North Carolina Institute for Public Health

August 19, 2020

Noel T. Brewer, PhD
Professor of Health Behavior
Gillings School of Global Public Health
University of North Carolina
Campus Box 7440
Chapel Hill, NC 27599

Dear Dr. Brewer:

I am writing to offer our services as New Media Campaigns(NMC) to support your NCI P01 proposal,"Improving Provider Announcement Communication Training (IMPACT)" Program Project. New Media Campaigns has extensive experience serving a wide array of clients, including researchers, clinicians, and public health practitioners. Our mission is to develop communication strategies and intervention resources that are evidence-based, client-centered, and creative.

NMC is an award-winning digital agency of talented strategists, designers, and developers located in North Carolina. The firm was launched in 2006 and has consistently and organically grown since then to work with clients ranging from Fortune 50 companies and international advocacy campaigns to startups and local non-profits. Additionally, NMC has a strong track record in non-profit, research, and educational web design. NMC has helped clients such as RTI International, IntraHealth International, UNC-Chapel Hill, Duke Health, Columbia University, Georgetown University, and many others build compelling digital properties for various initiatives and research projects.

NMC is a leader in the space due to it's team members' exceptional work, contributions to open source projects, and thought leadership. The agency's technical depth and appealing design is paired with its exceptional service. NMC seamlessly blends all aspects of the web into a single in-house team.

To support your study, we will provide graphic design services to ensure that your protocols and other printed materials are attractive, accessible, and engaging. We will also update the HPVIQ.org website that we previously developed for your team in a prior project to host relevant web content, intervention materials, and on-line trainings. We understand that our responsibilities to support your Program will be carried out over a 5-year period. During Year 1 and 2 of the Program, we will provide design services for the Provider Training presentation to be posted on the website, update content on the "Communication Training Tools" section of the website, and update design and training tools included in the "Publications & Resources Archive." In Years 3-5, we will

NEW MEDIA CAMPAIGNS

refresh the website to update intervention materials, videos, and study findings, provide design services for the comprehensive intervention manual and procedures for dissemination to healthcare systems, and format "research-to-practice" policy briefs and social media content to disseminate findings to healthcare practices and policy makers.

We understand that this 5-year project will require attention to detail and the ability to update the website in a timely manner to reflect the most current information and research findings. We are accustomed to the fast pace of an academic research setting, and can assure you quick turnaround from our talented and responsive staff.

We look forward to supporting this important work to prevent HPV-related cancers.

Sincerely,

Clay Schossow
Partner, New Media Campaigns

Wake Forest™
School of Medicine

Sarah A. Birken, PhD
Associate Professor
Department of Implementation Science
Comprehensive Cancer Center
Division of Public Health Sciences

August 4, 2020

Noel Brewer, PhD
Professor, Department of Health Behavior
Gillings School of Global Public Health
University of North Carolina at Chapel Hill

Dear Dr. Brewer,

I would like to express my enthusiastic support for your NCI P01 Proposal "Improving Provider Announcement Communication Training (IMPACT)" Program Project. I am pleased to serve as a co-investigator in the Intervention Core, Administrative Core and Projects 1-4 of the Program Project. The proposed research projects offer an excellent opportunity to examine novel strategies for improving provider communication about HPV vaccination, especially among rural populations. I look forward to the opportunity to contribute to this effort.

In the event of funding, I will support the Program Project in several ways. Primarily, I will consult the Intervention Core on strategies for effective implementation of intervention components and enhancing the evidence-based Announcement Approach Training for use with a variety of healthcare settings and providers. I will lead coordination of the Clinical Advisory Board and will consult on the harmonization of data collection across projects. Additionally, I will advise the Program Project on how to meaningfully translate evidence from the research projects into tools that can be disseminated and implemented in a variety of healthcare settings.

As a health services researcher and implementation scientist with over fifteen years of experience in quality improvement, innovations in cancer care, and translating evidence into practice, I am well suited for this role. My work has focused on implementation of evidence-based practices, healthcare delivery, and the application of implementation theories to deliver patient-centered care. I have collaborated on or led numerous federally-funded projects that examine optimization of cancer care and prevention and other preventive health services to rural populations.

Finding novel and effective ways to increase HPV vaccination is critical to decreasing the burden of HPV-related cancers in the US. Key to this is examining ways to successfully implement strategies for improving provider vaccine recommendations. You and your team have the track

Medical Center Boulevard | Winston-Salem, NC 27157 | p 336.713.5084

record and experience in developing novel ways to improve provider HPV vaccine communication. I look forward to contributing my expertise to this effort and to collaborating with the entire Program Project team.

Sincerely,

Sarah A. Birken, PhD

RESOURCE SHARING PLAN – Intervention Core

We agree with the NIH principle that data sharing is essential for expedited translation of research results into knowledge, products, and procedures to improve human health. All projects and cores will follow the same procedures. We will make data collection instruments available online for public use after data collection and analyses are complete. Leads of the research projects and the Data Core will oversee sharing of de-identified data produced by the Program Project. Dr. Brewer will oversee this process.

The Intervention Core is primarily responsible for supporting the Program Project's research projects' implementation, evaluation, and dissemination and does not have plans to be the primary home of any data generated by this Program Project. The research projects will be responsible for data sharing as it relates to their trials. For protocols on sharing these data, see the Resource Sharing Plans for the individual projects and overall Program.

OMB Number: 4040-0010
Expiration Date: 12/31/2022

APPLICATION FOR FEDERAL ASSISTANCE
SF 424 (R&R)

5. APPLICANT INFORMATION **Organizational DUNS*:** 608195277

Legal Name*:	The University of North Carolina at Chapel Hill
Department:	Office of Sponsored Research
Division:	Research
Street1*:	104 Airport Drive
Street2:	Campus Box 1350
City*:	Chapel Hill
County:	Orange
State*:	NC: North Carolina
Province:	
Country*:	USA: UNITED STATES
ZIP / Postal Code*:	27599-1350

Person to be contacted on matters involving this application

Prefix:	First Name*:	Middle Name:	Last Name*:	Suffix:
	Andrea		Cogdill	

Position/Title:	Grants Analyst
Street1*:	130 Mason Farm Road
Street2:	CB 9525, Bioinformatics Bldg.
City*:	Chapel Hill
County:	Orange
State*:	NC: North Carolina
Province:	
Country*:	USA: UNITED STATES
ZIP / Postal Code*:	27599-9525

Phone Number*: (919) 962-3950 Fax Number: (919) 843-7094 Email: grants@unc.edu

7. TYPE OF APPLICANT* H: Public/State Controlled Institution of Higher Education

Other (Specify):

Small Business Organization Type ❍ Women Owned ❍ Socially and Economically Disadvantaged

11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT*
Data Core – Improving Provider Announcement Communication Training (IMPACT)

12. PROPOSED PROJECT

Start Date*	Ending Date*
07/01/2021	06/30/2026

OMB Number: 4040-0010
Expiration Date: 12/31/2022

Project/Performance Site Location(s)

Project/Performance Site Primary Location

❍ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name:	The University of North Carolina at Chapel Hill
Duns Number:	608195277
Street1*:	104 Airport Drive
Street2:	Campus Box 1350
City*:	Chapel Hill
County:	Orange
State*:	NC: North Carolina
Province:	
Country*:	USA: UNITED STATES
Zip / Postal Code*:	27599-1350
Project/Performance Site Congressional District*:	NC-004

Project/Performance Site Location 1

❍ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name:	WebMD
DUNS Number:	602670742
Street1*:	395 Hudson Street, 3rd Floor
Street2:	
City*:	New York
County:	
State*:	NY: New York
Province:	
Country*:	USA: UNITED STATES
Zip / Postal Code*:	20014-0000
Project/Performance Site Congressional District*:	NY-010

Additional Location(s) File Name:

Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED Other Project Information

1. Are Human Subjects Involved?* ● **Yes** ○ **No**

1.a. If YES to Human Subjects

Is the Project Exempt from Federal regulations? ○ Yes ● No

If YES, check appropriate exemption number: _ 1 _ 2 _ 3 _ 4 _ 5 _ 6 _ 7 _ 8

If NO, is the IRB review Pending? ○ **Yes** ○ **No**

IRB Approval Date:

Human Subject Assurance Number 00004801

2. Are Vertebrate Animals Used?* ○ **Yes** ● **No**

2.a. If YES to Vertebrate Animals

Is the IACUC review Pending? ○ Yes ○ No

IACUC Approval Date:

Animal Welfare Assurance Number

3. Is proprietary/privileged information included in the application?* ○ **Yes** ● **No**

4.a. Does this project have an actual or potential impact - positive or negative - on the environment?* ○ **Yes** ● **No**

4.b. If yes, please explain:

4.c. If this project has an actual or potential impact on the environment, has an exemption been authorized or an environmental assessment (EA) or environmental impact statement (EIS) been performed? ○ Yes ○ No

4.d. If yes, please explain:

5. Is the research performance site designated, or eligible to be designated, as a historic place?* ○ **Yes** ● **No**

5.a. If yes, please explain:

6. Does this project involve activities outside the United States or partnership with international collaborators?* ○ **Yes** ● **No**

6.a. If yes, identify countries:

6.b. Optional Explanation:

	Filename
7. Project Summary/Abstract*	AbstractDCr1045595127.pdf
8. Project Narrative*	NarrativeDCr1045595131.pdf
9. Bibliography & References Cited	ReferencesDCr1045595123.pdf
10.Facilities & Other Resources	FacilitiesDCr1045595124.pdf
11.Equipment	EquipmentDCr1045595130.pdf
12. Other Attachments	AcronymsDCr1045595133.pdf

Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

ABSTRACT – Data Core

The Data Core will centralize data-related services across research projects for the P01 Program Project, “Improving Provider Announcement Communication Training (IMPACT),” at the University of North Carolina. The IMPACT Program Project will make a significant contribution to cancer prevention by developing new evidence on effective strategies to improve provider communication and human papillomavirus (HPV) vaccine uptake. Drs. Justin Trogdon and Nisha Gottfredson will be the co-leads of the Data Core. The Data Core’s functions include managing a national primary care team survey, cleaning and standardizing effectiveness data across research projects and providing statistical support for randomization and analysis. The three Specific Aims of the Data Core are as follows. **Aim 1 is to develop, oversee, and manage the national primary care team survey.** The Data Core will survey 2,500 primary care team members: 1,500 HPV vaccine providers (physicians, physician assistants, and nurse practitioners) and 1,000 registered nurses and medical assistants involved in adolescent vaccination. The Data Core will be responsible for coordinating and integrating survey measures for use across projects, collaborating with the survey subcontractor to oversee survey implementation, and managing and preparing data for use by the research projects. **Aim 2 is to facilitate access to, and standardize the structure of, large vaccination datasets generated by research project randomized clinical trials.** The Data Core will be a central hub for managing, harmonizing, storing, and distributing randomized clinical trial vaccine outcomes data that will be used to evaluate intervention impact across Projects 1 through 3. The Core will also provide the resulting data to Project 4 to support budget impact and cost-effectiveness modelling. **Aim 3 is to provide statistical and methodological support to research projects.** The Data Core team will connect project investigators with appropriate statistical and study design expertise to design and consult on analyses as needed by the research projects. The Data Core activities will result in a national primary care team survey, high-quality, standardized data and appropriate and rigorous statistical analysis in an efficient manner that will increase the collective scientific impact of the P01 Program Project. The Data Core addresses the **IMPACT Program Project theme** by helping the research projects to build capacity for HPV vaccine communication interventions among primary care teams in healthcare systems.

NARRATIVE – Data Core

The Data Core will centralize data-related services across research projects for the P01 Program Project. The Data Core's functions include managing a national primary care team survey, cleaning and standardizing effectiveness data across research projects and providing statistical support for randomization and analysis.

FACILITIES AND OTHER RESOURCES – Data Core

Refer to Overall Component for both Data Core and WebMD Facilities and Other Resources.

EQUIPMENT – Data Core

None.

LIST OF ACRONYMS – Data Core

AAT	Announcement Approach Training
AMA	American Medical Association
CASRO	Council of American Survey Research Organizations
EHR	Electronic health records
ESOMAR	European Society for Opinion and Marketing Research
HPV	Human papillomavirus
ICC	Intra-class correlation
ICD-10	International Classification of Diseases, 10th Edition
IMPACT	Improving Provider Announcement Communication Training
LCCC	Lineberger Comprehensive Cancer Center
RCT	Randomized clinical trial
RUCC	Rural-Urban Continuum Codes
UNC	University of North Carolina
US	United States

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED Senior/Key Person Profile (Expanded)

PROFILE - Project Director/Principal Investigator

Prefix: First Name*: Nisha Middle Name Claire Last Name*: Gottfredson Suffix:

Position/Title*: Assistant Professor
Organization Name*: The University of North Carolina at Chapel Hill
Department: Health Behavior
Division: Gillings Sch. of Public Hlth
Street1*: 319C Rosenau Hall
Street2: CB 7440
City*: Chapel Hill
County: Orange
State*: NC: North Carolina
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 27599-7440

Phone Number*: (919) 445-9385 Fax Number: (919) 966-4520

E-Mail*: gottfredson@unc.edu

Credential, e.g., agency login: eRA COMMONS USER NAME

Project Role*: Other (Specify) Other Project Role Category: Core Lead

Degree Type: PhD Degree Year: 2011

Attach Biographical Sketch*: File Name: BioGottfredsonDCr1045595132.pdf

Attach Current & Pending Support: File Name:

Tracking Number: GRANT13205496 Funding Opportunity Number: PAR-20-077 . Received Date: 2020-09-18T11:41:16.000-04:00

PROFILE - Senior/Key Person

Prefix: First Name*: Justin Middle Name G. Last Name*: Trogdon Suffix:

Position/Title*: Professor
Organization Name*: The University of North Carolina at Chapel Hill
Department: Health Policy and Management
Division: Gillings Sch. of Public Hlth
Street1*: 1101-B McGavran-Greenberg
Street2: 135 Dauer Drive, CB 7411
City*: Chapel Hill
County: Orange
State*: NC: North Carolina
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 27599-7411

Phone Number*: (919) 962-2433 Fax Number: (919) 843-6380

E-Mail*: justintrogdon@unc.edu

Credential, e.g., agency login: eRA COMMONS USER NAME

Project Role*: Other (Specify) Other Project Role Category: Co-Core Lead

Degree Type: PhD Degree Year: 2004

Attach Biographical Sketch*: File Name:

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Noel Middle Name T. Last Name*: Brewer Suffix:

Position/Title*: Professor
Organization Name*: The University of North Carolina at Chapel Hill
Department: Health Behavior
Division: Gillings Sch. of Public Hlth
Street1*: 325 Rosenau Hall
Street2: CB 7440
City*: Chapel Hill
County: Orange
State*: NC: North Carolina
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 27599-7440

Phone Number*: (919) 966-3282 Fax Number: (919) 966-2921

E-Mail*: ntb@unc.edu

Credential, e.g., agency login: eRA COMMONS USER NAME

Project Role*: Co-Investigator Other Project Role Category:

Degree Type: PhD Degree Year: 2002

Attach Biographical Sketch*: File Name:

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Joseph Middle Name G. Last Name*: Ibrahim Suffix:

Position/Title*: Professor
Organization Name*: The University of North Carolina at Chapel Hill
Department: Biostatistics
Division: Gillings Sch. of Public Health
Street1*: 3109 McGavran-Greenberg Hall
Street2: CB7420
City*: Chapel Hill
County: Orange
State*: NC: North Carolina
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 27599-7420

Phone Number*: (919) 843-2715 Fax Number: (919) 966-3804

E-Mail*: ibrahim@bios.unc.edu

Credential, e.g., agency login: eRA COMMONS USER NAME

Project Role*: Co-Investigator Other Project Role Category:

Degree Type: PhD Degree Year: 1988

Attach Biographical Sketch*: File Name: BioIbrahimDCr1045595134.pdf

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Audrey Middle Name Last Name*: Rosen Suffix:

Position/Title*: Vice President, Market Research
Organization Name*: WebMD
Department:
Division:
Street1*: 395 Hudson Street
Street2: 3rd Floor
City*: New York
County:
State*: NY: New York
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 10014-0000

Phone Number*: (646) 856-3860 Fax Number:

E-Mail*: arosen@webmd.net

Credential, e.g., agency login:

Project Role*: Other (Specify) Other Project Role Category: Project Oversight

Degree Type: MBA Degree Year: 1992

Attach Biographical Sketch*: File Name: BioRosenDCr1045595383.pdf

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Stanislav Middle Name Last Name*: Zakharkin Suffix:

Position/Title*: Associate Director
Organization Name*: WebMD
Department: Marketing Science
Division:
Street1*: 395 Hudson Street
Street2: 3rd Floor
City*: New York
County:
State*: NY: New York
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 10014-0000

Phone Number*: (212) 417-9988 Fax Number:

E-Mail*: szakharkin@webmd.net

Credential, e.g., agency login:

Project Role*: Other (Specify) Other Project Role Category: Statistical Lead

Degree Type: PhD Degree Year: 2002

Attach Biographical Sketch*: File Name: BioZakharkinDCr1045595381.pdf

Attach Current & Pending Support: File Name:

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 1

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2021 **End Date*:** 06-30-2022 **Budget Period: 1**

A. Senior/Key Person

Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.	Nisha	Claire	Gottfredson		Core Lead	CAL. MONTHS, INST. BASE SALARY				16,271.00	5,189.00	21,460.00
2.	Justin	G.	Trogdon		Co-Investigator					13,238.00	3,948.00	17,186.00
3.	Noel	T	Brewer		Co-Investigator					9,362.00	2,749.00	12,111.00
4.	Joseph	G	Ibrahim		Co-Investigator					19,730.00	5,759.00	25,489.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **76,246.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
1	Graduate Students	6			12,780.00	3,282.00	16,062.00
	Undergraduate Students						
	Secretarial/Clerical						
1	Project Manager	3.36			18,746.00	6,677.00	25,423.00
1	Statistician (Survey)	3			20,387.00	6,906.00	27,293.00
3	**Total Number Other Personnel**					**Total Other Personnel**	**68,778.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**145,024.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 1

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2021 **End Date*:** 06-30-2022 **Budget Period: 1**

C. Equipment Description	
List items and dollar amount for each item exceeding $5,000	
Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	
Additional Equipment: File Name:	

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	
2. Foreign Travel Costs	
Total Travel Cost	

E. Participant/Trainee Support Costs		**Funds Requested ($)***
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other:		
Number of Participants/Trainees	**Total Participant Trainee Support Costs**	

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 1

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2021 **End Date*:** 06-30-2022 **Budget Period: 1**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	5,417.00
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	206,386.00
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8. Tuition	5,346.00
Total Other Direct Costs	**217,149.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**362,173.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. Organized Research_On Campus	55.5	175,441.00	97,370.00
		Total Indirect Costs	**97,370.00**

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number): DHHS, Darryl Mayes, 202-401-2808

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**459,543.00**

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	459,543.00

L. Budget Justification* File Name: BudgetJustificationDCrV31045711695.pdf (Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

Tracking Number: GRANT13205496 Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 2

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2022 **End Date*:** 06-30-2023 **Budget Period: 2**

A. Senior/Key Person

Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.	Nisha	Claire	Gottfredson		Core Lead	CAL. MONTHS, INST. BASE SALARY				19,525.00	6,227.00	25,752.00
2.	Justin	G.	Trogdon		Co-Investigator					16,547.00	4,935.00	21,482.00
3.	Noel	T.	Brewer		Co-Investigator					0.00	0.00	0.00
4.	Joseph	G.	Ibrahim		Co-Investigator					19,730.00	5,759.00	25,489.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **72,723.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
1	Graduate Students	6			12,780.00	3,282.00	16,062.00
	Undergraduate Students						
	Secretarial/Clerical						
1	Statistician (Programmer)	3			23,740.00	7,774.00	31,514.00
1	Project Manager	2.4			13,390.00	4,769.00	18,159.00
1	Statistician (Survey)	3			20,387.00	6,906.00	27,293.00
4	**Total Number Other Personnel**					**Total Other Personnel**	**93,028.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**165,751.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 2

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2022 **End Date*:** 06-30-2023 **Budget Period: 2**

C. Equipment Description	
List items and dollar amount for each item exceeding $5,000	
Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	
Additional Equipment: File Name:	

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	
2. Foreign Travel Costs	
Total Travel Cost	

E. Participant/Trainee Support Costs		**Funds Requested ($)***
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other:		
Number of Participants/Trainees	**Total Participant Trainee Support Costs**	

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 2

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2022 **End Date*:** 06-30-2023 **Budget Period: 2**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	3,417.00
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8. Tuition	5,506.00
9. Other Costs	1,000.00
Total Other Direct Costs	**9,923.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**175,674.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. Organized Research_On Campus	55.5	170,168.00	94,443.00
		Total Indirect Costs	**94,443.00**

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number): DHHS, Darryl Mayes, 202-401-2808

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**270,117.00**

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	270,117.00

L. Budget Justification* File Name: BudgetJustificationDCrV31045711695.pdf

(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

Tracking Number: GRANT13205496 Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 3

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2023 **End Date*:** 06-30-2024 **Budget Period: 3**

A. Senior/Key Person

Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.	Nisha	Claire	Gottfredson		Core Lead	CAL. MONTHS, INST. BASE SALARY				19,525.00	6,227.00	25,752.00
2.	Justin	G.	Trogdon		Co-Investigator					18,202.00	5,429.00	23,631.00
3.	Noel	T.	Brewer		Co-Investigator					0.00	0.00	0.00
4.	Joseph	G.	Ibrahim		Co-Investigator					19,730.00	5,759.00	25,489.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **74,872.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
1	Graduate Students	6			12,780.00	3,282.00	16,062.00
	Undergraduate Students						
	Secretarial/Clerical						
1	Statistician (Programmer)	3			23,740.00	7,774.00	31,514.00
1	Project Manager	2.4			13,390.00	4,769.00	18,159.00
3	**Total Number Other Personnel**					**Total Other Personnel**	**65,735.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**140,607.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 3

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2023 **End Date*:** 06-30-2024 **Budget Period: 3**

C. Equipment Description	
List items and dollar amount for each item exceeding $5,000	
Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	
Additional Equipment: File Name:	

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	
2. Foreign Travel Costs	
Total Travel Cost	

E. Participant/Trainee Support Costs		**Funds Requested ($)***
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other:		
Number of Participants/Trainees	**Total Participant Trainee Support Costs**	

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 3

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2023 **End Date*:** 06-30-2024 **Budget Period: 3**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	3,417.00
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8. Tuition	5,671.00
9. Other Costs	1,000.00
Total Other Direct Costs	**10,088.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**150,695.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. Organized Research_On Campus	55.5	145,024.00	80,488.00
		Total Indirect Costs	**80,488.00**

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number): DHHS, Darryl Mayes, 202-401-2808

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**231,183.00**

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	231,183.00

L. Budget Justification* File Name: BudgetJustificationDCrV31045711695.pdf

(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

Tracking Number: GRANT13205496 Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 4

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2024 **End Date*:** 06-30-2025 **Budget Period: 4**

A. Senior/Key Person

Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.	Nisha	Claire	Gottfredson		Core Lead	CAL. MONTHS, INST. BASE SALARY				20,609.00	6,573.00	27,182.00
2.	Justin	G.	Trogdon		Co-Investigator					18,202.00	5,429.00	23,631.00
3.	Noel	T.	Brewer		Co-Investigator					0.00	0.00	0.00
4.	Joseph	G.	Ibrahim		Co-Investigator					19,730.00	5,759.00	25,489.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **76,302.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
1	Graduate Students	12			25,560.00	6,563.00	32,123.00
	Undergraduate Students						
	Secretarial/Clerical						
1	Statistician (Programmer)	3			23,740.00	7,774.00	31,514.00
1	Project Manager	3			13,390.00	4,769.00	18,159.00
3	**Total Number Other Personnel**					**Total Other Personnel**	**81,796.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**158,098.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 4

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2024 **End Date*:** 06-30-2025 **Budget Period: 4**

C. Equipment Description	
List items and dollar amount for each item exceeding $5,000	
Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	
Additional Equipment: File Name:	

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	
2. Foreign Travel Costs	
Total Travel Cost	

E. Participant/Trainee Support Costs		**Funds Requested ($)***
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other:		
Number of Participants/Trainees	**Total Participant Trainee Support Costs**	

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 4

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2024 **End Date*:** 06-30-2025 **Budget Period: 4**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	6,417.00
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8. Tuition	11,682.00
9. Other Costs	1,000.00
Total Other Direct Costs	**19,099.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**177,197.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. Organized Research_On Campus	55.5	165,515.00	91,861.00
		Total Indirect Costs	**91,861.00**

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number): DHHS, Darryl Mayes, 202-401-2808

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**269,058.00**

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	269,058.00

L. Budget Justification* File Name: BudgetJustificationDCrV31045711695.pdf

(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 5

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2025 **End Date*:** 06-30-2026 **Budget Period: 5**

A. Senior/Key Person

Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.	Nisha	Claire	Gottfredson		Core Lead	CAL. MONTHS, INST. BASE SALARY				21,694.00	6,919.00	28,613.00
2.	Justin	G.	Trogdon		Co-Investigator					18,202.00	5,429.00	23,631.00
3.	Noel	T.	Brewer		Co-Investigator					0.00	0.00	0.00
4.	Joseph	G.	Ibrahim		Co-Investigator					19,730.00	5,759.00	25,489.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **77,733.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
1	Graduate Students	12			25,560.00	6,563.00	32,123.00
	Undergraduate Students						
	Secretarial/Clerical						
1	Statistician (Programmer)	3			23,740.00	7,774.00	31,514.00
1	Project Manager	2.4			13,390.00	4,769.00	18,159.00
3	**Total Number Other Personnel**					**Total Other Personnel**	**81,796.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**159,529.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 5

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2025 **End Date*:** 06-30-2026 **Budget Period: 5**

C. Equipment Description	
List items and dollar amount for each item exceeding $5,000	
Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	
Additional Equipment: File Name:	

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	
2. Foreign Travel Costs	
Total Travel Cost	

E. Participant/Trainee Support Costs		**Funds Requested ($)***
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other:		
Number of Participants/Trainees	**Total Participant Trainee Support Costs**	

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 5

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2025 **End Date*:** 06-30-2026 **Budget Period: 5**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	3,417.00
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8. Tuition	12,033.00
9. Other Costs	1,000.00
Total Other Direct Costs	**16,450.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**175,979.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. Organized Research_On Campus	55.5	163,946.00	90,990.00
		Total Indirect Costs	**90,990.00**

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number): DHHS, Darryl Mayes, 202-401-2808

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**266,969.00**

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	266,969.00

L. Budget Justification* File Name: BudgetJustificationDCrV31045711695.pdf

(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

Tracking Number: GRANT13205496 Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

BUDGET JUSTIFICATION – Data Core

Key Personnel

Nisha C. Gottfredson, PhD, Core Co-Lead

Year 1	Year 2	Year 3	Year 4	Year 5
CAL. MONTHS				

Dr. Gottfredson will serve as Core Co-Lead for the Data Core. Dr. Gottfredson is an Assistant Professor of Health Behavior in the UNC Gillings School of Global Public Health. As Co-Lead, Dr. Gottfredson will have overall budgetary and administrative for the Data Core and will coordinate and implement activities essential to carrying out the aims and achieving the core's goals. These activities include meeting with co-investigators, supervising project staff, coordinating the work of external advisors, overseeing data collection, and overseeing data analysis. Dr. Gottfredson will be the contact lead, responsible for the Data Core's administration, reports to the funding agency, and interface with IMPACT research projects and cores. She will also oversee the national provider survey (Aim 1) and provide analytic consultation for Projects (Aim 3).

Justin Trogdon, PhD, Core Co-Lead

Year 1	Year 2	Year 3	Year 4	Year 5
CAL. MONTHS				

Dr. Trogdon will serve as Core Co-Lead for the Data Core. Dr. Trogdon is a Professor of Health Policy and Management in the UNC Gillings School of Global Public Health. He has been a Principal Investigator on 16 funded research grants and contracts, including two R01 awards, totaling nearly $12 million in total costs. His HPV vaccine research includes geospatial analysis of HPV vaccination patterns and vaccine providers, time series estimates of the effects of the release of the latest version of the HPV vaccine, analysis of claims and survey data to assess the effects of state-level policies on HPV vaccination, and costing and cost-effectiveness modelling of interventions to increase HPV vaccination. As Co-Lead, Dr. Trogdon will have overall budgetary and administrative for the Data Core and will coordinate and implement activities essential to carrying out the aims and achieving the core's goals. These activities include meeting with co-investigators, supervising project staff, coordinating the work of external advisors, overseeing data collection, and overseeing data analysis. Dr. Trogdon will oversee Aim 2, facilitating access to and standardizing the structure of large datasets.

Noel Brewer, PhD, Co-Investigator

Year 1	Year 2	Year 3	Year 4	Year 5
CAL. MONTHS				

Dr. Brewer will serve as Co-Investigator for the Data Core. Dr. Brewer is a Professor of Health Behavior in the UNC Gillings School of Global Public Health and the P01 Program Principal Investigator. Dr. Brewer will consult on the development and implementation of the national primary care team survey.

Joseph Ibrahim, PhD, Co-Investigator

Year 1	Year 2	Year 3	Year 4	Year 5
CAL. MONTHS				

Dr. Ibrahim will serve as Co-Investigator for the Data Core. Dr. Ibrahim is a Distinguished Professor of Biostatistics in the UNC Gillings School of Global Public Health. He has extensive clinical trial experience and will assist in the design and analysis plans for project RCTs (Aim 3). *Dr. Ibrahim's salary is over the current NIH Salary Cap, and his budget allocation is entered at the NIH Salary Cap.*

Other Personnel

TBD, Statistician (Programmer)

Year 1	Year 2	Year 3	Year 4	Year 5
-	3.0 CM	3.0 CM	3.0 CM	3.0 CM

The Statistician Programmer will be the lead programmer and database manager for Aim 2 (integration of large data streams). As a Programmer for this study, they will assist with data cleaning and data analysis for the electronic health records and immunization information system data.

TBD, Statistician (Survey)

Year 1	Year 2	Year 3	Year 4	Year 5
3.0 CM	3.0 CM	-	-	-

The Survey Statistician will be responsible for managing, documenting, and cleaning survey data. They will also provide projects with descriptive reports from National Survey data.

TBD, Project Manager

Year 1	Year 2	Year 3	Year 4	Year 5
3.36 CM	2.4 CM	2.4 CM	2.4 CM	2.4 CM

The Project Manager will assist Drs. Gottfredson and Trogdon with administration, scheduling, budgeting, and other tasks to ensure core tasks are completed on time and within budget. The Project Manager will manage the project budget, oversee IRB protocols, and prepare progress reports.

TBD, Graduate Research Assistant

Year 1	Year 2	Year 3	Year 4	Year 5
6.0CM	6.0CM	6.0CM	12 CM	12 CM

The Graduate Research Assistant will have training in bioinformatics and biostatistics. They will assist Dr. Trogdon and the Programmer with data management, standardization, visualization, and analysis for Aim 2. They will also assist project directors with analysis of RCT data for Aim 3.

Total Expenses for Personnel=$769,009

Fringe Benefits

Fringe benefits associated with the salary request for this budget has been calculated in accordance with our Institution's DHHS Rate Agreement. The University of North Carolina at Chapel Hill applies appropriate fringe benefit rates to the personnel on this proposal: Basic permanent employee benefits are **25.889%** of annual salary plus **$6,512/FTE/YR** for fixed health insurance. Graduate Student employee benefits are **9.490%** of annual salary plus **$4,137.60/FTE/YR** for fixed health insurance.

Supplies

Data Storage

Year 1	Year 2	Year 3	Year 4	Year 5	Total
$3,000	$1,000	$1,000	$4,000	$1,000	$10,000

Two computers for staff will be purchased in Year 1 ($1,500 X 2 computers = $3,000 in Year 1). After their warranties expire, two additional computers will be purchased in Year 4 ($1,500 X 2 computers = $3,000 in Year 4). Costs for secure server space for the large databases for Aim 2 are budgeted at $1,000 in Years 2-5.

Software

Year 1	Year 2	Year 3	Year 4	Year 5	Total
$1,800	$1,800	$1,800	$1,800	$1,800	$9,000

Statistical and reference management software will be purchased for up to 3 computers as necessary in Years 1-5. The software will be used to perform data analyses as described in Aims 1-3, as well as to manage references to aid in dissemination of study findings. ($600 per license x 3 computers = $1,800 per year).

Computer Service Fees

Year 1	Year 2	Year 3	Year 4	Year 5	Total
$617	$617	$617	$617	$617	$3,085

We have budgeted $3,085 for computer service fees in Years 1-5. The Department of Biostatistics distributes the cost of maintaining its shared computing infrastructure among all projects through its Computer Services Recharge Center. Rates are calculated based upon salary distributions of personnel in the Department of Biostatics ($6,170/FTE). Computer Service Fees apply to Dr. Ibrahim for his effort in Years 1-5.

Total Expenses for Supplies=$22,085

Tuition

Year 1	Year 2	Year 3	Year 4	Year 5	Total
$5,346	$5,506	$5,671	$11,682	$12,033	$40,238

We will provide annual in-state tuition at the UNC Gillings School of Global Public Health to the Graduate Research Assistant as compensation for work in Years 1-5. Tuition cost is based on the Department of Health Policy and Management tuition rate. Tuition support is calculated by multiplying the graduate student's predicted percent effort on the project times the tuition cost of his/her graduate program.

Total Expenses for Tuition=$40,238

Other Expenses

Data Use Agreements

Year 1	Year 2	Year 3	Year 4	Year 5	Total
-	$1,000	$1,000	$1,000	$1,000	$4,000

Costs to enter into data use agreements and work with vendors to access the large databases required for Aim 2 are budgeted in Years 2-5.

Total Expenses for Other Expenses=$4,000

Indirect Costs

At UNC-Chapel Hill, F&A costs are calculated on a Modified Total Direct Costs (MTDC) base. This base consists of all direct salaries and wages, applicable fringe benefits, materials and supplies, services, travel and up to the first $25,000 of each subaward (regardless of the period of performance of the subawards under the award). Modified total direct costs shall exclude equipment, capital expenditures, charges for patient care, rental costs, tuition remission, scholarships and fellowships, participant support costs and the portion of each subaward in excess of $25,000.

Per UNC-Chapel Hill's current federally negotiated rate agreement (dated 11/23/2016), F&A costs associated with the proposed research project are calculated at the approved on-campus research rate of 55.5% of MTDC in all years. The cognizant agency for UNC-Chapel Hill is the U.S. Department of Health and Human Services. The cognizant agency point of contact is Darryl Mayes, (202) 401-2808.

Consortium/Contractual Costs

WebMD

Year 1	Year 2	Year 3	Year 4	Year 5	Total
$206,385	-	-	-	-	$206,385

WebMD will conduct the national primary care team survey (Aim 1). To our knowledge, WebMD is the only survey company in the US that can provide large samples of HPV vaccine providers, registered nurses and medical assistants from across all regions of the United States, as well as a substantial sample of rural providers. WebMD will recruit 2500 healthcare professionals who are involved in HPV vaccination for adolescent patients in primary care settings. We propose to include 1,500 HPV vaccine providers (physicians, physician assistants and nurse practitioners) and 1,000 registered nurses and medical assistants. WebMD will pretest and screen the questionnaire using in-depth phone interviews with physicians and supporting providers. Next, they will conduct a soft launch with 25 providers, allowing the Data Core and projects to check that skip patterns are yielding the expected data. WebMD expects to field survey for approximately 25 days. They will provide the survey responses electronically, using a password protected online data vault. The WebMD subcontract budget provides a more detailed accounting of costs.

Total Expenses for Consortium/Contractual Costs=$206,385

RESEARCH & RELATED BUDGET - Cumulative Budget

	Totals ($)	
Section A, Senior/Key Person		377,876.00
Section B, Other Personnel		391,133.00
Total Number Other Personnel	16	
Total Salary, Wages and Fringe Benefits (A+B)		769,009.00
Section C, Equipment		
Section D, Travel		
1. Domestic		
2. Foreign		
Section E, Participant/Trainee Support Costs		
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other		
6. Number of Participants/Trainees		
Section F, Other Direct Costs		272,709.00
1. Materials and Supplies	22,085.00	
2. Publication Costs		
3. Consultant Services		
4. ADP/Computer Services		
5. Subawards/Consortium/Contractual Costs	206,386.00	
6. Equipment or Facility Rental/User Fees		
7. Alterations and Renovations		
8. Other 1	40,238.00	
9. Other 2	4,000.00	
10. Other 3		
Section G, Direct Costs (A thru F)		1,041,718.00
Section H, Indirect Costs		455,152.00
Section I, Total Direct and Indirect Costs (G + H)		1,496,870.00
Section J, Fee		
Section K, Total Direct and Fee (I + J)		1,496,870.00

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 1

ORGANIZATIONAL DUNS*: 6026707420000

Budget Type*: ○ Project ● Subaward/Consortium

Enter name of Organization: WebMD

Start Date*: 07-01-2021 **End Date*:** 06-30-2022 **Budget Period: 1**

A. Senior/Key Person

Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.	Stanislav		Zakharkin		Statistical Lead		CAL. MONTHS			2,531.00	844.00	3,375.00
2.	Audrey		Rosen		Project-Oversight					2,719.00	906.00	3,625.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name: **Total Senior/Key Person** **7,000.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
1	Senior Research Manager	0.17			2,813.00	938.00	3,751.00
1	Research Manager	0.47			6,225.00	2,075.00	8,300.00
1	Survey Programmer	0.17			2,250.00	750.00	3,000.00
3	**Total Number Other Personnel**					**Total Other Personnel**	**15,051.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**22,051.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 1

ORGANIZATIONAL DUNS*: 6026707420000
Budget Type*: ❍ Project ● Subaward/Consortium
Enter name of Organization: WebMD

Start Date*: 07-01-2021 **End Date*:** 06-30-2022 **Budget Period: 1**

C. Equipment Description	
List items and dollar amount for each item exceeding $5,000	
Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	

Additional Equipment: File Name:

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	0.00
2. Foreign Travel Costs	0.00
Total Travel Cost	**0.00**

E. Participant/Trainee Support Costs		**Funds Requested ($)***
1. Tuition/Fees/Health Insurance		0.00
2. Stipends		0.00
3. Travel		0.00
4. Subsistence		0.00
5. Other:		
Number of Participants/Trainees	**Total Participant Trainee Support Costs**	**0.00**

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 1

ORGANIZATIONAL DUNS*: 6026707420000

Budget Type*: ❍ Project ● Subaward/Consortium

Enter name of Organization: WebMD

Start Date*: 07-01-2021 **End Date*:** 06-30-2022 **Budget Period: 1**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8. Panel Costs	57,285.00
9. Panel Incentives	113,450.00
10. Other Field Costs and pre tests	13,600.00
Total Other Direct Costs	**184,335.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**206,386.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
		Total Indirect Costs	

Cognizant Federal Agency
(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**206,386.00**

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	206,386.00

L. Budget Justification*	File Name: BudgetJustificationDCWebMDr1045595137.pdf (Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 2

ORGANIZATIONAL DUNS*: 6026707420000

Budget Type*: ○ Project ● Subaward/Consortium

Enter name of Organization: WebMD

Start Date*: 07-01-2022 **End Date*:** 06-30-2023 **Budget Period: 2**

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.		Stanislav		Zakharkin	PhD	Statistical Lead		CAL. MONTHS			0.00	0.00	0.00
2.		Audrey		Rosen		Project Oversight					0.00	0.00	0.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **0.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Total Number Other Personnel					**Total Other Personnel**	
						Total Salary, Wages and Fringe Benefits (A+B)	**0.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 2

ORGANIZATIONAL DUNS*: 6026707420000
Budget Type*: ❍ Project ● Subaward/Consortium
Enter name of Organization: WebMD

Start Date*: 07-01-2022 **End Date*:** 06-30-2023 **Budget Period: 2**

C. Equipment Description	
List items and dollar amount for each item exceeding $5,000	
Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	

Additional Equipment: File Name:

D. Travel	Funds Requested ($)*
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	0.00
2. Foreign Travel Costs	0.00
Total Travel Cost	**0.00**

E. Participant/Trainee Support Costs		Funds Requested ($)*
1. Tuition/Fees/Health Insurance		0.00
2. Stipends		0.00
3. Travel		0.00
4. Subsistence		0.00
5. Other:		
Number of Participants/Trainees	**Total Participant Trainee Support Costs**	**0.00**

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 2

ORGANIZATIONAL DUNS*: 6026707420000
Budget Type*: ❍ Project ● Subaward/Consortium
Enter name of Organization: WebMD

Start Date*: 07-01-2022 **End Date*:** 06-30-2023 **Budget Period: 2**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
Total Other Direct Costs	**0.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**0.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
		Total Indirect Costs	

Cognizant Federal Agency
(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**0.00**

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	0.00

L. Budget Justification*	File Name: BudgetJustificationDCWebMDr1045595137.pdf (Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 3

ORGANIZATIONAL DUNS*: 6026707420000

Budget Type*: ○ Project ● Subaward/Consortium

Enter name of Organization: WebMD

Start Date*: 07-01-2023 **End Date*:** 06-30-2024 **Budget Period: 3**

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.		Stanislav		Zakharkin	PhD	Statistical Lead		CAL. MONTHS			0.00	0.00	0.00
2.		Audrey		Rosen		Project Oversight					0.00	0.00	0.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **0.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Total Number Other Personnel					**Total Other Personnel**	
						Total Salary, Wages and Fringe Benefits (A+B)	**0.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 3

ORGANIZATIONAL DUNS*: 6026707420000
Budget Type*: ❍ Project ● Subaward/Consortium
Enter name of Organization: WebMD

Start Date*: 07-01-2023 **End Date*:** 06-30-2024 **Budget Period: 3**

C. Equipment Description	
List items and dollar amount for each item exceeding $5,000	
Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	

Additional Equipment: File Name:

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	0.00
2. Foreign Travel Costs	0.00
Total Travel Cost	**0.00**

E. Participant/Trainee Support Costs		**Funds Requested ($)***
1. Tuition/Fees/Health Insurance		0.00
2. Stipends		0.00
3. Travel		0.00
4. Subsistence		0.00
5. Other:		
Number of Participants/Trainees	**Total Participant Trainee Support Costs**	**0.00**

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 3

ORGANIZATIONAL DUNS*: 6026707420000
Budget Type*: ❍ Project ● Subaward/Consortium
Enter name of Organization: WebMD

Start Date*: 07-01-2023 **End Date*:** 06-30-2024 **Budget Period: 3**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
Total Other Direct Costs	**0.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**0.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
		Total Indirect Costs	

Cognizant Federal Agency
(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**0.00**

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	0.00

L. Budget Justification*	File Name: BudgetJustificationDCWebMDr1045595137.pdf (Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 4

ORGANIZATIONAL DUNS*: 6026707420000

Budget Type*: ○ Project ● Subaward/Consortium

Enter name of Organization: WebMD

Start Date*: 07-01-2024 **End Date*:** 06-30-2025 **Budget Period: 4**

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.		Stanislav		Zakharkin	PhD	Statistical Lead		CAL. MONTHS			0.00	0.00	0.00
2.		Audrey		Rosen		Project Oversight					0.00	0.00	0.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **0.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Total Number Other Personnel					**Total Other Personnel**	
						Total Salary, Wages and Fringe Benefits (A+B)	**0.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 4

ORGANIZATIONAL DUNS*: 6026707420000
Budget Type*: ❍ Project ● Subaward/Consortium
Enter name of Organization: WebMD

Start Date*: 07-01-2024 **End Date*:** 06-30-2025 **Budget Period: 4**

C. Equipment Description	
List items and dollar amount for each item exceeding $5,000	
Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	
Additional Equipment: File Name:	

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	0.00
2. Foreign Travel Costs	0.00
Total Travel Cost	**0.00**

E. Participant/Trainee Support Costs		**Funds Requested ($)***
1. Tuition/Fees/Health Insurance		0.00
2. Stipends		0.00
3. Travel		0.00
4. Subsistence		0.00
5. Other:		
Number of Participants/Trainees	**Total Participant Trainee Support Costs**	**0.00**

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 4

ORGANIZATIONAL DUNS*: 6026707420000
Budget Type*: ❍ Project ● Subaward/Consortium
Enter name of Organization: WebMD

Start Date*: 07-01-2024 **End Date*:** 06-30-2025 **Budget Period: 4**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
Total Other Direct Costs	**0.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**0.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
		Total Indirect Costs	

Cognizant Federal Agency
(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**0.00**

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	0.00

L. Budget Justification*	File Name: BudgetJustificationDCWebMDr1045595137.pdf (Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 5

ORGANIZATIONAL DUNS*: 6026707420000

Budget Type*: ○ Project ● Subaward/Consortium

Enter name of Organization: WebMD

Start Date*: 07-01-2025 **End Date*:** 06-30-2026 **Budget Period: 5**

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.		Stanislav		Zakharkin	PhD	Statistical lead		CAL. MONTHS			0.00	0.00	0.00
2.		Audrey		Rosen		Project Oversight					0.00	0.00	0.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **0.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Total Number Other Personnel					**Total Other Personnel**	
						Total Salary, Wages and Fringe Benefits (A+B)	**0.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 5

ORGANIZATIONAL DUNS*: 6026707420000
Budget Type*: ❍ Project ● Subaward/Consortium
Enter name of Organization: WebMD

Start Date*: 07-01-2025 **End Date*:** 06-30-2026 **Budget Period: 5**

C. Equipment Description	
List items and dollar amount for each item exceeding $5,000	
Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	

Additional Equipment: File Name:

D. Travel	Funds Requested ($)*
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	0.00
2. Foreign Travel Costs	0.00
Total Travel Cost	**0.00**

E. Participant/Trainee Support Costs		Funds Requested ($)*
1. Tuition/Fees/Health Insurance		0.00
2. Stipends		0.00
3. Travel		0.00
4. Subsistence		0.00
5. Other:		
Number of Participants/Trainees	**Total Participant Trainee Support Costs**	**0.00**

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 5

ORGANIZATIONAL DUNS*: 6026707420000
Budget Type*: ❍ Project ● Subaward/Consortium
Enter name of Organization: WebMD

Start Date*: 07-01-2025 **End Date*:** 06-30-2026 **Budget Period: 5**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
Total Other Direct Costs	**0.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**0.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
		Total Indirect Costs	

Cognizant Federal Agency
(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**0.00**

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	0.00

L. Budget Justification*	File Name: BudgetJustificationDCWebMDr1045595137.pdf (Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

BUDGET JUSTIFICATION – WebMD

WebMD will conduct the Program Project's national primary care team survey in Year 1. The WebMD subcontract is not active in Years 2-5.

Key Personnel

Stanislav Zakharkin, PhD, PStat, Associate Director Marketing Sciences, Quota management and Statistical Lead

Year 1	Year 2	Year 3	Year 4	Year 5
CAL. MONTHS				

This position will be responsible for: sample selection, ensuring that the quota goals of the project are met and ensuring the quality of the work.

Audrey Rosen, VP Market Research, Project Oversight

Year 1	Year 2	Year 3	Year 4	Year 5
CAL. MONTHS				

This position will be the liaison between WebMD and the principal investigator, providing the leadership necessary to ensure the success of the project, including the following: enforce schedule, ensure quality control, coordinate budget review, maintain close customer contact, and ensure quality of work.

TBN, Senior Research Manager

Year 1	Year 2	Year 3	Year 4	Year 5
0.30 CM	-	-	-	-

This position will serve as the project director and will be responsible for overseeing project execution. He will supervise the setting up and conducting of the project, including final development and approval of the sample design and the questionnaire programming.

TBN, Research Manager

Year 1	Year 2	Year 3	Year 4	Year 5
1.40 CM	-	-	-	-

Responsible for conducting day-to-day operations, including coordinating with the sampling statistician and programmer, overseeing client design and changes to survey instrument with internal scripting department and ensuring that Medscape survey standards are met, and processing incentive payments.

TBN, Survey Programmer

Year 1	Year 2	Year 3	Year 4	Year 5
0.17 CM	-	-	-	-

This position is responsible for all programming and technical services necessary to conduct the survey. It includes sending invitations using a proprietary scripting language, as well as processing participants' survey status on the back end.

Other Direct Costs

Other Costs

Year 1	Year 2	Year 3	Year 4	Year 5	Total
$184,335	-	-	-	-	$184,335

Other Costs are the corporately allocated costs for a specific project based on the costs of recruiting, maintaining, and using WebMD for research purposes. For a client-specific project, these costs are determined by the length of the survey, the number of cases for which completed surveys are required, and the overall incidence within the health care professional specialty. The cost of basic incentive payments are included in this category.

TOTAL DIRECT AND INDIRECT COSTS REQUESTED: $206,385 (Year 1)

RESEARCH & RELATED BUDGET - Cumulative Budget

	Totals ($)	
Section A, Senior/Key Person		7,000.00
Section B, Other Personnel		15,051.00
Total Number Other Personnel	3	
Total Salary, Wages and Fringe Benefits (A+B)		22,051.00
Section C, Equipment		
Section D, Travel		
1. Domestic		
2. Foreign		
Section E, Participant/Trainee Support Costs		
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other		
6. Number of Participants/Trainees		
Section F, Other Direct Costs		184,335.00
1. Materials and Supplies		
2. Publication Costs		
3. Consultant Services		
4. ADP/Computer Services		
5. Subawards/Consortium/Contractual Costs		
6. Equipment or Facility Rental/User Fees		
7. Alterations and Renovations		
8. Other 1	57,285.00	
9. Other 2	113,450.00	
10. Other 3	13,600.00	
Section G, Direct Costs (A thru F)		206,386.00
Section H, Indirect Costs		
Section I, Total Direct and Indirect Costs (G + H)		206,386.00
Section J, Fee		
Section K, Total Direct and Fee (I + J)		206,386.00

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OMB Number: 0925-0001

Expiration Date: 02/28/2023

1. Vertebrate Animals Section

Are vertebrate animals euthanized? ○ Yes ○ No

If "Yes" to euthanasia

Is the method consistent with American Veterinary Medical Association (AVMA) guidelines?

○ Yes ○ No

If "No" to AVMA guidelines, describe method and provide scientific justification

2. *Program Income Section

*Is program income anticipated during the periods for which the grant support is requested?

○ Yes ● No

If you checked "yes" above (indicating that program income is anticipated), then use the format below to reflect the amount and source(s). Otherwise, leave this section blank.

*Budget Period *Anticipated Amount ($) *Source(s)

Tracking Number: GRANT13205496

Funding Opportunity Number: PAR-20-077 . Received Date: 2020-09-18T11:41:16.000-04:00

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3. Human Embryonic Stem Cells Section

*Does the proposed project involve human embryonic stem cells? ○ Yes ● No

If the proposed project involves human embryonic stem cells, list below the registration number of the specific cell line(s) from the following list: http://grants.nih.gov/stem_cells/registry/current.htm. Or, if a specific stem cell line cannot be referenced at this time, check the box indicating that one from the registry will be used:

Specific stem cell line cannot be referenced at this time. One from the registry will be used.

Cell Line(s) (Example: 0004):

4. Human Fetal Tissue Section

*Does the proposed project involve human fetal tissue obtained from elective abortions? ○ Yes ● No

If "yes" then provide the HFT Compliance Assurance

If "yes" then provide the HFT Sample IRB Consent Form

5. Inventions and Patents Section (Renewal applications)

*Inventions and Patents: ○ Yes ○ No

If the answer is "Yes" then please answer the following:

*Previously Reported: ○ Yes ○ No

6. Change of Investigator/Change of Institution Section

❑ Change of Project Director/Principal Investigator

Name of former Project Director/Principal Investigator

Prefix:

*First Name:

Middle Name:

*Last Name:

Suffix:

❑ Change of Grantee Institution

*Name of former institution:

Tracking Number: GRANT13205496 Funding Opportunity Number: PAR-20-077 . Received Date: 2020-09-18T11:41:16.000-04:00

PHS 398 Research Plan

OMB Number: 0925-0001
Expiration Date: 02/28/2023

Introduction	
1. Introduction to Application (for Resubmission and Revision applications)	IntroApplicationDCr1045595126.pdf
Research Plan Section	
2. Specific Aims	SpecificAimsDCrV21045663943.pdf
3. Research Strategy*	ResearchStrategyDCr1045595128.pdf
4. Progress Report Publication List	
Other Research Plan Section	
5. Vertebrate Animals	
6. Select Agent Research	
7. Multiple PD/PI Leadership Plan	MultiplePIplanDCr1045595129.pdf
8. Consortium/Contractual Arrangements	ConsortWebMdDCr1045595121.pdf
9. Letters of Support	
10. Resource Sharing Plan(s)	ResourceSharingDCr1045663972.pdf
11. Authentication of Key Biological and/or Chemical Resources	
Appendix	
12. Appendix	

Tracking Number: GRANT13205496
Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

INTRODUCTION TO APPLICATION – Data Core

CRITIQUE, RESPONSE TO CRITIQUE

SPECIFIC AIMS – Data Core

Low human papillomavirus (HPV) vaccination coverage is a pressing cancer prevention concern in the US that improved provider communication can address. The Data Core is a service core created to support data acquisition, data management, and data analysis needs of the P01 Program Project, "Improving Provider Announcement Communication Training (IMPACT)," at the University of North Carolina (UNC). The Core will support integration and create efficiencies and cost-savings across research projects by centralizing data-related services. To support formative research, centralized administration of the national primary care team survey will give IMPACT research projects access to a larger and more diverse group of primary care professionals than would be possible if each project independently conducted the survey. To support the planned trials and subsequent budget impact and cost-effectiveness analysis, **the Data Core will provide centralized, and therefore more integrated and efficient, services that include acquisition and harmonization of large datasets of vaccination outcomes, data analysis, and consulting.**

Diverse in methodological expertise, the Data Core team is well-suited for overseeing and executing the mission of the Data Core. The Data Core is co-led by Drs. Justin Trogdon, a health economist with training in econometrics and Nisha Gottfredson, a quantitative psychologist with expertise in longitudinal and nested data. Dr. Joseph Ibrahim, a distinguished biostatistician with expertise in innovative clinical trial designs and analysis of cluster randomized trial data, will serve as a co-investigator. The Data Core will also draw upon resources housed within the UNC Lineberger Comprehensive Cancer Center, including their Biostatistics Core. Specific aims for the Data Core are as follows.

Aim 1. Manage the national primary care team survey. *Activities to reach this aim:*

a. Collaborate with WebMD Market Research to conduct national survey with 2,500 primary care team members, including physicians, physician assistants, nurse practitioners, registered nurses and medical assistants. Stratify sampling based on on primary care professionals' role and quota sample to ensure adequate representation from rural areas.
b. Coordinate and integrate the research projects' survey measures and core demographic measures.
c. Prepare and document data, including survey materials, survey methods, and data dictionary, for use by the research projects.
d. Manage survey data sharing across projects and with external requestors.

Aim 2. Facilitate access to, and standardize structure of, large vaccination datasets generated by research project randomized clinical trials.

a. Manage multiple complex streams of vaccination data from electronic health records to make it usable for all projects.
b. Standardize measures and resulting datasets across all four research projects.
c. Implement data quality checking protocol.
d. Store and distribute vaccine outcomes data across the research projects, including data dictionary and standardized summary spreadsheets required for budget impact and cost-effectiveness analysis.

Aim 3. Provide statistical and methodological support to research projects.

a. Randomize clinics to arms for ccluster randomized trials in Projects 1-3.
b. Design and consult on statistical analyses of complex survey data resulting from the provider survey and clustered randomized clinical trial data, including power analyses, as needed by the research projects.

The Data Core will increase the collective scientific contribution of IMPACT. Aim 1 will result in a national primary care team survey that will contribute to formative aims of IMPACT research projects. Aim 2 will result in high-quality, clean data on HPV vaccination outcomes for all research projects. Aim 3 will ensure that all research projects are using appropriate and rigorous statistical analysis to answer their research questions. In this way, the Data Core contributes to the **IMPACT Program Project theme** of amplifying the impact of a Research-Tested Intervention Program to improve HPV vaccine communication. Ultimately, program-wide dissemination of research findings, the integrated AAT Intervention Package, and related training opportunities to healthcare systems across the US will greatly improve public health by reducing the incidence of HPV and HPV cancers.

RESEARCH STRATEGY – Data Core

OVERVIEW

Low human papillomavirus (HPV) vaccination coverage in the US is a missed opportunity for cancer prevention. Improved provider communication about HPV vaccine can have a large impact on helping the nation meet its goal of 80% coverage. The Data Core is a service core created to support data acquisition, management and analysis needs of the P01 Program Project, “Improving Provider Announcement Communication Training (IMPACT),” at the University of North Carolina (UNC). The Data Core will support integration and create efficiencies and cost-savings across research projects by centralizing data-related services. To support formative research, centralized administration of the national primary care team survey will give research projects access to a larger and more diverse group of healthcare professionals than would be possible if each project conducted a survey independently. To support the trials and subsequent budget impact and cost-effectiveness analysis, the Data Core will provide centralized, and therefore more integrated and efficient, services that include acquisition and standardization of large vaccination datasets. Finally, the Data Core will facilitate randomization for trials and consult on data analyses.

APPROACH

Research Team

The IMPACT Data Core will be co-led by Drs. Nisha Gottfredson and Justin Trogdon. The Data Core will be housed within the UNC Lineberger Comprehensive Cancer Center (LCCC), a National Cancer Institute (NCI)-designated comprehensive cancer center with more than 300 faculty members. As described below, each team member brings unique strengths to the Data Core to support research projects. Data Core scientists have a long track record of research accomplishments in survey design and statistical methods that will ensure cutting edge methods in research design, data collection and analyses of data.

Nisha Gottfredson, PhD, a quantitative psychologist, is Assistant Professor of Health Behavior in the UNC Gillings School of Global Public Health. Trained in the L. L. Thurstone Psychometric Lab at UNC, Dr. Gottfredson will apply her expertise in psychometric measurement to support the questionnaire design, psychometric modeling, and data integration across projects and data sources.[11,12] Dr. Gottfredson specializes in the analysis of complex, multilevel data and has published extensively on statistical techniques for handling missing data.[13,14] She will apply her expertise in generalized linear mixed models and structural equation modeling to assist research projects.[15–19] Dr. Gottfredson will oversee the Data Core’s Aims 1 and 3.

Justin Trogdon, PhD, is a health economist and Professor of Health Policy and Management in the UNC Gillings School of Global Public Health. He has extensive experience managing and analyzing large, secondary databases including electronic health records (EHRs), immunization information systems, national surveys, and administrative claims.[1–10] Dr. Trogdon will oversee the Data Core’s second aim of acquiring, managing, and standardizing large data streams.

Joseph Ibrahim, PhD, is Alumni Distinguished Professor of Biostatistics in the Gillings School of Global Public Health at UNC; Director of the UNC Gillings-based Laboratory for Innovative Clinical Trials (which includes faculty from UNC, Duke, and NC State University); and Director of the NCI-funded Biostatistics Core at LCCC. Dr. Ibrahim is an elected fellow of the American Statistical Association with extensive experience in clinical trials, generalized liner models, missing data, and Bayesian inference. He will advise the research projects and Data Core on trial design and analytic strategy.

Noel Brewer, PhD, Professor of Health Behavior in the UNC Gillings School of Global Public Health and the P01 Program Principal Investigator, will consult on development and implementation of the national survey and will help to ensure integration between the Data Core and the other program projects and cores.

Multiple Project Lead Plan

Drs. Gottfredson and Trogdon will use a collaborative approach to lead the Data Core. Dr. Gottfredson will be the contact lead, responsible for the Data Core’s administration and interface with IMPACT research projects and cores. To manage Core activities, Dr. Gottfredson will lead activities for Aims 1 and 3, and Dr. Trogdon will lead activities for Aim 2. Meeting in person monthly together with Co-Is Ibrahim and Brewer and other Data Core staff members, they will jointly decide on issues related to strategic planning, staffing, and budget. In the event of conflicting views that prove difficult to resolve, they will consult with the P01’s Principal Investigator, Dr. Brewer, for a third view. Drs. Gottfredson and Trogdon will also participate in the IMPACT Integration Committee meetings to coordinate the core’s activities with other projects and cores. The Administrative Core provides more information on collaboration across IMPACT.

Aim 1. Manage the national primary care team survey.

Three of IMPACT's research projects will collaborate on the national primary care team survey in Year 1 to support intervention refinement and other formative work. This web-based survey, drawn from a broad panel of healthcare professionals hosted by WebMD Market Research, will be the first of its kind to investigate HPV vaccine communication among a large sample of primary care team members, including physicians, physician assistants, nurse practitioners, registered nurses and medical assistants. The Data Core will play a central role in coordinating all aspects of the survey. The Data Core recognizes that conducting high-quality surveys requires a commitment to well-established professional standards. The Data Core supports and adheres to standards for conducting surveys, as set by the Survey Research Methods Section of the American Statistical Association and the American Association of Public Opinion Research.

1a. Collaborate with subcontractor to conduct national survey

Survey company. The provider survey will inform the Program Projects' objective of supporting implementation of provider communication interventions using a multidisciplinary perspective. Central to this objective is obtaining perspectives from physician *and non-physician* healthcare professionals who are directly involved in HPV vaccination, as well as obtaining perspectives from a geographically diverse set of healthcare professionals. After interviewing six potential survey companies, we selected WebMD Market Research to administer our survey. A letter of agreement form WebMD is included in the proposal.

To our knowledge, WebMD is the only survey company that can provide large samples of HPV vaccine providers, registered nurses and medical assistants from across all regions of the United States, as well as a substantial sample of rural providers. The reason is that WebMD has regular access to, and is esteemed by, a high proportion of healthcare professionals who frequent Medscape's website. We will rely on WebMD's standing panel of practicing healthcare professionals who joined Medscape to access clinical content, continuing medical education activities, and clinical tools. Because of Medscape's professional utility, 60% of US pediatricians and other physicians use it, giving the company unique access to healthcare professionals.

WebMD's expected response rates are much higher, and are thus more representative across several domains, than a fully population-based sample that would promise a response rate significantly below 10%. Most of the healthcare professionals in the WebMD panel participate in two to four surveys per year, with an average response rate of approximately 60%. This is the highest response rate offered by any of the potential vendors and it is in the upper range of what has been observed in published provider surveys.[20,21]

WebMD uses multiple strategies to verify the identity of respondents and ensure the validity of findings. First, for physicians, WebMD restricts survey recruitment to physicians in the American Medical Association Physician Masterfile. Second, each panelist is assigned a unique Medscape ID to confirm that the person invited is the same person who completes the survey. Third, when the company identifies "speeders" or "cheaters," they mark the respondent's profile and exclude them from the panel. Fourth, WebMD works with Lexis Nexis to provide additional fraud detection, requiring participants to go through a series of identity vetting questions before they can qualify for their first survey. Finally, WebMD adheres to the ICC/ESOMAR Code on Market and Social Research and the CASRO/Insights Association guidelines.

Participants. We will recruit 2,500 healthcare professionals who are involved in HPV vaccination for adolescent patients in primary care settings: 1,500 HPV vaccine providers (physicians, physician assistants and nurse practitioners) and 1,000 registered nurses and medical assistants. We worked with WebMD to devise a sampling strategy that recruits MAs from clinics where current panel members work.

Table 1. Example of representativeness of WebMD panel

Characteristic	WebMD	AMA Physician Master File
Male	65.1%	65.4%
Pediatrician	7.8%	7.4%
Geography example: NC	2.9%	2.9%

Because rural-nonrural disparities in HPV vaccination are a focus of IMPACT, we will employ quota sampling of healthcare professionals from rural areas to facilitate high-quality comparisons based on rurality. Our goal will be to achieve a sample that is at least 20% rural. Rurality will be determined by Rural-Urban Continuum Codes (RUCC) of professionals' counties: metropolitan (RUCC=1, 2 or 3) or nonmetro (RUCC greater than 3), whom we will consider rural. Importantly, Medscape member characteristics are largely representative of the physician population in the US (**Table 1**).

WebMD has agreed to increase their standard honorarium to ensure a high response rate. Participants will receive a $30 to $45 honorarium, depending on clinical roles, paid in the form of an Amazon.com gift card. WebMD has regularly achieved a response rate of 60% for their provider surveys using honoraria of this size and has established that response rate as the goal for our survey. High-quality recruitment tactics include direct email, targeted ads on their website to users who are invited to the survey, and invitations via

Medscape and embedded in online articles. One-click opt-out is available on all survey invitations.

Survey programming. The Data Core will provide the survey to WebMD as a Word document, including the questions, response scales, instructions, and skip patterns. WebMD will program and quality check the software. The Data Core and Projects will review the survey for errors and readability. WebMD will pretest and screen the questionnaire using in-depth phone interviews with healthcare professionals. Next, they will conduct a soft launch with 25 healthcare professionals for 25 days, allowing the Data Core and projects to check that skip patterns are yielding the expected data. They will provide the survey responses electronically, using a password protected online data vault.

IRB. The Data Core will write the protocol for the survey, including informed consent procedures, and manage IRB submission, correspondence, and renewal.

1b. Coordinate and integrate survey measures

Research projects have proposed the research questions shown in **Table 2** for the primary care team survey. The Data Core has already worked with projects to ensure their research questions address distinct topics and will continue to do so throughout survey development. The projects will draft their own survey items, at least 15 items per project. Another 15 items will be shared demographic measures that the Data Core will develop in consultation with the projects. Projects and the Data Core will work with the Clinical Advisory Board for feedback on their items. The projects will then cognitively test their survey items and a quarter of the demographic items with relevant healthcare professional populations.

Table 2. Research questions for national primary care team survey

Project	Research Questions	Providers	RNs/MAs
1	What role should RNs and MAs have in HPV vaccine communication?	•	•
	What do RNs and MAs want in HPV vaccine communication training?		•
	How are standing orders for HPV vaccines implemented in primary care?	•	•
2	How do providers receive information on their vaccination performance?	•	
	How willing are providers to share data on their HPV vaccination performance with other providers in their clinic?	•	
	How does the healthcare team perceive “pay-for-performance” initiatives for HPV vaccination or other care?	•	•
4	How do AAT implementation opportunities differ between rural and nonrural areas?	•	•
	How do AAT implementation challenges differ between rural and nonrural areas?	•	•
Shared	Zip-code, Rurality (RUCC), Clinic size, Practice setting	•	•

Note. AAT = Announcement Approach Training. RUCC = Rural urban continuum codes.

Next, the Data Core will gather survey items and coordinate with projects to create an appropriate order for the survey, adding introductory and transitional language as needed. The core will standardize response scales and will confirm this in the final phases. When constructing the survey, we will follow the Dillman Approach to maximize data quality and minimize participant burden (e.g., ask one question at a time, place instructions exactly where they are needed).[22] Project leads and the Clinical Advisory Board will review the draft survey in dedicated survey meetings and the Data Core will coordinate necessary updates.

1c. Prepare and document data

Data management. Working with the research projects, the Data Core will create a data dictionary. This dictionary will contain the full survey, frequencies for each item, and fully document the creation of derived variables and treatment of missing data. The Data Core will then create composite variables and ensure a clean final dataset ready for analyses by all projects. The dataset will be fully anonymized.

Power. Because the survey will address many research questions, we used a general approach to estimate the minimum sample size required to detect moderately small effects. Specifically, we estimated the sample size required to detect a 10% change in endorsement of a low-prevalence outcome between two groups of unequal size (i.e., 10% endorsement in group 1, containing 75% of the sample, and 20% endorsement in group 2, containing 25% of the sample). With alpha = 0.05 and two-tailed tests, an effective sample size of 500 per respondent type (for a total of 2,500 respondents) is required to obtain 80% power.

1d. Manage survey data sharing

The Data Core will manage sharing the survey dataset within and outside IMPACT. We will provide the research projects with a final dataset, stored on a password protected server accessible only to key research staff from password protected computers. The Data Core will also archive the syntax used to generate the final dataset from the raw data provided by WebMD. Projects will store their working datasets in the same environment, archiving their dataset and analytic syntax for each published paper. The Data Core will create a data use document to orient users to the appropriate use and storage of IMPACT datasets to supplement the required IRB training. When population estimates are available, the Data Core will conduct preliminary descriptive analyses to compare demographic features of the sample with population averages.

For data requests from researchers outside UNC, we will use the University of North Carolina Dataverse repository. The Dataverse Project, developed at the Institute for Quantitative Social Science at Harvard University, is an open-source software solution for archiving, searching, discovering, publishing, and analyzing data. Users can browse meta-data about the survey. Investigators interested in accessing the survey will contact the Data Core to establish a data use agreement as required by UNC. The Data Core will ask the relevant research project to draft a data use agreement specifying the variables to be included. They will have the university counsel review and sign the agreement on behalf of IMPACT (as required by UNC policy). The Data Core will then cut the dataset and provide it to the requesting group by secure means. **Aim 1 will result in a national survey of a diverse spectrum of primary care professionals that is critical to the formative aims of IMPACT research projects.**

Aim 2. Facilitate access to and standardize structure of large vaccination datasets generated by research project RCTs.

The Program's three RCTs will yield voluminous datasets on vaccination outcomes from EHR databases. Analysis of EHR data requires advanced programming skills to manage and clean. In Years 2-5, the Data Core will manage multiple complex streams of data to make it usable for all projects. Specifically, the Data Core will be a central hub for managing, standardizing, storing, and distributing RCT vaccination outcomes data that will be used to evaluate intervention impact across Projects 1-3. The Core will also provide the resulting data to Project 4 to support budget impact and cost-effectiveness modelling.

2a. Manage multiple streams of EHR data

The Data Core will manage EHR data used by Projects 1 through 3. The healthcare systems that Project 1 will work with will provide clinic-level data on HPV vaccination coverage; Projects 2 and 3 will pull patient-level records from the EHRs of their participating systems. We anticipate multiple EHR vendors across projects. One of the tasks of the Data Core will be to standardize and create common definitions (e.g., HPV vaccination initiation) across EHR vendors. Dr. Trogdon has experience with standardizing data from multiple EHR vendors (AHRQ Grant 5R18 HS023912-02 [PI: Cykert]).

With Project 1, the Data Core will develop an Excel spreadsheet to solicit the data from the systems, and then work with the systems to ensure they have used the correct data definitions to complete the spreadsheet. Once clinics and systems have been recruited into the Project 2 and 3 trials, but before the trials begin, Data Core staff will assist participating clinics to produce the discrete EHR data fields necessary to accrue the measures and reliably transfer them for processing. We will use a clinical data questionnaire and interview process prior to data collection to understand clinic documentation procedures, EHR capabilities and data flows. Next, we will work with clinic teams to create processes for high-quality data entry into appropriate fields. We will distribute measure definitions and ensure that each required element exists in the EHR and is recorded appropriately.

Once the initial review is complete, we will begin the data extraction process either through a data aggregation software (e.g., UNC Data Warehouse) or direct data feeds from the clinic EHR. For the first data captures, we will review with the clinics a series of use cases or sample patient sets to examine the data. An analyst will verify locations, providers, patients, results, and dates to ensure that the data extraction and transmission will be accurate and complete.

2b. Standardize measures and datasets

Projects 1-3 will share a common outcome measure of 12-month changes in HPV vaccination initiation among 11 and 12-year-olds. This will ensure that the cost effectiveness analysis in Project 4 can compare effectiveness across the three trials. The Data Core will be responsible for developing coding algorithms to identify doses delivered and eligible cohorts similarly across data sources.

For all variables, the Data Core will establish common protocols for data storage formats (e.g.,

categorical variables stored as integers, continuous variables stored in double precision), variable names, and scrambled identifiers. For the latter, the Data Core will create and maintain a crosswalk between clinic identifiers (e.g., names, addresses) and de-identified analytic identifiers. The Data Core will also blind the analysts for Projects 1-3 to the intervention arm of each clinic (and providers within those clinics).

2c. Implement data quality checking protocol

Once the data feeds for the EHRs are established, we will review the feeds monthly to confirm the data are complete, properly formatted and accurate for all data types. Several automated data checks will be applied using algorithms we have developed in prior studies. First, we will check that data elements have valid ranges (e.g., clinic-level coverage between 0% and 100%). Second, we will use algorithms to compare clinics' coverage estimates across vaccine types, age groups, and time periods to identify outliers and other unexpected values (e.g., higher coverage for HPV vaccine than for meningococcal vaccine), which we can then check for accuracy. Finally, we will analyze time series plots to detect large changes in measures or denominators indicative of lost feed or missing measures. From prior experience, we anticipate the data delays in electronic health records to be very minimal (<2 weeks). We will build in a four-week lag at the end of each trial to allow for delays in data acquisition.

By continuously monitoring data collection in this way, we will be able to quickly identify and correct any problems that may arise as data are extracted. Such problems can include errors in data entry procedures, changes in the administrative codes used to populate records (e.g., ICD-10 codes), and the closing or merging of clinics. We will store encrypted and secure data submitted from the EHRs of participating clinics on password protected LCCC servers accessible only to IMPACT personnel.

Measures. Trials will assess the impact of their interventions using vaccination data from EHRs. Our **common trial outcome** is change in the proportion of patients, ages 11-12, who have initiated HPV vaccination (≥1 dose) at 12-month follow-up. We prioritize 11- to 12-year-olds versus older adolescents because national guidelines recommend this age group for routine HPV vaccination.[17] We prioritize HPV vaccine series initiation versus completion because initiation is more sensitive to the communication and clinical interventions planned in the trials.

2d. Store and distribute vaccine outcomes data across the research projects

The Data Core will create data dictionaries that explain each measure and key features of the analytic data sets. We will develop data handling and sharing procedures for the RCT vaccination data matching those in Aim 1. We will work with each research project to develop and fill data templates to support budget impact and cost-effectiveness modelling by Project 4. Templates will include a summary that will report changes in HPV vaccination from Projects 1-3 in a standardized format for each comparison. **Aim 2 will result in a high-quality, clean data on HPV vaccination outcomes for Project 1-3's RCTs.**

Aim 3. Provide statistical and methodological support to research projects.

3a. Randomize clinics for trials in Projects 1-3.

Research Projects 1-3 propose to conduct cluster randomized trials consisting of patient-level vaccination data nested within clinics for baseline and 12-month follow-up. The Data Core will provide independent randomization to trial arm for Projects 1-3, stratifying on baseline HPV vaccine initiation coverage and rurality of clinic population based on RUCC. We include these two factors due to the limited number of clinics available and they are the most influential factors for the primary outcome.

3b. Design, consult, conduct, and write-up statistical analyses as needed by the research projects.

Power analyses are described in detail in the proposals for Projects 1-3. Power analyses for these projects assumed ICC for vaccination initiation among patients nested within clinics ranging between 0.03-0.04 (this value was estimated from existing data). We determined the minimum number of clinics per arm (c) required to obtain 80% power with a two-sided test of the intervention effect with α=.05 using the formula in Equation 1, where $\boldsymbol{z_{\beta}}$ and $\boldsymbol{z_{\frac{\alpha}{2}}}$ are the $(1-\boldsymbol{\beta})$ **and** $(\mathbf{1}-\frac{\boldsymbol{\alpha}}{\mathbf{2}})$ quantile of normal distribution, π_0 is the post vaccination rate in control arm, δ is the non-inferiority margin of testing $H_0: \pi_1 \geq \pi_0 - \delta$ and assumed to be 0 if a regular hypothesis $H_0: \pi_1 \geq \pi_0$ is tested, π_1 is the post vaccination rate in control arm, m is the average number of patients per clinic, $R^2_{y,\mathbf{X}}$ is the variance in the log odds of vaccination rates explained by covariates in **X**, and $R^2_{Tx,\mathbf{X}}$ is the squared multiple correlation between trial arm and the covariates in **X**.

$$c = 1 + \left(z_\beta - z_{\frac{\alpha}{2}}\right)^2 \frac{[\pi_0(1-\pi_0)+\pi_1(1-\pi_1)][1+(m-1)\rho(1-R^2_{y,X})]}{m(\pi_0-\delta-\pi_1)^2(1-R^2_{Tx,X})} \quad (1)$$

Projects 1-3 will follow 11- and 12- year-old patients who were unvaccinated before the intervention and use generalized estimating equations to determine the difference in 12-month follow-up vaccine initiation rates for treatment arms versus AAT-only arms. The general form of the analytic models is shown in Equation 2 where *i* indicates patient and *j* represents clinic. Tx_j is the treatment arm indicator (=1 for treatment arm and =0 for control arm). Because the analytic sample is unvaccinated adolescents, we model the probability of post vaccination only. The b_0 coefficient will reflect the log odds of vaccination for the control group at follow up. The treatment effect is reflected in the b_1 term, which indicates the additive effect of treatment on the log odds of vaccination at follow-up over and above the trend observed in the control condition. The K variables in **X** are clinic-level covariates that might reduce unexplained variation in changes in vaccination rates over time (thereby increasing our power), including RUCC, practice type, baseline vaccination rates, and clinic size. **S** contains M fixed effect indicators to control for healthcare system membership. Clinic-level data are used in Project 1, such that the within clinics average of the covariates X_{jk} and S_{jm} will be used instead of the individual information X_{ijk} and S_{ijm}. ICC are handled in GEE by setting a blockwise correlation structure in the GEE model.

$$\log\left(\frac{P(Vax_{ij}=1)}{1-P(Vax_{ij}=1)}\right) = b_0 + b_1 Tx_j + \sum_{k=1}^{K} b_{k+1} X_{ijk} + \sum_{m=1}^{M} b_{m+K+1} S_{ijm} \quad (2)$$

Data Core investigators have extensive experience implementing these models. The Data Core will consult quarterly with projects on data analysis planning and offer support. Our primary role will not be to lead day-to-day data analysis for individual projects. Rather, the role of the Data Core will be to provide high-level consultation to help projects finalize and coordinate their analytic plans. Consultation will focus on two areas across the Program. First, for analyses of the national survey, the core will consult on analyses to confirm that the survey data are handled appropriately (e.g., statistical models appropriate for the response scales, appropriate use of control variables). Second, for analyses of the RCT data, the Data Core will consult on analyses to confirm the success of randomization. We will advise on best practices for creation of the flow diagram as well as intent-to-treat analysis. Data Core investigators will also consult with project personnel to ensure that non-independent data from RCTs are handled appropriately (e.g., with generalized estimating equations, or fixed effects models). **Aim 3 will ensure that all research projects are using appropriate and rigorous statistical analyses.**

Relevance to Program Project Theme

The **IMPACT Program Project theme** amplifies the impact of a Research-Tested Intervention Program to improve HPV vaccine communication in healthcare systems. The Data Core supports this theme by providing each research project access to integrated and efficient data and analytic services. The Data Core will lead the national survey, which provides each research project access to a higher-quality sample of a more diverse group of health professionals than would be possible if each project conducted a survey independently. The Data Core will also help provide standardized impact information from Projects 1-3 with Project 4 for budget impact and cost-effectiveness modeling. Together, IMPACT can help reduce the incidence of HPV cancers by increasing adoption of HPV communication interventions in healthcare systems, especially those serving rural populations.

Table 3. Timeline

		Year 1				Year 2				Year 3				Year 4				Year 5			
	Quarter	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
Hire staff, IRB application		■																			
Aim 1	a. Manage subcontractor	■	■																		
	b. Coordinate measures	■	■	■	■																
	c. Prepare data				■																
	d. Manage data sharing				■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■
Aim 2	a. Facilitate data streams						■	■	■	■	■	■	■	■	■	■	■	■	■		
	b. Standardize measures						■	■													
	c. Data quality checking						■	■	■	■	■	■	■	■	■	■	■	■	■		
	d. Distribute data													■	■	■	■	■	■		
Aim 3	a. Randomize clinics						■				■				■						
	b. Support data analysis						■	■	■	■	■	■	■	■	■	■	■	■	■	■	■

PHS Human Subjects and Clinical Trials Information

OMB Number: 0925-0001

Expiration Date: 02/28/2023

Use of Human Specimens and/or Data

Does any of the proposed research in the application involve human specimens and/or data *	❍ Yes ● No
Provide an explanation for any use of human specimens and/or data not considered to be human subjects research.	
Are Human Subjects Involved	● Yes ❍ No
Is the Project Exempt from Federal regulations?	❍ Yes ● No
Exemption Number	❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑ 6 ❑ 7 ❑ 8
Other Requested Information	

Human Subject Studies

Study#	Study Title	Clinical Trial?
1	Data Core: Improving Provider Announcement Communication Training (IMPACT)	No

Section 1 - Basic Information (Study 1)

OMB Number: 0925-0001

Expiration Date: 02/28/2023

1.1. Study Title *

Data Core: Improving Provider Announcement Communication Training (IMPACT)

1.2. Is this study exempt from Federal Regulations * ○ Yes ● No

1.3. Exemption Number ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑ 6 ❑ 7 ❑ 8

1.4. Clinical Trial Questionnaire *

1.4.a. Does the study involve human participants?	● Yes	○ No
1.4.b. Are the participants prospectively assigned to an intervention?	○ Yes	● No
1.4.c. Is the study designed to evaluate the effect of the intervention on the participants?	○ Yes	● No
1.4.d. Is the effect that will be evaluated a health-related biomedical or behavioral outcome?	○ Yes	● No

1.5. Provide the ClinicalTrials.gov Identifier (e.g. NCT87654321) for this trial, if applicable

Section 2 - Study Population Characteristics (Study 1)

2.1. Conditions or Focus of Study

- The Data Core will manage the P01-wide national primary care team survey and will facilitate access to and standardize the structure of large vaccination datasets generated by research project randomized clinical trials.

2.2. Eligibility Criteria

Aim 1: 1) HPV vaccine providers (physicians, physician assistants, and nurse practitioners) and registered nurses and medical assistants2) Provided HPV vaccine to adolescent patients aged 9-17 in the prior two years3) Member of WebMD healthcare professional panel

2.3. Age Limits	Min Age: 18 Years	Max Age: 99 Years
2.3.a. Inclusion of Individuals Across the Lifespan	InclusionofLifespanDCr1045595174.pdf	
2.4. Inclusion of Women and Minorities	InclusionWomenMinoritiesDCr1045595175.pdf	
2.5. Recruitment and Retention Plan	RecruitmentDCr1045595176.pdf	
2.6. Recruitment Status	Not yet recruiting	
2.7. Study Timeline	TimelineDCr1045595177.pdf	
2.8. Enrollment of First Participant	12/01/2021	Anticipated

INCLUSION OF INDIVIDUALS ACROSS THE LIFESPAN – Data Core

The survey will focus on primary care professionals, and so only adults working in their professional roles in pediatric primary care will be included in the studies. Children will be included in the EHR data for Aim 2. In Aim 2, we will manage electronic health record data for patients aged 9-17 years who receive care at the participating clinics in Projects 1-3. We will not interact with children.

INCLUSION OF WOMEN AND MINORITIES – Data Core

The proposed research will include women and minorities throughout. We anticipate the inclusion of women and minorities in the national primary care team survey in Aim 1 to be representative of the distribution of women and minorities in the population sampled. Our estimates for the inclusion of women and minorities appear in the targeted/planned enrollment table. To arrive at these estimates, we used recent US Census data and published data on the sex distribution of healthcare professionals in the US.

In Aim 2, we will manage electronic health record data for the adolescent patients at the randomized healthcare clinics from Projects 1-3. We anticipate the inclusion of women and minorities in these calculations to be representative of the distribution of adolescent women and minorities receiving care at pediatric and family medicine clinics in participating states.

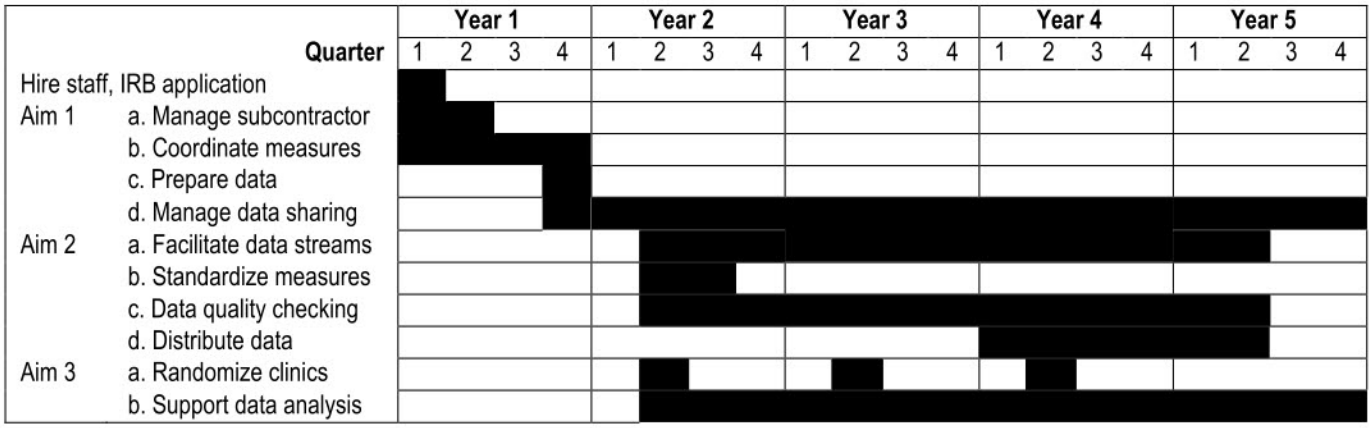
RECRUITMENT AND RETENTION PLAN – Data Core

Under Aim 1 we will manage the national primary care team survey. The survey will be a one-time, web-based survey administered by subcontractor WebMD Market Research. WebMD has a large panel of US healthcare professionals from all regions of the United States, as well as a substantial sample or rural providers.

We will recruit 2,500 primary care team members, including 1,500 HPV vaccine providers (physicians, physician assistants, and nurse practitioners) and 1,000 registered nurses and medical assistants, from WebMD's standing panel of practicing healthcare professionals. Because urban-rural disparities in HPV vaccination are a focus of IMPACT, especially Project 4, we will employ quota sampling of health professionals from rural areas to facilitate high-quality comparisons based on rurality. Our goal will be to achieve a sample of at least 20% rural professionals. Rurality will be determined by Rural-Urban Continuum Codes (RUCC) of respondents' counties. We will define counties as metropolitan areas (RUCC=1, 2 or 3) or nonmetro (RUCC greater than 3). Respondents in nonmetro counties will be considered rural.

WebMD has agreed to increase their standard honorarium beyond typical levels to ensure a high response rate: Participants will receive a $30 to $45 honorarium, depending on clinical roles, paid in the form of an Amazon.com gift card. WebMD has regularly achieved a response rate of 60% for their provider surveys using honoraria of this size and has established that as the goal for our survey. To ensure a large enough sample is recruited, they will leverage high-quality recruitment tactics, including direct email, targeted ads on their website to users who are invited to the survey, invitations via Medscape, and invitation notices embedded in online articles. Survey and demographic items will be cognitively tested by the research projects to ensure readability and comprehension.

STUDY TIMELINE – Data Core



Aim 1

The national primary care team survey (Activities 1a, 1b, and 1c) will be conducted during Year 1. Key to our ability to meet this timeline is having a research team that has worked together in the past on successful projects, having team members work parallel on tasks, and relying on the extensive previous work of our experienced investigators. WebMD's existing panel of healthcare professionals allows us to quickly access large national samples. The Data Core will manage sharing the national survey data within and outside of the P01 Program throughout Years 2-5.

Aim 2

In Years 2-5, the Data Core will manage multiple complex streams of data to make it usable across all projects. Under Activity 2c, data feeds from the electronic health records (EHRs) in Projects 1 through 3 will be reviewed monthly in order to quickly identify and correct problems that may arise as data are extracted. Finally, under Activity 2d, data from Projects 1 through 3 will be distributed across research projects and to Project 4 to support cost-effectiveness modeling in Years 4 and 5.

Aim 3

The Data Core will provide independent randomization to trial arms for Projects 1 through 3 in Years 2, 3, and 4. In Years 2-5, The Data Core will consult quarterly with projects on design of analyses and offer support. As projects have their own researchers and data analysts, the primary role of the Data Core will not be to lead day-to-day data analysis for individual projects. Rather, the role of the Data Core will be to provide high-level consultation to help projects finalize and coordinate their analytic plans, including assessing primary and secondary analyses and conducting exploratory analyses to character interventions' impact among rural-dwelling adolescents.

2.9. Inclusion Enrollment Reports

IER ID#	Enrollment Location Type	Enrollment Location
Study 1, IER 1	Domestic	Web-based survey

Inclusion Enrollment Report 1

1. Inclusion Enrollment Report Title* : Data Core: Improving Provider Announcement Communication Training (IMPACT)

2. Using an Existing Dataset or Resource* : ❍ Yes ● No

3. Enrollment Location Type* : ● Domestic ❍ Foreign

4. Enrollment Country(ies): USA: UNITED STATES

5. Enrollment Location(s): Web-based survey

6. Comments: Aim 1: national primary care team survey (n=2,500)

Planned

Racial Categories	Ethnic Categories				Total
	Not Hispanic or Latino		Hispanic or Latino		
	Female	Male	Female	Male	
American Indian/ Alaska Native	17	10	4	2	33
Asian	80	44	17	9	150
Native Hawaiian or Other Pacific Islander	3	1	1	0	5
Black or African American	173	96	36	20	325
White	1027	569	212	117	1925
More than One Race	33	18	7	4	62
Total	1333	738	277	152	2500

Cumulative (Actual)

Racial Categories	Ethnic Categories									Total
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			
	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	
American Indian/ Alaska Native	0	0	0	0	0	0	0	0	0	0
Asian	0	0	0	0	0	0	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0	0	0	0	0	0	0
Black or African American	0	0	0	0	0	0	0	0	0	0
White	0	0	0	0	0	0	0	0	0	0
More than One Race	0	0	0	0	0	0	0	0	0	0
Unknown or Not Reported	0	0	0	0	0	0	0	0	0	0
Total	0	0	0	0	0	0	0	0	0	0

Section 3 - Protection and Monitoring Plans (Study 1)

3.1. Protection of Human Subjects	ProtectionHsDCr1045595178.pdf
3.2. Is this a multi-site study that will use the same protocol to conduct non-exempt human subjects research at more than one domestic site?	● Yes ○ No ○ N/A
If yes, describe the single IRB plan	MultisiteStudyDCr1045595179.pdf
3.3. Data and Safety Monitoring Plan	DsmpDCr1045595180.pdf
3.4. Will a Data and Safety Monitoring Board be appointed for this study?	○ Yes ● No
3.5. Overall structure of the study team	StudyTeamDCr1045595181.pdf

PROTECTION OF HUMAN SUBJECTS – Data Core

Risk to Subjects

Human Subjects Involvement

The Data Core will manage a national, web-based survey of 2,500 primary care team members for use across P01 Projects. Participants will be recruited by subcontractor WebMD Market Research from their existing panel of healthcare professionals.

Source of Materials

National primary care team survey. The one-time, web-based survey will be administered by subcontractor WebMD Market Research, a national online survey company with large samples of US healthcare professionals from all regions of the United States, as well as a substantial sample or rural providers. Participants will be recruited from WebMD's standing panel of practicing healthcare professionals. Survey participants will be a national sample of 2,500 primary care team members, consisting of 1,500 HPV vaccine providers (physicians, physician assistants, and nurse practitioners) and 1,000 registered nurses and medical assistants. Because urban-rural disparities in HPV vaccination are a focus of the P01 Program, especially Project 4, we will employ quota sampling of primary care team members from rural areas to facilitate high-quality comparisons based on rurality. Our goal will be to achieve a sample of at least 20% rural healthcare professionals. Rurality will be determined by Rural-Urban Continuum Codes (RUCC) of respondents' counties. We will define counties as metropolitan areas (RUCC=1, 2 or 3) or nonmetro (RUCC greater than 3). Respondents in nonmetro counties will be considered rural.

EHR data. Under Aim 2, we will facilitate access to and harmonize structure of large vaccination datasets generated by research project randomized clinical trials. Data Core staff will assist participating clinics to produce the discrete EHR data fields necessary to accrue the measures and reliably transfer them for processing. We will work with clinic teams to create processes for high-quality data entry into appropriate fields. We will distribute measure definitions and ensure that each required element exists in the EHR and is recorded appropriately. Once the initial review is complete, we will begin the data extraction process either through a data aggregation software (e.g., UNC Data Warehouse) or direct data feeds from the clinic EHR.

Potential Risks

We anticipate that risks to participants will be minimal and manageable. There are no biospecimens that will be collected or stored for the purpose of this proposed study. We are not specifically targeting any of the following special classes of people: prisoners, institutionalized individuals, or other special classes of subjects who may be considered vulnerable populations.

No patients will be contacted directly for the proposed study. Adolescents whose EHR data are being used in Aim 2 will not be contacted directly. Providers participating in our data collection efforts will answer questions about their professional and work beliefs and behaviors. We are not discussing highly personal or sensitive topics with any provider participants.

The main risk is breach of confidentiality. The plan for mitigating this risk is discussed below (under Protections against Risk). All information about human subjects will be maintained by UNC. All members of the study team will abide by applicable laws and regulations regarding the protection of patient privacy and confidentiality in human subjects research.

Adequacy of Protection against Risks

Recruitment and Informed Consent

National primary care team survey. We will recruit 2,500 primary care team members for the national survey through our subcontractor WebMD's existing healthcare professional panel. Survey participants will read an electronic version of the informed consent form before beginning the survey and will be asked to select a checkbox to confirm their consent. The consent forms for these surveys will include information about the study's purpose, potential risks, expected benefits, protection of confidentiality and time expectations. The form will also include contact information for the IRB and Principal Investigator in case participants have concerns or questions about the study.

EHR data. EHR data will be stored on a password-protected secure server and all study members who access the EHR data will be bound by a signed Data Use Agreement (DUA) to keep confidential all personal

identifiers and information. The data contain information on medical procedures, diagnoses, prescriptions, and patient demographics and will be stripped of names, telephone numbers, addresses, social security numbers, and medical record numbers. We anticipate the query to be exempt from the informed consent process since data are collected for administrative purposes at the time of service, no interactions with patients will take place, and direct identifiers are not available in the data.

Protection against Risk

The informed consent process will ensure that participants are aware of the potential risks of participating in the study. One-click opt-out is available on all survey invitations. We will not share information or data provided by study participants, nor will we share EHR data. All information will be kept confidential, and identification numbers will be used rather than the names of study participants. Survey vendors will provide us with de-identified datasets. All study materials will be kept in a locked file accessible only to key study personnel. All computer files will be stored on a secure, password-protected server and accessed on computers that are password-protected, with IRB-approved personnel having access. Staff members must complete an online IRB research ethics training course and other confidentiality certification procedures upon employment. Policies regarding the confidential nature of the data collected, processed, and stored will be explained to all personnel, who must then sign a confidentiality agreement before being allowed access to the confidential information. In addition to this initial training, we will reinforce the need for careful and confidential handling of data at staff meetings.

Potential Benefits

By taking part in this study, participants may increase their awareness of strategies to improve HPV vaccine communication and provision. Participants may also experience personal satisfaction of knowing they have contributed to a research project aimed at improving HPV vaccine communication and provision. They will also receive monetary compensation for the time they invest in the study.

Importance of Knowledge to be Gained

Given that the risk to participants is minimal and manageable, the knowledge to be gained has the potential to fill an important research gap. Specifically, scientific findings will provide evidence on HPV vaccine communication practices and will be used to support intervention refinement and other formative work for the P01. Ultimately, this work will greatly improve public health by reducing the incidence of HPV-associated cancers.

MULTI-SITE STUDY: SINGLE IRB PLAN – Data Core

The Data Core for “Improving Provider Announcement Communication Training (IMPACT)” will implement a single IRB plan. Under Aim 1, UNC will collect data from a web-based national survey subcontracted through WebMed. Under Aim 2, we will facilitate access to and harmonize structure of large vaccination datasets generated by research project randomized clinical trials, including electronic health record data. The Co-Leads, Drs. Trogdon and Gottfredson, will provide oversight of the research at all participating sites.

UNC will exercise authority and responsibility on behalf of our research partners and submit a single IRB application for review of human subjects research, in accordance with NIH policy for research protocols that are carried out at more than one site in the United States. Our research partners have agreed to rely on the proposed single IRB. The Co-Leads and Project Manager will communicate directly with our research partners to ensure all study related procedures and documents are approved by UNC’s IRB. Prior to initiating the study, we will sign an authorization/reliance agreement that will clarify the roles and responsibilities of the single IRB and participating sites with our research partners. UNC will maintain records of the authorization/reliance agreements and of the communication plan.

DATA AND SAFETY MONITORING PLAN – Data Core

The Data Core will be co-led by Drs. Justin Trogdon and Nisha Gottfredson, both of whom will be responsible for monitoring of the data and safety of the study participants. The proposed study will be monitored by the UNC IRB. Any unanticipated problems, serious and unexpected adverse events, deviations, or protocol changes will be promptly reported by the co-leaders to the IRB and sponsor agency, if appropriate.

The Data Core will be responsible for the national survey. We will ensure the safety of the survey data collection and storage as described in the research strategy and the Human Subjects sections.

The Data Core will be responsible for management of harmonized vaccination data from the randomized clinical trials in Projects 1-3 (their proposals describe their data and safety monitoring plans in detail). We will work with those projects to establish protocols for data monitoring and reporting. We will also rely on existing data safety monitoring systems already in place at UNC.

UNC Lineberger Comprehensive Cancer Care Center has an established Data Safety Monitoring Plan in place for clinical trials. The UNC Lineberger's Director and the Associate Director for Clinical Research have the overall responsibility for policy on the data and safety monitoring of clinical trials. The Data Safety Monitoring Subcommittee (DSMS) is the primary agent for the assuring data and safety monitoring. The DSMS meets monthly and has the following responsibilities: 1) Reviewing serious adverse event reports from all active clinical trials and assuring that these have also been reported to the IRB and other appropriate agencies; 2) Reviewing data and safety monitoring reports that are required of all active clinical trials; and 3) Recommending appropriate actions (closure, increased monitoring, etc.) to the IRB based on reviews of serious adverse events and periodic reports.

The DSMS findings, when necessary, will be sent to IRB and to the School of Medicine's Data and Safety Monitoring Board (SOM-DSMB). Following a joint session that will include the SOM-DSMB and a representative of the DSMS, a final report and recommendation regarding continuation or closure of a study will be made to the IRB, reflecting input from both groups. Final responsibility and authority for closing or amending such trials will rest with the IRB.

NIH grant applications require clinical trials to have a data safety and monitoring plan, but some do not require a data safety monitoring board (DSMB) or data monitoring committee (DMC). The NCI in 2001 stated, "there is no longer a blanket requirement for DSMB (DMC) in the cases of low-risk behavioral and nutritional trials... All such trials should include a data…monitoring plan, but this may or may not include a DSMB (DMC)". We believe that our research projects are low risk and do not meet the definition of clinical trials requiring a data safety monitoring board. However, to the ensure maximum protection of human subjects, we will submit our research project information to the SOM-DSMB listed above and allow them to make the final decision regarding risk to participants and whether our studies should receive their supervision. We do not anticipate that our studies will require ongoing supervision by the SOM-DSMB.

OVERALL STRUCTURE OF THE STUDY TEAM – Data Core

The organizational structure of the study team as it pertains to IMPACT Data Core's proposal is below. The Data Core will be co-led by Drs. Justin Trogdon and Nisha Gottfredson. As described below, each team member brings unique strengths to the Data Core to support research projects. Data Core scientists have a long track record of research accomplishments in survey design and statistical methods that will ensure cutting edge methods in research design, data collection and analyses of data.

UNC Study Team

- *Nisha Gottfredson*, PhD, will serve as the contact lead, responsible for the Data Core's administration and interface with IMPACT research projects and cores. Dr. Gottfredson, a quantitative psychologist, is Assistant Professor of Health Behavior at UNC. Trained in the L.L. Thurstone Psychometric Lab at UNC, Dr. Gottfredson will apply her expertise in psychometrics to support the questionnaire design, psychometric modeling, and data integration across projects and data sources. Dr. Gottfredson specializes in the analysis of complex, multilevel data and has published extensively on statistical techniques for handling missing data. She will apply her expertise in generalized linear mixed models and structural equation modeling to assist research projects under aims one and three.
- *Justin Trogdon*, PhD, will oversee the Data Core's second aim of acquiring, managing, and standardizing large data streams. He is a health economist and an Professor in the Department of Health Policy and Management at UNC. He has extensive experience managing and analyzing large, secondary databases including electronic health records, immunization information systems, national surveys, and administrative claims.
- *Joseph Ibrahim*, PhD, Distinguished Professor of Biostatistics, Director of the Laboratory for Innovative Clinical Trials, and Principal Statistician for UNC Lineberger Comprehensive Cancer Center, is an expert in trial design, including the design of clustered randomized clinical trials. Dr. Ibrahim will provide advice regarding trial design and analysis of cluster randomized trials.
- *Noel Brewer*, PhD, will serve as Co-Investigator for the Data Core. Dr. Brewer is a Professor of Health Behavior in the UNC Gillings School of Global Public Health and the P01 Program Principal Investigator. Dr. Brewer will consult on the development and implementation of the national primary care team survey.
- The *Statistician (Programmer)*, to be named, will be the lead programmer and database manager for Aim 2 (integration of large data streams). As a Programmer for this study, they will assist with data cleaning and data analysis for the electronic health records data.
- The *Statistician (Trialist)*, to be named, will assist with randomization of clinical trials for Program Projects and will provide data analysis consultation.
- The *Project Manager*, to be named, will assist Drs. Gottfredson and Trogdon with administration, scheduling, budgeting, and other tasks to ensure core tasks are completed on time and within budget. The Project Manager will manage the project budget, oversee IRB protocols, and prepare progress reports.
- The *Graduate Research Assistant*, to be named, will have training in bioinformatics. They will assist Dr. Trogdon and the Programmer with data management, standardization, visualization, and analysis for Aim 2.

WebMD

- WebMD Market Research will implement the national survey and will assume responsibility for recruitment, survey programming, and data collection efforts. WebMD has a standing panel of practicing healthcare professionals that is representative of the healthcare professional population in the United States.

Clinical Advisory Board

- We will periodically consult the Clinical Advisory Board convened by the Intervention Core. The Board includes pediatricians, nurses, medical assistants, and other supporting providers and meets quarterly. We will bring questions about the clinical context for survey recruitment and items.

Section 4 - Protocol Synopsis (Study 1)

4.1. Study Design

4.1.a. Detailed Description

4.1.b. Primary Purpose

4.1.c. Interventions

Type	Name	Description

4.1.d. Study Phase

Is this an NIH-defined Phase III Clinical Trial? ❍ Yes ❍ No

4.1.e. Intervention Model

4.1.f. Masking ❍ Yes ❍ No

❑ Participant ❑ Care Provider ❑ Investigator ❑ Outcomes Assessor

4.1.g. Allocation

4.2. Outcome Measures

Type	Name	Time Frame	Brief Description

4.3. Statistical Design and Power

4.4. Subject Participation Duration

4.5. Will the study use an FDA-regulated intervention? ❍ Yes ❍ No

4.5.a. If yes, describe the availability of Investigational Product (IP) and Investigational New Drug (IND)/ Investigational Device Exemption (IDE) status

4.6. Is this an applicable clinical trial under FDAAA? ❍ Yes ❍ No

4.7. Dissemination Plan

Delayed Onset Studies

Delayed Onset Study#	Study Title	Anticipated Clinical Trial?	Justification
The form does not have any delayed onset studies			

MULTIPLE PD/PI LEADERSHIP PLAN – Data Core

Governance/Organizational Structure

Dr. Justin Trogdon (UNC-Health Policy and Management) and Dr. Nisha Gottfredson (UNC-Health Behavior) will serve as Data Core Co-Leads. Each co-lead brings unique strengths to the Data Core to support research projects. Drs. Trogdon and Gottfredson have a long track record of research accomplishments in survey design and statistical methods that will ensure cutting edge methods in research design, data collection and analyses of data. They also have considerable experience participating in large multi-center research projects, often in positions of leadership, ensuring that they both have the management skills necessary to successfully conduct the proposed research.

Dr. Gottfredson will lead activities for Aims 1 and 3 and serve as the contact lead, responsible for the Data Core's administration and interface with IMPACT research projects and cores. Dr. Trogdon's primary responsibilities in the Data Core will be to lead activities for Aim 2. Both Drs. Trogdon and Gottfredson will provide oversight of the entire Data Core, including scientific direction, allocation of resources, and implementation of the specific aims, while ensuring that systems are in place to guarantee institutional compliance with US laws and NIH policies, including protection of human subjects and management of data and facilities.

Communication

Drs. Trogdon and Gottfredson will use a collaborative approach to lead the Data Core. Meeting in person monthly, they will jointly decide on issues related to strategic planning, staffing, and budget. These meetings will be used to develop Core priorities, coordinate the Core, review progress, discuss analyses, and interpret results. Operational matters of grant progress as well as potential problems, anticipated upcoming issues, and general program oversight will also be discussed at these meetings. With input from co-investigators, the Leads will make strategic decisions such as modifications of priorities, procedures, or timelines. Drs. Trogdon and Gottfredson will also participate in the IMPACT Integration Committee meetings to coordinate the core's activities with other projects and cores. The Administrative Core provides more information on collaboration across IMPACT.

Conflict Resolution

If any conflict arises as to scientific direction, the Leads will meet to try and resolve the disagreement. If they fail to resolve the dispute, they will consult with the P01's Principal Investigator, Noel Brewer, for a third view.

Change in Lead location

No relocation for either Lead is anticipated. If, however, in the highly unlikely event that a Lead moves to a different institution, attempts will be made to transfer the relevant portions of the grant to the new institution. If transfer is not possible, an appropriate replacement Lead from UNC will be recruited, as necessary.

REFERENCES – Data Core

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2. Hussong AM, Gottfredson NC, Bauer DJ, et al. Approaches for creating comparable measures of alcohol use symptoms: Harmonization with eight studies of criminal justice populations. *Drug Alcohol Depend*. 2019;194:59-68. doi:10.1016/j.drugalcdep.2018.10.003
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CONSORTIUM/CONTRACTUAL ARRANGEMENTS – Data Core

The Data Core proposal includes a collaborative effort between UNC and WebMD Market Research. UNC will serve as the prime institution for the Data Core, and WedMD will serve as the subrecipient. The proposed activities include a subcontract with WebMD to conduct the national primary care team survey in Aim 1. The appropriate programmatic and administrative personnel of each organization involved in this grant application are aware of the NIH consortium agreement policy and are prepared to establish the necessary interorganizational agreement(s) consistent with that policy.

Dr. Nisha Gottfredson is the Project Lead responsible for ensuring proper conduct of the project at the consortium site of UNC. Ms. Audrey Rosen is the Consortium Lead responsible for ensuring proper conduct of the project at WebMD. UNC will manage the programmatic, fiscal, and administrative tasks necessary to ensure the overall success of this subcontract. Dr. Nisha Gottfredson will lead bi-weekly meetings in Year 1 to coordinate sampling, recruitment, survey feedback, survey programming, data collection, data cleaning, and delivery of the final dataset to UNC.

The grantee and subrecipient organizations are prepared to make a formal consortium agreement with terms and conditions stipulating ownership of all data, reports, materials, inventions and if applicable, future use. This agreement will be developed in accordance with NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards Subpart B: Terms and Conditions for Specific Types of Grants, Grantees, and Activities (15 Consortium Agreements).

RESEARCH

University of North Carolina at Chapel Hill
Subrecipient Letter of Intent

To be completed by Subrecipient

SUBRECIPIENT	SPONSOR
Legal Name: WebMD	Legal Name: The University of North Carolina at Chapel Hill
DUNS: 602670742	DUNS: 608195277
Lead PI: Stanislav Zakharkin,	Lead PI: Noel T. Brewer

Subrecipient Administrative Contact:	*Sponsor Administrative Contact:*
Name/Title: Audrey Rosen/VP Market Research	Name/Title: David Paul/Assistant Vice Chancellor
Address: 395 Houston Street 3rd Floor Ny, NY 10014	Address: 104 Airport Drive, Suite 2200 Chapel Hill, NC, 27599
Phone: 646-856-3860	Phone: 919-966-3411
Email: arosen@webmd.net	Email: ResAdminOSR@unc.edu

GENERAL INFORMATION

Project Title: Program Project- Improving Provider Announcement Communication Training (IMPACT)

Prime Awarding Agency: National Cancer Institute

RFA/RFP: PAR-20-077

Project Period: Start 7/01/2021 End 06/30/2022

UNC-CH Proposal Number: (Enter UNC IPF Number)

BUDGET INFORMATION

Choose as appropriate below:

○ Federal Rate ○ Sponsor Rate ◉ Other

Applicable F&A Rate: _____ %

Direct Costs: $206,385.00

Indirect Costs:

Total Request: $206,385.00

COMPLIANCE INFORMATION

Human Subjects: ◉ Yes ○ No

Animal Subjects: ○ Yes ◉ No

Is your institution a participant of Federal Demonstration Partnership (FDP) Clearing House? ○ Yes ◉ No

This LETTER OF INTENT confirms the appropriate program and administrative personnel have reviewed and approve the above referenced Solicitation/ RFP/RFA. Further, the institution and its Principal Investigator certify that:

Information submitted within this application is true, complete, and accurate to the best of the institution's and PI's knowledge; any false, fictitious, or fraudulent statements or claims may subject the institution and PI to criminal, civil, or administrative penalties; PI agrees to accept responsibility for the scientific conduct of the project and to provide the required progress reports if an award is made, and a mutually agreeable subcontract is executed as a result thereof.

Included: • Statement of Work • Budget • Budget Justification Other: _____

Subrecipient Principal Investigator: Stanislav Zakharkin

Subrecipient Authorized Official: Audrey Rosen

Date: _____

Date: 7-31-2020

Form Approved Through 02/28/2023 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Application

Do not exceed character length restrictions indicated.

LEAVE BLANK—FOR PHS USE ONLY.

Type	Activity	Number
Review Group		Formerly
Council/Board (Month, Year)		Date Received

1. TITLE OF PROJECT *(Do not exceed 81 characters, including spaces and punctuation.)*
Program Project- Improving Provider Announcement Communication Training (IMPACT)

2. RESPONSE TO SPECIFIC REQUEST FOR APPLICATIONS OR PROGRAM ANNOUNCEMENT OR SOLICITATION ☐ NO ☒ YES
(If "Yes," state number and title)
Number: PAR-20-077 Title: National Cancer Institute Program Project Applications

3. PROGRAM DIRECTOR/PRINCIPAL INVESTIGATOR

3a. NAME (Last, first, middle)	3b. DEGREE(S)	3h. eRA Commons User Name
Zakharkin, Stanislav	PhD, PStat	N/A

3c. POSITION TITLE
Associate Director

3e. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Marketing Science

3f. MAJOR SUBDIVISION
WedMD/Medscape

3d. MAILING ADDRESS *(Street, city, state, zip code)*
395 Houston Street 3rd Floor
Ny, NY 10014

3g. TELEPHONE AND FAX *(Area code, number and extension)*
TEL: FAX:

E-MAIL ADDRESS:
szakharkin@webmd.net

4. HUMAN SUBJECTS RESEARCH	4a. Research Exempt	If "Yes," Exemption No.
☐ No ☒ Yes	☒ No ☐ Yes	

4b. Federal-Wide Assurance No.	4c. Clinical Trial	4d. NIH-defined Phase III Clinical Trial
N/A	☒ No ☐ Yes	☒ No ☐ Yes

5. VERTEBRATE ANIMALS ☒ No ☐ Yes — 5a. Animal Welfare Assurance No.

6. DATES OF PROPOSED PERIOD OF SUPPORT *(month, day, year—MM/DD/YY)*		7. COSTS REQUESTED FOR INITIAL BUDGET PERIOD		8. COSTS REQUESTED FOR PROPOSED PERIOD OF SUPPORT	
From	Through	7a. Direct Costs ($)	7b. Total Costs ($)	8a. Direct Costs ($)	8b. Total Costs ($)
07/01/2021	06/30/2022	$206,385	$206,385	$206,385	$206,385

9. APPLICANT ORGANIZATION
Name WebMD
Address 395 Hudson Street 3rd Floor
New York, NY 10014

10. TYPE OF ORGANIZATION
Public: → ☐ Federal ☐ State ☐ Local
Private: → ☐ Private Nonprofit
For-profit: → ☒ General ☐ Small Business
☐ Woman-owned ☐ Socially and Economically Disadvantaged

11. ENTITY IDENTIFICATION NUMBER
20-2783228
DUNS NO. 602670742 Cong. District 10th

12. ADMINISTRATIVE OFFICIAL TO BE NOTIFIED IF AWARD IS MADE
Name Audrey Rosen
Title VP Market Research, WebMD
Address 395 Hudson St 3rd Floor
NY, NY 20014
Tel: 6468563860 FAX:
E-Mail: arosen@webmd.net

13. OFFICIAL SIGNING FOR APPLICANT ORGANIZATION
Name Audrey Rosen
Title VP Market Research, WebMD
Address 395 Hudson St 3rd Floor
NY, NY 10014
Tel: 646 856 3860 FAX:
E-Mail: arosen@webmed.net

14. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

SIGNATURE OF OFFICIAL NAMED IN 13. *(In ink. "Per" signature not acceptable.)*
Audrey Rosen

DATE
7-31-20

SCOPE OF WORK – WebMD

Target Population

WebMD will recruit Medscape members to have 2,500 adolescent vaccine providers complete the national primary care team survey: 1,000 physicians (pediatricians and family physicians) and 1,500 supporting providers (physician assistants, nurse practitioners, registered nurses, and medical assistants) involved in adolescent vaccination.

Fielding/Sample Specifications

Fielding/Sample Specifications										
Respondent Type	Specialty	Quantity	LOI	IR	CPC	Honorarium	CPC Total	Honorarium Total	Handling	Total
Pre tests 4	1 of each above (MD, NPPA, Nurse, Med asst)	4	40	40%	$120.00	$150.00	$480.00	$600.00	$20.00	$1,100.00
MD **pre recruit**	Peds, FP, PCP	1670	3	40%	$1.50	$5.00	$2,505.00	$8,350.00		$10,855.00
HCP **pre recruit**	NPPA ped, FP, PCP	840	3	40%	$1.50	$5.00	$1,260.00	$4,200.00		$5,460.00
HCP **pre recruit**	Nurses Ped, FP, PCP	840	3	40%	$1.50	$5.00	$1,260.00	$4,200.00		$5,460.00
HCP **pre recruit**	Medical assistants Ped, FP, PCP	840	3	40%	$1.50	$5.00	$1,260.00	$4,200.00		$5,460.00
MD	Peds, FP, PCP	1000	20	60%	$22.00	$45.00	$22,000.00	$45,000.00	$5,000.00	$72,000.00
HCP	NPPA Ped, FP, PCP	500	20	60%	$20.00	$35.00	$10,000.00	$17,500.00	$2,500.00	$30,000.00
HCP	Nurses Ped, FP, PCP	500	20	60%	$19.00	$30.00	$9,500.00	$15,000.00	$2,500.00	$27,000
HCP	Med assistants	500	20	60%	$19.00	$30.00	$9,500.00	$15,000.00	$2,500.00	$27,000.00
Total		6690					$57,285.00	$113,450.00	$12,500.00	$184,335.00
Number of waves				1					Recruiting Total	$184,335.00
									Pre- recruit and soft launch labor	$3,400.00
Panel									Pre test screen & scheduling	$1,450.00
									Main survey - Programming and hosting	$7,800.00
									Sample partner fee if needed	$3,200.00
Days in field	**25**	Handling fee	$5.00						Project and quota management	$6,200.00
CPC Total minimum		***$2,000.00***							**Project Total**	**$206,385.00**

Mode of Data Collection

Interviews will be conducted online only.

Survey Programming

WebMD will program the client-provided questionnaire for the online mode of data collection. WebMD will format the questionnaire for programming and return to the Client for approval. The questionnaire is expected to be approximately 20 minutes.

All-Inclusive Fixed Price: $206,385 (Year 1)

Draft Schedule

The total project schedule (from survey programming through project completion) for a study similar to this one would take approximately eight to ten weeks. We can work with you on a customized schedule, if required for your Client's needs. Below is a typical schedule:

- Survey programming of 3 minute pre-recruit screener and 20 min main survey: 1-2 weeks
- Client review of online programmed surveys, changes to programmed survey: Timing based upon client requirements
- Survey pretesting (online mode only; interviews to be scheduled by WebMD and conducted by you and client): 2-3 days
- Final survey revisions and programming: 2-3 days
- Pre-recruit 1 ½-2 weeks
- Main survey field period: 2-3 weeks
- Delivery of SPSS/excel data file: 3-5 days

Final Deliverables

The pricing for the study includes a commitment by WebMD to deliver the Client the following deliverables for the project listed above:

- Fully labeled, SPSS file for all pretest and main study interviews in Excel
- Project report in MS Word documenting:
  - Sampling protocol
  - Interview sample sizes
  - Study execution and data collection methodology

RESOURCE SHARING PLAN – Data Core

We agree with the NIH principle that data sharing is essential for expedited translation of research results into knowledge, products, and procedures to improve human health. All projects and cores will follow the same procedures. We will make data collection instruments available online for public use after data collection and analyses are complete. Leads of the research projects and the Data Core will oversee sharing of de-identified data produced by the Program Project. Dr. Brewer will oversee this process.

The Data Core will produce a de-identified dataset and codebook from the Program's national primary care team survey for sharing with external investigators. The Data Core will contact the projects for approval as requests are received for this survey and follow procedures outlined in the Overall Program's Resource Sharing Plan. For other project data, the research projects will be responsible for resource sharing. For protocols on sharing these project-specific data, see Resource Sharing Plans for the individual projects.

OMB Number: 4040-0010
Expiration Date: 12/31/2022

APPLICATION FOR FEDERAL ASSISTANCE

SF 424 (R&R)

5. APPLICANT INFORMATION **Organizational DUNS*:** 608195277

Legal Name*:	The University of North Carolina at Chapel Hill
Department:	Office of Sponsored Research
Division:	Research
Street1*:	104 Airport Drive, Suite 2200
Street2:	Campus Box 1350
City*:	Chapel Hill
County:	Orange
State*:	NC: North Carolina
Province:	
Country*:	USA: UNITED STATES
ZIP / Postal Code*:	27599-1350

Person to be contacted on matters involving this application

Prefix:	First Name*:	Middle Name:	Last Name*:	Suffix:
	Andrea		Cogdill	

Position/Title:	Grants Analyst
Street1*:	130 Mason Farm Road
Street2:	CB 9525, Bioinformatics Bldg.
City*:	Chapel Hill
County:	Orange
State*:	NC: North Carolina
Province:	
Country*:	USA: UNITED STATES
ZIP / Postal Code*:	27599-9525

Phone Number*: (919) 962-3950 Fax Number: (919) 843-7094 Email: grants@unc.edu

7. TYPE OF APPLICANT* H: Public/State Controlled Institution of Higher Education

Other (Specify):

Small Business Organization Type ❍ Women Owned ❍ Socially and Economically Disadvantaged

11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT*

IMPACT Project 1 – The impact of standing orders support on HPV vaccine communication and uptake

12. PROPOSED PROJECT

Start Date*	Ending Date*
07/01/2021	06/30/2026

OMB Number: 4040-0010
Expiration Date: 12/31/2022

Project/Performance Site Location(s)

Project/Performance Site Primary Location

❍ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name:	The University of North Carolina at Chapel Hill
Duns Number:	608195277
Street1*:	104 Airport Drive, Suite 2200
Street2:	Campus Box 1350
City*:	Chapel Hill
County:	NC
State*:	NC: North Carolina
Province:	
Country*:	USA: UNITED STATES
Zip / Postal Code*:	27599-1350
Project/Performance Site Congressional District*:	NC-004

Project/Performance Site Location 1

❍ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name:	The Ohio State University
DUNS Number:	832127323
Street1*:	1960 Kenny Road
Street2:	
City*:	Columbus
County:	
State*:	OH: Ohio
Province:	
Country*:	USA: UNITED STATES
Zip / Postal Code*:	43210-1016
Project/Performance Site Congressional District*:	OH-003

Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

Project/Performance Site Location 2

❍ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name:	AMGA Analytics, LLC
DUNS Number:	143834070
Street1*:	One Prince Street
Street2:	
City*:	Alexandria
County:	
State*:	VA: Virginia
Province:	
Country*:	USA: UNITED STATES
Zip / Postal Code*:	22314-0000
Project/Performance Site Congressional District*:	VA-008

Additional Location(s) File Name:

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED Other Project Information

1. Are Human Subjects Involved?* ● **Yes** ○ **No**

1.a. If YES to Human Subjects

Is the Project Exempt from Federal regulations? ○ Yes ● No

If YES, check appropriate exemption number: _ 1 _ 2 _ 3 _ 4 _ 5 _ 6 _ 7 _ 8

If NO, is the IRB review Pending? ○ **Yes** ○ **No**

IRB Approval Date:

Human Subject Assurance Number 00004801

2. Are Vertebrate Animals Used?* ○ **Yes** ● **No**

2.a. If YES to Vertebrate Animals

Is the IACUC review Pending? ○ Yes ○ No

IACUC Approval Date:

Animal Welfare Assurance Number

3. Is proprietary/privileged information included in the application?* ○ **Yes** ● **No**

4.a. Does this project have an actual or potential impact - positive or negative - on the environment?* ○ **Yes** ● **No**

4.b. If yes, please explain:

4.c. If this project has an actual or potential impact on the environment, has an exemption been authorized or an environmental assessment (EA) or environmental impact statement (EIS) been performed? ○ Yes ○ No

4.d. If yes, please explain:

5. Is the research performance site designated, or eligible to be designated, as a historic place?* ○ **Yes** ● **No**

5.a. If yes, please explain:

6. Does this project involve activities outside the United States or partnership with international collaborators?* ○ **Yes** ● **No**

6.a. If yes, identify countries:

6.b. Optional Explanation:

	Filename
7. Project Summary/Abstract*	AbstractP1r1045594776.pdf
8. Project Narrative*	NarrativeP1r1045594777.pdf
9. Bibliography & References Cited	ReferencesP1r1045594778.pdf
10.Facilities & Other Resources	FacilitiesP1r1045594779.pdf
11.Equipment	EquipmentP1r1045594780.pdf
12. Other Attachments	AcronymsP1r1045594817.pdf

Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

ABSTRACT – Project 1

An ongoing and pressing cancer prevention challenge in the US is low HPV vaccine coverage, due in part to infrequent and low-quality provider recommendations. Our 1-hour Announcement Approach Training (AAT) teaches providers to use *presumptive announcements* that presume the child will receive vaccines and to use best practices for respectfully addressing parent concerns when they arise. The AAT increases HPV vaccine initiation and is an NCI-designated Research-Tested Intervention Program. To increase the impact of the AAT, we propose to leverage the whole primary care team, including registered nurses (RNs) and medical assistants (MAs), by supporting the implementation of existing standing orders. Standing orders are widely available but often underused. As part of the P01 Program Project, "Improving Provider Announcement Communication Training (IMPACT)," Project 1 will focus on AAT enhanced with standing orders support to expand the whole primary care team's involvement in HPV vaccine recommendations. We will do this work in healthcare systems serving rural and nonrural areas. **Aim 1 is to characterize the role of RNs and MAs and standing orders in HPV vaccination.** We will conduct formative interviews (*n*=20) and then a national primary care team survey (*n*=2,500) with our P01's Data Core to better understand how to expand the role of RNs and MAs in recommending HPV vaccine and to implement existing standing orders for HPV vaccine. **Aim 2 is to evaluate the impact of supporting the implementation of existing standing orders for the whole primary care team on HPV vaccine communication and uptake in an RCT.** The standing orders support will be a series of activation meetings that use persuasion and skills building with system leaders, clinic leaders and clinic staff. We will conduct a trial in 40 primary care clinics in Mississippi, Missouri, and Texas that have HPV vaccination standing orders, serve patients from rural and nonrural areas, and are part of a healthcare system. Clinics will be randomized to AAT or AAT enhanced with standing orders support. The primary trial outcome will be clinic-verified HPV vaccine initiation among children ages 11-12. We hypothesize that AAT with standing orders support increases HPV vaccine uptake by improving HPV vaccine communication. **Aim 3 is to generate guidance for healthcare systems to support implementation of HPV vaccine standing orders** to leverage the whole primary care team. We will gather and share intervention data (cost, impact, and implementation data) with Project 4 to support cost-effectiveness analyses and development of their decision support tool. We will examine intervention implementation determinants and outcomes with our P01's Intervention Core. Finally, we will contribute modules to the AAT Intervention Package that provides guidance to healthcare systems for improving HPV vaccination. Project 1 addresses the **IMPACT Program Project theme** by building capacity for HPV vaccine communication interventions among primary care teams in healthcare systems.

NARRATIVE – Project 1

Our proposed research will expand the role of all primary care team members and support the use of standing orders in HPV vaccination. The Program Project will disseminate findings via the Announcement Approach Training Intervention Package, publications, and hpvIQ.org.

FACILITIES AND OTHER RESOURCES – Project 1

Refer to Overall component for Project 1, AMGA Analytics, and the Ohio State University Facilities and Other Resources.

EQUIPMENT – Project 1

None.

LIST OF ACRONYMS – Project 1

AAPOR	American Association for Public Opinion Research
AA	Announcement Approach
ACIP	Advisory Committee on Immunization Practices
AMGA	American Medical Group Association
CDC	Centers for Disease Control and Prevention
CE	Continuing education
CFIR	Consolidated Framework for Implementation Research
CME	Continuing medical education
Covid-19	Coronavirus disease 2019
EHR	Electronic health record
GRA	Graduate research assistant
GEE	Generalized estimating equations
HPV	Human papillomavirus
ICC	Intra-class correlation
IMPACT	Improving Provider Announcement Communication Training
IRB	Institutional review board
IAC	Immunization Action Coalition
MA	Medical assistant
MO	Missouri
MI	Mississippi
NC	North Carolina
NCI	National Cancer Institute
NIH	National Institutes of Health
NIS-Teen	National Immunization Survey-Teen
NP	Nurse practitioner
OSU	The Ohio State University
PA	Physician assistant
PBC	Perceived behavioral control
QI	Quality improvement
RCT	Randomized clinical trial
RA	Research assistant
RN	Registered nurse
RTIP	Research Tested Intervention Program
RUCC	Rural-Urban Continuum Codes
SO	Standing orders
TDAP	Tetanus, diphtheria, and pertussis
TX	Texas
UNC	University of North Carolina
US	United States

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED Senior/Key Person Profile (Expanded)

PROFILE - Project Director/Principal Investigator

Prefix: First Name*: Noel Middle Name T. Last Name*: Brewer Suffix:

Position/Title*: Professor
Organization Name*: The University of North Carolina at Chapel Hill
Department: Health Behavior
Division: Gillings Sch. of Public Hlth
Street1*: 325 Rosenau Hall
Street2: CB 7440
City*: Chapel Hill
County: Orange
State*: NC: North Carolina
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 27599-7440

Phone Number*: (919) 966-3282 Fax Number: (919) 966-2921

E-Mail*: ntb@unc.edu

Credential, e.g., agency login: eRA COMMONS USER NAME

Project Role*: Other (Specify) Other Project Role Category: Project Lead

Degree Type: PhD Degree Year: 2002

Attach Biographical Sketch*: File Name:

Attach Current & Pending Support: File Name:

Tracking Number: GRANT13205496 Funding Opportunity Number: PAR-20-077 . Received Date: 2020-09-18T11:41:16.000-04:00

PROFILE - Senior/Key Person

Prefix: First Name*: Paul Middle Name L. Last Name*: Reiter Suffix:

Position/Title*: Associate Professor
Organization Name*: The Ohio State University
Department: Health Behavior & Health Prom.
Division: College of Public Health
Street1*: 1841 Neil Avenue
Street2: Room 359B
City*: Columbus
County:
State*: OH: Ohio
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 43210-0000

Phone Number*: (614) 292-4803 Fax Number:

E-Mail*: reiter.36@osu.edu

Credential, e.g., agency login: eRA COMMONS USER NAME

Project Role*: Co-Investigator Other Project Role Category:

Degree Type: PhD Degree Year: 2008

Attach Biographical Sketch*: File Name: BioReiterP1rV21045663947.pdf

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Elizabeth Middle Name L. Last Name*: Ciemins Suffix:

Position/Title*: Vice President
Organization Name*: AMGA Analytics, LLC
Department: Research and Analytics
Division:
Street1*: One Price Street
Street2:
City*: Alexandria
County:
State*: VA: Virginia
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 22314-0000

Phone Number*: (703) 838-0033 Fax Number: (703) 548-1890

E-Mail*: ECiemins@amga.org

Credential, e.g., agency login: eRA COMMONS USER NAME

Project Role*: Other (Specify) Other Project Role Category: Research Director

Degree Type: PhD Degree Year: 2003

Attach Biographical Sketch*: File Name: BioCiemensP1rV21045663945.pdf

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Paul Middle Name Last Name*: Darden Suffix:

Position/Title*:
Organization Name*: N/A
Department:
Division:
Street1*: 6504 Southshore Drive
Street2:
City*: Oklahoma City
County:
State*: OK: Oklahoma
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 73162-0000

Phone Number*: (614) 292-4803 Fax Number:

E-Mail*: dardenpm@gmail.com

Credential, e.g., agency login: eRA COMMONS USER NAME

Project Role*: Consultant Other Project Role Category:

Degree Type: MD Degree Year: 1981

Attach Biographical Sketch*: File Name: BioDardenP1r1045594801.pdf

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Sarah Middle Name A. Last Name*: Birken Suffix:

Position/Title*: Associate Professor
Organization Name*: Wake Forest University Health Sciences
Department: Implementation Science
Division: School of Medicine
Street1*: Medical Center Boulevard
Street2:
City*: Winston-Salem
County: Forsyth
State*: NC: North Carolina
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 27157-0000

Phone Number*: (336) 713-4231 Fax Number:

E-Mail*: sbirken@wakehealth.edu

Credential, e.g., agency login: eRA COMMONS USER NAME

Project Role*: Co-Investigator Other Project Role Category:

Degree Type: PhD Degree Year: 2011

Attach Biographical Sketch*: File Name:

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Lisa Middle Name N. Last Name*: Mansfield Suffix:

Position/Title*:
Organization Name*: University of California Los Angeles
Department:
Division:
Street1*: 732 North Hudson Avenue
Street2: Apt.3
City*: Los Angeles
County: Los Angeles
State*: CA: California
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 90038-0000

Phone Number*: (203) 260-3250 Fax Number:

E-Mail*: lmansfield_90@yahoo.com

Credential, e.g., agency login: eRA COMMONS USER NAME

Project Role*: Consultant Other Project Role Category:

Degree Type: PhD Degree Year: 2016

Attach Biographical Sketch*: File Name: BioMansfieldP1r1045595182.pdf

Attach Current & Pending Support: File Name:

Tracking Number: GRANT13205496 Funding Opportunity Number: PAR-20-077 . Received Date: 2020-09-18T11:41:16.000-04:00

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 1

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2021 **End Date*:** 06-30-2022 **Budget Period: 1**

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.		Noel	T.	Brewer		Project Lead	CAL. MONTHS, INST. BASE SALARY				46,808.00	13,746.00	60,554.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name: **Total Senior/Key Person** **60,554.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
1	Post Doctoral Associates	7.8			33,475.00	6,302.00	39,777.00
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
1	Project Manager	12			66,950.00	23,845.00	90,795.00
1	Research Assistant	1.74			6,787.00	2,700.00	9,487.00
1	AAT Facilitator	0.24			2,575.00	966.00	3,541.00
1	SOS Facilitator	0.6			6,438.00	2,415.00	8,853.00
5	**Total Number Other Personnel**					**Total Other Personnel**	**152,453.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**213,007.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 1

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2021 **End Date*:** 06-30-2022 **Budget Period: 1**

C. Equipment Description	
List items and dollar amount for each item exceeding $5,000	
Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	
Additional Equipment: File Name:	

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	3,000.00
2. Foreign Travel Costs	
Total Travel Cost	**3,000.00**

E. Participant/Trainee Support Costs	**Funds Requested ($)***
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant Trainee Support Costs**	

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 1

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2021 **End Date*:** 06-30-2022 **Budget Period: 1**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	6,350.00
2. Publication Costs	1,500.00
3. Consultant Services	7,000.00
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	52,555.00
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8. Other Costs	6,300.00
Total Other Direct Costs	**73,705.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**289,712.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. Organized Research_On Campus	55.5	287,157.00	159,372.00
		Total Indirect Costs	**159,372.00**

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number): DHHS, Darryl Mayes, 202-401-2808

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**449,084.00**

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	449,084.00

L. Budget Justification* File Name: BudgetJustificationP1rV21045663948.pdf

(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 2

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2022 **End Date*:** 06-30-2023 **Budget Period: 2**

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.		Noel	T.	Brewer		Project Lead	CAL. MONTHS, INST. BASE SALARY				46,808.00	13,746.00	60,554.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **60,554.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
1	Post Doctoral Associates	12			51,500.00	9,696.00	61,196.00
1	Graduate Students	1.32			2,812.00	722.00	3,534.00
	Undergraduate Students						
	Secretarial/Clerical						
1	Project Manager	12			66,950.00	23,845.00	90,795.00
1	Research Assistant	3.84			14,995.00	5,966.00	20,961.00
1	AAT Facilitator	0.24			2,575.00	966.00	3,541.00
1	SOS Facilitator	2.4			25,750.00	9,661.00	35,411.00
6	**Total Number Other Personnel**					**Total Other Personnel**	**215,438.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**275,992.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 2

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2022 **End Date*:** 06-30-2023 **Budget Period: 2**

C. Equipment Description	
List items and dollar amount for each item exceeding $5,000	
Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	
Additional Equipment: File Name:	

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	3,000.00
2. Foreign Travel Costs	
Total Travel Cost	**3,000.00**

E. Participant/Trainee Support Costs	**Funds Requested ($)***
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant Trainee Support Costs**	

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 2

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2022 **End Date*:** 06-30-2023 **Budget Period: 2**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	5,300.00
2. Publication Costs	1,500.00
3. Consultant Services	7,000.00
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	71,374.00
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8. Tuition	2,138.00
9. Other Costs	20,400.00
Total Other Direct Costs	**107,712.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**386,704.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. Organized Research_On Campus	55.5	313,192.00	173,822.00
		Total Indirect Costs	**173,822.00**

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number): DHHS, Darryl Mayes, 202-401-2808

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**560,526.00**

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	560,526.00

L. Budget Justification* File Name: BudgetJustificationP1rV21045663948.pdf

(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

Tracking Number: GRANT13205496 Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 3

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2023 **End Date*:** 06-30-2024 **Budget Period: 3**

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.		Noel	T.	Brewer		Project Lead	CAL. MONTHS, INST. BASE SALARY				46,808.00	13,746.00	60,554.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **60,554.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
1	Post Doctoral Associates	12			51,500.00	9,696.00	61,196.00
1	Graduate Students	1.32			2,812.00	722.00	3,534.00
	Undergraduate Students						
	Secretarial/Clerical						
1	Project Manager	12			66,950.00	23,845.00	90,795.00
1	Research Assistant	0.6			2,343.00	932.00	3,275.00
1	SOS Facilitator	2.4			25,750.00	9,661.00	35,411.00
5	**Total Number Other Personnel**					**Total Other Personnel**	**194,211.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**254,765.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 3

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2023 **End Date*:** 06-30-2024 **Budget Period: 3**

C. Equipment Description	
List items and dollar amount for each item exceeding $5,000	
Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	
Additional Equipment: File Name:	

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	3,000.00
2. Foreign Travel Costs	
Total Travel Cost	**3,000.00**

E. Participant/Trainee Support Costs	**Funds Requested ($)***
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant Trainee Support Costs**	

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 3

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2023 **End Date*:** 06-30-2024 **Budget Period: 3**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	3,800.00
2. Publication Costs	3,000.00
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	77,278.00
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8. Tuition	2,202.00
9. Other Costs	21,400.00
Total Other Direct Costs	**107,680.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**365,445.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. Organized Research_On Campus	55.5	285,965.00	158,711.00
		Total Indirect Costs	**158,711.00**

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number): DHHS, Darryl Mayes, 202-401-2808

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**524,156.00**

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	524,156.00

L. Budget Justification* File Name: BudgetJustificationP1rV21045663948.pdf

(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

Tracking Number: GRANT13205496 Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 4

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2024 **End Date*:** 06-30-2025 **Budget Period: 4**

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.		Noel	T.	Brewer		Project Lead	CAL. MONTHS, INST. BASE SALARY				46,808.00	13,746.00	60,554.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **60,554.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
1	Post Doctoral Associates	6.6			28,325.00	5,333.00	33,658.00
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
1	Project Manager	12			66,950.00	23,845.00	90,795.00
1	Research Assistant	1.28			5,014.00	1,995.00	7,009.00
3	**Total Number Other Personnel**					**Total Other Personnel**	**131,462.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**192,016.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 4

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2024 **End Date*:** 06-30-2025 **Budget Period: 4**

C. Equipment Description	
List items and dollar amount for each item exceeding $5,000	
Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	
Additional Equipment: File Name:	

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	3,000.00
2. Foreign Travel Costs	
Total Travel Cost	**3,000.00**

E. Participant/Trainee Support Costs	**Funds Requested ($)***
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant Trainee Support Costs**	

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 4

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2024 **End Date*:** 06-30-2025 **Budget Period: 4**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	6,800.00
2. Publication Costs	3,000.00
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	47,832.00
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8. Other Costs	1,400.00
Total Other Direct Costs	**59,032.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**254,048.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. Organized Research_On Campus	55.5	206,216.00	114,450.00
		Total Indirect Costs	**114,450.00**

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number): DHHS, Darryl Mayes, 202-401-2808

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**368,498.00**

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	368,498.00

L. Budget Justification* File Name: BudgetJustificationP1rV21045663948.pdf

(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

Tracking Number: GRANT13205496 Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 5

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2025 **End Date*:** 06-30-2026 **Budget Period: 5**

A. Senior/Key Person

Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.	Noel	T.	Brewer		Project Lead	CAL. MONTHS, INST. BASE SALARY				46,808.00	13,746.00	60,554.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **60,554.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
1	Post Doctoral Associates	12			51,500.00	9,696.00	61,196.00
1	Graduate Students	12			25,560.00	6,563.00	32,123.00
	Undergraduate Students						
	Secretarial/Clerical						
1	Project Manager	12			66,950.00	23,845.00	90,795.00
1	Research Assistant	2.04			7,966.00	3,169.00	11,135.00
4	**Total Number Other Personnel**					**Total Other Personnel**	**195,249.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**255,803.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 5

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2025 **End Date*:** 06-30-2026 **Budget Period: 5**

C. Equipment Description	
List items and dollar amount for each item exceeding $5,000	
Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	
Additional Equipment: File Name:	

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	3,000.00
2. Foreign Travel Costs	
Total Travel Cost	**3,000.00**

E. Participant/Trainee Support Costs		**Funds Requested ($)***
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other:		
Number of Participants/Trainees	**Total Participant Trainee Support Costs**	

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 5

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2025 **End Date*:** 06-30-2026 **Budget Period: 5**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	3,250.00
2. Publication Costs	6,000.00
3. Consultant Services	1,000.00
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	17,964.00
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8. Tuition	21,234.00
Total Other Direct Costs	**49,448.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**308,251.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. Organized Research_On Campus	55.5	269,053.00	149,324.00
		Total Indirect Costs	**149,324.00**

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number): DHHS, Darryl Mayes, 202-401-2808

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**457,575.00**

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	457,575.00

L. Budget Justification* File Name: BudgetJustificationP1rV21045663948.pdf

(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

Tracking Number: GRANT13205496 Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

BUDGET JUSTIFICATION – Project 1

Key Personnel

Noel T. Brewer, PhD, Project Lead

Year 1	Year 2	Year 3	Year 4	Year 5
CAL. MONTHS				

Dr. Brewer will serve as Project Lead for Project 1. He is Professor of Health Behavior at the UNC Gillings School of Global Public Health with expertise in HPV vaccination, including provider communication training. Dr. Brewer was the founding chair of the National HPV Vaccination Roundtable and regularly advises WHO, CDC, and other organizations on vaccine communication. He has served in a leadership capacity as a member of the National Vaccine Advisory Committee working group on HPV vaccine, co-chair of a workshop for the President's Cancer Panel, and special advisor to the Chair of the Panel. Dr. Brewer has extensive expertise leading multidisciplinary teams with cross-institution collaborations, including overseeing large center projects, and conducting complex research studies. As Project Lead, Dr. Brewer will have overall responsibility for design and implementation of the studies as well as dissemination of findings. Specifically, he will have overall budgetary, administrative, and scientific responsibility for the research project and will coordinate and implement activities essential to carrying out the research aims and achieving the project's goals. These activities include maintaining scientific integrity throughout the project, developing instruments and protocols, meeting with co-investigators, supervising project staff, coordinating the work of external advisors, overseeing data collection, and overseeing data analysis. Along with his study team, Dr. Brewer will develop reports, papers, presentations, and other materials for dissemination.

Sarah A. Birken, PhD, Co-Investigator (CM, Years 1-5 charged to Intervention Core)

Dr. Birken is Associate Professor of Implementation Science in the Division of Public Health Sciences at Wake Forest University Health Sciences. Dr. Birken is an implementation scientist and health services researcher with over 15 years of experience in quality improvement, innovations in cancer care, and translating evidence-based interventions into practice. She has been a principal investigator or co-investigator on numerous grants that have examined the optimization of cancer care and preventive health services, especially for rural patients. Dr. Birken will collaborate closely with the IMPACT Principal Investigator, Noel T. Brewer, at the University of North Carolina and colleagues on Project 1. In Years 1-4 of the Program Project, Dr. Birken will consult on developing and carrying out strategies for effective implementation of intervention components and enhancing the Announcement Approach Training. Additionally, in all five years of the Program Project, Dr. Birken will coordinate the Clinical Advisory Board and will consult on harmonization of implementation measures across projects. Finally, in Years 4-5 of the Program Project, she will advise the team on how to meaningfully translate evidence from the research projects into tools that can be disseminated and implemented in a variety of settings. In Year 5, Dr. Birken will also contribute to manuscript preparation. The cost for her effort is kept administratively in the Intervention Core to simplify subcontracts to her home institution.

Other Personnel

TBD, Project Manager

Year 1	Year 2	Year 3	Year 4	Year 5
12 CM	12 CM	12 CM	12 CM	12 CM

The Project Manager will be responsible for managing daily project operations for Project 1 and will serve as the liaison between Dr. Brewer, the project team, and study contractors. The Project Manager will also coordinate research activities, such as developing research protocols, managing the project budget, submitting IRB protocols and revisions, developing data collection instruments, managing data collection, and preparing reports, conference presentations, and manuscripts to disseminate findings.

TBD, Research Assistant

Year 1	Year 2	Year 3	Year 4	Year 5
1.74 CM	3.84 CM	0.6 CM	1.28 CM	2.04 CM

We will employ a Research Assistant to help the study team with research activities including developing interview guides, new survey measures, conducting cognitive interviews, supporting training implementation activities, and developing dissemination materials such as presentations, manuscripts, and the training modules.

TBD, AAT Facilitator

Year 1	Year 2	Year 3	Year 4	Year 5
0.24 CM	0.24 CM	-	-	-

We will employ a physician or other primary care professional who has previously presented AAT workshops to provide feedback on new AAT materials and processes. The AAT Facilitator will deliver the pilot clinic AAT workshops and may deliver AAT workshops to clinics if remote training is necessary.

TBD, Standing Orders Support Facilitator

Year 1	Year 2	Year 3	Year 4	Year 5
0.6 CM	2.4 CM	2.4 CM	-	-

We will employ a physician or other primary care professional to lead and attend meetings that guide systems and clinics through the process of reviewing existing standing orders, procedures, clinic flow, communication with staff, and problem-solving around challenges.

TBD, Postdoctoral Research Associate

Year 1	Year 2	Year 3	Year 4	Year 5
7.8 CM	12 CM	12 CM	6.6 CM	12 CM

We will employ a Postdoctoral Research Associate to work with the study team to develop qualitative interview guides and new survey measures, and to enhance the current training materials. The Postdoctoral Research Associate will also support data analysis, and develop dissemination materials such as conference posters, presentations, and manuscripts.

TBD, Graduate Research Assistant

Year 1	Year 2	Year 3	Year 4	Year 5
-	1.32 CM	1.32 CM	-	12 CM

We will employ a Graduate Research Assistant to help the study team with research activities that pertain to the RCT in Years 2 and 3 and to help with dissemination and publication of findings in Year 5. The Graduate Research Assistant will also support data analysis of the provider surveys and the change in vaccine uptake.

Total Expenses for Personnel=$1,191,583

Fringe Benefits

Fringe benefits associated with the salary request for this budget has been calculated in accordance with our Institution's DHHS Rate Agreement. The University of North Carolina at Chapel Hill applies appropriate fringe benefit rates to the personnel on this proposal: Basic permanent employee benefits are **25.889%** of annual salary plus **$6,512/FTE/YR** for fixed health insurance. Post-Doctoral Appointee employee benefits are **9.490%** of annual salary plus **$4,808.76/FTE/YR** for fixed health insurance. Graduate Student employee benefits are **9.490%** of annual salary plus **$4,137.60/FTE/YR** for fixed health insurance. P&A Practice Plan member benefits calculate at **30.796%** of annual salary plus **$8,652.80/FTE/YR** for fixed health insurance.

Travel

Travel for Conferences

Year 1	Year 2	Year 3	Year 4	Year 5	Total
$3,000	$3,000	$3,000	$3,000	$3,000	$15,000

A member of the project team will attend 2 national conferences in Years 1-5 to disseminate findings (each trip budgeted at $1,500). Attending national conferences will allow Dr. Brewer and colleagues to disseminate project findings to a broad audience including public health practitioners, researchers, and policymakers. Additionally, attending conferences will expose Dr. Brewer and colleagues to the latest research in the field which will inform the Program Project's research activities.

Total Expenses for Travel=$15,000

Supplies

Data Storage

Year 1	Year 2	Year 3	Year 4	Year 5	Total
$3,000	$1,500	-	$3,000	-	$7,500

Two computers will be purchased in Year 1 ($1,500 X 2 = $3,000) for project staff use and data storage and management purposes. In Year 2, one laptop computer will be purchased for the Standing Orders Support facilitator to use to coordinate meetings with healthcare systems and clinics ($1,500 X 1 = $1,500). After warranties expire on staff computers, additional laptops will be purchased in Year 4 ($1,500 X 2 = 3,000). The Standing Orders Support Facilitator laptop computer will not be in use once the warranty expires and thus will not need to be replaced.

Mailings

Year 1	Year 2	Year 3	Year 4	Year 5	Total
$200	$500	$500	$500	$200	$1,900

We have allocated $200 in Years 1 & 5 and $500 in Years 2-4 for mailing recruitment materials and incentives to providers and for mailing research correspondence to out-of-state consultants. ($200 X 2 +$500 X 3 = $1,900).

Project Supplies

Year 1	Year 2	Year 3	Year 4	Year 5	Total
$1,000	$1,000	$1,000	$1,000	$1,000	$5,000

Each year, $1,000 will be used for general project supplies needed to carry out research activities including office supplies and printing of data collection instruments, protocols, meeting materials, posters to present study findings, and other documents as necessary in Years 1-4. In Year 5, $1,000 is allocated for printing and organizing project deliverables and publications for dissemination.

Photocopying

Year 1	Year 2	Year 3	Year 4	Year 5	Total
$250	$500	$500	$500	$250	$2,000

We have allocated $250 for Years 1 and 5, and $500 per year for years 2-4 for photocopying expenses incurred by study personnel. Study personnel will photocopy qualitative interview guides (Aim 1), training materials for educators, and participant materials for trainings (Aim 2).

Audio Recorders

Year 1	Year 2	Year 3	Year 4	Year 5	Total
$100	-	-	-	-	$100

We have allocated $100 in Year 1 to purchase two digital audio recorders for qualitative interviews with providers (Aim 1). Additionally, these funds are budgeted for purchasing relevant accessories that include batteries, protective cases, and any software required to prepare the files (i.e., recordings) for transcription.

Software

Year 1	Year 2	Year 3	Year 4	Year 5	Total
$1,800	$1,800	$1,800	$1,800	$1,800	$9,000

Statistical and reference management software will be purchased for up to 3 computers as necessary in Years 1-5. The software will be used to perform data analyses as described in Aims 1-3, as well as to manage references to aid in dissemination of study findings ($600 per license x 3 computers = $1,800 per year).

Total Expenses for Supplies=$25,500

Journal Publication Charges

Year 1	Year 2	Year 3	Year 4	Year 5	Total
$1,500	$1,500	$3,000	$3,000	$6,000	$15,000

It is increasingly common for top journals to charge publication fees. Thus, we have budgeted for one article in Years 1-2, 2 articles in Years 3-4, and 4 articles in Year 5 (at a rate of $1,500 per article).

Total Expenses for Journal Publication Charges=$15,000

Consultants

Paul Darden, MD

Year 1	Year 2	Year 3	Year 4	Year 5	Total
CONSULTANT(S) FEES					

Dr. Darden is a pediatrician and a noted primary care researcher at the Oklahoma University School of Medicine. He is the Section Chief of General and Community Pediatrics and Director of the Oklahoma Child Health Research Network (OCHRN). He has worked with the American Academy of Pediatrics (AAP) and the Academic Pediatric Association (APA). Dr. Darden has extensive experience in practice-based research and standing orders research. As a physician, he will provide valuable insight into both the clinic and the training perspective to ensure the interventions offered through the RCT are viable. Dr. Darden's expertise on research involving standing orders will also help the research team with logistics of implementing and evaluating standing orders within clinics. Dr. Darden will serve as a consultant and will participate in study team discussions via conference call. Specifically, he will advise on the standing orders protocol trainings to be implemented as part of the RCT and help troubleshoot standing orders intervention implementation. He will also record a short video for the standing orders intervention. In Year 5, Dr. Darden will review the AAT Intervention Package.

Lisa Mansfield, BSN, PhD

Year 1	Year 2	Year 3	Year 4	Year 5	Total
CONSULTANT(S) FEES					

Dr. Mansfield is a nurse with experience in HPV vaccine communication research and can provide valuable insight and feedback on training materials from the perspective of the primary care team. Her research has focused on improving HPV vaccination among racial/ethnic minority adolescents. In addition, having practiced as a registered nurse in primary care for several years, she brings a unique perspective on the challenges nurses face when communicating and educating patients about vaccinations in practice. Dr. Mansfield will

provide expertise on qualitative data analysis, including for analysis of qualitative data gathered in Year 1, as well as expertise on nurses' roles and clinic workflow.

Total Expenses for Consultants=$15,000

Tuition

Year 1	Year 2	Year 3	Year 4	Year 5	Total
-	$2,138	$2,202	-	$21,234	$25,573

We will provide half of the annual in-state tuition at the UNC Gillings School of Global Public Health to the Graduate Research Assistant as compensation for work in Years 2, 3, and 5 based on their percentage FTE. Tuition cost is based on the Department of Health Behavior tuition rate. Tuition support is calculated by multiplying the graduate student's predicted percent effort on the project times the tuition cost of his or her graduate program.

Total Expenses for Tuition=$25,573

Other Expenses

Interview Incentives

Year 1	Year 2	Year 3	Year 4	Year 5	Total
$2,800	$400	$800	$800	-	$4,800

In Year 1, the study team will conduct 20 formative interviews with providers to discuss supporting clinicians' role in recommending HPV vaccine and the use of standing orders and to cognitively test survey items. In Year 1, we will also conduct additional cognitive interviews, if needed, to test potential survey items with an additional 8 participants. We will give each of the providers a $100 gift card for completing an interview with one of our study team members (28 participants @ $100/gift card = $2,800). In Year 2 we will conduct in-depth interviews with 2 clinical staff from each of the pilot clinics and will give each of them a $100 gift card for participating in the interview. (4 participants @ $100/gift card = $400). In Years 3 and 4, we will conduct key informant interviews with 2 staff from each system to assess implementation outcomes (8 participants in Year 3 and 8 participants in Year 4 @ $100/gift card = $1,600).

Transcription Services

Year 1	Year 2	Year 3	Year 4	Year 5	Total
$1,500	-	$600	$600	-	$2,700

In Year 1 we have allocated $1,500 for transcription services for our 20 in-depth interviews (20 interviews @ $75/interview = $1,500). (The 8 additional cognitive interviews will not need to be transcribed.) In Year 4, we are allocating an additional $1,200 for the 16 key informants we will conduct to assess implementation outcomes.

Training Participant Follow-up Survey Incentives

Year 1	Year 2	Year 3	Year 4	Year 5	Total
-	$20,000	$20,000	-	-	$40,000

We will offer $100 incentive gift cards for completing training participant surveys to up to 10 providers per clinic in the RCT, as well as the 2 pilot clinics. In Year 2, we will conduct trainings in 20 clinics. (20 X 10 X $100 = $20,000). In Year 3, we will conduct trainings in an additional 20 clinics (20 X 10 X $100 = $20,000).

Videography Services

Year 1	Year 2	Year 3	Year 4	Year 5	Total
$2,000	-	-	-	-	$2,000

As part of Aim 2, enhancing the AAT and preparing standing orders training materials, we will contract with a videographer to record one video to support the enhanced version of the AAT. We will also record short videos with Dr. Paul Darden and an executive from a large healthcare system talking about the benefits of standing orders for clinics and patients. This video will be used as part of the consultation step with clinics who will implement standing orders. Videography will include production, editing and post-production activities.

Total Expenses for Other Expenses=$49,500

Indirect Costs

At UNC-Chapel Hill, F&A costs are calculated on a Modified Total Direct Costs (MTDC) base. This base consists of all direct salaries and wages, applicable fringe benefits, materials and supplies, services, travel and up to the first $25,000 of each subaward (regardless of the period of performance of the subawards under the award). Modified total direct costs shall exclude equipment, capital expenditures, charges for patient care, rental costs, tuition remission, scholarships and fellowships, participant support costs and the portion of each subaward in excess of $25,000.

Per UNC-Chapel Hill's current federally negotiated rate agreement (dated 11/23/2016), F&A costs associated with the proposed research project are calculated at the approved on-campus research rate of 55.5% of MTDC in all years. The cognizant agency for UNC-Chapel Hill is the U.S. Department of Health and Human Services. The cognizant agency point of contact is Darryl Mayes, (202) 401-2808.

Consortium/Contractual Costs

The Ohio State University – Paul Reiter, PhD

Year 1	Year 2	Year 3	Year 4	Year 5	Total
INST. BASE SALARY					

A subcontract with the Ohio State University will support costs associated with Dr. Paul Reiter collaborating on the project, including his salary and travel to UNC. Dr. Reiter will serve as a Co-Investigator on Project 1, providing expertise in assessing and increasing HPV vaccination as well as data collection methodologies. He is Associate Professor of Health Behavior and Health Promotion at the Ohio State University. His extensive experience in this field includes current work on an R37 project to test a mobile health intervention to increase HPV vaccination among young sexual minority men. He has served as the Director of the Behavioral Measurement Shared Resource at The Ohio State University Comprehensive Cancer Center and as co-leader of the Recruitment, Survey, and Retention Core for the OSU Center for Excellence in Regulatory Tobacco Science. Dr. Reiter has a long history of successful collaboration with Dr. Brewer. His effort on the project will be [%] in Year 1, and [%] in Years 2-5. He will also travel to UNC in Years 1 and 4. The Ohio State University subcontract budget provides a more detailed accounting of costs.

The American Medical Group Association – Elizabeth Ciemens, PhD

Year 1	Year 2	Year 3	Year 4	Year 5	Total
INST. BASE SALARY					

A subcontract with the American Medical Group Association (AMGA) will support Dr. Elizabeth Ciemens' salary and staff support for facilitating the recruitment of healthcare systems to participate in the formative interviews, RCT, primary care professional surveys, and key informant interviews. AMGA has already identified healthcare systems that have expressed interest in participating in these activities, in Mississippi, Missouri, and Texas. AMGA will support the payment of honoraria to healthcare systems to offset the administrative costs of participating in this research, as well as honoraria to local AAT facilitators who will be trained to deliver the AAT intervention. Dr. Ciemens will provide expertise in partnering with healthcare systems on research studies and augment efforts to disseminate study results and products. The AMGA budget for the subcontract is provided.

Total Expenses for Consortium/Contractual Costs=$267,003

RESEARCH & RELATED BUDGET - Cumulative Budget

	Totals ($)	
Section A, Senior/Key Person		302,770.00
Section B, Other Personnel		888,813.00
Total Number Other Personnel	23	
Total Salary, Wages and Fringe Benefits (A+B)		1,191,583.00
Section C, Equipment		
Section D, Travel		15,000.00
1. Domestic	15,000.00	
2. Foreign		
Section E, Participant/Trainee Support Costs		
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other		
6. Number of Participants/Trainees		
Section F, Other Direct Costs		397,577.00
1. Materials and Supplies	25,500.00	
2. Publication Costs	15,000.00	
3. Consultant Services	15,000.00	
4. ADP/Computer Services		
5. Subawards/Consortium/Contractual Costs	267,003.00	
6. Equipment or Facility Rental/User Fees		
7. Alterations and Renovations		
8. Other 1	33,274.00	
9. Other 2	41,800.00	
10. Other 3		
Section G, Direct Costs (A thru F)		1,604,160.00
Section H, Indirect Costs		755,679.00
Section I, Total Direct and Indirect Costs (G + H)		2,359,839.00
Section J, Fee		
Section K, Total Direct and Fee (I + J)		2,359,839.00

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 1

ORGANIZATIONAL DUNS*: 8321273230000

Budget Type*: ○ Project ● Subaward/Consortium

Enter name of Organization: The Ohio State University

Start Date*: 07-01-2021 **End Date*:** 06-30-2022 **Budget Period: 1**

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.		Paul		Reiter		Co-Investigator		CAL. MONTHS			12,536.00	2,636.00	15,172.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **15,172.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*

Total Number Other Personnel **Total Other Personnel**

Total Salary, Wages and Fringe Benefits (A+B) **15,172.00**

RESEARCH & RELATED Budget (A-B) (Funds Requested)

Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 1

ORGANIZATIONAL DUNS*: 8321273230000

Budget Type*: ❍ Project ● Subaward/Consortium

Enter name of Organization: The Ohio State University

Start Date*: 07-01-2021 **End Date*:** 06-30-2022 **Budget Period: 1**

C. Equipment Description	
List items and dollar amount for each item exceeding $5,000	
Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	
Additional Equipment: File Name:	

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	2,000.00
2. Foreign Travel Costs	
Total Travel Cost	**2,000.00**

E. Participant/Trainee Support Costs		**Funds Requested ($)***
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other:		
Number of Participants/Trainees	**Total Participant Trainee Support Costs**	

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 1

ORGANIZATIONAL DUNS*: 8321273230000

Budget Type*: ❍ Project ● Subaward/Consortium

Enter name of Organization: The Ohio State University

Start Date*: 07-01-2021 **End Date*:** 06-30-2022 **Budget Period: 1**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
Total Other Direct Costs	**0.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**17,172.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. MTDC	56	17,172.00	9,616.00
		Total Indirect Costs	**9,616.00**

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number): DHHS, Ernest Kinnear 214-767-3261

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**26,788.00**

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	26,788.00

L. Budget Justification* File Name: BudJustOhioP1r1045594774.pdf

(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

Tracking Number: GRANT13205496 Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 2

ORGANIZATIONAL DUNS*: 8321273230000

Budget Type*: ○ Project ● Subaward/Consortium

Enter name of Organization: The Ohio State University

Start Date*: 07-01-2022 **End Date*:** 06-30-2023 **Budget Period: 2**

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.		Paul		Reiter		Co-Investigator		CAL. MONTHS			6,268.00	1,318.00	7,586.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **7,586.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*

Total Number Other Personnel **Total Other Personnel**

Total Salary, Wages and Fringe Benefits (A+B) **7,586.00**

RESEARCH & RELATED Budget (A-B) (Funds Requested)

Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 2

ORGANIZATIONAL DUNS*: 8321273230000

Budget Type*: ❍ Project ● Subaward/Consortium

Enter name of Organization: The Ohio State University

Start Date*: 07-01-2022 **End Date*:** 06-30-2023 **Budget Period: 2**

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	

Additional Equipment: File Name:

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	
2. Foreign Travel Costs	
Total Travel Cost	

E. Participant/Trainee Support Costs	**Funds Requested ($)***
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant Trainee Support Costs**	

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 2

ORGANIZATIONAL DUNS*: 8321273230000

Budget Type*: ❍ Project ● Subaward/Consortium

Enter name of Organization: The Ohio State University

Start Date*: 07-01-2022 **End Date*:** 06-30-2023 **Budget Period: 2**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
Total Other Direct Costs	**0.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**7,586.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. MTDC	56	7,586.00	4,248.00
		Total Indirect Costs	**4,248.00**

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number): DHHS, Ernest Kinnear 214-767-3261

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**11,834.00**

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	11,834.00

L. Budget Justification* File Name: BudJustOhioP1r1045594774.pdf

(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

Tracking Number: GRANT13205496 Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 3

ORGANIZATIONAL DUNS*: 8321273230000

Budget Type*: ○ Project ● Subaward/Consortium

Enter name of Organization: The Ohio State University

Start Date*: 07-01-2023 **End Date*:** 06-30-2024 **Budget Period: 3**

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.		Paul		Reiter		Co-Investigator		CAL. MONTHS			6,268.00	1,318.00	7,586.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **7,586.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*

Total Number Other Personnel **Total Other Personnel**

Total Salary, Wages and Fringe Benefits (A+B) **7,586.00**

RESEARCH & RELATED Budget (A-B) (Funds Requested)

Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 3

ORGANIZATIONAL DUNS*: 8321273230000

Budget Type*: ❍ Project ● Subaward/Consortium

Enter name of Organization: The Ohio State University

Start Date*: 07-01-2023 **End Date*:** 06-30-2024 **Budget Period: 3**

C. Equipment Description	
List items and dollar amount for each item exceeding $5,000	
Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	
Additional Equipment: File Name:	

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	
2. Foreign Travel Costs	
Total Travel Cost	

E. Participant/Trainee Support Costs		**Funds Requested ($)***
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other:		
Number of Participants/Trainees	**Total Participant Trainee Support Costs**	

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 3

ORGANIZATIONAL DUNS*: 8321273230000
Budget Type*: ❍ Project ● Subaward/Consortium
Enter name of Organization: The Ohio State University

Start Date*: 07-01-2023 **End Date*:** 06-30-2024 **Budget Period: 3**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
Total Other Direct Costs	**0.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**7,586.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. MTDC	56	7,586.00	4,248.00
		Total Indirect Costs	**4,248.00**

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number): DHHS, Ernest Kinnear 214-767-3261

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**11,834.00**

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	11,834.00

L. Budget Justification* File Name: BudJustOhioP1r1045594774.pdf
(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

Tracking Number: GRANT13205496 Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 4

ORGANIZATIONAL DUNS*: 8321273230000

Budget Type*: ○ Project ● Subaward/Consortium

Enter name of Organization: The Ohio State University

Start Date*: 07-01-2024 **End Date*:** 06-30-2025 **Budget Period: 4**

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.		Paul		Reiter		Co-Investigator		CAL. MONTHS			6,268.00	1,318.00	7,586.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **7,586.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*

Total Number Other Personnel **Total Other Personnel**

Total Salary, Wages and Fringe Benefits (A+B) **7,586.00**

RESEARCH & RELATED Budget (A-B) (Funds Requested)

Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 4

ORGANIZATIONAL DUNS*: 8321273230000
Budget Type*: ❍ Project ● Subaward/Consortium
Enter name of Organization: The Ohio State University

Start Date*: 07-01-2024 **End Date*:** 06-30-2025 **Budget Period: 4**

C. Equipment Description	
List items and dollar amount for each item exceeding $5,000	
Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	
Additional Equipment: File Name:	

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	2,000.00
2. Foreign Travel Costs	
Total Travel Cost	**2,000.00**

E. Participant/Trainee Support Costs		**Funds Requested ($)***
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other:		
Number of Participants/Trainees	**Total Participant Trainee Support Costs**	

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 4

ORGANIZATIONAL DUNS*: 8321273230000
Budget Type*: ❍ Project ● Subaward/Consortium
Enter name of Organization: The Ohio State University

Start Date*: 07-01-2024 **End Date*:** 06-30-2025 **Budget Period: 4**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
Total Other Direct Costs	**0.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**9,586.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. MTDC	56	9,586.00	5,368.00
		Total Indirect Costs	**5,368.00**

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number): DHHS, Ernest Kinnear 214-767-3261

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**14,954.00**

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	14,954.00

L. Budget Justification* File Name: BudJustOhioP1r1045594774.pdf
(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

Tracking Number: GRANT13205496 Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 5

ORGANIZATIONAL DUNS*: 8321273230000

Budget Type*: ○ Project ● Subaward/Consortium

Enter name of Organization: The Ohio State University

Start Date*: 07-01-2025 **End Date*:** 06-30-2026 **Budget Period: 5**

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.		Paul		Reiter		Co-Investigator		CAL. MONTHS			6,268.00	1,318.00	7,586.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **7,586.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*

Total Number Other Personnel **Total Other Personnel**

Total Salary, Wages and Fringe Benefits (A+B) **7,586.00**

RESEARCH & RELATED Budget (A-B) (Funds Requested)

Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 5

ORGANIZATIONAL DUNS*: 8321273230000

Budget Type*: ❍ Project ● Subaward/Consortium

Enter name of Organization: The Ohio State University

Start Date*: 07-01-2025 **End Date*:** 06-30-2026 **Budget Period: 5**

C. Equipment Description	
List items and dollar amount for each item exceeding $5,000	
Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	
Additional Equipment: File Name:	

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	
2. Foreign Travel Costs	
Total Travel Cost	

E. Participant/Trainee Support Costs		**Funds Requested ($)***
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other:		
Number of Participants/Trainees	**Total Participant Trainee Support Costs**	

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 5

ORGANIZATIONAL DUNS*: 8321273230000

Budget Type*: ❍ Project ● Subaward/Consortium

Enter name of Organization: The Ohio State University

Start Date*: 07-01-2025 **End Date*:** 06-30-2026 **Budget Period: 5**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
Total Other Direct Costs	**0.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**7,586.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. MTDC	56	7,586.00	4,248.00
		Total Indirect Costs	**4,248.00**

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number): DHHS, Ernest Kinnear 214-767-3261

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**11,834.00**

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	11,834.00

L. Budget Justification* File Name: BudJustOhioP1r1045594774.pdf

(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

Tracking Number: GRANT13205496 Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

BUDGET JUSTIFICATION – The Ohio State University

Key Personnel

Paul Reiter, PhD, Co-Investigator

Year 1	Year 2	Year 3	Year 4	Year 5
CAL. MONTHS				

Dr. Reiter is an Associate Professor in the Division of Health Behavior and Health Promotion, the College of Public Health at the Ohio State University. He is an expert in vaccination behaviors and testing interventions to increase such behaviors. He has specific expertise increasing HPV vaccination among adolescents and young adults and working in health clinics to implement interventions. Additionally, he contributes extensive knowledge on data collection methodologies. Dr. Reiter has successfully collaborated with Dr. Brewer and his team on numerous studies. As a Co-Investigator on this research project, he will provide scientific guidance on survey item development, validating measures, developing intervention protocols, and interpreting research findings.

Total Expenses for Personnel= $45,516

Fringe Benefits

Fringe Benefits are budgeted per our approved F&A rate agreement at 23.4% for faculty academic, 13.9% for faculty summer.

Travel

Travel for Study Team meetings

Year 1	Year 2	Year 3	Year 4	Year 5	Total
2,000	-	-	2,000	-	$4,000

$2,000 travels funds for flight, lodging, and per diem to Chapel Hill are budgeted for Year 1 and Year 4 for Dr. Reiter to meet with the study team.

Indirect Costs

The Ohio State University has a federally approved indirect cost rate agreement dated March 5, 2020, that specifies an indirect cost rate of 56%.

RESEARCH & RELATED BUDGET - Cumulative Budget

	Totals ($)	
Section A, Senior/Key Person		45,516.00
Section B, Other Personnel		
Total Number Other Personnel		
Total Salary, Wages and Fringe Benefits (A+B)		45,516.00
Section C, Equipment		
Section D, Travel		4,000.00
1. Domestic	4,000.00	
2. Foreign		
Section E, Participant/Trainee Support Costs		
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other		
6. Number of Participants/Trainees		
Section F, Other Direct Costs		
1. Materials and Supplies		
2. Publication Costs		
3. Consultant Services		
4. ADP/Computer Services		
5. Subawards/Consortium/Contractual Costs		
6. Equipment or Facility Rental/User Fees		
7. Alterations and Renovations		
8. Other 1		
9. Other 2		
10. Other 3		
Section G, Direct Costs (A thru F)		49,516.00
Section H, Indirect Costs		27,728.00
Section I, Total Direct and Indirect Costs (G + H)		77,244.00
Section J, Fee		
Section K, Total Direct and Fee (I + J)		77,244.00

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 1

ORGANIZATIONAL DUNS*: 143834070

Budget Type*: ○ Project ● Subaward/Consortium

Enter name of Organization: AMGA Analytics, LLC

Start Date*: 07-01-2021 **End Date*:** 06-30-2022 **Budget Period: 1**

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.		Elizabeth	L.	Ciemins	PhD	Research Director		CAL. MONTHS			13,812.00	2,762.00	16,574.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name: **Total Senior/Key Person** **16,574.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
1	Research Coordinator	0.72			4,860.00	972.00	5,832.00
1	**Total Number Other Personnel**					**Total Other Personnel**	**5,832.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**22,406.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 1

ORGANIZATIONAL DUNS*: 143834070

Budget Type*: ❍ Project ● Subaward/Consortium

Enter name of Organization: AMGA Analytics, LLC

Start Date*: 07-01-2021 **End Date*:** 06-30-2022 **Budget Period: 1**

C. Equipment Description	
List items and dollar amount for each item exceeding $5,000	
Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	
Additional Equipment: File Name:	

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	
2. Foreign Travel Costs	
Total Travel Cost	

E. Participant/Trainee Support Costs		**Funds Requested ($)***
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other:		
Number of Participants/Trainees	**Total Participant Trainee Support Costs**	

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 1

ORGANIZATIONAL DUNS*: 143834070

Budget Type*: ❍ Project ● Subaward/Consortium

Enter name of Organization: AMGA Analytics, LLC

Start Date*: 07-01-2021 **End Date*:** 06-30-2022 **Budget Period: 1**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
Total Other Direct Costs	**0.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**22,406.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. indirect	15	22,406.00	3,361.00
		Total Indirect Costs	**3,361.00**

Cognizant Federal Agency
(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**25,767.00**

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	25,767.00

L. Budget Justification*	File Name: BudJustAMGAP1r1045594775.pdf (Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 2

ORGANIZATIONAL DUNS*: 143834070

Budget Type*: ○ Project ● Subaward/Consortium

Enter name of Organization: AMGA Analytics, LLC

Start Date*: 07-01-2022 **End Date*:** 06-30-2023 **Budget Period: 2**

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.	.	Elizabeth	L.	Ciemins	PhD	Research Director		CAL. MONTHS			14,226.00	2,845.00	17,071.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **17,071.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
1	Research Coordinator	0.72			5,006.00	1,001.00	6,007.00
1	**Total Number Other Personnel**					**Total Other Personnel**	**6,007.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**23,078.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 2

ORGANIZATIONAL DUNS*: 143834070

Budget Type*: ❍ Project ● Subaward/Consortium

Enter name of Organization: AMGA Analytics, LLC

Start Date*: 07-01-2022 **End Date*:** 06-30-2023 **Budget Period: 2**

C. Equipment Description	
List items and dollar amount for each item exceeding $5,000	
Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	
Additional Equipment: File Name:	

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	
2. Foreign Travel Costs	
Total Travel Cost	

E. Participant/Trainee Support Costs		**Funds Requested ($)***
1. Tuition/Fees/Health Insurance		
2. Stipends		33,000.00
3. Travel		
4. Subsistence		
5. Other:		
Number of Participants/Trainees	**Total Participant Trainee Support Costs**	**33,000.00**

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 2

ORGANIZATIONAL DUNS*: 143834070

Budget Type*: ❍ Project ● Subaward/Consortium

Enter name of Organization: AMGA Analytics, LLC

Start Date*: 07-01-2022 **End Date*:** 06-30-2023 **Budget Period: 2**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
Total Other Direct Costs	**0.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**56,078.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. indirect	15	23,078.00	3,462.00
		Total Indirect Costs	**3,462.00**

Cognizant Federal Agency
(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**59,540.00**

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	59,540.00

L. Budget Justification*	File Name: BudJustAMGAP1r1045594775.pdf (Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 3

ORGANIZATIONAL DUNS*: 143834070

Budget Type*: ○ Project ● Subaward/Consortium

Enter name of Organization: AMGA Analytics, LLC

Start Date*: 07-01-2023 **End Date*:** 06-30-2024 **Budget Period: 3**

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.		Elizabeth	L.	Ciemins	PhD	Research Director		CAL. MONTHS			10,467.00	2,093.00	12,560.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **12,560.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*

Total Number Other Personnel **Total Other Personnel**

Total Salary, Wages and Fringe Benefits (A+B) **12,560.00**

RESEARCH & RELATED Budget (A-B) (Funds Requested)

Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 3

ORGANIZATIONAL DUNS*: 143834070

Budget Type*: ❍ Project ● Subaward/Consortium

Enter name of Organization: AMGA Analytics, LLC

Start Date*: 07-01-2023 **End Date*:** 06-30-2024 **Budget Period: 3**

C. Equipment Description	
List items and dollar amount for each item exceeding $5,000	
Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	
Additional Equipment: File Name:	

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	
2. Foreign Travel Costs	
Total Travel Cost	

E. Participant/Trainee Support Costs		**Funds Requested ($)***
1. Tuition/Fees/Health Insurance		
2. Stipends		51,000.00
3. Travel		
4. Subsistence		
5. Other:		
Number of Participants/Trainees	**Total Participant Trainee Support Costs**	**51,000.00**

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 3

ORGANIZATIONAL DUNS*: 143834070

Budget Type*: ❍ Project ● Subaward/Consortium

Enter name of Organization: AMGA Analytics, LLC

Start Date*: 07-01-2023 **End Date*:** 06-30-2024 **Budget Period: 3**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
Total Other Direct Costs	**0.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**63,560.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. indirect	15	12,560.00	1,884.00
		Total Indirect Costs	**1,884.00**

Cognizant Federal Agency
(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**65,444.00**

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	65,444.00

L. Budget Justification*	File Name: BudJustAMGAP1r1045594775.pdf (Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 4

ORGANIZATIONAL DUNS*: 143834070

Budget Type*: ○ Project ● Subaward/Consortium

Enter name of Organization: AMGA Analytics, LLC

Start Date*: 07-01-2024 **End Date*:** 06-30-2025 **Budget Period: 4**

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.		Elizabeth	L.	Ciemins	PhD	Research Director		CAL. MONTHS			10,781.00	2,156.00	12,937.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **12,937.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*

Total Number Other Personnel **Total Other Personnel**

Total Salary, Wages and Fringe Benefits (A+B) **12,937.00**

RESEARCH & RELATED Budget (A-B) (Funds Requested)

Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 4

ORGANIZATIONAL DUNS*: 143834070

Budget Type*: ❍ Project ● Subaward/Consortium

Enter name of Organization: AMGA Analytics, LLC

Start Date*: 07-01-2024 **End Date*:** 06-30-2025 **Budget Period: 4**

C. Equipment Description	
List items and dollar amount for each item exceeding $5,000	
Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	
Additional Equipment: File Name:	

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	
2. Foreign Travel Costs	
Total Travel Cost	

E. Participant/Trainee Support Costs		**Funds Requested ($)***
1. Tuition/Fees/Health Insurance		
2. Stipends		18,000.00
3. Travel		
4. Subsistence		
5. Other:		
Number of Participants/Trainees	**Total Participant Trainee Support Costs**	**18,000.00**

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 4

ORGANIZATIONAL DUNS*: 143834070

Budget Type*: ❍ Project ● Subaward/Consortium

Enter name of Organization: AMGA Analytics, LLC

Start Date*: 07-01-2024 **End Date*:** 06-30-2025 **Budget Period: 4**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
Total Other Direct Costs	**0.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**30,937.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. indirect	15	12,937.00	1,941.00
		Total Indirect Costs	**1,941.00**

Cognizant Federal Agency

(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**32,878.00**

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	32,878.00

L. Budget Justification*	File Name: BudJustAMGAP1r1045594775.pdf (Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 5

ORGANIZATIONAL DUNS*: 143834070

Budget Type*: ○ Project ● Subaward/Consortium

Enter name of Organization: AMGA Analytics, LLC

Start Date*: 07-01-2025 **End Date*:** 06-30-2026 **Budget Period: 5**

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.		Elizabeth	L.	Ciemins	PhD	Research Director		CAL. MONTHS			4,442.00	888.00	5,330.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **5,330.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*

Total Number Other Personnel **Total Other Personnel**

Total Salary, Wages and Fringe Benefits (A+B) **5,330.00**

RESEARCH & RELATED Budget (A-B) (Funds Requested)

Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 5

ORGANIZATIONAL DUNS*: 143834070

Budget Type*: ❍ Project ● Subaward/Consortium

Enter name of Organization: AMGA Analytics, LLC

Start Date*: 07-01-2025 **End Date*:** 06-30-2026 **Budget Period: 5**

C. Equipment Description	
List items and dollar amount for each item exceeding $5,000	
Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	
Additional Equipment: File Name:	

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	
2. Foreign Travel Costs	
Total Travel Cost	

E. Participant/Trainee Support Costs		**Funds Requested ($)***
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other:		
Number of Participants/Trainees	**Total Participant Trainee Support Costs**	

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 5

ORGANIZATIONAL DUNS*: 143834070

Budget Type*: ❍ Project ● Subaward/Consortium

Enter name of Organization: AMGA Analytics, LLC

Start Date*: 07-01-2025 **End Date*:** 06-30-2026 **Budget Period: 5**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
Total Other Direct Costs	**0.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**5,330.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. indirect	15	5,330.00	800.00
		Total Indirect Costs	**800.00**

Cognizant Federal Agency

(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**6,130.00**

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	6,130.00

L. Budget Justification*	File Name: BudJustAMGAP1r1045594775.pdf (Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

BUDGET JUSTIFICATION – AMGA Analytics

Key Personnel

Elizabeth Ciemins, Research Director

Year 1	Year 2	Year 3	Year 4	Year 5
CAL. MONTHS				

Dr. Ciemins is Vice President of Research and Analytics at AMGA. She is an expert in health services research, implementation studies in particular. She will provide key guidance and oversight on the recruitment of up to 8 large AMGA-member health care organizations for this project. She will also contribute to major project activities, coordination and liaison with health care organizations, requested data pulls from participating sites, coordination of honoraria distribution, interpretation of evaluation results, and publication and presentation of study findings.

Monette McKinnon, Research Coordinator

Year 1	Year 2
CAL. MONTHS	

Ms. McKinnon will lead the recruitment of up to 8 large AMGA-member health care organizations for participation in this project, under the direction of Dr. Ciemins. Ms. McKinnon will provide support to Dr. Ciemins on all project activities, including site recruitment, site coordination, requested data pulls, and with the publication of results, as needed. Ms. McKinnon will be responsible for distribution of honoraria to participating study sites.

Total Expenses for Personnel = $63,594.00

Fringe Benefits

$12,718.80

Other Direct Costs (ODCs)

Healthcare System Honoraria

Year 1	Year 2	Year 3	Year 4	Year 5	Total
-	$18,000	$36,000	$18,000	-	$72,000

AMGA will facilitate payments made to health care organizations for participating in the RCT. Health care organizations will receive payment based on how many of their clinic practice sites participate. Participating health care organizations will receive payment in two installments—the first installment will happen at the beginning of the trial and the second installment will occur after the second data pull has happened. We anticipate enrolling up to 8 health care organizations. Payments are expected to be made in Year 2 (25%) Year 3 (50%) and Year 4 (25%).

Announcement Approach Training Facilitator Honoraria

Year 1	Year 2	Year 3	Year 4	Year 5	Total
-	$12,500	$12,500	-	-	$25,000

Announcement Approach Training Facilitators will be recruited from the systems that agree to participate in the RCT. We anticipate having one AAT Facilitator per system and each facilitator will deliver AAT workshops to approximately 5 clinics. AMGA will provide honoraria to facilitators for completing the Train-the-Trainer Orientation ($1,500) as well as honoraria for each AAT workshop they deliver ($325 x 5 = $1,625). All facilitators will be asked to complete time logs for training activities and meetings to allow the project administrators to calculate the total costs. Thus the total honoraria provided will be [($1,500 x 8) + ($1,625 x8)]= $25,000. As the RCT will take place across Years 2 and 3, we have divided the cost across these years.

Mileage for Travel to Clinics

Year 1	Year 2	Year 3	Year 4	Year 5	Total
-	$2,500	$2,500	-	-	$5,000

Some health care systems will be more geographically dispersed than others. Because of this, at the time we engage the AAT Facilitators, we will offer an additional amount for mileage based on the amount of travel required to reach the participating clinics. We are allowing $2,500 for each year of the RCT to cover mileage.

Indirect Costs
$11,466.92

TOTAL DIRECT AND INDIRECT COSTS REQUESTED YEARS 1-5 $189,759.72

RESEARCH & RELATED BUDGET - Cumulative Budget

	Totals ($)	
Section A, Senior/Key Person		64,472.00
Section B, Other Personnel		11,839.00
Total Number Other Personnel	2	
Total Salary, Wages and Fringe Benefits (A+B)		76,311.00
Section C, Equipment		
Section D, Travel		
1. Domestic		
2. Foreign		
Section E, Participant/Trainee Support Costs		102,000.00
1. Tuition/Fees/Health Insurance		
2. Stipends	102,000.00	
3. Travel		
4. Subsistence		
5. Other		
6. Number of Participants/Trainees		
Section F, Other Direct Costs		
1. Materials and Supplies		
2. Publication Costs		
3. Consultant Services		
4. ADP/Computer Services		
5. Subawards/Consortium/Contractual Costs		
6. Equipment or Facility Rental/User Fees		
7. Alterations and Renovations		
8. Other 1		
9. Other 2		
10. Other 3		
Section G, Direct Costs (A thru F)		178,311.00
Section H, Indirect Costs		11,448.00
Section I, Total Direct and Indirect Costs (G + H)		189,759.00
Section J, Fee		
Section K, Total Direct and Fee (I + J)		189,759.00

PHS 398 Cover Page Supplement

OMB Number: 0925-0001

Expiration Date: 02/28/2023

1. Vertebrate Animals Section

Are vertebrate animals euthanized? ○ Yes ○ No

If "Yes" to euthanasia

Is the method consistent with American Veterinary Medical Association (AVMA) guidelines?

○ Yes ○ No

If "No" to AVMA guidelines, describe method and provide scientific justification

2. *Program Income Section

*Is program income anticipated during the periods for which the grant support is requested?

○ Yes ● No

If you checked "yes" above (indicating that program income is anticipated), then use the format below to reflect the amount and source(s). Otherwise, leave this section blank.

*Budget Period *Anticipated Amount ($) *Source(s)

Tracking Number: GRANT13205496 Funding Opportunity Number: PAR-20-077 . Received Date: 2020-09-18T11:41:16.000-04:00

PHS 398 Cover Page Supplement

3. Human Embryonic Stem Cells Section

*Does the proposed project involve human embryonic stem cells? ○ Yes ● No

If the proposed project involves human embryonic stem cells, list below the registration number of the specific cell line(s) from the following list: http://grants.nih.gov/stem_cells/registry/current.htm. Or, if a specific stem cell line cannot be referenced at this time, check the box indicating that one from the registry will be used:

Specific stem cell line cannot be referenced at this time. One from the registry will be used.

Cell Line(s) (Example: 0004):

4. Human Fetal Tissue Section

*Does the proposed project involve human fetal tissue obtained from elective abortions? ○ Yes ● No

If "yes" then provide the HFT Compliance Assurance

If "yes" then provide the HFT Sample IRB Consent Form

5. Inventions and Patents Section (Renewal applications)

*Inventions and Patents: ○ Yes ○ No

If the answer is "Yes" then please answer the following:

*Previously Reported: ○ Yes ○ No

6. Change of Investigator/Change of Institution Section

❑ Change of Project Director/Principal Investigator

Name of former Project Director/Principal Investigator

Prefix:

*First Name:

Middle Name:

*Last Name:

Suffix:

❑ Change of Grantee Institution

*Name of former institution:

PHS 398 Research Plan

OMB Number: 0925-0001
Expiration Date: 02/28/2023

Introduction	
1. Introduction to Application (for Resubmission and Revision applications)	IntroApplicationP1rV21045663949.pdf
Research Plan Section	
2. Specific Aims	SpecificAimsP1rV21045663950.pdf
3. Research Strategy*	ResearchStrategyP1r1045594816.pdf
4. Progress Report Publication List	
Other Research Plan Section	
5. Vertebrate Animals	
6. Select Agent Research	
7. Multiple PD/PI Leadership Plan	
8. Consortium/Contractual Arrangements	ConsortAMGAOhioP1rV21045663951.pdf
9. Letters of Support	LOSP1Combinedr1045594822.pdf
10. Resource Sharing Plan(s)	ResourceSharingP1r1045594819.pdf
11. Authentication of Key Biological and/or Chemical Resources	
Appendix	
12. Appendix	

Tracking Number: GRANT13205496
Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

INTRODUCTION TO APPLICATION – Project 1

CRITIQUE, RESPONSE TO CRITIQUE

SPECIFIC AIMS – Project 1

Low HPV vaccination coverage is an ongoing challenge to cancer prevention in the US, especially in rural areas. To help providers make more effective HPV vaccine recommendations for adolescents, we developed a 1-hour, in-clinic Announcement Approach Training (AAT) to strengthen providers' motivation for delivering announcements and to build skills for respectfully addressing parent concerns. AAT increased HPV vaccine initiation by 5 percentage points compared to a control arm in a randomized clinical trial (RCT) and is now an NCI-designated Research-Tested Intervention Program that has been delivered in 15 states.

To increase the impact of AAT, **we propose to expand the capacity of the whole primary care team by supporting the implementation of existing standing orders for HPV vaccine**. About half of parents who discuss HPV vaccine during clinic visits do so with a nurse. Registered nurses (RNs) and medical assistants (MAs) are well-trusted by parents but have been largely ignored in research on HPV vaccine communication. AAT provides language that is appropriate for RNs and MAs to use and suggests that clinics establish a defined role for these team members in HPV vaccine recommendations. We propose to further enhance the AAT with support for implementing standing orders, which specify the clinical staff who can deliver vaccines as appropriate and based on state laws. Most healthcare systems have standing vaccine orders but their implementation, especially for HPV vaccination, is suboptimal. Furthermore, research shows that standing orders increase vaccine uptake, but these trials have not examined the impact of standing orders support on HPV vaccination coverage. We propose to study standing orders support that uses persuasion and skills building in a series of activation meetings with system leaders, clinic leaders, and clinic staff.

As part of the P01 Program Project, "Improving Provider Announcement Communication Training (IMPACT)," Project 1 will increase the impact of recommendations through an AAT enhanced to include RNs and MAs through standing orders support. Because healthcare is increasingly centralized and rural areas have notably low HPV vaccine coverage, the proposed RCT will be with clinics in healthcare systems serving rural and nonrural patient populations.

Aim 1. Characterize the role of primary care team members and standing orders in HPV vaccination.

a. Conduct formative interviews with a provider and an RN or MA from 10 clinics (n=20) in healthcare systems. Use qualitative analyses to identify topics and language for the national survey.
b. Conduct a national primary care team survey of 1,500 providers and 1,000 RNs and MAs with the Data Core. Oversample rural primary care team professionals to support rural and nonrural comparisons.

Aim 2. Evaluate the impact of standing orders support for the whole primary care team on HPV vaccine communication and uptake in a cluster RCT.

a. Enhance AAT and standing orders support materials to leverage the whole primary care team, including RNs and MAs. Update existing AAT intervention materials including slides and script. Adapt Immunization Action Coalition trainings on adolescent vaccine standing orders to complement AAT.
b. Pilot test the AAT enhanced with standing orders support in 2 clinics in healthcare systems.
c. Conduct cluster RCT with 40 nonrural and rural clinics in healthcare systems in MO, MS and TX. Randomize clinics to receive AAT alone or enhanced with standing orders support. Examine 12-month change in HPV vaccine initiation (patients ages 11-12). Explore whether the impact differs by rurality.
d. Survey 400 AAT workshop participants about HPV vaccine communication practices 3 months later.

Hypothesis: AAT with standing orders support improves HPV vaccine communication and uptake.

Aim 3. Generate guidance for healthcare systems to implement standing orders support.

a. Establish cost per additional adolescent initiating HPV vaccine due to standing orders support.
b. Examine other implementation outcomes using surveys, checklists, and key informant interviews.
c. Examine implementation determinants (e.g., facilitators and barriers) using key informant interviews.
d. Contribute modules to the IMPACT AAT Intervention Package.

The proposed research addresses NCI's priority of increasing HPV vaccination uptake. This research is **significant** in expanding the role of RNs and MAs and **innovative** in optimizing healthcare systems' use of HPV vaccination standing orders. The Program Project will establish the cost-effectiveness of standing orders support and develop the AAT Intervention Package to facilitate **dissemination** to healthcare systems across the US. Project 1 addresses the **IMPACT Program Project theme** by building capacity for HPV vaccine communication interventions among primary care teams in healthcare systems.

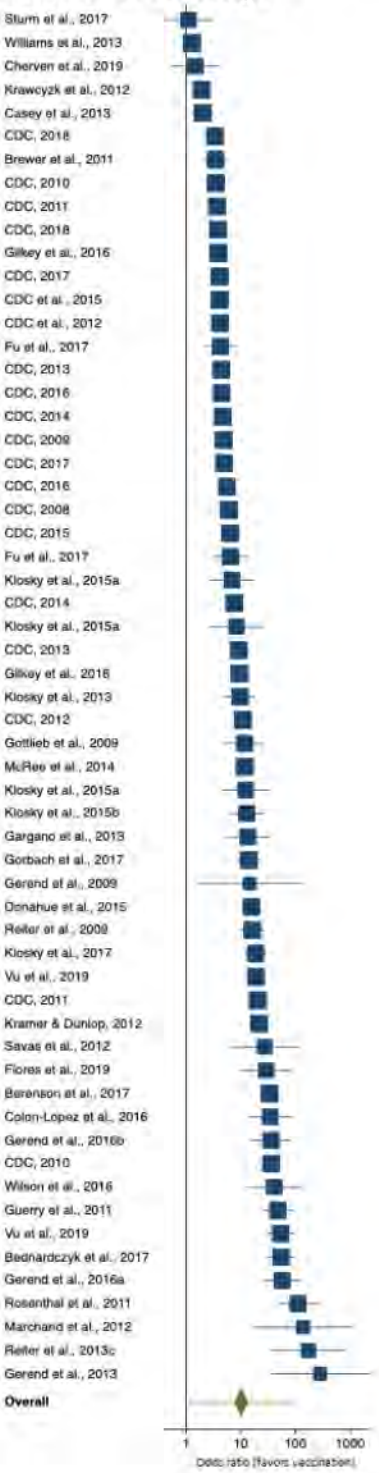
RESEARCH STRATEGY – Project 1

SIGNIFICANCE

HPV vaccine coverage remains low in the US. HPV vaccination presents an extraordinary opportunity for cancer prevention,[2–4] with the potential to prevent 6 cancers that affect women (cervical, vaginal, vulvar), men (penile), and both sexes (anal, oropharyngeal).[5,6] National recommendations call for adolescents to routinely receive HPV vaccine at age 11 or 12.[7] However, only 72% of adolescents ages 13-17 have initiated HPV vaccination, and only 54% have received the recommended doses (i.e., "up-to-date").[8] This low coverage leaves many children unnecessarily at risk for HPV cancers when they are adults.[9] Now in the second decade of HPV vaccination, addressing low coverage in the US has become a national priority.[10,11]

HPV vaccine uptake is 10% lower in rural areas, a difference that is persistent and notable.[8] This geographic disparity is especially worrisome as rural areas also have higher rates of HPV cancers.[12,13]

Figure 1. Provider recommendation and HPV vaccination coverage[14–38]



Scientific premise

A provider's recommendation is the most potent intervention for increasing HPV vaccine uptake.[39] Across 59 US studies of the association of provider recommendation and HPV vaccine uptake, the pooled odds ratio is 10.1 (95% CI: 7.6-13.4) (**Figure 1**). HPV vaccine initiation was substantially higher among adolescents whose parents had received a provider recommendation compared to those who had not (64% vs 20%).[14–38]

The most effective way to recommend HPV vaccine is a *presumptive announcement*,[23,40,41] an approach that presumes the child will receive HPV vaccination. An example of an announcement is, "Now that Sophia is 12, she is due for 3 vaccines. Today, she'll get vaccines to prevent meningitis, HPV cancers, and whooping cough." Observational studies show presumptive announcements are associated with more same-day uptake[23,40,41] and less refusal of HPV vaccine,[42] as compared to having longer conversations.

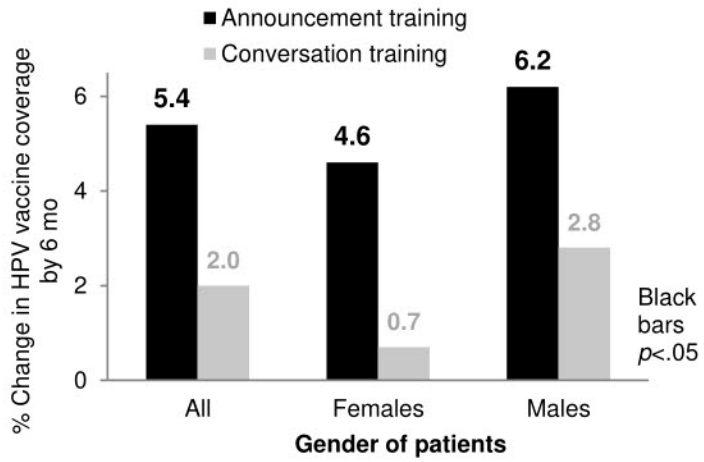
Training in presumptive announcements is effective. Our 3-arm randomized clinical trial (RCT) with 29 primary care clinics evaluated 2 *brief* (~60 minute) physician trainings.[43] One trial arm ("Announcement Training") trained physicians to use presumptive announcements for introducing adolescent vaccination to parents. A second arm ("Conversation Training") trained physicians to use an open-ended approach to introducing adolescent vaccination. Both trainings included a structured communication approach for easing common concerns about HPV vaccination and suggested follow-up for families who declined. At 6-months, the Announcement Approach Training (AAT) improved HPV vaccine initiation among adolescents ages 11-12 by 5 percentage points over the control ($p<.05$, **Figure 2**).[43] In contrast, the Conversation Training did not improve vaccination coverage.[43,44] The time required to recommend HPV vaccine decreased by ~40%.[45] After the training, physicians had more positive attitudes, social norms, and perceived behavioral control related to recommending HPV vaccine than before the training (all $p<.001$).[45] Importantly, participating physicians rated AAT highly on acceptability.[45] **AAT is now an NCI-designated Research-Tested Intervention Program** that has been delivered to over 1,700 providers in 15 states.[46]

Presumptive provider communication about adolescent vaccination is increasingly common but not yet universal.[47–49,23] Nationally, 65% of pediatricians and 52% of family physicians report typically using presumptive language when recommending HPV vaccine,[42] an estimate that may be a best-case scenario. Indeed, our earlier study that recorded clinic visits found as few as 15% of providers used presumptive announcements.[41] Thus, many providers do not reliably use presumptive announcements, and even those who do may have room to improve their communication with patients.

Literature review

Having RNs and MAs participate in making announcements for HPV vaccination can increase the reach of AAT. These primary care team members are an important resource, with about 3 times as many nurses as physicians in the US.[50–52] Furthermore, nurses are trusted by 82% of Americans, higher than any other profession, including physicians (65%).[53] **About half of parents who discuss HPV vaccine during clinic visits do so with a nurse.**[54] However, RNs and MAs have been largely ignored in research on HPV vaccine communication.[55] Nurses and MAs have typically attended our AAT, but the training did not try to expand their roles in making recommendations. An optimal contact point during the clinic flow, when RNs and MAs could use the Announcement Approach, is when they room patients and check vitals, before a physician sees the patient. In this context, the announcement becomes a default activity done by RNs and MAs who may more reliably follow guidelines.[56] Physicians could then address hesitant parents as needed.

Figure 2. RCT of HPV vaccine communication trainings.



Standing orders can expand the role of RNs and MAs in vaccination. *Standing orders* are clinic or healthcare system protocols that allow designated primary care team members, such as RNs or MAs, to deliver vaccines according to certain criteria, such as patient age, without first consulting a physician. All states allow RNs to administer vaccines, either under their own authority (23 states), under delegated authority (47 states), or because their laws do not address the topic (3 states).[57] All states but one allow MAs to administer vaccines, often under supervision by a provider.[57] In 2018, 59% of US physicians had standing orders for vaccination[58] and 40% of pediatricians had them for HPV vaccination.[42]

Standing orders increase vaccine uptake. Across 29 studies evaluating standing orders for vaccination, the median increase in vaccine uptake was 24%.[59] Three RCTs of standing orders alone found increased vaccination in adults,[60–62] and at least 4 studies have examined standing orders for vaccination of children (median increase 28%).[63–66] Several trials have included standing orders as part of multimodal interventions that increased HPV vaccine uptake.[67] A quasi-experiment by Tan and colleagues with young adults, ages 19-26, found that implementing HPV vaccine standing orders increased uptake by 7 percentage points. [68]

Real-world use of standing orders faces several challenges. Clinics with standing orders for vaccines are more likely to have strong practice teamwork, access to an electronic health record (EHR), and an immunization champion.[69] Barriers to use of standing orders include potential errors in administration, physician desire to be the person recommending vaccines, belief that parents prefer to talk with a physician, and staff discomfort with addressing questions.[58] No randomized trials we are aware of have isolated the impact of supporting implementation of existing HPV vaccination standing orders to overcome these barriers.

Healthcare systems need guidance on ways to increase HPV vaccination. Healthcare systems are important settings for increasing HPV vaccine uptake. Care is increasingly centralized, with as few as 15% of new physicians going to work in private practice.[70] As healthcare systems choose among interventions to increase HPV vaccine uptake, decision makers consider an intervention's cost-effectiveness; how it will be received (e.g., acceptability, appropriateness); and whether it can be integrated into practice (e.g., feasibility, fidelity, sustainability).[71,72] Furthermore, employees tasked with implementing the intervention need information about potential implementation facilitators and barriers to ensure new initiatives' integration into practice.

Significance of expected research contribution

We propose to study *standing orders support* to optimize implementation of existing standing orders. Well-implemented standing orders can empower the whole primary care team to communicate effectively about HPV vaccine. This intervention has great potential to increase HPV vaccine uptake in healthcare systems and thus would be clinically useful and increase capacity for cancer prevention. As part of the P01 Program Project, "Improving Provider Announcement Communication Training (IMPACT)," Project 1 will focus on expanding the impact of the primary care team's HPV vaccine recommendations through an AAT enhanced with standing orders support. Furthermore, we will work with the other IMPACT projects to develop an AAT Intervention Package to provide guidance for healthcare systems. The proposed research addresses NCI's priority to "Broaden the Prevention of HPV-Associated Cancers" by increasing HPV vaccine uptake.

INNOVATION

Our research project offers an innovative approach to improving HPV vaccine communication and uptake. **First, we propose to leverage the whole primary care team through HPV vaccine standing orders support paired with AAT.** Healthcare systems' activation and implementation of *existing* HPV vaccine standing orders has not been studied to our knowledge. Standing orders for RNs and MAs are widely in place for vaccination and often underused, but little is known about how to optimize their use. Standing orders can help nurses to operate at the top of their license and establish their role in HPV vaccine communication, building on their demonstrated capacity for successfully routinizing new clinical procedures. These actions can free providers to address HPV vaccine hesitancy and declination. Many previous provider communication trainings, including our own, have focused on the needs of physicians.[43,44] Previous trials have included *creating new* HPV vaccine standing orders along with other active intervention components. In contrast, our RCT will isolate the impact and cost of *supporting existing* standing orders in the context of AAT.

Second, the standing orders support intervention will be tailored to the needs of healthcare systems and packaged for their eventual use. Few interventions have been developed that meet healthcare systems' specific goals and needs. Systems look to evidence-based practices to reduce costs, meet quality benchmarks for vaccine coverage, and increase patient satisfaction. We propose to conduct our formative research and RCT in healthcare systems. We will then provide guidance to systems on implementing standing orders support, using metrics that address their specific needs. Thus, we will report on cost, impact on quality benchmarks[73] including HPV vaccine coverage and patient satisfaction, and how to create sustained change.

Third, our innovative research ensures inclusion of rural areas to allow us to study and meet the needs of rural populations. Rural areas have the lowest rates of HPV vaccination coverage,[8] but little empirical research has yielded insights into the causes of and solutions to this disparity. Our formative work, national survey, and standing orders support RCT will all include clinics that serve rural areas and identify ways to ensure that AAT enhanced with standing orders support meets rural clinics' needs.

APPROACH

Research Team

The research team will be led by **Noel Brewer, PhD**, Professor of Health Behavior at the University of North Carolina (UNC). Dr. Brewer is an expert in provider communication and developer of the Announcement Approach Training. Dr. Brewer was founding chair of the National HPV Vaccination Roundtable and has advised several federal panels, the Centers for Disease Control and Prevention, and the World Health Organization on behavioral aspects of vaccination. Co-Investigator **Paul Reiter, PhD**, Associate Professor of Health Behavior and Health Promotion at Ohio State University, will advise on survey development and the RCT. Co-Investigator **Sarah Birken, PhD**, Associate Professor of Implementation Science at Wake Forest University, will lead implementation measure development and analysis. **Paul Darden, MD**, Professor of Pediatrics at University of Oklahoma and a practicing pediatrician who has worked to implement standing orders for HPV vaccination in 2 healthcare systems, will advise on standing orders. **Litjen (LJ) Tan, PhD**, Chief Strategy Officer for the Immunization Action Coalition, will be an external advisor on optimizing standing orders. **Lisa Mansfield, PhD**, an RN who has conducted mixed-methods research on HPV vaccination, will advise on nurses' training needs. We will also regularly consult with IMPACT's Clinical Advisory Board which includes a broad range of primary care professionals including nurses and a medical assistant (see Intervention Core). The research team has a long history of collaboration with over 60 joint publications.

Dr. Brewer has conducted several large RCTs to increase HPV vaccination uptake in addition to the AAT trial described previously. One RCT found that quality improvement visits increased adolescent vaccination at 91 medical clinics in North Carolina that served 107,443 adolescents.[74] In other research, we have tested risk communication strategies to support smoking cessation in a multi-site RCT of pictorial warnings (n=2,149 smokers)[75] and cigarette smoke chemical disclosures (n=719 smokers).[76] **These trials show our team's experience designing and conducting high-impact RCTs, including clinical interventions.**

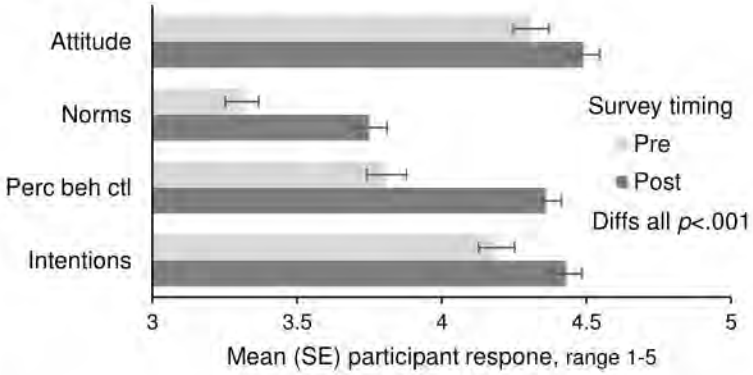
Pilot Studies

To gather pilot data about AAT focused on the whole primary care team, Dr. Brewer worked with 2 healthcare systems in a Midwest state to deliver AAT workshops for 21 clinics. He trained their providers to lead the workshops. Three-quarters of participants were RNs (n=65), MAs (n=60), nurse practitioners (n=16), or physician assistants (n=4). AAT increased the following Theory of Planned Behavior[85] constructs: positive HPV vaccination attitudes, social norms, perceived behavioral control, and intentions to recommend the vaccine (all p<.001, **Figure 3**). The training also increased HPV vaccine initiation over 9 months (p<.002).

Participants expressed very high satisfaction with the trainings and the Announcement Approach (>90%).

We delivered an AAT workshop with 29 nursing students, half of whom had clinical experience as nurses, followed by a listening session to understand their training needs. Participants said they are often the first to tell parents which vaccines are due, and that including a specific role for them in the AAT would be valuable. They also said that the AAT provided needed information about HPV disease and HPV vaccine safety, but they had some continued discomfort around the vaccine.

Figure 3. Impact of AAT on participants



We also conducted a national survey with 429 registered nurses and nurse practitioners working in pediatric primary care in healthcare systems. Most (82%) were "often or always" the first person to bring up HPV vaccine with families. Nurses saw great value in standing orders, indicating that they save families time (91%), save the clinic time (90%), ensure adolescents get recommended vaccines (95%), and facilitate clinic workflow (92%). Furthermore, most nurses agreed that their clinic should have standing orders for nurses to administer all HPV vaccine doses (81% for first dose, 83% for second dose). **These studies show nurses' and other primary care team members' receptivity to the AAT and standing orders for HPV vaccine.**

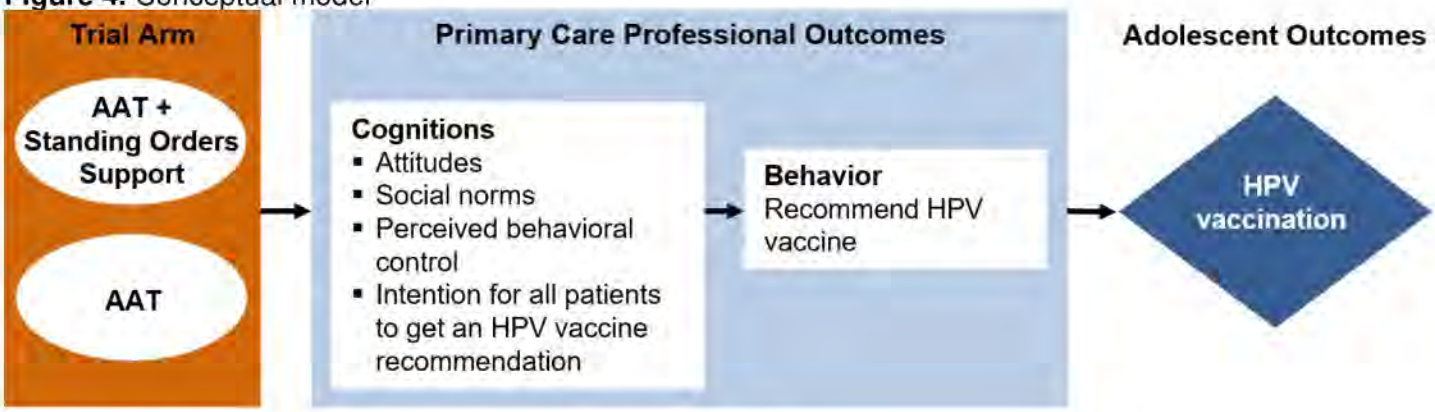
Conceptual Model

We will evaluate AAT enhanced with standing orders support as an intervention to improve HPV vaccine communication. **AAT and our standing orders support intervention both use persuasion, social norming, and skill building.** As shown in our conceptual model (**Figure 4**), these intervention activities should change constructs in the Theory of Planned Behavior.[85] AAT workshops improve team members' cognitions about patients receiving HPV vaccine recommendations: positive attitudes, social norms, perceived behavioral control, and intention to ensure patients get HPV vaccine recommendations. These changes all lead to more frequent recommendations of HPV vaccine and higher HPV vaccine uptake. Standing orders support further improves cognitions about recommending HPV vaccine. For example, system and clinic meetings to activate existing standing orders reinforce the **importance** of HPV vaccine recommendations, make them the **norm**, and increase **perceived behavioral control** over the process. The clarified roles of RNs and MAs and routinizing of recommendations increase perceived behavioral control over recommendations. Involving RNs, who are especially effective at implementing routines, and MAs will ensure patients get HPV vaccine recommendations and increase uptake. **Thus, we hypothesize that AAT with standing orders support improved HPV vaccine communication and uptake.**

Recruiting healthcare systems

Much of the proposed research will be conducted in **42 primary care clinics** that are part of **6-8 healthcare systems**. The American Medical Group Association (AMGA) will recruit and retain the healthcare systems. AMGA is a national trade organization that represents 440 healthcare systems (see letter of support) and also hosts an HPV Vaccination Best Practices Learning Collaborative (through early 2021) with 60 systems.

Figure 4. Conceptual model



This demonstrates ongoing interest from and ability to effectively recruit systems. AMGA has identified interested systems that meet our inclusion criteria in Mississippi, Missouri, and Texas, states with high HPV cancer prevention need (**Table 1**). If AMGA is unable to identify enough clinics, we have secured a commitment from the American Cancer Society, which has experience recruiting over 100 healthcare systems for HPV vaccine efforts and with whom Dr. Brewer has collaborated for the past 5 years (see letter of support).

Table 1. Characteristics of states for planned research

	Rural areas[30]	HPV vacc initiation[9]	Cervical ca deaths*
US Overall	19%	72%	2.0
Mississippi	51%	50%	3.6
Missouri	30%	69%	2.4
Texas	15%	65%	3.0

ca = cancer *per 100,000 women/year in 2017[31]

Health system inclusion criteria are 1) having 4+ eligible clinics (see below), and 2) commitment to provide EHR data on HPV vaccine. Each system will receive $9,000 to defray staff costs associated with providing vaccination data, an amount AMGA has used effectively in previous work with healthcare systems. The healthcare system will recruit clinics into the trial, and we will offer our expertise in using a multiple contact approach that has been highly successful in our previous trials.[43,74,86] Our approach is to meet with the system's quality improvement coordinator, using our standard slide set for recruitment; gather information on the clinics, including the name of the clinic's vaccination coordinator; contact the clinics through fax describing the training and trial and call using a script with standard language to describe the training and trial; and if needed, have an AAT facilitator (described below) visit an all-staff meeting to describe the training and trial.

Clinic inclusion criteria are 1) having standing orders for HPV vaccination because the intervention is meant to support clinics that already have standing orders to use them; 2) having at least 50 patients ages 11-12, the recommended age for HPV vaccine, as of January 1 in the first year of the trial; 3) having low HPV vaccine coverage (defined below); 4) at least a quarter of recruited clinics have at least 40% of patients in rural counties, and 5) have not hosted AAT workshops in the previous 3 years and are not currently part of HPV vaccine communication trainings. We define low coverage as being below 72%, the rate for HPV vaccine initiation for the US (for adolescents ages 13-17, according to NIS-Teen 2019).[8] Rurality of the clinics' populations will be determined by Rural-Urban Continuum Codes (RUCC) for patients' home counties using addresses from the EHR. We will define counties as either nonrural counties (sometimes called metropolitan areas, RUCC=1, 2, or 3) or rural counties (sometimes called nonmetropolitan areas, RUCC>3). If the trial meets the nonrural clinic maximum (75%), we will thereafter enroll only rural clinics.

Aim 1. Characterize the role of primary care team members and standing orders in HPV vaccination.

To accomplish Aim 1, we will conduct formative interviews about the role of RNs and MAs in recommending HPV vaccine (Activity 1a) and conduct the national survey (Activity 1b), all in Year 1.

1a. Conduct formative interviews to better understand RNs' and MAs' roles in HPV vaccination.

Participants. We will recruit a provider (i.e., physician, nurse practitioner, or physician assistant) and an RN or MA from 10 of the primary care clinics participating in the RCT (20 participants in total).

Procedures. We will build a semi-structured interview guide to ask about the roles of RNs and MAs in making HPV vaccine recommendations and about standing orders for HPV vaccination, addressing the research questions in **Table 2**. The guide will also gather feedback on the planned standing orders support intervention components. We will vet the interview guide with the IMPACT Clinical Advisory Board. Drs. Birken and Mansfield, who are experienced in qualitative research, will obtain informed consent and do the formative interviews by telephone. We will audio record the interviews, store recordings on a password-protected server, have the recordings transcribed using a professional transcription service, and delete recordings after analysis is complete. The interviewer will also take case notes during the interviews and afterwards make an action-oriented summary of the main ideas shared during the interview, an approach we have used in several studies.[88–90] We will interview participants until we reach thematic saturation (up to 20 interviews). Participants will receive $100 for their participation, which we expect to take about 40 minutes.

Table 2. Research questions for formative interviews and national primary care team survey

Research Questions	Asked of RNs, MAs	Providers
What role should RNs and MAs have in HPV vaccine communication?	•	•
What do RNs and MAs want in HPV vaccine communication training?	•	
How are standing orders for HPV vaccine implemented in primary care?	•	•
What do standing orders for HPV vaccine cover?	•	•
What are the main barriers to implementing standing orders for HPV vaccination?	•	•

Analyses. Drs. Birken and Mansfield will independently conduct open coding of interview transcripts to identify topics and develop a codebook. We will systematically apply the codes in NVivo software and then go code by code to find areas of agreement and disagreement in the data. We will use template analysis to identify opportunities to 1) refine topics in the national survey, 2) adjust language to use in the survey, and 3) improve the process and content of the Aim 2 standing orders support intervention. Opportunities might include clinic flow problems that planning checklists should address or team support needs for "all-staff" meetings to address. We will also qualitatively assess differences between those working with high versus low proportions of rural patients. After finishing these analyses, we will again read the transcripts to confirm our findings and check for dissenting views that may call for additional analysis. We will perform member checking by presenting the findings to our Clinical Advisory Board for their feedback.

1b. Conduct a national primary care team survey.

The national primary care team survey will be conducted in partnership with IMPACT research Projects 2 and 4 and coordinated by our Data Core. The full methodology appears in the Data Core and in summary here.

Participants and procedures. Participants will be a national sample of 1,500 providers (1,000 physicians and 500 nurse practitioners and physician assistants) and 1,000 RNs and MAs working in primary care clinics that provide HPV vaccine. We have substantial experience with recruiting large survey samples, including primary care professionals.[78–80,84–86,88–94] We will work with the WebMD Market Research panel of primary care professionals that covers, for example, ~60% of US pediatricians, giving the company's unique access to these populations. Most panel members participate in 2-4 surveys per year. Based on similar previous surveys with the panel, the expected survey response rate is 60%, calculated using AAPOR definition 5.[95]

The panel already includes the providers and RNs, who will complete the survey and also be asked to refer MAs who work in their clinics. The final sample will include at least 20% rural respondents to support rural-nonrural comparisons. We will determine rurality of respondents by RUCC of the respondents' primary work addresses. The survey will be online and will be pilot tested with 20 providers, RNs, and MAs.

Measures. The survey will have around 75 survey items, for a target length of ~15 minutes. Each of the Program's 4 research projects will have ~15 items on the survey with another 15 core items for demographics. These survey items will address the research questions in **Table 2** related to the roles of RNs and MAs in making HPV vaccine recommendations and standing orders.

Before use in the national survey, we will cognitively test each of the items, make changes to them as needed, and test them again. Cognitive testing participants will each receive about half of the survey items. We will ask them to answer the question and explain how they came to their answers. We will also ask them what they believe we wanted to ask with specific terms. For the sake of efficiency, we will do some cognitive testing at the end of the qualitative interviews in Activity 1a. If additional participants are needed to reach saturation, we will cognitively test revised survey items with local providers and members of our Clinical Advisory Board.

Analyses. The main analyses of the national survey data will be descriptive. To inform revisions to the AAT and standing orders support intervention, we will examine the extent to which primary care team members are open to having RNs and MAs play an active role in HPV vaccine communication and what RNs and MAs want from a communication training. To inform our standing orders support intervention, we will also examine barriers and facilitators to implementing HPV vaccination standing orders.

The main product of Aim 1 is a better understanding of RNs' and MAs' role in HPV vaccine communication and opportunities for supporting existing standing orders to expand their role. Findings will suggest opportunities to successfully leverage the whole primary care team in HPV vaccine communication and implementing standing orders and inform Aim 2.

Aim 2. Evaluate the impact of standing orders support for the whole primary care team on HPV vaccine communication and uptake in a cluster RCT.

To accomplish Aim 2, we will develop enhanced intervention materials that meet the needs of RNs and MAs (Activity 2a). We will pilot test the RCT procedures (Activity 2b) and conduct the cluster RCT (Activity 2c). Finally, we will survey AAT workshop participants (Activity 2d). These activities will happen in Years 2-4.

2a. Develop enhanced intervention materials.

The trial will have 2 arms: AAT and AAT enhanced with standing orders support. We considered including a trial arm of only standing orders support (without AAT), but we believe it is important to build the HPV vaccine communication skills of RNs and MAs before supporting the implementation of standing orders.

Standing orders support. **The purpose of standing orders support is to increase use of best practices for HPV vaccine communication.** For vaccination, standing orders policies codify and extend the role of RNs and MAs in discussions, delivery, and documentation of vaccines. With standing orders in place, the whole primary care team can use the evidence-based best practices included in the Announcement Approach, thus involving the whole primary care team in recommending HPV vaccine.

A series of meetings will activate each system, its clinics, and the clinics' primary care teams to implement existing HPV vaccine standing orders. The meetings will focus on the needs of systems and clinics and build agreement on action steps. In each system, AMGA will host an introduction to the systemwide quality improvement (QI) lead, during which we will explain the trial, review the system's current standing orders, and agree on holding a series of structured meetings to activate optimization of standing orders. **Table 3** shows the next meetings' objectives, how they link to the Theory of Planned Behavior, logistics, and content. We will provide flexibility for meeting structure and attendees to fit the needs and culture of each healthcare system.

1) **System Meeting** (held 3 months before the AAT workshop). System and intervention clinic QI leads will establish a timeline for implementing standing orders and metrics for success. Our facilitator will lead this videoconference using standard slides and materials. The facilitator will be a physician with at least 2 years of clinical experience recommending pediatric vaccines and training to lead AAT workshops.
2) **Standing Orders Teams Meeting** (2 months before AAT workshop). The standing orders teams will establish clinics' implementation plans including planned workflow, a plan to get buy-in from clinic staff and identify their needs (e.g., training on contraindications), and expected challenges and solutions.
3) **"All Hands" Clinic Meetings** (1 month before AAT workshop). At each all-staff meeting, the clinic's standing orders lead will share the plan to clarify new roles and metrics for success.
4) **Learning Collaborative** (meets bimonthly after AAT workshop). The Learning Collaborative will review metrics, share success stories, and find solutions to problems related to standing orders implementation.

The number of people in the meetings will depend on the number and size of clinics in healthcare systems. We will assemble existing intervention materials for these meetings (e.g., planning template that includes 3 workflow examples), relying on resources developed by the Immunization Action Coalition that we will adapt (standingorders.org/resources). We will develop new materials as needed (e.g., agendas, slides). We will develop a 1-page flier with solutions for challenges identified by Cataldi et al.,[58] (e.g., patients may receive the wrong vaccine). We will vet the materials with Dr. Tan who developed the Coalition's materials, Dr. Darden who has advocated for standing orders in his clinics, and the Clinical Advisory Board managed by the Intervention Core. We will also incorporate findings from the mixed-methods data collected in Aim 1.

Table 3. HPV vaccine standing orders support intervention

Section	Objectives	Logistics	Activities and content
System Meeting	1. Promote positive **attitudes** toward using standing orders 2. Increase **intentions** to use standing orders **Outcome.** Milestones and timeline for implementation	3 months before AAT ▪ 2 hours ▪ Lead: UNC facilitator ▪ With: system QI lead clinic QI leads	▪ Present brief overview ▪ Discuss standing orders policy, implementation challenges and solutions ▪ Identify milestones and timeline (standing orders plan template, buy-in from clinic leadership, identifying clinic SO teams) ▪ Review the next meeting agenda
Standing Orders Teams Meeting	3. **Norm** standing orders 4. Build **perceived behavioral control** for standing orders **Outcome.** Standing orders plans, clinic meeting dates	2 months before AAT ▪ 2 hours ▪ Lead: system QI lead ▪ With: clinic SO teams (includes physician, RN/MA, staff) UNC facilitator	▪ Prework: Clinics draft plan template ▪ Present brief overview ▪ Identify workflow for each clinic ▪ Make a plan for getting buy-in from clinic staff and identifying their needs (e.g., training on schedule, contraindications etc.) ▪ Identify expected challenges and solutions
"All Hands" Clinic Meeting	Objectives 1 – 4 **Outcome.** Clinic team understands their roles and responsibilities	1 month before AAT ▪ 20 mins ▪ Lead: clinic SO lead ▪ With: Primary care team (all staff)	▪ Explain rationale for standing orders ▪ Review standing orders plan ▪ Discuss role of all primary care team members in HPV vaccine communication ▪ Mention metrics
Learning Collabor-ative	Objectives 3 – 4 **Outcome.** Plan new approaches and address challenges	1 month after AAT and then bi-monthly ▪ 20 mins ▪ Lead: system QI lead ▪ With: clinic SO teams	▪ Check in with clinic team on how the standing orders and AAT are working ▪ Share 1-2 successes. ▪ Identify and address any challenges ▪ Review metrics

AAT. **The purpose of the AAT is to build capacity for using for HPV vaccine communication best practices.** In the Announcement Approach, the team member starts with a presumptive announcement that: 1) notes the child's age to indicate that what follows is part of routine care; 2) announces that children this age are due for vaccines that prevent 3 diseases, placing HPV cancers in the middle of the list; and 3) says that a team member will give the vaccines today. They can then move on with the visit. If at this point parents have questions or concerns, the team member can use the second part of the Announcement Approach: "Connect and Counsel." To do this, the team member: 1) connects with the parent by confirming the main question about HPV vaccine and using reflective listening (e.g., "I hear you. You said…"); and 2) counsels the parent about what the evidence shows using a research-tested message, suggesting again that they vaccinate today. If parents decline same-day vaccination, the team member addresses HPV vaccination at the next visit.

We have embedded the Announcement Approach into a standardized training, the AAT, which is delivered in-clinic, as a 1-hour workshop. Providers receive 1 CME credit for attending the full workshops and RNs and MAs can receive the equivalent continuing education (CE) credit. Other clinic staff, including front desk staff, will also be invited to attend the workshop. The AAT is led by a trained facilitator who is a primary care professional with at least 2 years of experience recommending pediatric vaccines (e.g., a pediatrician or a primary care nurse). Facilitators use the standardized script and PowerPoint slide set to present the workshops. Clinic staff attend the AAT in-person (or online as we have done for over 50 clinics). Clinic staff who cannot attend the workshop will watch a recording of it and then practice the Announcement Approach with a peer who attended in-person. Participants will complete surveys before, immediately after, and 3 months after the workshop. We will provide an information sheet and apply for a waiver of written consent.

We will revise AAT materials to better address the needs of RNs and MAs, by providing additional basic information on HPV vaccination, adjusting language to include RNs and MAs, and expanding the section on implementation in the practice to include a role for RNs and MAs. We will also incorporate findings from our national survey on helping patients feel safe about coming in for vaccination during the Covid-19 pandemic.

2b. Pilot test the procedures for the AAT and standing orders support.

Clinics. We will pilot test the RCT procedures by conducting AAT and standing orders support interventions with 2 clinics in 1 healthcare system recruited for the RCT. We will ensure at least 1 of the clinics serves primarily rural patients (defined as having at least 40% of their patients from rural counties, RUCC >3). These clinics will not be included in the main trial.

Training facilitators. We will train 1 local facilitator per system to deliver AAT workshops. To orient these new facilitators, we will use our standard process, as coordinated by the Intervention Core. First, the facilitators will attend an AAT workshop to experience the training from the perspective of a participant. Second, facilitators will attend an interactive online orientation on the objectives of the AAT, use of the script and slides, troubleshooting the videos, leading the practice exercise, handling participant questions, and establishing staff support to manage logistics. Third, facilitators will receive the script, presentation slides, and other materials in print and electronic format, with back-up materials available online. Fourth, facilitators will practice presenting the AAT on their own and then at least twice with primary care teams. For 1 of the practice sessions, study staff will observe and then provide feedback on strengths of the presentation and areas for improvement. A physician, assisted by the project manager, will facilitate the standing orders support calls after a similarly structured orientation. She will also facilitate AAT workshops that need to be held remotely.

Procedures and measures. The interventions will follow procedures developed in Activity 2a. HPV vaccination data will come from healthcare systems' EHR (see Activity 2c). Surveys of AAT participants will assess healthcare professional outcomes in our conceptual model (see Activity 2d) and implementation measures including cost (see Activity 3a-3c). We will also interview a provider and an RN or MA from each clinic in the pilot about ways to improve the AAT and standing orders support intervention. Study staff will attend all standing orders support meetings and take process notes.

Analyses. Analyses will focus on ensuring that the RCT procedures work as intended. First, the Data Core will obtain the vaccination data from the EHR and examine data quality using procedures developed for previous vaccine trials (e.g., check whether Tdap coverage is higher than HPV vaccine initiation and HPV vaccine initiation is higher than completion). We will calculate HPV vaccine initiation and up-to-date rates at baseline. Second, working with the Intervention Core, we will analyze the data for implementation measures. We will examine AAT satisfaction ratings, considering a success to be >90%. Third, we will examine AAT participant surveys to ensure that we have completed surveys from most participants (>90%) with minimal missing data (<5%). Based on these findings, we will adjust the training procedures as needed. Our experience is that changes are made largely to administrative procedures and research staff training.

2c. Conduct cluster RCT.

Participants. AMGA will recruit 40 clinics in 6-8 healthcare systems. An independent biostatistician from the Data Core will randomize clinics to trial arm in a 1:1 ratio: AAT only or AAT enhanced with standing orders support. The biostatistician will match clinics based on HPV vaccine initiation coverage and rurality to balance trial arms on these important metrics; vaccination coverage and rurality of clinic populations (at least 40% RUCC >3) will come from EHR in January of Year 2. Using protocols we developed for previous trials to avoid contamination across trial arms,[43,74,86] we will exclude clinics in different arms that share providers.

Procedures. The cluster RCT will follow the procedures developed in Activity 2a and refined in Activity 2b. We will conduct AAT workshops primarily in April-July of Years 2 and 3, with standing orders support provided in the months before and after AAT workshops as described in **Table 3**. Half the clinics will participate in Year 2 and half in Year 3 to make conducting the interventions more feasible. This timing corresponds to the months just before and during the annual peak in adolescent vaccine uptake.[96] We will register the trial with ClinicalTrials.gov and maintain a data and safety monitoring plan (see Human Subjects section).

Measures. The **primary trial outcome** is HPV vaccine initiation by the 12-month follow-up among patients ages 11-12 at baseline. We will examine this primary outcome for children who had received no doses of HPV vaccine by baseline. Recommendations are for routine vaccination of adolescents at ages 11-12, and initiation is likely to be more sensitive to our intervention than being up to date. We chose the 12-month follow-up to assess HPV vaccination at a similar point in its annual cycle.[96] Our **secondary trial outcomes** include HPV vaccine series up-to-date (received recommended number of doses) for ages 11-12 as well as initiation and up-to-date status for patients ages 13-17 (**Table 4**).

Table 4. Vaccination outcomes for RCT, Aim 2

Outcome	HPV vaccine	Ages
Primary	Initiation at 12 months	11-12 years
Secondary	Initiation at 12 months	13-17 years
	Up to date at 12 months	11-12 years
	Up to date at 12 months	13-17 years

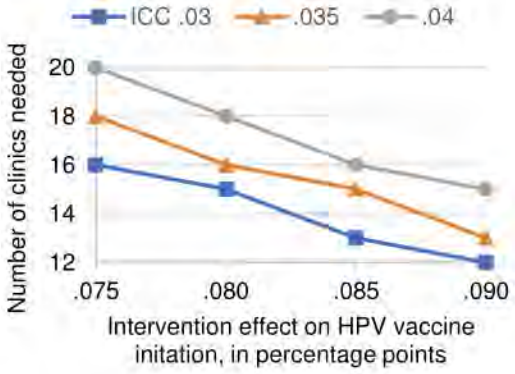
Clinic-level data on vaccination coverage will allow us to infer binary vaccination outcomes for individual patients using cross-tabbed vaccination rates as a function of demographic covariates (gender and age) to simulate patient-level data. It is statistically feasible to do this because we can infer the intra-class correlation between patients within clinics based on this formula: $ICC=VAR(p_1,p_2,\ldots,p_k)/(\pi(1-\pi))$, where π is the population proportion of vaccination and p_k is the vaccination rate for each of the K clinics in our sample.

Analyses. The analysis cohort will be adolescents who attended a clinic visit during the previous year, followed from baseline (date of AAT) to 12-month follow-up. We considered comparing 2 overlapping cohorts (e.g., children age 11-12 at baseline and children age 11-12 at 12-month follow-up), but we were concerned that any differences between them could be attributed to variation in cohort characteristics.

Analyses will examine our hypothesis that AAT enhanced with standing orders support increases HPV vaccination. We will use intent-to-treat analyses, including all clinics enrolled at baseline.[97] The main analyses will use generalized estimating equations to model the log odds of vaccination at follow-up, among patients not vaccinated at baseline, while accounting for dependence between patients. The predictor will be trial arm; outcomes will be the trial's primary and secondary vaccination outcomes.

Power analyses relied on estimates from our previous research[43,68] and pilot work delivering AAT in health systems. Tan and colleagues found a 7% increase for standing orders support for HPV vaccination of adults ages 19-26 after a single workshop;[68] we expect a larger intervention effect due to a more structured and higher intensity intervention for a younger patient population whose vaccination rates change more quickly. Thus, we varied the expected intervention effect around an increase of 8.5%. Our pilot work with systems found a clinic-level ICC of .033 for change in HPV vaccine initiation over 9 months. Thus, we varied ICC around .035. Finally, we assumed 200 unvaccinated children per clinic, a 15% increase in HPV vaccine initiation in both arms due to secular trends and AAT, and alpha=.05. The analyses found that the planned 20 clinics per arm will provide at least 80% power to detect a difference as low as 7.5% in the primary trial outcome with ICC up to .04 (**Figure 5**). Exploratory analyses will add these variables and interactions with trial arm to the model: rurality, gender, and standing order implementation at baseline. For statistically significant interactions, we will stratify the analyses. Project 4 will provide a spreadsheet to gather these effectiveness data in a standard

Figure 5. Clinics needed for RCT in Aim 2 for power > .80.



format to support cost-effectiveness modelling. We will work with the Data Core to complete the spreadsheet using the same approach as the other projects and share it with Project 4.

2d. Survey AAT workshop participants.

Participants. We expect to have 10-20 AAT workshop participants per clinic across 40 clinics. Based on our past studies, we expect that almost all will complete the pre- and post-training surveys (*n*=400-800). For the participant follow-up surveys, expecting a response rate of 75%, we will send surveys to 400-533 participants to yield 300-400 completed surveys. In the past, we have had 70%-100% completion of follow-up surveys because we kept them brief and gave trainings that primary care team members valued.

Procedures. Participants will complete 3-minute surveys immediately before and after the AAT workshop. They must complete a post-training survey to receive CME or CE credit. Three months after AAT, we will contact participants by email and mail to complete a follow-up survey. We chose 3 months to balance the goal of getting a high response rate (sooner is better) and showing changes over time (later is better). We will pay respondents $100 for completing the follow-up surveys. Contacts will use the Dillman method to increase response rates for online and mailed surveys.[98]

Measures. Surveys will use previously validated measures, modified for this context, to assess the intermediate outcomes in the conceptual model related to healthcare professionals' HPV vaccine recommendation cognitions and behavior (**Table 5)**. The pre-training survey will assess respondent, clinic, and patient-volume characteristics.[43,74,86,99] Surveys will also assess some constructs for Activity 3a and 3b.

Table 5. Examples of AAT participant survey items, Aim 2

Construct	Sample item	Pre	Post	3m
Attitude	It's important to me that my patients get a recommendation for HPV vaccine before age 13.	•	•	•
Norms	It's the norm for our team to routinely recommend HPV vaccine for patients before age 13.	•	•	•
PBC	I feel confident our team can recommend HPV vaccine effectively for our adolescent patients.	•	•	•
Intentions	I intend to make sure all patients get an HPV vaccine recommendation before they turn 13.	•	•	•
Vacc rec	Our team recommends HPV vaccine to all patients before they turn 13.	•		•

Note. PBC = perceived behavioral control. Vacc rec = HPV vaccine recommendation.

Analyses. **Analyses will examine our hypothesis that AAT with standing orders support improves HPV vaccine communication**. We expect that, by 3-month follow-up, the standing orders support arm will have more positive attitudes about recommending HPV vaccination, social norms, perceived behavioral control, and intentions to recommend than the AAT-only arm. We also expect HPV vaccine recommendations to be more common. Generalized estimating equation analyses will include data for training participants who completed at least 1 of the surveys and allow us to include participants with missing data for specific survey items. We will explore whether findings differ by rurality and primary care team member role and probe interactions using post-hoc analyses stratified by the moderator variable with Bonferroni corrections.

The main products of Aim 2 are the results of the RCT. The trial findings will establish the impact of integrating the whole primary care team into HPV vaccine recommendations through standing orders support.

Aim 3. Generate guidance for healthcare systems to implement standing orders support.

We will assess intervention costs in Activity 3a; other implementation outcomes in Activity 3b, and implementation determinants in Activity 3c. We will use these findings to contribute modules to the AAT Intervention Package for improving HPV vaccination in healthcare systems in Activity 3d. These activities will happen largely at the end of Year 4 through Year 5.

3a. Establish the cost per additional adolescent initiating HPV vaccine.

We will gather micro-costing data for delivering AAT workshops and standing orders support in the Aim 2 RCT (**Table 6**).

Participants, procedures and measures. First, AAT facilitators and standing orders activation meetings facilitators will complete 2-3 minute, online time logs to the nearest quarter hour and travel and intervention materials expense logs. They will report their time expended and related travel during the main activities and after the bi-monthly learning collaborative meetings end. Logs will include train-the-trainer orientation, practice, planning, preparation, facilitating AAT or meetings, and related tasks. Using these methods in prior studies, we have achieved response rates of >95%. Second, we will use logs of attendance at AAT workshops and standing orders activation meetings to calculate time others spent on these activities. Third, AAT participants will report time spent on HPV vaccine recommendations and documentation for the last 5 patients ages 11-12, on the pre-training and 3-month follow-up surveys (*n*=400, see Activity 2d). Fourth, we will tabulate time and

expenses associated with intervention start-up activities, from trial records, excluding entries associated only with research study processes that would not be part of real-world implementation.

Analysis. We will calculate costs from the perspective of a healthcare system. We will also separate fixed costs (e.g., program startup) from ongoing variable costs (e.g., attending standing orders activation meetings). We will not include costs for routine clinic operations or costs of trial data collection.

We will calculate the total cost of delivering the activities for each trial arm. We will use these totals to calculate cost per clinic and cost associated with improving HPV vaccine initiation by 1 adolescent age 11-12 for each trial arm. We will calculate the differences between arms and use *t*-tests to compare them.

Table 6. Data sources for implementation outcomes, Aim 3

Data source	Interventions: AAT and SO support	Behavior: AA and SO
Intervention expense records Facilitator time, travel, materials	Cost	Cost
Tracking log of participants 1/clinic, 40 total	Cost, reach	
Checklist of content 1/workshop, 40 total	Cost, fidelity	
Survey of AAT participants 10/clinic, 400 total	Acceptability	All outcomes
Key informant interview 2/system, 12-16 total	All outcomes	All outcomes

Note. All outcomes = acceptability, adoption, appropriateness, cost, feasibility, fidelity, reach, sustainability.[103] SO = standing orders.

Integration. Project 4 will provide a spreadsheet to gather these costs in a standard format to support cost-effectiveness modelling. We will work with the IMPACT Intervention Core to complete the spreadsheet using the same assumptions as the other projects and share it with Project 4.

3b. Examine other implementation outcomes.

Interventions: AAT and standing orders support. We will use sequential, explanatory mixed methods to assess implementation outcomes for AAT and standing orders support interventions (**Table 6**).[104] We will use instruments with established validity and reliability[105] and cognitively test new items (as described in Activity 1b). To assess *reach* (who attended AAT workshops and standing orders support meetings), facilitators will complete brief tracking logs (1 log/clinic, 40 total). We will calculate the total attendees per intervention activity. To assess *fidelity* (whether interventions were delivered as intended), facilitators will complete checklists (1 checklist/clinic, 40 total). We will calculate the percentage of the intervention curriculum covered as intended. To assess *acceptability* (satisfaction with the intervention activities), intervention participants will complete a 3-month follow-up survey (described in Activity 2d). We expect acceptability to be above 90% (agree or strongly agree they are satisfied with the workshop and communication approach), based on our previous trainings that achieved this goal. We will use *t*-tests to compare trial arms on these outcomes. To assess *adoption* (intervention use), *appropriateness* (intervention relevance), *feasibility* (ability to use intervention), and *sustainability* (ability to use intervention over time), will use key informant interview procedures and analyses described in Activity 3c. We will integrate quantitative and qualitative results using a joint data display.[104]

Behavior: Use of Announcement Approach and standing orders. The 3-month follow-up survey will assess implementation outcomes regarding use of the Announcement Approach and standing orders. We will use *t*-tests to compare trial arms on these outcomes. We will share findings with Project 4 for inclusion in the web-based decision support tool.

3c. Examine implementation determinants.

Participants. Participants will be 2 key informants per system (12-16 total). We will select people with knowledge of AAT and standing orders support implementation, such as the system or clinic QI leads.

Procedures, and measures. We will pilot the interview guide to ensure clarity and comprehensiveness; these results will not be included in final analyses. Using the refined interview guide, an experienced interviewer will conduct 25-30 minute, semi-structured interviews over the phone in a private room. We will develop standardized interview guides with a detailed script to elicit information regarding the appropriateness, feasibility, sustainability, and determinants of implementing AAT and standing orders support. We will derive interview questions from Proctor's conceptualization of implementation outcomes (for Activity 3b) and the Consolidated Framework for Implementation Research (CFIR) for questions about implementation determinants.[106] Open-ended probes will allow stakeholders the opportunity to answer questions in their own way and follow-up probes will clarify answers, recording, storing, and transcribing interviews as in Activity 1a.

Analysis. We will use template analysis to apply a priori codes based on Proctor (implementation outcomes) and CFIR (implementation determinants) and to identify additional themes. Coders will iteratively meet to discuss and reconcile discrepancies in coding until consensus is reached. From code reports, we will inductively identify themes related to each code (e.g., key staff availability to support implementation).

3d. Contribute modules to the AAT Intervention Package.

Project 1 will contribute 2 modules to the AAT Intervention Package, developed by the IMPACT Program Project to provide guidance to healthcare systems seeking to improve their HPV vaccination coverage. **The first module will describe the AAT**, including its impact in previous trials and implementation findings from the current trial. The module will describe how to orient AAT facilitators, conduct workshops, and evaluate them and will link to online AAT materials (slides, script, and exercise materials) available at hpvIQ.org, a website hosted by Dr. Gilkey (Project 3) and Dr. Brewer.

The second module will describe standing orders support using a similar structure. We will report on standing orders support impact (Activities 2c-2d), and implementation outcomes including cost (Activities 3a-3c). The module will link to online standing orders support materials (agendas, slides, planning template, and common problems flier) to be made available at hpvIQ.org and standingorders.org. The Intervention Core will assist with integrating these findings into Project 4's decision tool for choosing AAT interventions. To inform quality improvement managers' implementation efforts, we will also include a context assessment tool based on Activity 3c findings regarding determinants of AAT and standing orders support implementation.

The main products of Aim 3 are the cost estimates and other implementation insights and modules for the AAT Intervention Package for healthcare systems. These findings will add depth to our understanding of promising practices for successfully integrating the whole primary care team into HPV vaccine recommendations and fully implementing standing orders.

Potential Challenges and Solutions

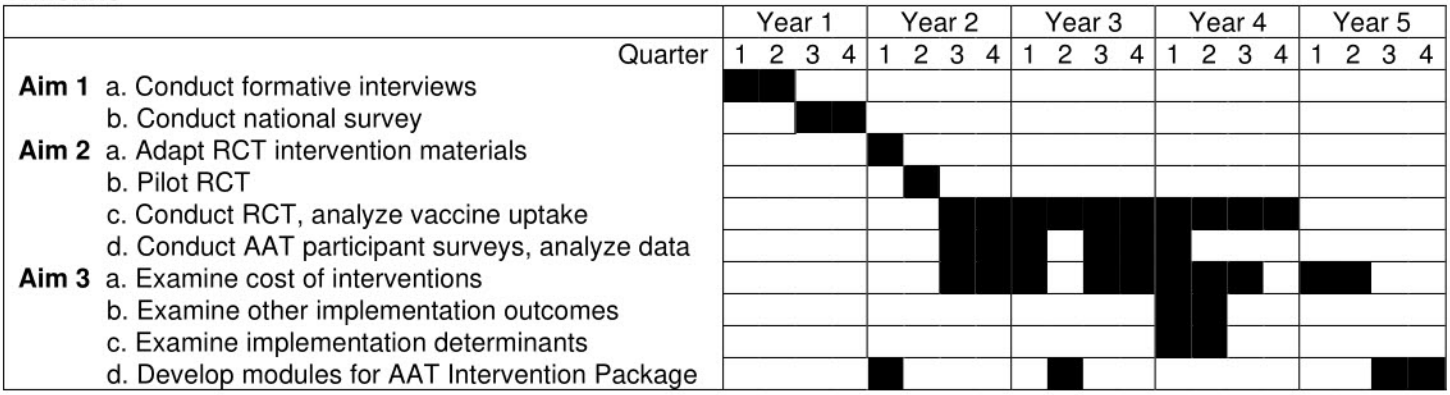
What if Covid-19 prevents in-person research activities? Our meetings with national experts suggest a strong desire in primary care systems and clinics to get vaccination back on track. While the Covid-19 pandemic had interrupted care, our ongoing work with systems has now fully restarted. The proposed research activities can be conducted remotely. For example, interviews can be done by Zoom and online surveys. We have experience delivering AAT by interactive webinar, having done so for over 50 AAT workshops.

What if fewer patients go to clinics because of Covid-19? Our power calculations are fairly robust to changes in assumptions regarding population coverage, intervention effects, and ICC. For example, lower baseline HPV vaccine coverage will move intervention effects toward to a region of the power curve where the trial will have more power. We can also weather a slightly smaller intervention effect or higher ICC.

Relevance to Program Project Theme

Project 1 addresses the **Program Project's shared theme** of amplifying the impact of a Research-Tested Intervention Program to improve HPV vaccine communication in healthcare systems. In Aim 1, we will generate new national findings on opportunities for expanding RNs' and MAs' roles in HPV vaccine recommendations. In Aim 2, we will generate causal evidence for the impact of standing orders support to involve the whole primary care team. In Aim 3, we and the other projects and cores will contribute impact, cost, and implementation insights to the AAT Intervention Package. These findings will dramatically expand the reach and potential impact of AAT on cancer prevention by leveraging the whole primary care team.

Timeline



PHS Human Subjects and Clinical Trials Information

OMB Number: 0925-0001

Expiration Date: 02/28/2023

Use of Human Specimens and/or Data

Does any of the proposed research in the application involve human specimens and/or data *	❍ Yes ● No
Provide an explanation for any use of human specimens and/or data not considered to be human subjects research.	
Are Human Subjects Involved	● Yes ❍ No
Is the Project Exempt from Federal regulations?	❍ Yes ● No
Exemption Number	❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑ 6 ❑ 7 ❑ 8
Other Requested Information	

Human Subject Studies

Study#	Study Title	Clinical Trial?
1	The impact of standing orders support on HPV vaccine communication and uptake	Yes

Section 1 - Basic Information (Study 1)

OMB Number: 0925-0001

Expiration Date: 02/28/2023

1.1. Study Title *

The impact of standing orders support on HPV vaccine communication and uptake

1.2. Is this study exempt from Federal Regulations * ○ Yes ● No

1.3. Exemption Number ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑ 6 ❑ 7 ❑ 8

1.4. Clinical Trial Questionnaire *

1.4.a. Does the study involve human participants?	● Yes	○ No
1.4.b. Are the participants prospectively assigned to an intervention?	● Yes	○ No
1.4.c. Is the study designed to evaluate the effect of the intervention on the participants?	● Yes	○ No
1.4.d. Is the effect that will be evaluated a health-related biomedical or behavioral outcome?	● Yes	○ No

1.5. Provide the ClinicalTrials.gov Identifier (e.g. NCT87654321) for this trial, if applicable

Section 2 - Study Population Characteristics (Study 1)

2.1. Conditions or Focus of Study

- This research project focuses on primary care teams' communication about HPV vaccine with families.

2.2. Eligibility Criteria

Activity 1a1) Ages 18+2) Physicians and other primary care team members, including nurse practitioners (NPs), physician assistants (PAs), registered nurses(RNs), medical assistants (MAs).Activity 1b1) Ages 18+2) Primary care team members (physicians, PAs, NPs, RNs, MAs)Activity 2a 1) Enhance materials to be tested (no population component)Activities 2b and 2c (clinical trial)1) Primary care clinics and primary care team members in clinics that provide the HPV vaccine to patients ages 11-12 and are part of large health systems.2) Clinic agrees to host an Announcement Approach Training (AAT)or receive standing orders support during the intervention period. 3) Primary care team members agree to attend the training and complete pre- and post- training surveys as well as a 3-month follow up survey.

2.3. Age Limits	Min Age: 18 Years	Max Age: 99 Years
2.3.a. Inclusion of Individuals Across the Lifespan	InclusionofLifespanP1r1045594802.pdf	
2.4. Inclusion of Women and Minorities	InclusionWomenMinoritiesP1r1045594803.pdf	
2.5. Recruitment and Retention Plan	RecruitmentP1r1045594804.pdf	
2.6. Recruitment Status	Not yet recruiting	
2.7. Study Timeline	TimelineP1r1045594805.pdf	
2.8. Enrollment of First Participant	12/01/2021	Anticipated

INCLUSION OF INDIVIDUALS ACROSS THE LIFESPAN – Project 1

The proposed studies – including interviews, surveys, and trial – will include only adults working in their professional roles in pediatric primary care. These studies have no upper age limit for inclusion. Our focus on adults employed in professional medical roles will naturally limit the number of older adults we are in contact with.

The primary and secondary outcomes of the Aim 2 trial will be anonymized adolescent immunization rates provided by individual health systems' EHR for each clinic in the trial. However, we will not have any access to children's medical records or interact with children as part of the trial or other planned studies.

INCLUSION OF WOMEN AND MINORITIES – Project 1

The proposed research will include women and minorities throughout. We will recruit primary care team members to take part in this study. We anticipate including women and minorities as participants throughout the study in proportion to their representation in the general populations in the United States. Our estimates for inclusion of women and minorities appear in the targeted/planned enrollment tables. To arrive at these estimates, we used recent US Census data.

RECRUITMENT AND RETENTION PLAN – Project 1

Aim 1 Formative and cognitive interviews and larger web-based survey

Formative interviews

We will conduct formative interviews with a provider and a registered nurse or medical assistant in 10 primary care clinics participating in the trial, for a total of 20 interviews. These interviews will include cognitive testing of items for the national primary care team survey. We will work with the systems in the trial to recruit participants. We will recruit up to 8 additional participants as needed. Interested participants will be asked to contact the project manager to participate. Recruitment is expected to take 2-3 weeks and interviews will be conducted by phone on a rolling basis. We will offer each participant a $100 gift card for completing the ~40-minute interview.

National primary care team survey

Project 1 will work with the Data Core, Project 2, and Project 4 to conduct a national online survey of primary care professionals. Project 1 will add questions related to the role of registered nurses and medical assistants in recommending HPV vaccine and the use of standing orders to support HPV vaccination. The Data Core will contract with WebMD Market Research to recruit 2,500 members from its existing, online panel of pediatric primary care professionals. The company will use quota-based sampling to recruit ~500 participants from each of 5 groups: pediatricians; family physicians; nurse practitioners and physician assistants; registered nurses; and medical assistants. WebMD will invite panel members to join the survey via email and targeted ads. Participants will receive up to $45 for participating. Based on the panel's prior performance, we anticipate a response rate of ≥60% as calculated using the American Association for Public Opinion Research Response Rate 5 calculation.

Aim 2 Trial

System and clinic recruitment

We will partner with the American Medical Group Association to recruit 6-8 healthcare systems to participate in the trial, and then work with systems to recruit clinics that meet the inclusion criteria to participate in our research studies. Systems may have their preferred method for recruiting, but we will offer our approach, which is to meet with the system's quality improvement coordinator, present our standard, brief slide set, and then gather information about the clinics. We will then recruit individual clinics within their system through multiple contacts that involve a letter, a fax, and several phone calls by the AAT facilitator and study team staff. The clinic leadership, including the clinic manager and the lead physician, will consent on behalf of the clinic. Healthcare systems will receive $9,000 to offset the costs of participating in the study (such as administrative time).

Electronic health record (EHR) data

In Aim 2, we will recruit 40 clinics to participate in the trial, with equal numbers of clinics (20) in each trial arm. Two additional clinics will be recruited for pilot testing the interventions and study protocols. Clinic-level vaccination coverage will be assessed before the interventions and one year after the interventions with the collaboration of the healthcare system. They will provide anonymized data on vaccination coverage for the enrolled clinics. We will use vaccination coverage data to measure the change in initiation and up-to-date status of adolescents ages 11-12 and 13-17, for patients not vaccinated at baseline.

Pre- and post-training AAT participant surveys

For each AAT workshop, each participant will complete pre- and post-training surveys that assess participant, clinic, and patient characteristics as well as changes in participant attitudes, social norms, perceived behavioral control, and intentions. With a total of 42 clinics recruited (including pilot clinics), we expect between 10-20 participants in each training from each clinic for a maximum total of 840 participants. The post-training survey is part of the requirement for earning continuing medical education (CME) and continuing education (CE) credit.

AAT participant follow-up surveys

Three months after the AAT workshops take place in the clinics, we will recruit 10 of the AAT participants from each of the 42 clinics in the pilot and main trial to complete an online follow-up survey for a total of approximately 420 respondents. Those who complete the follow-up online surveys will be paid $100. To improve response rates, participants will also have the option to complete a paper form of the survey and mail it back to us. We chose the 3-month follow-up period to balance the desire to assess impact over time (longer time to follow-up) and to ensure a high response rate (shorter time).

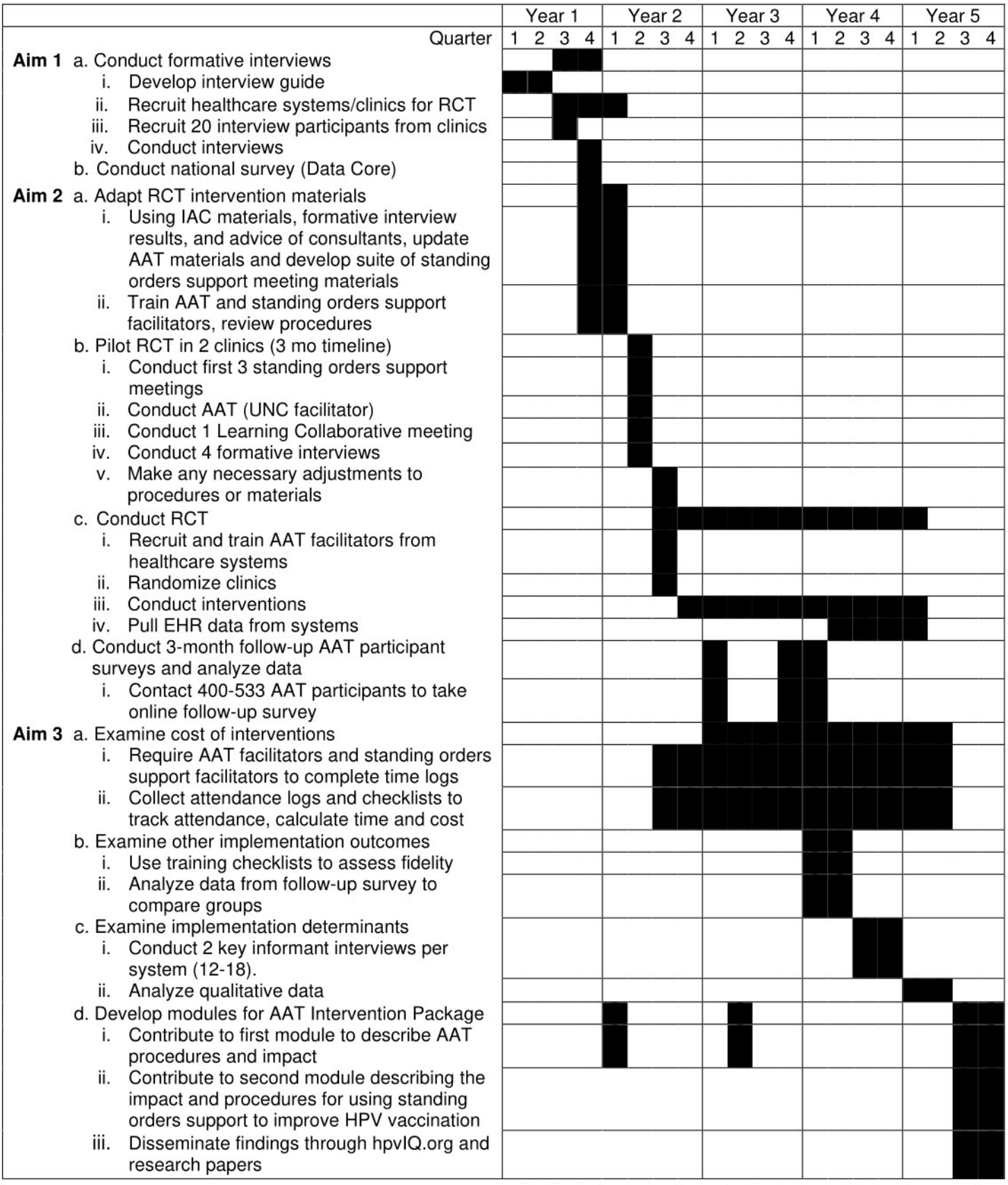
Key informant interviews

We will interview 2 key informants from each of the pilot clinics and an additional 12-16 key informants from clinics in the main RCT to understand the implementation of the interventions. These interviews will follow the same procedures and protections as described for the formative interviews. Participants will be given $100 gift cards for participating in these interviews.

Microcosting records, attendance logs, and checklists

We will record all costs associated with providing the interventions using online time logs completed by AAT and standing orders support facilitators, obtain attendance records of which (and how many of each) provider types attended the AAT and standing orders support meetings, and use checklists to document what material was covered in the intervention activities.

STUDY TIMELINE – Project 1



Aim 1

Our ability to implement these activities within the timeframe described comes from having an experienced team that has worked extensively on projects with similar components. The team will work simultaneously on multiple tasks, guided by experienced investigators.

In Year 1, we will focus on data collection. In the first six months, we will develop an interview guide for the formative interviews, and survey items to contribute to the national survey. We will simultaneously be working with AMGA to identify the healthcare systems and the clinics that will participate in the RCT. From 10 of these clinics, we will recruit one physician and one MA or nurse to participate in formative interviews (20 total). The formative interviews will be used to test items for the national survey, to inform updates to the AAT and the development of the standing orders support meeting materials. In the second half of the year, the Data Core will conduct the national survey. These activities will help us characterize the roles of primary care team members and standing orders in HPV vaccination and inform our intervention materials.

Aim 2

The study team will work to adapt training materials for both the Announcement Approach Training (AAT) and the standing orders support arms starting in Year 1. We will then recruit 2 clinics for the pilot and 40 clinics in 6-8 healthcare systems for the main intervention phase to take place in Years 2 and 3. The pilot will take place at the beginning of Year 2 in a condensed, 4-month period. Changes to procedures or materials will be incorporated into the full study protocol and design.

For the mail RCT, clinics will be randomized and interventions will be carried out across Years 2 and 3. Most clinics will have received interventions by the end of Year 3. We will conduct surveys before and after AAT workshops as well as 3 months afterward. We will allow 12 months between the intervention and the collection of follow-up vaccination data from healthcare systems' electronic health records. Year 4 will allow for some delay in recruitment, but we will spend most of the year analyzing data from the trial and on implementation.

Aim 3

We will assess costs and other implementation outcomes throughout the trial (Years 2-4). We will assess implementation determinants in key informant interviews in Years 3 and 4. In Year 5, the study team will refine the materials developed for the interventions to determine the best practices to be included in the AAT Intervention Package and disseminated to healthcare systems.

2.9. Inclusion Enrollment Reports

IER ID#	Enrollment Location Type	Enrollment Location
Study 1, IER 1	Domestic	Mississippi, Missouri, Texas
Study 1, IER 2	Domestic	Mississippi, Missouri, Texas
Study 1, IER 3	Domestic	Mississippi, Missouri, Texas
Study 1, IER 4	Domestic	Mississippi, Missouri, Texas

Inclusion Enrollment Report 1

1. Inclusion Enrollment Report Title* : Formative Interviews

2. Using an Existing Dataset or Resource* : ❍ Yes ● No

3. Enrollment Location Type* : ● Domestic ❍ Foreign

4. Enrollment Country(ies): USA: UNITED STATES

5. Enrollment Location(s): Mississippi, Missouri, Texas

6. Comments: Aim 1: Activity 1a (formative interviews)Note: For Activity 1b, the national primary care team survey, please refer to the Data Core for Inclusion Enrollment Report and other Human Subjects information.

Planned

Racial Categories	Ethnic Categories				Total
	Not Hispanic or Latino		Hispanic or Latino		
	Female	Male	Female	Male	
American Indian/ Alaska Native	0	0	0	0	0
Asian	1	1	0	0	2
Native Hawaiian or Other Pacific Islander	0	0	0	0	0
Black or African American	1	1	0	0	2
White	7	6	2	1	16
More than One Race	0	0	0	0	0
Total	9	8	2	1	20

Cumulative (Actual)

Racial Categories	Ethnic Categories									Total
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			
	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	
American Indian/ Alaska Native	0	0	0	0	0	0	0	0	0	0
Asian	0	0	0	0	0	0	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0	0	0	0	0	0	0
Black or African American	0	0	0	0	0	0	0	0	0	0
White	0	0	0	0	0	0	0	0	0	0
More than One Race	0	0	0	0	0	0	0	0	0	0
Unknown or Not Reported	0	0	0	0	0	0	0	0	0	0
Total	0	0	0	0	0	0	0	0	0	0

Inclusion Enrollment Report 2

1. Inclusion Enrollment Report Title* : RCT

2. Using an Existing Dataset or Resource* : ❍ Yes ● No

3. Enrollment Location Type* : ● Domestic ❍ Foreign

4. Enrollment Country(ies): USA: UNITED STATES

5. Enrollment Location(s): Mississippi, Missouri, Texas

6. Comments: Aim 2: Activity 2b and 2c For the RCT we are recruiting at the clinic level. The enrollment tables below pertain to the intervention-related provider surveys and assume an average of 20 staff for each of the 40 (+ 2 pilot) clinics.

Planned

Racial Categories	Ethnic Categories				Total
	Not Hispanic or Latino		Hispanic or Latino		
	Female	Male	Female	Male	
American Indian/ Alaska Native	4	4	1	1	10
Asian	20	20	4	4	48
Native Hawaiian or Other Pacific Islander	1	1	0	0	2
Black or African American	44	42	9	9	104
White	259	251	53	52	615
More than One Race	9	8	2	2	21
Total	337	326	69	68	800

Cumulative (Actual)

Racial Categories	Ethnic Categories									Total
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			
	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	
American Indian/ Alaska Native	0	0	0	0	0	0	0	0	0	0
Asian	0	0	0	0	0	0	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0	0	0	0	0	0	0
Black or African American	0	0	0	0	0	0	0	0	0	0
White	0	0	0	0	0	0	0	0	0	0
More than One Race	0	0	0	0	0	0	0	0	0	0
Unknown or Not Reported	0	0	0	0	0	0	0	0	0	0
Total	0	0	0	0	0	0	0	0	0	0

Inclusion Enrollment Report 3

1. Inclusion Enrollment Report Title* : Follow-up Survey

2. Using an Existing Dataset or Resource* : ❍ Yes ● No

3. Enrollment Location Type* : ● Domestic ❍ Foreign

4. Enrollment Country(ies): USA: UNITED STATES

5. Enrollment Location(s): Mississippi, Missouri, Texas

6. Comments: Activity 2d. 3-month follow-up survey

Planned

Racial Categories	Ethnic Categories				Total
	Not Hispanic or Latino		Hispanic or Latino		
	Female	Male	Female	Male	
American Indian/ Alaska Native	2	2	0	1	5
Asian	10	10	2	2	24
Native Hawaiian or Other Pacific Islander	0	0	0	0	0
Black or African American	22	21	5	4	52
White	130	126	27	26	309
More than One Race	4	4	1	1	10
Total	168	163	35	34	400

Cumulative (Actual)

Racial Categories	Ethnic Categories									Total
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			
	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	
American Indian/ Alaska Native	0	0	0	0	0	0	0	0	0	0
Asian	0	0	0	0	0	0	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0	0	0	0	0	0	0
Black or African American	0	0	0	0	0	0	0	0	0	0
White	0	0	0	0	0	0	0	0	0	0
More than One Race	0	0	0	0	0	0	0	0	0	0
Unknown or Not Reported	0	0	0	0	0	0	0	0	0	0
Total	0	0	0	0	0	0	0	0	0	0

Inclusion Enrollment Report 4

1. Inclusion Enrollment Report Title* : Key Informant Interviews (post-RCT)

2. Using an Existing Dataset or Resource* : ❍ Yes ● No

3. Enrollment Location Type* : ● Domestic ❍ Foreign

4. Enrollment Country(ies): USA: UNITED STATES

5. Enrollment Location(s): Mississippi, Missouri, Texas

6. Comments: Up to 16 key informant interviews will be conducted in clinics that participated in the RCT.

Planned

Racial Categories	Ethnic Categories				Total
	Not Hispanic or Latino		Hispanic or Latino		
	Female	Male	Female	Male	
American Indian/ Alaska Native	0	0	0	0	0
Asian	1	1	0	0	2
Native Hawaiian or Other Pacific Islander	0	0	0	0	0
Black or African American	1	1	0	0	2
White	5	5	1	1	12
More than One Race	0	0	0	0	0
Total	7	7	1	1	16

Cumulative (Actual)

Racial Categories	Ethnic Categories									Total
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			
	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	
American Indian/ Alaska Native	0	0	0	0	0	0	0	0	0	0
Asian	0	0	0	0	0	0	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0	0	0	0	0	0	0
Black or African American	0	0	0	0	0	0	0	0	0	0
White	0	0	0	0	0	0	0	0	0	0
More than One Race	0	0	0	0	0	0	0	0	0	0
Unknown or Not Reported	0	0	0	0	0	0	0	0	0	0
Total	0	0	0	0	0	0	0	0	0	0

Section 3 - Protection and Monitoring Plans (Study 1)

3.1. Protection of Human Subjects	ProtectionHsP1r1045594806.pdf
3.2. Is this a multi-site study that will use the same protocol to conduct non-exempt human subjects research at more than one domestic site?	● Yes ○ No ○ N/A
If yes, describe the single IRB plan	MultisiteStudyP1r1045594807.pdf
3.3. Data and Safety Monitoring Plan	DsmpP1r1045594808.pdf
3.4. Will a Data and Safety Monitoring Board be appointed for this study?	● Yes ○ No
3.5. Overall structure of the study team	StudyTeamP1r1045594809.pdf

PROTECTION OF HUMAN SUBJECTS – Project 1

Risk to subjects

We acknowledged that our studies involve populations that could be considered vulnerable: adolescents and primary care professionals trained in their places of work. We have worked closely with our IRB to successfully conduct multiple similar studies with similar data sources (anonymized health records of adolescent vaccination and anonymized participant surveys). We will again work closely with the IRB to ensure the protection of all study participants.

Human subjects involvement

The proposed studies will focus on expanding the impact of HPV vaccine recommendations through the Announcement Approach training (AAT) enhanced with standing orders support. We will first collect data through formative interviews and a national primary care team survey on attitudes about the role of registered nurses (RNs) and medical assistants (MAs) in making HPV vaccine recommendations as well as on the use of standing orders for HPV vaccine delivery. These data will inform refinements to training materials for the AAT and standing orders support interventions. The trial will have two arms: the AAT and the AAT enhanced with standing orders support. The trial will evaluate the impact of standing orders support on HPV vaccination uptake using electronic health record (EHR) data, AAT participant pre- and post-training surveys, AAT participant follow-up surveys, and microcosting.

Source of materials

Interviews. In Aim 1, a trained interviewer will conduct formative interviews by phone with one provider and one RN or MA from 10 clinics participating in the RCT for a total of 20 interviews. Interview questions will focus on the role of RNs and MAs in making HPV vaccine recommendations, as well as the use of standing orders for HPV vaccination. Some of these participants will also take part in cognitive testing of national survey items on the same topics. If needed, we will do cognitive testing with an additional 8 primary care professionals. The cognitive testing will consist of asking participants to answer an item that will be included in the web-based survey, asking what they believe the question was trying to ask, and what they intended by their answer. We will temporarily have participants' names and contact information for the purpose of scheduling and conducting the interview and providing incentives. However, identifying information will not be linked to participants' data. Interview participants will be given $100 gift cards for their time.

National primary care team survey. Also, as part of Aim 1, we will work in collaboration with the Data Core and research Projects 2 through 4 to conduct a national survey with 2,500 primary care professionals who treat adolescent patients. Please refer to the Data Core for Inclusion Enrollment Report and other Human Subjects information for the national survey.

Electronic health record data. For the Aim 2 trial, we will recruit 6-8 healthcare systems and 40 clinics from those systems to participate in the RCT with equal numbers of clinics (20) in each arm. An additional 2 clinics will be recruited for pilot testing the interventions and study protocols. Healthcare systems will receive a $9,000 honoraria to offset the administrative burden of participating in this research. Clinic-level vaccination coverage will be assessed before the interventions and 12 months after the interventions using anonymized data on vaccination coverage for the enrolled clinics. We will use vaccination coverage data to measure the change in HPV vaccination and up-to-date status of adolescents ages 11-12 and 13-17, for patients not vaccinated at baseline. We will comply with UNC IRB requirements, which do not call for HIPAA authorization or consent for anonymized electronic health record (EHR) data.

AAT participant pre- and post-training surveys. For each AAT workshop, pre- and post-training surveys will be collected from each participant to assess provider, clinic, and patient-volume characteristics as well as changes in participant attitudes, social norms, perceived behavioral control, intentions, recommendation behavior, and implementation outcomes. With a total of 42 clinics recruited (including the pilot clinics), we expect to have between 10-20 participants in each training from each clinic for a total of approximately 420 - 840 participants. Surveys will take 3-5 minutes each. We will obtain a written consent waiver and distribute an information sheet to participants with the other training materials. The post-training survey is part of the requirement for earning continuing medical education (CME) credit and continuing education credit (CE) for the training, however neither survey will request any identifying information or sensitive data from participants. Participants will complete a sign-in sheet that will allow us to distribute CME and CE credits, but this sign-in sheet will not be kept with survey data.

AAT participant follow-up surveys. Three months after the AAT workshops take place in the clinics, 10 training participants from each clinic will be recruited to complete an online follow-up survey. For the follow-up survey, we will email and mail participants a link. Expecting a response rate of 75%, we will send surveys to 400-533 of the AAT participants to yield 300-400 completed surveys. Survey items will assess the quality of the recommendations and use of the Announcement Approach. The study team will have participants' contact information for the purpose of providing $100 incentives, but this data will not be linked to participants' data.

Microcosting records, attendance logs, and checklists. We will record all costs associated with providing the interventions, obtain attendance records of which (and how many of each) primary care professional types attended the AAT and standing orders support meetings, and which material was covered in the intervention activities.

Key informant interviews. We will interview 2 key informants from the pilot clinics and an additional 12-16 key informants from clinics in the main RCT to understand the implementation of the interventions. These interviews will follow the same procedures and protections as described for the formative interviews. Participants will receive $100 gift cards for participating in these interviews.

Potential risks

We anticipate that the risks to participants will be minimal and manageable. We are not collecting biological specimens or discussing highly personal or sensitive topics. All study participants will be adults. The main risk is breach of confidentiality. The plan for mitigating this risk is discussed below (under "Protections against risk").

Adequacy of protection against risks

Recruitment and informed consent

Formative Interviews. We will recruit providers, registered nurses, and medical assistants from 10 clinics that will be part of the RCT (20 people in total) to participate in formative phone interviews. We will work with the healthcare systems and clinics in the trial to recruit participants. We will recruit up to 8 additional participants as needed. Interested participants will be asked to contact the project manager to participate. The study manager will explain the study. If the potential participant is eligible, the project manager will schedule the interview and email the consent form in advance. At the start of the interview, the study team member conducting the interview will welcome the participant and review the consent form. During this process, the study team member will point out that participation is voluntary, that there is minimal risk involved, that they can stop the interview or not answer any question at any time, that responses are confidential, and how to contact someone if they have any questions. The study team member will give the respondent time to review the consent form. If the participant gives verbal consent to the interview, the study team member will then proceed with the interview. We anticipate obtaining informed consent verbally will be appropriate given that participants are adults and the interviews will not cover sensitive information. These interviews will be recorded and transcribed for accuracy. Audio recordings will be destroyed once they have been transcribed and any identifying information will be redacted from the transcriptions. The cognitive testing portion of the interviews will not be recorded, but the study team member will take notes on the participants' understanding of the survey instructions, questions, and response scales.

National primary care team survey. In collaboration with the Data Core, Project 2, and Project 4, we will recruit 2,500 primary care professionals for the national survey through our subcontractor WebMD Market Research's existing healthcare professional panel. Please refer to the Data Core for "Inclusion Enrollment Report and other human subjects information for the national survey.

Electronic health record data. Six to eight healthcare systems will be recruited to participate in the trial. We will arrange a meeting to discuss the two interventions involved in the study. If they agree to participate, we will then recruit individual clinics within their system through multiple contacts that involve a letter, a fax, and several phone calls by the AAT facilitator and study team staff. The clinic leadership, including the clinic manager and the lead physician, will consent on behalf of the clinic. We will apply for a waiver of written consent; and we will comply with all UNC IRB requirements, which do not call for HIPAA authorization for anonymized EHR data.

Pre- and post-training AAT participant surveys. Pre- and post-training surveys will take place in the context of the AAT workshops. The UNC IRB has previously considered this activity to be quality improvement rather than human subjects research, and therefore has not required consent. If the IRB deems this activity to be

human subjects research, we will provide an information sheet to participants and use a process of passive consent used in previous trainings in which a consent form is included in the participant materials and is referenced by the facilitator before starting the training. At that point, participants are given the opportunity to ask questions about the study.

AAT participant follow-up surveys. For the 3-month follow-up survey, we will contact participants from the post-training survey who agreed to be contacted again. Participants will be recruited by mail and email, with instructions for accessing the online survey. Once the participant accesses the survey, the consent form will be embedded on the first page of the online survey along with an information sheet. The consent form will describe the purpose of the study, emphasize that participation is voluntary, that there is minimal risk involved, that they can stop the survey or not answer any question at any time, that survey responses are confidential, and how to contact someone if they have any questions. If the participant consents to the survey, they will click "next" and will advance to the following page to start the survey.

Microcosting records, attendance logs, and checklists. Our cost records will concern costs of photocopies and supplies and thus will not have participant information. The attendance logs will be anonymized by recording only the role of the persons in attendance. The content checklists will similarly not include any human subjects information as they will be about topics covered by facilitators.

Key informant interviews. These interviews will follow the same procedures and protections as described for the formative interviews.

Protection against risk

The informed consent process used for the formative interviews, the national primary care team survey, and the AAT participant follow-up survey will ensure that participants are aware of the potential risks of participating in the study. If we need to provide informed consent for the pre- and post-training surveys, the participant consent form included with the training materials will also outline potential risks of participating in the study. We will also remind participants of their right to drop out of the study at any point, without consequence.

We will not share information or data provided by individual participants with their coworkers, clinic staff, or clinic leadership. All information provided by study participants will be kept confidential, and identification numbers will be used rather than names of study participants. For the national survey, WebMD Market Research will provide us with a deidentified dataset. All study materials will be kept in a locked file accessible only to key study personnel. All computer files will be stored on a secure, password-protected server and accessed on computers that are password-protected, with only IRB-approved study personnel having access. The interview audio recordings will be destroyed once we have completed analyses. UNC also requires all staff involved with RCTs to complete an online IRB research ethics training course and other confidentiality certification procedures upon employment. Policies regarding the confidential nature of the data collected, processed, and stored will be explained to all personnel, who must then sign a confidentiality agreement before being allowed access to the confidential information. In addition to this initial training, we will reinforce the need for careful and confidential handling of data at staff meetings.

Potential benefits

By taking part in this study, participants may increase their knowledge of HPV vaccine recommendations and standing orders in clinics. Participants may also experience personal satisfaction of knowing they have contributed to a research project aimed at understanding primary care professionals' views on clinical roles in HPV vaccine recommendations and the use of standing orders for HPV vaccine. They will also receive monetary compensation for the time they invest in the study.

Importance of knowledge to be gained

Given that the risk to participants is minimal and manageable, the knowledge to be gained has the potential to fill an important research gap. Specifically, scientific findings will advance cancer prevention efforts and improve communication efforts around HPV vaccine between primary care professionals and patients.

MULTI-SITE STUDY: SINGLE IRB PLAN – Project 1

The proposed research project, “The impact of standing orders support on HPV vaccine communication and uptake”, will implement a single IRB plan. Our study team at UNC will submit all IRB materials on behalf of our research partners. UNC will collect data in Aim 1 through in-depth interviews and an online national survey subcontracted through WebMD Market Research. Our Aim 2 trial will collect data through training participant surveys. As part of the trial, vaccination data will also be provided through the healthcare systems’ electronic health records. The Project Lead, Dr. Brewer, will provide oversight of the research at both sites.

UNC will exercise authority and responsibility on behalf of our research partners and submit a single IRB application for review of human subjects research, in accordance with NIH policy for research protocols that are carried out at more than one site in the US. Our research partners have agreed to rely on the proposed single IRB. The Project Lead and Project Manager at UNC will communicate directly with our research partners to ensure all study related procedures and documents are approved by UNC’s IRB. Prior to initiating the research activities, we will sign an authorization/reliance agreement that will clarify the roles and responsibilities of the single IRB and participating sites with our research partners. UNC will maintain records of the authorization/reliance agreements and of the communication plan.

DATA AND SAFETY MONITORING PLAN – Project 1

The Project Lead will be responsible for the monitoring of the data and safety of the study participants. The proposed studies will be monitored by the UNC IRB. Any unanticipated problems, serious and unexpected adverse events, deviations, or protocol changes will be promptly reported by the Project Lead to the IRB and by the Principal Investigator to the sponsor agency, if appropriate.

UNC Lineberger Comprehensive Cancer Center has an established Data Safety Monitoring Plan in place. The UNC Lineberger's Director and the Associate Director for Clinical Research have the overall responsibility for policy on the data and safety monitoring of clinical trials. The Data and Safety Monitoring Subcommittee (DSMS) is the primary agent for assuring data and safety monitoring. The DSMS includes a chair, a vice chair, representation from clinical researchers, and a biostatistician. The DSMS meets monthly and has the following responsibilities: 1) Reviewing serious adverse event reports from all active clinical trials and assuring that these have also been reported to the IRB and other appropriate agencies; 2) Reviewing data and safety monitoring reports that are required of all active clinical trials; and 3) Recommending appropriate actions (closure, increased monitoring, etc.) to the IRB based on reviews of serious adverse events and periodic reports.

The DSMS findings, when necessary, will be sent to the IRB and to the School of Medicine's Data and Safety Monitoring Board (SOM-DSMB). Following a joint session that will include the SOM-DSMB and a representative of the DSMS, a final report and recommendation regarding continuation or closure of a trial will be made to the IRB, reflecting input from both groups. Final responsibility and authority for closing or amending such trials will rest with the IRB.

NIH grant applications require clinical trials to have a data safety and monitoring plan, but some do not require a data safety monitoring board (DSMB) or data monitoring committee (DMC). In 2001, the NCI stated, “there is no longer a blanket requirement for DSMB (DMC) in the cases of low-risk behavioral and nutritional trials... All such trials should include a data monitoring plan, but this may or may not include a DSMB (DMC)". We believe that our research projects are low risk and do not meet the definition of clinical trials requiring a data safety monitoring board. However, to ensure maximum protection of human subjects, we will submit our research project information to the SOM-DSMB listed above and allow them to make the final decision regarding risk to participants and whether or not our studies should receive their supervision. We do not anticipate that our studies will require ongoing supervision by the SOM-DSMB.

OVERALL STRUCTURE OF THE STUDY TEAM – Project 1

The organizational structure of the Project 1 study team is below. Our multi-disciplinary group has collaborated successfully for the past decade and is well versed in the development of training materials for health care professionals, conducting online surveys, and conducting randomized clinical trials (RCTs) of HPV vaccine communication trainings.

UNC study team (Aims 1-3)

- *Noel T. Brewer*, PhD, will be the Project Lead for the research project and will take primary responsibility for the research and administration. He will meet weekly with the full study team to ensure high quality research is conducted on time, within budget, and in compliance with the ethical requirements of the institutional review board. Dr. Brewer will also lead dissemination activities including manuscript preparation and conference presentations.
- *Paul Reiter,* PhD, a Co-Investigator, will provide scientific guidance to the study team on surveying pediatric health care professionals and intervention development. He will regularly attend project meetings and contribute to dissemination of study findings. He is supported through a sub-contract.
- *Postdoctoral Research Associate*, to be named, will assist with study design, survey development, study implementation, data analysis, and dissemination of study findings in Years 1-5 of the project. He or she will also help with the development of the Aim 2 trial protocol, survey design, and analytic plan, as well as Aim 3 analyses and writing tasks. Dr. Brewer will mentor the postdoctoral research associate.
- *Project Manager*, to be named, will be responsible for managing daily project operations for the studies and will serve as the liaison between the project director, project team, and other contributors, such as advisors. The project manager will also coordinate research activities, such as writing research protocols, managing the project budget, submitting IRB protocols and revisions, developing data collection instruments, managing data collection, and preparing reports, conference presentations, and manuscripts to disseminate findings. Dr. Brewer will supervise the project manager.
- *Research Assistants*, to be named, will help the study team with carrying out administrative and research tasks including preparing for training sessions, supporting Announcement Approach Training (AAT) facilitators, data analysis, and interpretation of findings. The research assistants will also assist the study team in developing dissemination materials such as conference posters, presentations, and manuscripts. The project manager and Dr. Brewer will jointly manage the research assistants.
- *AAT Facilitator*, to be named, will provide feedback on updated AAT materials, and will lead workshops for both pilot clinics enrolled in the RCT.
- *Standing Orders Support Facilitator*, to be named, will provide guidance and expertise in leading the initial standing orders support meetings with systems, and then attend meetings with individual clinics.
- *Elizabeth Ciemens*, PhD will provide guidance on healthcare system recruitment and intervention implementation within these systems. She will attend project meetings in all years of the project and contribute to dissemination of study findings and implementation package. She is supported through a sub-contract.
- Paul Darden, MD, will collaborate with Dr. Brewer and colleagues to provide expertise on HPV vaccine communication interventions and specifically on the facilitation of the use of standing orders support for vaccine delivery. He will collaborate with our study team to develop the standing orders support intervention protocols and training materials.
- *L.J. Tan*, PhD, will provide expertise in adapting materials developed by the Immunization Action Coalition to the standing orders support interventions. He will also provide expertise on the practicality of implementing standing orders in clinics.
- *Lisa Mansfield*, BSN, PhD, will provide expertise in nursing communication and HPV vaccine from the perspective of the primary care team that will be essential in developing training materials and study protocols. Dr. Mansfield will also provide expertise on qualitative data analysis, including analysis of qualitative data gathered in Year 1 on nurses' roles and clinic workflow.

Clinical Advisory Board

We will periodically consult the Clinical Advisory Board convened quarterly by the Intervention Core. The Board includes primary care professionals who have clinical roles as pediatricians, family physicians, physician assistants, nurse practitioners, registered nurses, and medical assistants. We will bring questions about the clinical context for AAT workshops and standing orders support.

Section 4 - Protocol Synopsis (Study 1)

4.1. Study Design

4.1.a. Detailed Description

The purpose of the randomized clinical trial proposed in Activity 2b is to determine whether the AAT intervention with standing orders support leads to greater HPV vaccine uptake than the AAT intervention alone. In a previous trial, a version of the Announcement Approach training was shown to have a greater impact than a conversation-based approach. However, data on this enhanced version of the training and the impact of standing orders support on HPV vaccination is lacking. This trial will evaluate the impact of these HPV vaccine interventions by randomly assigning clinics to an AAT only training arm or an AAT training plus standing orders support arm. Recruitment: We will recruit 42 (2 for the pilot, and 40 for the main trial) primary care clinics that are part of 6-8 healthcare systems and provide HPV vaccine to adolescents ages 11-12 and are part of large healthcare systems. We will register the trial with ClinicalTrials.gov and maintain a data and safety monitoring plan. To identify systems and clinics, we will work with the American Medical Group Association (see Letter of Support). Healthcare systems will need to have at least 4 eligible clinics and commit to provide EHR data on HPV vaccine. We will pay each system $9,000 to defray staff costs associated with providing vaccination data, an amount AMGA has used effectively in previous work with healthcare systems.Clinics eligible to participate in the RCT will 1) have standing orders in place for HPV vaccination, 2 have at least 50 patients ages 11-12, 3) have low HPV vaccine coverage, 4)at least a quarter of recruited clinics have at least 40% of patients in rural counties, and 5) have not hosted an AAT workshop in the previous 3 years nor currently be part of HPV vaccine communication trainings. We define low coverage as being below 66%, the rate for HPV vaccine initiation for the US (for adolescents ages 13-17, according to NIS-Teen 2018). Rurality of the clinics' populations will be determined by RUCC for patients' home counties using addresses from the EHR. We will define counties as either nonrural counties (sometimes called metropolitan areas, RUCC=1, 2 or 3) or rural counties (sometimes called nonmetropolitan areas, RUCC>3). We will start recruiting nonrural and urban clinics. If we meet the nonrural clinic maximum (75%), we will thereafter recruit only rural clinics. The healthcare system will be responsible for recruiting the clinics into the trial, with our help. Systems are likely to recruit the clinics in different ways, but we will offer our expertise in using a multiple contact approach that has been highly successful in our previous trials. Our approach is to meet with the system's quality improvement coordinator, using our standard slide set for recruitment (5 slides that show what the clinic receives and what we expect); gather information on the clinics, including the name of the clinic's vaccination coordinator; contact them through fax describing the training and trial and calls using a script with standard language to describe the training and trial; and if needed, an AAT facilitator (described below) visits an all-staff meeting to describe the training and trial. Randomization and procedures: An independent biostatistician from the IMPACT Data Core will randomize clinics to trial arm in a 1:1 ratio: AAT or AAT enhanced with standing orders. The biostatistician will match clinics based on HPV vaccine initiation coverage and rurality to balance trial arms on these important metrics; vaccination coverage and rurality of clinic populations (least 40% RUCC >3) will come from EHR in January of Year 2. Using protocols we developed for previous trials to avoid contamination across trial arms we will exclude clinics in different arms that share providers. We will conduct the trainings primarily in April-July of Years 2 and 3; if needed, we will conduct trainings as late as August. This time period corresponds to the months just before and during an annual peak in adolescent vaccine uptake. Assessment: Clinics in both arms will receive AAT that take approximately 60 minutes. Clinics in the AAT + Standing Orders Support arm will receive a series of additional meetings in which they will receive technical assistance on the implementation of standing orders for HPV vaccine. For each intervention, training participants will take both a pre- and post-training survey. Three months after the AAT training, we will recruit 10 training participants from each clinic to take a follow-up survey.Detailed description of the intervention: AAT facilitators. Local training facilitators, trained by the IMPACT Intervention Core, will deliver trainings to clinics in each healthcare system. Facilitators will be trained according to our standard orientation process. First, the facilitators will participate in an AAT workshop to experience the training from the perspective of an attendee. Second, facilitators will attend an interactive online orientation where they will learn the objectives of the AAT. Facilitators will also learn to use the script and slides, troubleshoot the videos, lead the practice exercise, handle participant questions, and establish staff support to manage logistics. Third, facilitators will receive the script, presentation slides, and other materials in print and electronic format, with back-up materials available online. Fourth, facilitators will practice presenting the AAT on their own and then at least twice with primary care teams. For one of the practice sessions, study staff will observe and then provide feedback on strengths of the presentation and areas for improvement. Procedures for the AAT arm. AAT workshops will be scheduled and coordinated by the project manager and a healthcare system staff person. We will confirm AAT attendance by sending an email that lists the names of the primary care team members who have agreed to attend the training. Physicians and nurses will receive one continuing medical education (CME) or continuing education (CE) credit for attending the full in-person trainings. Facilitators will bring a computer as well as participant materials for the role-play exercise. Facilitators will use the standardized script and PowerPoint slide set to present the trainings.Procedures for the AAT enhanced with standing orders support arm. We will use the same procedures described above for clinics in this trial arm to deliver the AAT, and then we will also support implementation of standing orders using materials developed in Activity 2a. To support clinics' activation of standing orders, a UNC Standing Orders Support facilitator and project director will initiate a series of activation meetings, first facilitating the meetings and then transitioning responsibility for facilitating to the system QI lead and Standing Orders teams formed

within clinics. The first meeting, led by our facilitator, will take place at the system level and will present and overview, assess current standing orders practices, identify milestones for standing orders optimization, and prepare for the next meeting. The second meeting will be led by the system QI lead and will focus on identifying clinic workflow, a plan for clinic staff buy-in, and discuss expected challenges and solutions. The third meeting, led by the Standing Orders lead and attended by all clinic teams will review the standing orders plan, metrics, and discuss primary care team roles. The fourth meeting, called the Learning Collaborative, will be held initially 1 month after the AAT and then bi-monthly as needed. These meetings will be check-ins about how standing orders and AAT are working, the meetings will be used to address challenges and review metrics.

4.1.b. Primary Purpose: Prevention

4.1.c. Interventions

Type	Name	Description
Other	Announcement Approach training (AAT)(intervention)	The AAT materials will include updated statistics, videos, specific roles for RNs and MAs, and a discussion of clinic flow. The training will remain a 60 minute training, eligible for 1 hour of CME or CE.
Other	AAT + Standing Orders Support intervention (intervention)	The standing orders support intervention will consist of a series of activation meetings with clinic and system leadership to provide an overview of the benefits of standing orders optimization, and a process for addressing challenges to implementation, providing technical assistance and resources. The activities will happen before and after the AAT workshop.

4.1.d. Study Phase: N/A

Is this an NIH-defined Phase III Clinical Trial? ❍ Yes ● No

4.1.e. Intervention Model: Parallel

4.1.f. Masking ❍ Yes ● No

❑ Participant ❑ Care Provider ❑ Investigator ❑ Outcomes Assessor

4.1.g. Allocation: Randomized

4.2. Outcome Measures

Type	Name	Time Frame	Brief Description
Primary	Change in HPV vaccine initiation among adolescents ages 11-12	Just prior to intervention to one year post-intervention	Data will come from the healthcare systems' EHR will be pulled just prior to the interventions. This data will be used to calculate initiation of HPV vaccination for adolescents ages 11-12.
Secondary	Change in HPV vaccine up to date among adolescents ages 11-12	Just prior to intervention to one year post-intervention	Data will come from healthcare systems' EHR just prior to the interventions. This data will be used to calculate up to date for HPV vaccination for adolescents ages 11-12.
Secondary	Change in HPV vaccine initiation among adolescents ages 13-17	Just prior to intervention to one year post-intervention	Data will come from the healthcare systems' EHR just prior to the interventions. This data will be used to calculate initiation HPV vaccination for adolescents ages 13-17.
Secondary	Change in HPV vaccine up to date among adolescents ages 13-17	Just prior to intervention to one year post-intervention	Data will come from healthcare systems' EHR just prior to the interventions. This data will be used to calculate up to date for HPV vaccination for adolescents ages 13-17.

Secondary	Change in provider knowledge	Pre-training to 3 month follow-up	Survey items that assess a change in primary care team members' knowledge of HPV vaccination.
Secondary	Change in self-efficacy	Pre-training to 3 month follow-up	Survey items that assess how confident primary care team members feel in addressing parents' concerns about HPV vaccine.
Secondary	Change in collective efficacy	Pre-training to 3 month follow-up	Survey items that assess how confident primary care team members feel in the team's ability to work together to increase HPV vaccine uptake.
Secondary	Change in recommendation quality	Pre-training to 3 month follow-up	Survey items that assess how often primary care team members are recommending HPV vaccine, to which patients, and whether they recommend patients get the vaccine that day.
Secondary	Fidelity	3 months	Fidelity checklists that show the percentage of key AAT workshop content delivered
Other	Reach	3 months	Attendance logs that show the percentage of eligible primary care team members who attend the trainings.
Other	Change in positive outcome expectations	Pre-training to 3 month follow-up	Survey items that assess primary care team members' beliefs that HPV vaccine recommendations will be comfortable and well-received by patients and parents.
Other	Change in beliefs that HPV vaccination is normative	Pre-training to 3 month follow-up	Survey items that assess primary care team members' beliefs that HPV vaccination is the norm.
Other	Cost of intervention delivery	6 months	Cost and time logs assessing the per-clinic cost of delivering the interventions.
Other	Change in intention to recommend HPV vaccine	Pre-training to 3 month follow-up	Survey items that assess primary care team members' intention to recommend HPV vaccine.
Other	Change in perceived barriers	Pre-training to 3 month follow-up	Survey items that assess primary care team members' perception of barriers to HPV vaccination in their clinic.

4.3. Statistical Design and Power — StatDesignPowerP1r1045594810.pdf

4.4. Subject Participation Duration — Up to 3 months

4.5. Will the study use an FDA-regulated intervention? — ❍ Yes ● No

4.5.a. If yes, describe the availability of Investigational Product (IP) and Investigational New Drug (IND)/ Investigational Device Exemption (IDE) status

4.6. Is this an applicable clinical trial under FDAAA? — ❍ Yes ● No

4.7. Dissemination Plan — DissemPlanP1r1045594811.pdf

STATISTICAL DESIGN AND POWER – Project 1

National primary care team survey

Because projects will use data from the survey to address many research questions, we used a general approach to estimate the minimum sample size required to detect moderately small effects. Specifically, we estimated the sample size required to detect a 10% change in endorsement of a low-prevalence outcome between two groups of unequal size (i.e. 10% endorsement in group 1, containing 75% of the sample, and 20% endorsement in group 2, containing 25% of the sample). With a two-tailed alpha of .05, an effective sample size of 500 per primary care professional type (for a total of 2,500 respondents) is required to obtain 80% power.

Randomized controlled trial

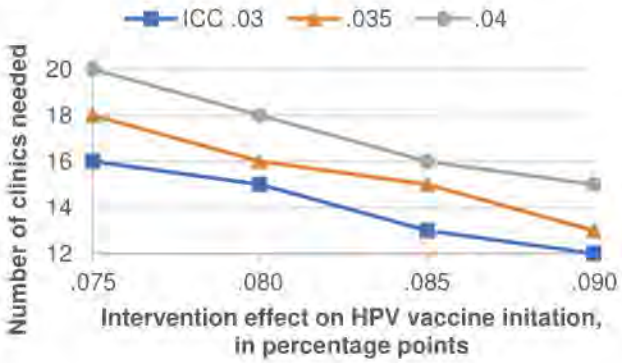
Trial vaccination outcomes

The analysis cohort will be adolescents who attended a clinic visit during the previous year, followed from baseline (date of AAT) to 12-month follow-up. We considered comparing two overlapping cohorts (e.g., children age 11-12 at baseline and children age 11-12 at 12-month follow-up), but we were concerned that any differences between them could be attributed to variation in cohort characteristics.

Analyses will examine our hypothesis that AAT enhanced with standing orders support increases HPV vaccination. We will use intent-to-treat analyses of trial outcomes, including all clinics enrolled at baseline. The main analyses will use generalized estimating equations to model the log odds of vaccination between baseline and follow-up, among patients not vaccinated at baseline, while accounting for dependence between patients. The predictor variables will be trial arm, with AAT-only as the reference group. The outcomes will be the trial's primary and secondary vaccination outcomes.

Power analyses relied on estimates from our previous research[43,68] and pilot work delivering AAT in health systems. Tan and colleagues found a 7% increase for standing orders support for HPV vaccination of adults ages 19-26 after a single workshop;[68] we expect a larger intervention effect due to a more structured and higher intensity intervention for a younger patient population whose vaccination rates change more quickly. Thus, we varied the expected intervention effect around an increase of 8.5%. Our pilot work with systems found a clinic-level intra-class correlation (ICC) of .033 for change in HPV vaccine initiation over 9 months. Thus, we varied ICC around .035. Finally, we assumed 200 unvaccinated children per clinic, a 15% increase in HPV vaccine initiation in both arms due to secular trends and AAT, and alpha=.05. The analyses found that the planned 20 clinics per arm will provide at least 80% power to detect a difference as low as 7.5% in the primary trial outcome with ICC up to .04 (**Figure**).

Figure. Clinics needed for RCT in Aim 2 for power > .80.



AAT participant surveys

We expect to have 10-20 participants per clinic at trainings in 40 clinics. Almost all will complete the pre- and post-training surveys (n=400-800). For the follow-up surveys and assuming a response rate of 75%, we will send surveys to 400-533 participants to yield 300-400 completed surveys. In the past, we have had a 70%-100% completion of follow-up surveys because we keep surveys brief and give trainings that provide value. Analyses will include any participants who completed at least one of the surveys; GEE will allow us to use all data without dropping participants with missing surveys or items. The predictor variables will be trial arm, time and their interaction. We will dummy code trial arm to compare each intervention to control. We will explore statistically significant interactions using post-hoc t-tests, examining the effect of trial arm, stratified by time. We are powered to detect effect sizes of $d = .18$ or larger, assuming alpha = .05.

Analyses will examine our hypothesis that AAT will improve HPV vaccination recommendations. Specifically, we expect that AAT will improve provider attitudes, social norms, perceived behavioral control, and intentions to recommend HPV vaccination. We propose that standing orders support will operate in a

similar way to increase uptake, with larger effects on providers within the clinics receiving both AAT and standing orders support.

DISSEMINATION PLAN – Project 1

A key dissemination activity for Project 1 will be to create two intervention modules for the AAT Intervention Package to provide guidance to healthcare systems. The first module will describe the AAT, including its impact in previous trials and implementation findings from the current trial. The module will describe how to orient AAT facilitators, conduct trainings, and evaluate them and will link to online AAT materials (slides, script, exercise materials) available at hpvIQ.org, a website hosted by Dr. Gilkey (Project 3) and Dr. Brewer.

The second module will describe standing orders support using a similar structure. We will report on standing orders support impact and cost, acceptability, and other implementation measures. The module will link to online standing orders support materials (agendas, slides, planning template, common problems flier) to be made available on hpvIQ.org and standingorders.org. The Intervention Core and Administrative Core will lead efforts to disseminate the Package.

In addition, for Aims 1-3, we will publish our findings in peer-reviewed journals and present at meetings and national conferences, such as annual meetings of the American Academy of Pediatrics, Society of Behavioral Medicine, and American Society of Preventive Oncology. We will produce press releases and other communications to document and share our research findings with the scientific community as well as other key stakeholders and advocates. As appropriate, we will update materials on hpvIQ.org for others to use. Dissemination of scientific findings will help advance HPV vaccine communication efforts specifically and cancer prevention more broadly, inform new communication campaigns for parents and adolescents, and through these efforts improve public health.

Specific to Aim 2, we will register the trial with ClinicalTrials.gov prior to enrollment of the first participant, and we will submit results and other required information to ClinicalTrials.gov within 1 year of the conclusion of the trial. We will include text in the informed consent information for this study that states that the results of the trial will be available on ClinicalTrials.gov. We will follow the UNC Gillings School of Global Public Health procedures for ensuring the clinical trials registration and results reporting are done in compliance with policy requirements.

Delayed Onset Studies

Delayed Onset Study#	Study Title	Anticipated Clinical Trial?	Justification
The form does not have any delayed onset studies			

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CONSORTIUM/CONTRACTUAL ARRANGEMENTS – Project 1

The Project 1 proposal includes a collaborative effort between UNC, The AMGA Analytics (in coordination with the American Medical Group Association), and the Ohio State University (OSU). UNC will serve as the prime institution for Project 1, and AMGA and OSU will serve as subrecipients.

The proposed activities include a subcontract with the AMGA to involve Dr. Elizabeth Ciemens in all proposed specific aims as the Research Director and with OSU to similarly involve Dr. Paul Reiter. The appropriate programmatic and administrative personnel of each organization involved in this grant application are aware of the NIH consortium agreement policy and are prepared to establish the necessary inter-organizational agreement(s) consistent with that policy.

Dr. Noel Brewer is the Project Lead responsible for ensuring proper conduct of the project at the consortium site of UNC Chapel Hill. Dr. Elizabeth Ciemens is the Consortium Lead responsible for ensuring proper conduct of the project at AMGA. Dr. Paul Reiter is the Consortium Lead responsible for ensuring proper conduct of the project at OSU. UNC will manage the programmatic, fiscal, and administrative tasks necessary to ensure the overall success of this subcontract. Dr. Noel Brewer will lead weekly meetings in all years of the project. Dr. Ciemens will attend these meetings by phone as needed, but especially in Years 1, 2, and 3 of the project as the healthcare systems are being recruited and the RCT is being conducted. Dr. Ceimens will provide scientific guidance on working with healthcare systems, facilitate data pulls, and manage payment of honoraria to systems and Announcement Approach Training facilitators based in each recruited healthcare system. Dr. Reiter will attend weekly meetings for the full 5 years of the study, providing expertise on HPV vaccination, survey design, conduct of clinical trials, and analysis of provider survey data.

The grantee and subrecipient organizations are prepared to make a formal consortium agreement with terms and conditions stipulating ownership of all data, reports, materials, inventions and if applicable, future use. This agreement will be developed in accordance with NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards Subpart B: Terms and Conditions for Specific Types of Grants, Grantees, and Activities (15 Consortium Agreements).

RESEARCH

University of North Carolina at Chapel Hill
Subrecipient Letter of Intent

To be completed by Subrecipient

SUBRECIPIENT	SPONSOR
Legal Name: AMGA Analytics, LLC	Legal Name: The University of North Carolina at Chapel Hill
DUNS: 1428240700000	DUNS: 608195277
Lead PI: Elizabeth Ciemins, PhD	Lead PI: Noel T. Brewer

Subrecipient Administrative Contact:

Name/Title: Cindy Shekailo, Sr. Director, Analytics Operations
Address: One Prince Street, Alexandria, VA 22314
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Address: 104 Airport Drive, Suite 2200
Chapel Hill, NC, 27599
Phone: 919-966-3411
Email: ResAdminOSR@unc.edu

GENERAL INFORMATION

Project Title: Program Project- Improving Provider Announcement Communication Training (IMPACT)

Prime Awarding Agency: National Cancer Institute
RFA/RFP: PAR-20-077

Project Period: Start 07/01/2021 End 06/30/2026
UNC-CH Proposal Number: (Enter UNC IPF Number)

BUDGET INFORMATION

Choose as appropriate below:

○ Federal Rate ○ Sponsor Rate ◉ Other

Applicable F&A Rate: 15 %

Direct Costs: $178,312.80
Indirect Costs: $11,446.92
Total Request: $189,759.72

COMPLIANCE INFORMATION

Human Subjects: ◉ Yes ○ No
Animal Subjects: ○ Yes ◉ No

Is your institution a participant of Federal Demonstration Partnership (FDP) Clearing House? ○ Yes ◉ No

This LETTER OF INTENT confirms the appropriate program and administrative personnel have reviewed and approve the above referenced Solicitation/ RFP/RFA. Further, the institution and its Principal Investigator certify that:

Information submitted within this application is true, complete, and accurate to the best of the institution's and PI's knowledge; any false, fictitious, or fraudulent statements or claims may subject the institution and PI to criminal, civil, or administrative penalties; PI agrees to accept responsibility for the scientific conduct of the project and to provide the required progress reports if an award is made, and a mutually agreeable subcontract is executed as a result thereof.

Included: • Statement of Work • Budget • Budget Justification Other:

Subrecipient Principal Investigator: Elizabeth Ciemins Digitally signed by Elizabeth Ciemins Date: 2020.08.04 14:14:11 -06'00'

Date: August 4, 2020

Subrecipient Authorized Official: Cindy Shekailo Digitally signed by Cindy Shekailo Date: 2020.08.17 09:27:09 -04'00'

Date: August 17, 2020

Form Approved Through 02/28/2023 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Application

Do not exceed character length restrictions indicated.

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Type	Activity	Number
Review Group		Formerly
Council/Board (Month, Year)		Date Received

1. TITLE OF PROJECT *(Do not exceed 81 characters, including spaces and punctuation.)*
Program Project-Improving Provider Announcement Communication Training (IMPACT)

2. RESPONSE TO SPECIFIC REQUEST FOR APPLICATIONS OR PROGRAM ANNOUNCEMENT OR SOLICITATION ☐ NO ☒ YES
(If "Yes," state number and title)
Number: PAR - 20-077 Title: National Cancer Institute Program Project Applications

3. PROGRAM DIRECTOR/PRINCIPAL INVESTIGATOR

3a. NAME (Last, first, middle)	3b. DEGREE(S)	3h. eRA Commons User Name
Ciemins, Elizabeth L.	Ph.D. MA MPH	eRA COMMONS USER NAME

3c. POSITION TITLE
Vice President, Research and Analytics

3e. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Research and Analytics

3f. MAJOR SUBDIVISION
AMGA Analytics, LLC

One Prince St.
Alexandria, VA 22314

3g. TELEPHONE AND FAX *(Area code, number and extension)*
TEL: 703-838-0033 FAX: 703-548-1890

E-MAIL ADDRESS:
ECiemins@amga.org

4. HUMAN SUBJECTS RESEARCH	4a. Research Exempt	If "Yes," Exemption No.
☐ No ☒ Yes	☒ No ☐ Yes	

4b. Federal-Wide Assurance No.	4c. Clinical Trial	4d. NIH-defined Phase III Clinical Trial
	☐ No ☒ Yes	☒ No ☐ Yes

5. VERTEBRATE ANIMALS	5a. Animal Welfare Assurance No.
☒ No ☐ Yes	

6. DATES OF PROPOSED PERIOD OF SUPPORT *(month, day, year—MM/DD/YY)*		7. COSTS REQUESTED FOR INITIAL BUDGET PERIOD		8. COSTS REQUESTED FOR PROPOSED PERIOD OF SUPPORT	
From	Through	7a. Direct Costs ($)	7b. Total Costs ($)	8a. Direct Costs ($)	8b. Total Costs ($)
7/1/2021	6/30/2026	22406.40	25767.36	178312.80	189759.72

9. APPLICANT ORGANIZATION
Name AMGA Analytics, LLC.
Address One Prince St.
Alexandria, VA 22314

10. TYPE OF ORGANIZATION
Public: → ☐ Federal ☐ State ☐ Local
Private: → ☐ Private Nonprofit
For-profit: → ☒ General ☐ Small Business
☐ Woman-owned ☐ Socially and Economically Disadvantaged

11. ENTITY IDENTIFICATION NUMBER
54-2020131
DUNS NO. 14-383-4070 Cong. District 8th

12. ADMINISTRATIVE OFFICIAL TO BE NOTIFIED IF AWARD IS MADE
Name Cindy Shekailo
Title Sr. Director, Analytics Operations
Address One Prince Street
Alexandria, VA 22314
Tel: 703-577-5556 FAX: 703-548-1890
E-Mail: cshekailo@amga.org

13. OFFICIAL SIGNING FOR APPLICANT ORGANIZATION
Name Cindy Shekailo
Title Sr. Director, Analytics Operations
Address One Prince Street
Alexandria, VA 22314
Tel: 703-577-5556 FAX: 703-548-1890
E-Mail: cshekailo@amga.org

14. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

SIGNATURE OF OFFICIAL NAMED IN 13. *(In ink. "Per" signature not acceptable.)*

DATE
11-Aug-2020

Program Director/Principal Investigator (Last, First, Middle):

SCOPE OF WORK

Dr. Ciemins will serve as the Research Director with AMGA on Project 1 of the NCI P01 proposal "Improving Provider Announcement Communication Training (IMPACT) Program Project" and will dedicate [ ] calendar months effort on the project for Years 1 and 2, and [ ] calendar months in Years 3 and 4, and [ ] calendar months in Year 5.of the study. In Years 1 and 2, Dr. Ciemins will facilitate the recruitment of healthcare systems and clinics to participate in the randomized clinical trial that will take place in years 2 and 3 of the grant. In Years 2-4, Dr. Ciemins and her staff will provide knowledge and expertise to facilitate the implementation of study activities and trainings in clinics to increase HPV vaccine uptake including the distribution of honoraria to healthcare systems and AAT facilitators. She will also work closely with the study team to monitor data pulls from system EHR ensuring data quality and security. In Year 5 she will assist in follow-up with the clinics to ensure all data and documentation is received and will also be involved in the writing and dissemination of the findings. During the course of the project Dr. Ciemins will attend study team meetings as needed by phone.

Regarding human subjects, UNC's prime proposal involves human subjects research. However, there are no plans for the AMGA staff to have contact with study participants or to have access to raw datasets containing identifiers. If, at some point in the future, UNC wishes AMGA investigators to work with human subjects data, IRB approval would be obtained.

RELEVANCE (See instructions):

PROJECT/PERFORMANCE SITE(S) (if additional space is needed, use Project/Performance Site Format Page)

Project/Performance Site Primary Location			
Organizational Name: AMGA Analytics, LLC			
DUNS: 14-383-4070			
Street 1: One Prince Street		Street 2:	
City: Alexandria	County: Fairfax		State: Virginia
Province:	Country: USA	Zip/Postal Code: 22314	
Project/Performance Site Congressional Districts:			

Additional Project/Performance Site Location			
Organizational Name:			
DUNS:			
Street 1:		Street 2:	
City:	County:		State:
Province:	Country:	Zip/Postal Code:	
Project/Performance Site Congressional Districts:			

RESEARCH

University of North Carolina at Chapel Hill
Subrecipient Letter of Intent

To be completed by Subrecipient

SUBRECIPIENT	SPONSOR
Legal Name: The Ohio State University	Legal Name: The University of North Carolina at Chapel Hill
DUNS: 832127323	DUNS: 608195277
Lead PI: Paul Reiter	Lead PI: (Enter Sponsor's PI)

Subrecipient Administrative Contact:	*Sponsor Administrative Contact:*
Name/Title: Mark Marbaugh	Name/Title: David Paul/Assistant Vice Chancellor
Address: 1960 Kenny Rd.	Address: 104 Airport Drive, Suite 2200 Chapel Hill, NC, 27599
Phone: 614-688-4050	Phone: 919-966-3411
Email: marbaugh.4@osu.edu	Email: ResAdminOSR@unc.edu

GENERAL INFORMATION

Project Title: Program Project- Improving Provider Announcement Communication Training (IMPACT)

Prime Awarding Agency: National Cancer Institute

RFA/RFP: PAR-20-077

Project Period: Start 07/01/2021 End 06/30/2026

UNC-CH Proposal Number: (Enter UNC IPF Number)

BUDGET INFORMATION

Choose as appropriate below:

(•) Federal Rate ( ) Sponsor Rate ( ) Other

Applicable F&A Rate: 56 %

Direct Costs: $49,516.00

Indirect Costs: $27,728.00

Total Request: $77,244.00

COMPLIANCE INFORMATION

Human Subjects: ( ) Yes (•) No

Animal Subjects: ( ) Yes (•) No

Is your institution a participant of Federal Demonstration Partnership (FDP) Clearing House? (•) Yes ( ) No

This LETTER OF INTENT confirms the appropriate program and administrative personnel have reviewed and approve the above referenced Solicitation/ RFP/RFA. Further, the institution and its Principal Investigator certify that:

Information submitted within this application is true, complete, and accurate to the best of the institution's and PI's knowledge; any false, fictitious, or fraudulent statements or claims may subject the institution and PI to criminal, civil, or administrative penalties; PI agrees to accept responsibility for the scientific conduct of the project and to provide the required progress reports if an award is made, and a mutually agreeable subcontract is executed as a result thereof.

Included: • Statement of Work • Budget • Budget Justification Other:

Subrecipient Principal Investigator: DocuSigned by: Paul L. Reiter E1CD707BDD354BB...

Date: 08/20/2020

Subrecipient Authorized Official: DocuSigned by: Kristin Cress 9F6382D1EE744C2...

Date: 08/19/2020

Form Approved Through 02/28/2023 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Application

Do not exceed character length restrictions indicated.

LEAVE BLANK—FOR PHS USE ONLY.

Type	Activity	Number
Review Group		Formerly
Council/Board (Month, Year)		Date Received

1. TITLE OF PROJECT *(Do not exceed 81 characters, including spaces and punctuation.)*
Program Project-Improving Provider Announcement Communication Training (IMPACT)

2. RESPONSE TO SPECIFIC REQUEST FOR APPLICATIONS OR PROGRAM ANNOUNCEMENT OR SOLICITATION ☐ NO ☒ YES
(If "Yes," state number and title)
Number: PAR – 20-077 Title: National Cancer Institute Program Project Applications

3. PROGRAM DIRECTOR/PRINCIPAL INVESTIGATOR

3a. NAME (Last, first, middle)	3b. DEGREE(S)	3h. eRA Commons User Name
Reiter, Paul L.	Ph.D.	eRA COMMONS USER NAME

3c. POSITION TITLE
Associate Professor

3d. MAILING ADDRESS *(Street, city, state, zip code)*
1841 Neil Ave.
Room 359B
Columbus, OH 43210

3e. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Division of Health Behavior and Health Promotion

3f. MAJOR SUBDIVISION
College of Public Health

3g. TELEPHONE AND FAX *(Area code, number and extension)*
TEL: 614-292-4803 FAX:

E-MAIL ADDRESS:
Reiter.36@osu.edu

4. HUMAN SUBJECTS RESEARCH	4a. Research Exempt	If "Yes," Exemption No.
☐ No ☒ Yes	☒ No ☐ Yes	

4b. Federal-Wide Assurance No.	4c. Clinical Trial	4d. NIH-defined Phase III Clinical Trial
00006378	☐ No ☒ Yes	☒ No ☐ Yes

5. VERTEBRATE ANIMALS ☒ No ☐ Yes — 5a. Animal Welfare Assurance No.

6. DATES OF PROPOSED PERIOD OF SUPPORT *(month, day, year—MM/DD/YY)*		7. COSTS REQUESTED FOR INITIAL BUDGET PERIOD		8. COSTS REQUESTED FOR PROPOSED PERIOD OF SUPPORT	
From	Through	7a. Direct Costs ($)	7b. Total Costs ($)	8a. Direct Costs ($)	8b. Total Costs ($)
7/1/2021	6/30/2026	17,1720.00	26,788.00	49,516.00	77,244.00

9. APPLICANT ORGANIZATION
Name The Ohio State University
Address 1960 Kenny Road, Columbus OH 43210-1016

10. TYPE OF ORGANIZATION
Public: → ☐ Federal ☒ State ☐ Local
Private: → ☐ Private Nonprofit
For-profit: → ☐ General ☐ Small Business
☐ Woman-owned ☐ Socially and Economically Disadvantaged

11. ENTITY IDENTIFICATION NUMBER
31-602598
DUNS NO. 832127323 Cong. District OH-003

12. ADMINISTRATIVE OFFICIAL TO BE NOTIFIED IF AWARD IS MADE
Name Mark Marbaugh
Title Sponsored Program Officer
Address 1960 Kenny Road, Columbus OH 43210-1016
Tel: 614-688-4050 FAX:
E-Mail: marbaugh.4@osu.edu

13. OFFICIAL SIGNING FOR APPLICANT ORGANIZATION
Name Kristin Cress
Title Associate Manager
Address 1960 Kenny Road, Columbus OH 43210-1016
Tel: 614-292-6847 FAX:
E-Mail: Cress.53@osu.edu

14. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

SIGNATURE OF OFFICIAL NAMED IN 13. DATE
Docusigned by: Kristin Cress
(In ink. "Per" signature not acceptable.)
8/26/2020

SCOPE OF WORK

Dr. Reiter will serve as the co-I on Project 1 of the NCI P01 proposal "Improving Provider Announcement Communication Training (IMPACT) Program Project" and will dedicate [ ] calendar months effort on the project for Year 1, and [ ] calendar months in Years 2-4 of the study. In Year 1, as the co-I on Project 1, Dr. Reiter will contribute to the design of research tools such as interview guides, survey items, and intervention protocols as well as the analytic plan. In Years 2-4, Dr. Reiter will provide knowledge and expertise to the project regarding RCT interventions that involve implementing trainings in clinics to increase HPV vaccine uptake. He will work closely with the study team to monitor data collection and analysis, ensuring data quality and security. He will also be involved in the writing and dissemination of the findings. During the course of the project Dr. Reiter will attend study team meetings as needed by phone, and plan to travel to Chapel Hill in Year 1 and Year 4.

Regarding human subjects, UNC's prime proposal involves human subjects research. However, there are no plans for the OSU investigators to have contact with study participants or to have access to raw datasets containing identifiers. OSU investigators will be working with de-identified and summarized data only, such as summary findings and reports that include no identifying information. If, at some point in the future, UNC wishes OSU investigators to work with human subjects data, IRB approval would be obtained.

RELEVANCE (See instructions):

PROJECT/PERFORMANCE SITE(S) (if additional space is needed, use Project/Performance Site Format Page)

Project/Performance Site Primary Location		
Organizational Name:		
DUNS:		
Street 1:	Street 2:	
City:	County:	State:
Province:	Country:	Zip/Postal Code:
Project/Performance Site Congressional Districts:		

Additional Project/Performance Site Location		
Organizational Name:		
DUNS:		
Street 1:	Street 2:	
City:	County:	State:
Province:	Country:	Zip/Postal Code:
Project/Performance Site Congressional Districts:		

AMGA
Advancing High Performance Health

One Prince Street
Alexandria, VA 22314-3318
O 703.838.0033
F 703.548.1890

August 11, 2020

Noel T. Brewer, PhD
Department of Health Behavior
Gillings School of Global Public Health
University of North Carolina
325 Rosenau Hall CB7440
Chapel Hill, NC 27599

Dear Dr. Brewer:

AMGA (American Medical Group Association) is pleased to support your NCI grant proposal "The impact of standing orders support on HPV vaccine communication and uptake" as a partner organization. This project is part of the P01 Program Project "Improving Provider Announcement Communication Training (IMPACT)."

As a national trade association representing multispecialty medical groups and integrated health care systems, AMGA has extensive experience working with health care organizations, recruiting them to participate in research studies, and facilitating data pulls for reporting. We also have experience helping systems implement quality improvement efforts around HPV vaccination and are trusted by our member health care organizations. Recently, we worked with a cohort of 8 health care organizations to increase their HPV vaccination rates as part of a 2-year best practices learning collaborative. We are currently in the beginning of project year 2.

AMGA staff will recruit 5–7 health care organizations or systems, for a total of 40 clinic practice sites, in Mississippi, Missouri and Texas to participate in your research study. Their roles will include participation in formative interviews, a randomized controlled trial, a survey of providers, and key informant interviews. We have a subcontract in place that covers our planned work together, which includes my role as research director for AMGA.

On behalf of AMGA, I look forward to collaborating with your research team on this timely and important research project.

Sincerely,

Elizabeth L. Ciemins, Ph.D., M.P.H., M.A.
Vice President, Research and Analytics

July 27, 2020

Noel T. Brewer, PhD
Department of Health Behavior
Gillings School of Global Public Health
University of North Carolina
325 Rosenau Hall CB7440
Chapel Hill, NC 27599

Dear Dr. Brewer:

The American Cancer Society (ACS) is pleased to support your NCI grant proposal "The impact of standing orders support on HPV vaccine communication and uptake". This project is part of the P01 Program Project "Improving Provider Announcement Communication Training (IMPACT)".

ACS has extensive existing relationships with healthcare systems interested in strengthening their HPV vaccine QI efforts, and we have worked with Dr. Brewer for several years on projects that implement the Announcement Approach Training in healthcare systems. We understand that you will work with AMGA to recruit healthcare systems for your RCT. Indeed, we had suggested you use them as the primary vendor. If needed, ACS is happy to provide introductions and recommendations to work with systems in rural areas with the requisite number of primary care clinics. We have substantial capacity in this area and would be pleased to partner should the need arise.

On behalf of ACS, I look forward to collaborating with your research team on this timely and important research project.

Sincerely,

Marcie Fisher-Borne, PhD, MPH, MSW
Managing Director, National Interventions and Implementation
Office of the Chief Medical and Scientific Officer
American Cancer Society
919-260-3680
Marcie.fisherborne@cancer.org

July 30, 2020

Noel T. Brewer, PhD
Department of Health Behavior
Gillings School of Global Public Health
University of North Carolina
325 Rosenau Hall CB7440
Chapel Hill, NC 27599

RE: Program Project – Improving Provider Announcement Communication Training (IMPACT)

Dear Dr. Brewer:

This letter confirms I am committed to serving as a subcontractor to your NCI P01 proposal "Improving Provider Announcement Communication Training (IMPACT) Program Project,". As part of your Project 1 research project titled "The impact of standing orders support on HPV vaccine communication and uptake", led by Dr. Noel Brewer, I will serve as the Co-Investigator.

I am excited to be supporting an innovative research project that will enhance the Announcement Approach Training (AAT) for healthcare providers and explore the impact of the use of standing orders for HPV vaccination. Given my expertise in HPV vaccine and provider communication, I will provide expertise in Years 1-5 of the grant to develop survey measures, interview tools, and to guide the interventions in the RCT.

I am eagerly looking forward to working with your group on this valuable research project.

Sincerely,

DocuSigned by:
Paul L. Reiter
07/30/2020

Paul L. Reiter, Ph.D.
Associate Professor
Division of Health Behavior and Health Promotion
College of Public Health
The Ohio State University

August 2, 2020

Noel T. Brewer, PhD
Department of Health Behavior
Gillings School of Global Public Health
University of North Carolina
325 Rosenau Hall CB7440
Chapel Hill, NC 27599

Dear Dr. Brewer:

The opportunity to collaborate with you and your research team on your NCI grant proposal "The impact of standing orders support on HPV vaccine communication and uptake" is very exciting. I understand that this project is part of the P01 Program Project "Improving Provider Announcement Communication Training (IMPACT)". This is an innovative research project that will enhance the empiric evidence for the Announcement Approach Training (AAT) for healthcare providers. Combining this approach with support of standing orders for HPV vaccination is needed, as the implementation and effect of standing orders have not been adequately studied for the delivery of HPV vaccine.

I am happy to support your project in any way and I am pleased to accept your invitation to participate as an expert consultant. As you know, I have long-standing expertise in practice-based research and experience in standing orders implementation, I will provide expertise from both the clinic and training perspectives to ensure that the interventions in the RCT are both rigorous and viable. In Years 1 and 2 of the grant, I will participate in quarterly study team meetings via conference call to help refine standing orders survey questions and intervention materials, and to help troubleshoot standing orders intervention implementation. In Year 1, I will record a short video for the standing orders intervention. In Year 5, I will review the AAT Intervention Package. I agree to be paid $ ($ in Years 1 and 2, and $ in Year 5) for serving as an expert consultant.

In the US, we have struggled to achieve adequate HPV vaccination rates. This project, with AAT and standing orders support, shows substantial promise for improving the delivery of HPV vaccine. I fully support this project and will help in any way that I can. I am looking forward to working with your group on this valuable research project.

Sincerely,

Paul M. Darden, MD

UNIVERSITY OF CALIFORNIA, Los Angeles UCLA

BERKELEY • DAVIS • IRVINE • LOS ANGELES • MERCED • RIVERSIDE • SAN DIEGO • SAN FRANCISCO SANTA BARBARA • SANTA CRUZ

DIVISION OF GENERAL INTERNAL MEDICINE
& HEALTH SERVICES RESEARCH
UCLA DEPARTMENT OF MEDICINE
DAVID GEFFEN SCHOOL OF MEDICINE AT
UCLA 1100 GLENDON AVE., SUITE 900
LOS ANGELES, CALIFORNIA 90024

August 6, 2020

Noel T. Brewer, PhD
Department of Health Behavior
Gillings School of Global Public Health
University of North Carolina
325 Rosenau Hall CB7440
Chapel Hill, NC 27599

Dear Dr. Brewer:

I am pleased to work with you and your research team on your NCI grant proposal, "The impact of standing orders support on HPV vaccine communication and uptake" as a nurse consultant. This project is part of the P01 Program Project "Improving Provider Announcement Communication Training (IMPACT)." I am hopeful that exploring new methods of increasing HPV vaccination rates through the Announcement Approach Training (AAT) and enhancing it with support for standing orders on HPV vaccination will move provider communication in this area forward.

My experience and background in nursing, HPV vaccination research, and qualitative research methods will be very useful as we develop research and intervention tools and interpret data. I have expertise in conducting content and thematic qualitative analysis and constructing interview guides surrounding questions about HPV vaccination. My nursing experience in reviewing standing orders for vaccine administration in clinic settings will help inform the nurse's role in HPV vaccination in the proposed study. In Years 1 and 2 of the grant, I will attend study team meetings; review research tools, assist in developing the interview guide and survey items, as well as new training scripts and slides; and participate in the planned qualitative research analysis. I agree to be paid [$] ([$] in Year 1, and [$] in Year 2) for serving as a nurse consultant.

I am eagerly looking forward to working with your group on this valuable research project.

Sincerely,

Lisa Mansfield PhD, RN
Postdoctoral Fellow
National Clinician Scholars Program
University of California, Los Angeles

August 2, 2020

Noel T. Brewer, PhD
Department of Health Behavior
Gillings School of Global Public Health
University of North Carolina
325 Rosenau Hall CB7440
Chapel Hill, NC 27599

Dear Dr. Brewer,

The Immunization Action Coalition (IAC) is pleased to accept your invitation to participate as an external advisor on your NCI grant proposal "The impact of standing orders support on HPV vaccine communication and uptake". This project is part of the P01 Program Project "Improving Provider Announcement Communication Training (IMPACT)". I am excited to support an innovative research project that will evaluate how increasing supporting providers' role in recommending HPV vaccine together with the use of standing orders can help increase HPV vaccination rates.

As the Chief Strategy Officer for the Immunization Action Coalition (IAC), I have extensive experience on a wide range of topics, including vaccine hesitancy, immunization quality measurement development, and practical approaches to improve vaccine delivery. Hence, for this project I can provide valuable feedback on the content and design of the standing orders training. To do so, I will act on behalf of the IAC as an external advisor, providing input on the adaptation of IAC standing orders materials in Year 1 and participating periodically in study team meetings by conference call.

I look forward to collaborating with your research team on this timely research project.

Sincerely,

L.J. Tan, MS, PhD
Chief Strategy Officer, Immunization Action Coalition (IAC)

RESOURCE SHARING PLAN – Project 1

We agree with the NIH principle that data sharing is essential for expedited translation of research results into knowledge, products, and procedures to improve human health. All projects and cores will follow the same procedures. We will make data collection instruments available online for public use after data collection and analyses are complete. Leads of the research projects and the Data Core will oversee sharing of de-identified data produced by the Program Project. Dr. Brewer will oversee this process.

One of the key products of the planned research is a shared national primary care team survey conducted with the Data Core who will be the primary contact for requests. The Data Core will contact the Project Lead for approval to share the de-identified dataset with external requestors. For the vaccine outcomes for the trial, the data are owned by the North Carolina Immunization Registry. Interested external requestors will be directed to contact the registry directly for approval to access the data. For the provider survey, as part of the trial we will follow the Program's standard procedure for sharing the de-identified dataset and codebooks. See the Program's Overall Resource Sharing Plan for more details. Interview data will not be shared because it would be difficult to protect participants' identities even if we were to remove all identifiers.

OMB Number: 4040-0010
Expiration Date: 12/31/2022

APPLICATION FOR FEDERAL ASSISTANCE

SF 424 (R&R)

5. APPLICANT INFORMATION **Organizational DUNS*:** 608195277

Legal Name*:	The University of North Carolina at Chapel Hill
Department:	Office of Sponsored Research
Division:	Research
Street1*:	104 Airport Drive
Street2:	Campus Box 1350
City*:	Chapel Hill
County:	Orange
State*:	NC: North Carolina
Province:	
Country*:	USA: UNITED STATES
ZIP / Postal Code*:	27599-1350

Person to be contacted on matters involving this application

Prefix:	First Name*:	Middle Name:	Last Name*:	Suffix:
	Andrea		Cogdill	

Position/Title:	Grants Analyst
Street1*:	130 Mason Farm Road
Street2:	CB 9525, Bioinformatics Bldg.
City*:	Chapel Hill
County:	Orange
State*:	NC: North Carolina
Province:	
Country*:	USA: UNITED STATES
ZIP / Postal Code*:	27599-9525

Phone Number*: (919) 962-3950 Fax Number: (919) 843-7094 Email: grants@unc.edu

7. TYPE OF APPLICANT* H: Public/State Controlled Institution of Higher Education

Other (Specify):

Small Business Organization Type ❍ Women Owned ❍ Socially and Economically Disadvantaged

11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT*

IMPACT Project 2 – The impact of clinic-level financial incentives on HPV vaccine communication and uptake

12. PROPOSED PROJECT

Start Date*	Ending Date*
07/01/2021	06/30/2026

OMB Number: 4040-0010
Expiration Date: 12/31/2022

Project/Performance Site Location(s)

Project/Performance Site Primary Location

❍ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name:	The University of North Carolina at Chapel Hill
Duns Number:	608195277
Street1*:	104 Airport Drive
Street2:	Campus Box 1350
City*:	Chapel Hill
County:	Orange
State*:	NC: North Carolina
Province:	
Country*:	USA: UNITED STATES
Zip / Postal Code*:	27599-1350
Project/Performance Site Congressional District*:	NC-004

Additional Location(s) File Name:

Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED Other Project Information

1. Are Human Subjects Involved?* ● **Yes** ○ **No**

1.a. If YES to Human Subjects

Is the Project Exempt from Federal regulations? ○ Yes ● No

If YES, check appropriate exemption number: _ 1 _ 2 _ 3 _ 4 _ 5 _ 6 _ 7 _ 8

If NO, is the IRB review Pending? ○ **Yes** ○ **No**

IRB Approval Date:

Human Subject Assurance Number 00004801

2. Are Vertebrate Animals Used?* ○ **Yes** ● **No**

2.a. If YES to Vertebrate Animals

Is the IACUC review Pending? ○ Yes ○ No

IACUC Approval Date:

Animal Welfare Assurance Number

3. Is proprietary/privileged information included in the application?* ○ **Yes** ● **No**

4.a. Does this project have an actual or potential impact - positive or negative - on the environment?* ○ **Yes** ● **No**

4.b. If yes, please explain:

4.c. If this project has an actual or potential impact on the environment, has an exemption been authorized or an environmental assessment (EA) or environmental impact statement (EIS) been performed? ○ Yes ○ No

4.d. If yes, please explain:

5. Is the research performance site designated, or eligible to be designated, as a historic place?* ○ **Yes** ● **No**

5.a. If yes, please explain:

6. Does this project involve activities outside the United States or partnership with international collaborators?* ○ **Yes** ● **No**

6.a. If yes, identify countries:

6.b. Optional Explanation:

	Filename
7. Project Summary/Abstract*	AbstractP2rV21045663952.pdf
8. Project Narrative*	NarrativeP2r1045594833.pdf
9. Bibliography & References Cited	ReferencesP2r1045594834.pdf
10.Facilities & Other Resources	FacilitiesP2r1045594835.pdf
11.Equipment	EquipmentP2r1045594836.pdf
12. Other Attachments	AcronymsP2r1045594837.pdf

Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

ABSTRACT – Project 2

Human papillomavirus (HPV) vaccination is effective and recommended to protect against six types of cancer, but HPV vaccine coverage remains low. Provider communication has a powerful influence on HPV vaccine uptake. Our program team has demonstrated that Announcement Approach Training (AAT) effectively improves provider communication and increases HPV vaccination uptake. A promising tool to expand the impact of AAT is clinic-level financial incentives, which can motivate providers to apply what they learn in the AAT workshop. Financial incentives are increasingly a central part of payment reform efforts focusing on better aligning financial incentives in healthcare systems with quality of care. No studies have adequately established whether financial incentives motivate providers to recommend HPV vaccination. As part of the proposed P01 Program Project, “Improving Provider Announcement Communication Training (IMPACT),” the goal of this randomized clinical trial (RCT) is to test promising alternatives to motivate providers to improve HPV vaccine communication. We propose to examine whether financial incentives tied to clinic-level improvement in HPV vaccination rates can improve HPV vaccine communication and uptake. To achieve this goal, **in Aim 1, we will characterize providers’ perceptions of financial incentives tied to HPV vaccination and behavioral nudges** via a national primary care team survey. We will also refine a feedback report to track HPV vaccination rates paired with improvement targets to providers and clinics. **In Aim 2, we will conduct the RCT**, randomizing clinics to one of two arms: 1) AAT and 2) AAT plus financial incentive tied to clinic-level improvement in HPV vaccination rates. **In Aim 3, we will evaluate intervention implementation, including cost** per additional adolescent initiating HPV vaccine. This RCT is significant because it will demonstrate whether and how financial incentives improve provider communication and increase vaccine uptake to achieve HPV vaccination goals. The proposed research addresses the **IMPACT Program Project theme** of amplifying the impact of a Research-Tested Intervention Program to improve HPV vaccine communication in healthcare systems via financial incentives to motivate providers to make needed recommendations.

NARRATIVE – Project 2

Our goal is to rigorously test promising alternatives to motivate providers to improve human papillomavirus (HPV) vaccination communication and HPV vaccination rates in healthcare systems. The proposed randomized clinical trial will demonstrate whether and how financial incentives improve provider communication and increase vaccine uptake to achieve HPV vaccination goals.

FACILITIES AND OTHER RESOURCES – Project 2

Refer to Overall Component for Project 2 Facilities and Other Resources.

EQUIPMENT – Project 2

None.

LIST OF ACRONYMS – Project 2

AA	Announcement Approach
AAT	Announcement Approach Training
ACIP	Advisory Committee on Immunization Practices
CFIR	Consolidated Framework for Implementation Research
CHAI	Connected Health Applications and Interventions
CMS	Centers for Medicare and Medicaid Services
Covid-19	Coronavirus disease 2019
EHR	Electronic health record
ERIC	Expert Recommendations for Implementing Change
GEE	Generalized estimating equation
HEDIS	Healthcare Effectiveness Data and Information Set
HPV	Human papillomavirus
IMPACT	Improving Provider Announcement Communication Training
IRB	Institutional Review Board
NCI	National Cancer Institute
RCT	Randomized clinical trial
RUCC	Rural-Urban Continuum Codes
UNC	University of North Carolina
US	United States

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED Senior/Key Person Profile (Expanded)

PROFILE - Project Director/Principal Investigator

Prefix: First Name*: Justin Middle Name G. Last Name*: Trogdon Suffix:

Position/Title*: Professor
Organization Name*: The University of North Carolina at Chapel Hill
Department: Health Policy and Management
Division: Gillings Sch. of Public Hlth
Street1*: 1101-B McGavran-Greenberg
Street2: 135 Dauer Drive, CB 7411
City*: Chapel Hill
County: Orange
State*: NC: North Carolina
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 27599-7411

Phone Number*: (919)962-2433 Fax Number: (919) 843-6380

E-Mail*: justintrogdon@unc.edu

Credential, e.g., agency login: eRA COMMONS USER NAME

Project Role*: Other (Specify) Other Project Role Category: Project Lead

Degree Type: PhD Degree Year: 2004

Attach Biographical Sketch*: File Name: BioTrogdonP2rV21045663954.pdf

Attach Current & Pending Support: File Name:

Tracking Number: GRANT13205496 Funding Opportunity Number: PAR-20-077 . Received Date: 2020-09-18T11:41:16.000-04:00

PROFILE - Senior/Key Person

Prefix: First Name*: Michelle Middle Name L Last Name*: Hernandez Suffix:

Position/Title*: Associate Professor
Organization Name*: The University of North Carolina at Chapel Hill
Department: Pediatrics
Division: School of Medicine
Street1*: 104 Mason Farm Road
Street2: CB 7310
City*: Chapel Hill
County: Orange
State*: NC: North Carolina
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 27599-7310

Phone Number*: (919) 962-5136 Fax Number:

E-Mail*: michelle_hernandez@med.unc.edu

Credential, e.g., agency login: eRA COMMONS USER NAME

Project Role*: Co-Investigator Other Project Role Category:

Degree Type: MD Degree Year: 2002

Attach Biographical Sketch*: File Name: BioHernandezP2rV21045663953.pdf

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Harsha Middle Name Last Name*: Thirumurthy Suffix:

Position/Title*:
Organization Name*: N/A
Department:
Division:
Street1*: 63 W. Lodges Lane
Street2:
City*: Bala Cynwyd
County:
State*: PA: Pennsylvania
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 19178-5541

Phone Number*: (202) 812-8567 Fax Number:

E-Mail*: hthirumurthy@gmail.com

Credential, e.g., agency login: eRA COMMONS USER NAME

Project Role*: Consultant Other Project Role Category:

Degree Type: PhD, Economics Degree Year: 2006

Attach Biographical Sketch*: File Name: BioThirumurthyP2r1045594826.pdf

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Sarah Middle Name A. Last Name*: Birken Suffix:

Position/Title*:	Associate Professor
Organization Name*:	Wake Forest University Health Sciences
Department:	Implementation Science
Division:	School of Medicine
Street1*:	Medical Center Boulevard
Street2:	
City*:	Winston-Salem
County:	Forsyth
State*:	NC: North Carolina
Province:	
Country*:	USA: UNITED STATES
Zip / Postal Code*:	27157-0000

Phone Number*: (336) 713-4231 Fax Number:

E-Mail*: sbirken@wakehealth.edu

Credential, e.g., agency login: eRA COMMONS USER NAME

Project Role*: Co-Investigator Other Project Role Category:

Degree Type: PhD Degree Year: 2011

Attach Biographical Sketch*: File Name:

Attach Current & Pending Support: File Name:

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 1

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2021 **End Date*:** 06-30-2022 **Budget Period: 1**

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.		Justin	G.	Trogdon		Project Lead	CAL. MONTHS, INST. BASE SALARY				41,367.00	12,338.00	53,705.00
2.		Michelle	L	Hernandez		Co-Investigator					9,788.00	3,447.00	13,235.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **66,940.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
1	Graduate Students	12			25,560.00	6,563.00	32,123.00
	Undergraduate Students						
	Secretarial/Clerical						
1	NCnet Project Manager	1.2			4,518.00	1,821.00	6,339.00
2	AAT Facilitators	0.12			1,512.00	552.00	2,064.00
1	Project Manager	8.4			46,865.00	16,691.00	63,556.00
1	Programmer	2.4			19,876.00	6,448.00	26,324.00
6	**Total Number Other Personnel**					**Total Other Personnel**	**130,406.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**197,346.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 1

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2021 **End Date*:** 06-30-2022 **Budget Period: 1**

C. Equipment Description	
List items and dollar amount for each item exceeding $5,000	
Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	
Additional Equipment: File Name:	

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	1,500.00
2. Foreign Travel Costs	
Total Travel Cost	**1,500.00**

E. Participant/Trainee Support Costs	**Funds Requested ($)***
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant Trainee Support Costs**	

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 1

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2021 **End Date*:** 06-30-2022 **Budget Period: 1**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	6,800.00
2. Publication Costs	
3. Consultant Services	12,000.00
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8. Tuition	18,866.00
9. Other Costs	11,390.00
Total Other Direct Costs	**49,056.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**247,902.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. Organized Research_On Campus	55.5	229,036.00	127,115.00
		Total Indirect Costs	**127,115.00**

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number): DHHS, Darryl Mayes, 202-401-2808

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**375,017.00**

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	375,017.00

L. Budget Justification* File Name: BudgetJustificationP2rV21045663955.pdf

(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

Tracking Number: GRANT13205496 Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 2

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2022 **End Date*:** 06-30-2023 **Budget Period: 2**

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.		Justin	G.	Trogdon		Project Lead	CAL. MONTHS, INST. BASE SALARY				41,367.00	12,338.00	53,705.00
2.		Michelle	L	Hernandez		Co-Investigator					19,575.00	6,894.00	26,469.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **80,174.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
1	Graduate Students	12			25,560.00	6,563.00	32,123.00
	Undergraduate Students						
	Secretarial/Clerical						
1	NCnet Project Manager	1.2			4,518.00	1,821.00	6,339.00
2	AAT Facilitators	0.84			10,549.00	3,852.00	14,401.00
1	Project Manager	8.4			46,865.00	16,691.00	63,556.00
1	Programmer	2.4			19,876.00	6,448.00	26,324.00
6	**Total Number Other Personnel**					**Total Other Personnel**	**142,743.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**222,917.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 2

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2022 **End Date*:** 06-30-2023 **Budget Period: 2**

C. Equipment Description	
List items and dollar amount for each item exceeding $5,000	
Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	
Additional Equipment: File Name:	

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	6,000.00
2. Foreign Travel Costs	
Total Travel Cost	**6,000.00**

E. Participant/Trainee Support Costs	**Funds Requested ($)***
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant Trainee Support Costs**	

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 2

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2022 **End Date*:** 06-30-2023 **Budget Period: 2**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	2,500.00
2. Publication Costs	1,500.00
3. Consultant Services	12,000.00
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8. Tuition	19,432.00
9. Other Costs	17,000.00
Total Other Direct Costs	**52,432.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**281,349.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. Organized Research_On Campus	55.5	261,917.00	145,364.00
		Total Indirect Costs	**145,364.00**

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number): DHHS, Darryl Mayes, 202-401-2808

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**426,713.00**

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	426,713.00

L. Budget Justification* File Name: BudgetJustificationP2rV21045663955.pdf

(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

Tracking Number: GRANT13205496 Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 3

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2023 **End Date*:** 06-30-2024 **Budget Period: 3**

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.		Justin	G.	Trogdon		Project Lead	CAL. MONTHS, INST. BASE SALARY				41,367.00	12,338.00	53,705.00
2.		Michelle	L	Hernandez		Co-Investigator					19,575.00	6,894.00	26,469.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **80,174.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
1	Graduate Students	12			25,560.00	6,563.00	32,123.00
	Undergraduate Students						
	Secretarial/Clerical						
1	NCnet Project Manager	1.2			4,518.00	1,821.00	6,339.00
2	AAT Facilitators	1.38			17,439.00	6,368.00	23,807.00
1	Project Manager	7.2			40,170.00	14,307.00	54,477.00
1	Programmer	2.4			19,876.00	6,448.00	26,324.00
6	**Total Number Other Personnel**					**Total Other Personnel**	**143,070.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**223,244.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 3

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2023 **End Date*:** 06-30-2024 **Budget Period: 3**

C. Equipment Description	
List items and dollar amount for each item exceeding $5,000	
Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	
Additional Equipment: File Name:	

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	5,500.00
2. Foreign Travel Costs	
Total Travel Cost	**5,500.00**

E. Participant/Trainee Support Costs	**Funds Requested ($)***
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant Trainee Support Costs**	

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 3

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2023 **End Date*:** 06-30-2024 **Budget Period: 3**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	2,800.00
2. Publication Costs	1,500.00
3. Consultant Services	12,000.00
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8. Tuition	20,015.00
9. Other Costs	120,733.00
Total Other Direct Costs	**157,048.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**385,792.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. Organized Research_On Campus	55.5	365,777.00	203,006.00
		Total Indirect Costs	**203,006.00**

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number): DHHS, Darryl Mayes, 202-401-2808

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**588,798.00**

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	588,798.00

L. Budget Justification* File Name: BudgetJustificationP2rV21045663955.pdf

(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 4

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2024 **End Date*:** 06-30-2025 **Budget Period: 4**

A. Senior/Key Person

Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.	Justin	G.	Trogdon		Project Lead	CAL. MONTHS, INST. BASE SALARY				41,367.00	12,338.00	53,705.00
2.	Michelle	L	Hernandez		Co-Investigator					19,575.00	6,894.00	26,469.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **80,174.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
1	Graduate Students	12			25,560.00	6,563.00	32,123.00
	Undergraduate Students						
	Secretarial/Clerical						
1	NCnet Project Manager	1.2			4,518.00	1,821.00	6,339.00
2	AAT Facilitators	0.69			8,730.00	3,188.00	11,918.00
1	Project Manager	6.6			36,823.00	13,115.00	49,938.00
1	Programmer	2.4			19,876.00	6,448.00	26,324.00
6	**Total Number Other Personnel**					**Total Other Personnel**	**126,642.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**206,816.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 4

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2024 **End Date*:** 06-30-2025 **Budget Period: 4**

C. Equipment Description	
List items and dollar amount for each item exceeding $5,000	
Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	
Additional Equipment: File Name:	

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	1,500.00
2. Foreign Travel Costs	
Total Travel Cost	**1,500.00**

E. Participant/Trainee Support Costs	**Funds Requested ($)***
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant Trainee Support Costs**	

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 4

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2024 **End Date*:** 06-30-2025 **Budget Period: 4**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	4,000.00
2. Publication Costs	1,500.00
3. Consultant Services	12,000.00
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8. Tuition	20,615.00
9. Other Costs	151,083.00
Total Other Direct Costs	**189,198.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**397,514.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. Organized Research_On Campus	55.5	376,899.00	209,179.00
		Total Indirect Costs	**209,179.00**

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number): DHHS, Darryl Mayes, 202-401-2808

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**606,693.00**

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	606,693.00

L. Budget Justification* File Name: BudgetJustificationP2rV21045663955.pdf

(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

Tracking Number: GRANT13205496 Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 5

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2025 **End Date*:** 06-30-2026 **Budget Period: 5**

A. Senior/Key Person

Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.	Justin	G.	Trogdon		Project Lead	CAL. MONTHS, INST. BASE SALARY				41,367.00	12,338.00	53,705.00
2.	Michelle	L	Hernandez		Co-Investigator					9,788.00	3,447.00	13,235.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **66,940.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
1	Graduate Students	12			25,560.00	6,563.00	32,123.00
	Undergraduate Students						
	Secretarial/Clerical						
1	NCnet Project Manager	0.6			2,259.00	910.00	3,169.00
1	Project Manager	6			33,475.00	11,922.00	45,397.00
1	Programmer	0.65			5,365.00	1,740.00	7,105.00
4	**Total Number Other Personnel**					**Total Other Personnel**	**87,794.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**154,734.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 5

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2025 **End Date*:** 06-30-2026 **Budget Period: 5**

C. Equipment Description	
List items and dollar amount for each item exceeding $5,000	
Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	
Additional Equipment: File Name:	

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	
2. Foreign Travel Costs	1,500.00
Total Travel Cost	**1,500.00**

E. Participant/Trainee Support Costs		**Funds Requested ($)***
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other:		
Number of Participants/Trainees	**Total Participant Trainee Support Costs**	

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 5

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2025 **End Date*:** 06-30-2026 **Budget Period: 5**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	2,800.00
2. Publication Costs	1,500.00
3. Consultant Services	12,000.00
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8. Tuition	21,234.00
9. Other Costs	48,000.00
Total Other Direct Costs	**85,534.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**241,768.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. Organized Research_On Campus	55.5	220,534.00	122,396.00
		Total Indirect Costs	**122,396.00**

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number): DHHS, Darryl Mayes, 202-401-2808

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**364,164.00**

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	364,164.00

L. Budget Justification* File Name: BudgetJustificationP2rV21045663955.pdf

(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

Tracking Number: GRANT13205496 Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

BUDGET JUSTIFICATION – Project 2

Key Personnel

Justin Trogdon, PhD, Project Lead

Year 1	Year 2	Year 3	Year 4	Year 5
CAL. MONTHS				

Dr. Trogdon will serve as Project Lead for the proposed P01 Program Project. Dr. Trogdon is Professor of Health Policy and Management at the UNC Gillings School of Global Public Health. He has been a Principal Investigator on 16 funded research grants and contracts, including two R01 awards, totaling nearly $12 million in total costs. His HPV vaccine research includes geospatial analysis of HPV vaccination patterns and vaccine providers, time series estimates of the effects of the release of the latest version of the HPV vaccine, analysis of claims and survey data to assess the effects of state-level policies on HPV vaccination, and costing and cost-effectiveness modelling of interventions to increase HPV vaccination. As Project Lead, Dr. Trogdon will have overall responsibility for design and implementation of the studies and dissemination of findings. Specifically, he will have overall budgetary, administrative, and scientific responsibility for the research project and will coordinate and implement activities essential to carrying out the research aims and achieving the project's goals. These activities include maintaining scientific integrity throughout the project, developing instruments and protocols, meeting with co-investigators, supervising project staff, coordinating the work of external advisors, overseeing data collection, and overseeing data analysis. Along with his study team, Dr. Trogdon will develop reports, papers, presentations, and other materials for dissemination.

Michelle Hernandez, MD, Co-Investigator

Year 1	Year 2	Year 3	Year 4	Year 5
CAL. MONTHS				

Dr. Hernandez is a pediatrician at UNC Healthcare and an Associate Professor of Pediatrics at UNC School of Medicine. She serves as the Pediatric and Adolescent Director at NCnet, a practice-based research network at UNC. As Co-Investigator on this research project, she will assist the research team with the recruitment of clinics for the trial and will support clinic relationships and communication throughout its duration. She will regularly attend meetings and contribute to dissemination of study findings.

Sarah A. Birken, PhD, Co-Investigator (CM, Years 1-5 charged to Intervention Core)
Dr. Birken is Associate Professor of Implementation Science in the Division of Public Health Sciences at Wake Forest University Health Sciences. Dr. Birken is an implementation scientist and health services researcher with over 15 years of experience in quality improvement, innovations in cancer care, and translating evidence-based interventions into practice. She has been a principal investigator or co-investigator on numerous grants that have examined the optimization of cancer care and preventive health services, especially for rural patients. Dr. Birken will work collaborate closely with the Project Lead, Dr. Trogdon, and colleagues on Project 2. In Years 1-4 of the Program Project, Dr. Birken will consult on developing and carrying out strategies for effective implementation of intervention components and enhancing the Announcement Approach Training. Additionally, in all five years of the Program Project, Dr. Birken will coordinate the Clinical Advisory Board and will consult on harmonization of implementation measures across projects. Finally, in Years 4-5 of the Program Project, she will advise the team on how to meaningfully translate evidence from the research projects into tools that can be disseminated and implemented in a variety of settings. In Year 5, Dr. Birken will also contribute to manuscript preparation. The cost for her effort is kept administratively in the Intervention Core to simplify subcontracts to her home institution.

Other Personnel

Kathleen Mottus, NCnet Project Manager

Year 1	Year 2	Year 3	Year 4	Year 5
CAL. MONTHS				

Ms. Mottus is a project manager at NCnet, a practice-based research network at UNC. She will assist Dr. Hernandez and the research team with the recruitment of clinics for the trial and will support clinic relationships and communication throughout its duration. She will regularly attend meetings.

TBD, Two Announcement Approach Training (ATT) Facilitators, MD

Year 1	Year 2	Year 3	Year 4	Year 5
0.12 CM	0.84 CM	1.38 CM	0.69 CM	-

The two AAT Facilitators will be physicians trained by the P0 Program team to deliver the AAT to clinics participating in the trial. The Facilitators will participate in training workshops, travel to every clinic in the trial, deliver the AAT workshop to each clinic and assist in post-AAT data collection.

TBD, Project Manager

Year 1	Year 2	Year 3	Year 4	Year 5
8.4 CM	8.4 CM	7.2 CM	6.6 CM	6.0 CM

The Program Manager will be responsible for managing daily project operations for the study and will serve as the liaison between the Project Lead, program projects and core teams, and study consultants. The Program Manager will manage the project budget, oversee IRB protocols, prepare progress reports, conference presentations, and manuscripts to disseminate findings.

TBD, Graduate Research Assistant

Year 1	Year 2	Year 3	Year 4	Year 5
12 CM	12 CM	12 CM	12 CM	12 CM

The Graduate Research Assistant will help the study team with carrying out administrative and research tasks including supporting data cleaning, data analysis, and interpretation of findings. The Graduate Research Assistant will also assist the study team in developing dissemination materials such as conference posters, presentations, and manuscripts.

Brian Cass, Programmer

Year 1	Year 2	Year 3	Year 4	Year 5
CAL. MONTHS				

Brian Cass is an Assistant Director for Database Systems and a Senior Web Developer at UNC Chapel Hill. As a Programmer for this study, he will assist with data cleaning and data analysis for the electronic health records data. In addition, he will work with the Connected Health Applications and Interventions (CHAI) Core on the development of the feedback report.

Total Expenses for Personnel=$1,005,057

Fringe Benefits

Fringe benefits associated with the salary request for this budget has been calculated in accordance with our Institution's DHHS Rate Agreement. The University of North Carolina at Chapel Hill applies appropriate fringe benefit rates to the personnel on this proposal: Basic permanent employee benefits are **25.889%** of annual salary plus **$6,512/FTE/YR** for fixed health insurance. Graduate Student employee benefits are **9.490%** of annual salary plus **$4,137.60/FTE/YR** for fixed health insurance. P&A Practice Plan member benefits calculate at **30.796%** of annual salary plus **$8,652.80/FTE/YR** for fixed health insurance.

Travel

Travel for Domestic Conferences

Year 1	Year 2	Year 3	Year 4	Year 5	Total
$1,500	$1,500	$1,500	$1,500	-	$6,000

Dr. Trogdon will attend 1 national conference each year in Years 1 through 4 to disseminate findings ($1,500 per year). Attending national conferences will allow Dr. Trogdon and colleagues to disseminate the Program's findings to a broad audience including public health practitioners, researchers, and policymakers.

Travel for Foreign Conferences

Year 1	Year 2	Year 3	Year 4	Year 5	Total
-	-	-	-	$1,500	$1,500

Dr. Trogdon will attend 1 foreign conference in Year 5 to disseminate findings. Attending a foreign conference will allow Dr. Trogdon and colleagues to disseminate the Program's findings to an international audience including public health practitioners, researchers, and policymakers. Additionally, attending conferences will expose Dr. Trogdon to the latest research in the field which will inform the Program's research activities.

Travel for Announcement Approach Training

Year 1	Year 2	Year 3	Year 4	Year 5	Total
-	$4,500	$4,000	-	-	$8,500

One team member will travel 9 times in Year 2 and 8 times in Year 3 to deliver the Announcement Approach Training to clinics participating in the trial ($500 per trip). UNC is centrally located within North Carolina. Therefore, we assume half of the participating clinics (17) can be trained within a standard business day. The other 17 clinics may require overnight stays for the Facilitator plus mileage and per diem costs.

Total Expenses for Travel=$16,000

Supplies

Data Storage

Year 1	Year 2	Year 3	Year 4	Year 5	Total
$3,000	$1,500	-	$3,000	-	$7,500

Two computers for project staff will be purchased in Year 1 ($1,500 X 2 computers = $3,000 in Year 1). An additional laptop for the AAT Facilitators will be purchased in Year 2. After warranty expires, two additional computers for staff will be purchased in Year 4 ($1,500 X 2 computers = $3,000 in Year 4). The AAT Facilitator laptop will not be in use once the warranty expires and thus will not need to be replaced.

Printing

Year 1	Year 2	Year 3	Year 4	Year 5	Total
$1,000	$1,000	$1,000	$1,000	$1,000	$5,000

We have budgeted $1,000 per year, totaling $5,000, for printing project materials, including surveys, training materials, consent forms, and letters.

Software

Year 1	Year 2	Year 3	Year 4	Year 5	Total
$1,800	-	$1,800	-	$1,800	$5,400

Statistical and reference management software will be purchased for up to 3 computers as necessary in Years 1, 3 and 5. The software will be used to perform data analyses as described in Aims 1-3, as well as to manage references to aid in dissemination of study findings. ($600 per license x 3 computers = $1,800 per year).

Screen, Projector and Speaker

Year 1	Year 2	Year 3	Year 4	Year 5	Total
$1,000	-	-	-	-	$1,000

A screen, projector and speaker will be purchased in Year 1 for use in the Announcement Approach Training.

Total Expenses for Supplies=$18,900

Journal Publication Charges

Year 1	Year 2	Year 3	Year 4	Year 5	Total
-	$1,500	$1,500	$1,500	$1,500	$6,000

It is increasingly common for top journals to charge publication fees. Thus, we have budgeted for 1 article in Years 2-5.

Total Expenses for Journal Publication Charges=$6,000

Consultants

Harsha Thirumurthy, PhD, Consultant

Year 1	Year 2	Year 3	Year 4	Year 5	Total
CONSULTANT(S) FEES					

Dr. Thirumurthy has been the Principal Investigator on multiple NIH R01 RCTs testing behavioral interventions, including financial incentives and peer referrals, to improve health behaviors. As a Consultant, Dr. Thirumurthy will advise the research team on scientific issues related to the design of study interventions and trial processes. He will review protocols and preliminary data, provide feedback to the team by email, and will attend teleconferences throughout the year. Consultant costs of [$] ([$] per year) were based on serving approximately [ ] hours per year as an expert advisor.

Total Expenses for Consultants=$60,000

Tuition

Year 1	Year 2	Year 3	Year 4	Year 5	Total
$18,866	$19,432	$20,015	$20,615	$21,234	$100,162

We will provide annual in-state tuition at the UNC Gillings School of Global Public Health to the Graduate Research Assistant as compensation for work in Years 1-5. Tuition cost is based on the Department of Health Policy and Management tuition rate. Tuition support is calculated by multiplying the graduate student's predicted percent effort on the project times the tuition cost of his/her graduate program.

Total Expenses for Tuition=$100,162

Other Expenses

Participation Incentives

Year 1	Year 2	Year 3	Year 4	Year 5	Total
-	$17,000	$34,000	$17,000	-	$68,000

Clinics participating in the trial will receive $1,000 upon completion of baseline data collection (17 clinics in Year 2 and 17 clinics in Year 3) and $1,000 upon completion of final data collection (17 clinics in Year 3 and 17 clinics in Year 4) for a total of $68,000.

Performance Incentives

Year 1	Year 2	Year 3	Year 4	Year 5	Total
-	-	$54,000	$102,000	$48,000	$204,000

Clinics in the intervention arm will be paid financial incentives for meeting HPV vaccine performance targets, scaled based on the number of providers at the clinic. Clinics in the control arm will be waitlisted to receive the financial incentives in the following year. We budgeted for each clinic reaching the highest tier performance targets. Based on average clinic sizes of 6 providers and incentives equal to $1000 per provider per clinic, we estimate performance incentives to equal $54,000 (9 intervention clinics), $102,000 (9 waitlist clinics and 8 intervention clinics) and $48,000 (8 waitlist clinics) in Years 3, 4, and 5, respectively for a total of $204,000.

Survey Incentives

Year 1	Year 2	Year 3	Year 4	Year 5	Total
-	-	$20,400	$20,400	-	$40,800

All providers in participating clinics will be surveyed at baseline (T0), immediately after the AAT workshop (T1), and at the end of the intervention 12 months later (T2). Providers will receive $100 to complete T0 and T1 and $100 to complete T2. Based on an average clinic size of 6 providers, we anticipate compensating $20,400 in Year 3 and Year 4 for a total of $40,800.

Cognitive Interviews and Usability

Year 1	Year 2	Year 3	Year 4	Year 5	Total
$1,600	-	-	-	-	$1,600

In Year 1, we will perform cognitive and pilot testing of items in the national provider survey with eight local providers, totaling $1,600.

Interview Incentives

Year 1	Year 2	Year 3	Year 4	Year 5	Total
-	-	$1,400	$1,300	-	$2,700

In Year 3 and Year 4 an experienced CHAI core team member will interview 3 personnel from 9 of the participating clinics (27 total). We budgeted $100 incentives for each interviewee, totaling $2,700.

Transcription Services

Year 1	Year 2	Year 3	Year 4	Year 5	Total
-	-	$1,050	$975	-	$2,025

We have allocated $2,025 for transcription services for our 27 in-depth interviews ($75/interview: 14 interviews in Year 3 and 13 interviews in Year 4).

CHAI Core Interviews and Design

Year 1	Year 2	Year 3	Year 4	Year 5	Total
$9,790	-	$9,883	$9,408	-	$29,080

We will work with CHAI Core to design the feedback report in Year 1, estimated to cost $9,790. We will also work with CHAI Core in Years 3 and 4 to conduct qualitative interviews with providers. Together with maintenance costs for the feedback report in Years 3 and 4, the CHAI Core costs are $9,883 and $9,409, respectively. The total estimated budget for the CHAI Core interviews and report design is $29,080.

Total Expenses for Other Expenses=$348,205

Indirect Costs

At UNC-Chapel Hill, F&A costs are calculated on a Modified Total Direct Costs (MTDC) base. This base consists of all direct salaries and wages, applicable fringe benefits, materials and supplies, services, travel and up to the first $25,000 of each subaward (regardless of the period of performance of the subawards under the award). Modified total direct costs shall exclude equipment, capital expenditures, charges for patient care, rental costs, tuition remission, scholarships and fellowships, participant support costs and the portion of each subaward in excess of $25,000.

Per UNC-Chapel Hill's current federally negotiated rate agreement (dated 11/23/2016), F&A costs associated with the proposed research project are calculated at the approved on-campus research rate of 55.5% of MTDC in all years. The cognizant agency for UNC-Chapel Hill is the U.S. Department of Health and Human Services. The cognizant agency point of contact is Darryl Mayes, (202) 401-2808.

RESEARCH & RELATED BUDGET - Cumulative Budget

	Totals ($)	
Section A, Senior/Key Person		374,402.00
Section B, Other Personnel		630,655.00
Total Number Other Personnel	28	
Total Salary, Wages and Fringe Benefits (A+B)		1,005,057.00
Section C, Equipment		
Section D, Travel		16,000.00
1. Domestic	14,500.00	
2. Foreign	1,500.00	
Section E, Participant/Trainee Support Costs		
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other		
6. Number of Participants/Trainees		
Section F, Other Direct Costs		533,268.00
1. Materials and Supplies	18,900.00	
2. Publication Costs	6,000.00	
3. Consultant Services	60,000.00	
4. ADP/Computer Services		
5. Subawards/Consortium/Contractual Costs		
6. Equipment or Facility Rental/User Fees		
7. Alterations and Renovations		
8. Other 1	100,162.00	
9. Other 2	348,206.00	
10. Other 3		
Section G, Direct Costs (A thru F)		1,554,325.00
Section H, Indirect Costs		807,060.00
Section I, Total Direct and Indirect Costs (G + H)		2,361,385.00
Section J, Fee		
Section K, Total Direct and Fee (I + J)		2,361,385.00

PHS 398 Cover Page Supplement

OMB Number: 0925-0001

Expiration Date: 02/28/2023

1. Vertebrate Animals Section

Are vertebrate animals euthanized? ○ Yes ○ No

If "Yes" to euthanasia

Is the method consistent with American Veterinary Medical Association (AVMA) guidelines?

○ Yes ○ No

If "No" to AVMA guidelines, describe method and provide scientific justification

2. *Program Income Section

*Is program income anticipated during the periods for which the grant support is requested?

○ Yes ● No

If you checked "yes" above (indicating that program income is anticipated), then use the format below to reflect the amount and source(s). Otherwise, leave this section blank.

*Budget Period *Anticipated Amount ($) *Source(s)

Tracking Number: GRANT13205496 Funding Opportunity Number: PAR-20-077 . Received Date: 2020-09-18T11:41:16.000-04:00

PHS 398 Cover Page Supplement

3. Human Embryonic Stem Cells Section

*Does the proposed project involve human embryonic stem cells? ○ Yes ● No

If the proposed project involves human embryonic stem cells, list below the registration number of the specific cell line(s) from the following list: http://grants.nih.gov/stem_cells/registry/current.htm. Or, if a specific stem cell line cannot be referenced at this time, check the box indicating that one from the registry will be used:

Specific stem cell line cannot be referenced at this time. One from the registry will be used.

Cell Line(s) (Example: 0004):

4. Human Fetal Tissue Section

*Does the proposed project involve human fetal tissue obtained from elective abortions? ○ Yes ● No

If "yes" then provide the HFT Compliance Assurance

If "yes" then provide the HFT Sample IRB Consent Form

5. Inventions and Patents Section (Renewal applications)

*Inventions and Patents: ○ Yes ○ No

If the answer is "Yes" then please answer the following:

*Previously Reported: ○ Yes ○ No

6. Change of Investigator/Change of Institution Section

❑ Change of Project Director/Principal Investigator

Name of former Project Director/Principal Investigator

Prefix:

*First Name:

Middle Name:

*Last Name:

Suffix:

❑ Change of Grantee Institution

*Name of former institution:

Tracking Number: GRANT13205496 Funding Opportunity Number: PAR-20-077 . Received Date: 2020-09-18T11:41:16.000-04:00

PHS 398 Research Plan

OMB Number: 0925-0001
Expiration Date: 02/28/2023

Introduction	
1. Introduction to Application (for Resubmission and Revision applications)	IntroApplicationP2rV21045663956.pdf
Research Plan Section	
2. Specific Aims	SpecificAimsP2rV21045663957.pdf
3. Research Strategy*	ResearchStrategyP2r1045594829.pdf
4. Progress Report Publication List	
Other Research Plan Section	
5. Vertebrate Animals	
6. Select Agent Research	
7. Multiple PD/PI Leadership Plan	
8. Consortium/Contractual Arrangements	
9. Letters of Support	LOSP2Combinedr1045594830.pdf
10. Resource Sharing Plan(s)	ResourceSharingP2r1045594831.pdf
11. Authentication of Key Biological and/or Chemical Resources	
Appendix	
12. Appendix	

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INTRODUCTION TO APPLICATION – Project 2

CRITIQUE, RESPONSE TO CRITIQUE

SPECIFIC AIMS – Project 2

Human papillomavirus (HPV) vaccination is effective and recommended to protect against six types of cancer, but HPV vaccine coverage remains low, especially in rural areas. Provider communication has a powerful influence on HPV vaccine uptake. We have demonstrated that Announcement Approach Training (AAT) effectively improves provider communication and increases HPV vaccination uptake. The AAT workshop is a 1-hour communication workshop designed to help primary care teams improve the frequency and effectiveness of provider recommendations for HPV vaccination.

A promising tool to expand the impact of AAT is clinic-level financial incentives. Policy innovation and payment reform efforts are focused on better aligning financial incentives in healthcare systems with quality of care. Many payment reforms also include insights from behavioral economics. Examples include structuring financial incentives to take advantage of loss aversion and providing peer comparison feedback on incentivized quality metrics (here, HPV vaccination rates). However, no studies have established whether financial incentives with behavioral nudges motivate providers to improve HPV vaccine communication and provision.

As part of the proposed P01 Program Project, "Improving Provider Announcement Communication Training (IMPACT)," the **overall goal of the proposed randomized clinical trial (RCT) is to test promising behavioral economic alternatives to amplify the impact of AAT** by motivating providers to apply what they learn in AAT. We propose to conduct an RCT to examine whether *clinic-level* financial incentives, with behavioral nudges, can improve HPV vaccination communication and uptake. The specific aims are as follows.

Aim 1. Characterize providers' perceptions of financial incentives with behavioral nudges tied to HPV vaccination. *Activities to reach this aim:*

a. Contribute to national survey of 2,500 primary care team members. Assess providers' perceptions of HPV vaccine-related financial incentives and behavioral nudges (e.g., prepayment contracts, peer comparison feedback).
b. Refine feedback report using electronic health record (EHR) data to calculate provider-level HPV vaccine up-to-date and initiation rates. Interview and conduct usability testing with 6-8 providers.

Aim 2. Demonstrate the impact of clinic-level financial incentives on HPV vaccine communication and uptake in healthcare systems.

a. Randomly assign 34 clinics to 1) AAT or 2) AAT plus financial incentives, with behavioral nudges, tied to clinic-level improvement in HPV vaccination rates.
b. Assess HPV vaccination uptake (up-to-date and initiation) at 6, 12, and 18 months using EHR data and whether uptake varies by rurality.
c. Examine change in provider cognitions and behavior from baseline to 12 months via provider survey.

Hypothesis: Clinic-level financial incentives and AAT increase HPV vaccine communication and uptake relative to AAT alone.

Aim 3. Generate guidance for systems to compare and implement AAT and financial incentives.

a. Assess cost per additional adolescent initiating the HPV vaccine in partnership with the Intervention Core. Share with Project 4 to support cost-effectiveness analyses.
b. Examine other implementation outcomes: acceptability, adoption, appropriateness, feasibility, fidelity, reach, and sustainability using surveys, checklists, and key informant interviews.
c. Characterize determinants of AAT and financial incentives implementation and strategies for improving HPV vaccination that providers and clinics use in response to financial incentives.
d. Contribute module to the AAT Intervention Package for improving HPV vaccination in healthcare systems.

Hypothesis: Financial incentives with AAT is cost-effective relative to AAT alone.

The proposed RCT is **significant** because it will demonstrate whether and how financial incentives improve provider communication and increase HPV vaccine uptake. The proposed research is **innovative** in adopting behavioral economic principles to improve effectiveness of pay-for-performance strategies in pediatrics. The proposed research addresses the **IMPACT Program Project theme** of amplifying the impact of a Research-Tested Intervention Program to improve HPV vaccine communication by providing much-needed evidence for the value of HPV communication interventions within healthcare systems. Ultimately, program-wide **dissemination** of research findings, the AAT Intervention Package, and related training opportunities to healthcare systems across the United States (US) will greatly improve public health by reducing the incidence of HPV and HPV cancers.

RESEARCH STRATEGY – Project 2

SIGNIFICANCE

HPV vaccination rates are far short of national goals. HPV vaccination could eliminate 32,100 cancers in the US annually, which represents over 80% of cervical and anal cancers and the majority of the other HPV cancers as well.[1] In 2006, the Advisory Committee on Immunization Practices (ACIP) recommended the routine HPV vaccination of adolescent females ages 11-12 and in 2011 extended this recommendation to adolescent males.[2,3] Although rates of HPV vaccination have increased in the US in the past decade, only 72% of adolescents aged 13-17 initiate the HPV vaccine series and just over half (54%) complete it.[3] HPV vaccination rates are lower, and incidence of HPV-associated cancers higher, in rural areas. These patterns are also evident in North Carolina, a state with a large rural population.[3] These facts, together with recent Covid-19 related delays in adolescent vaccination,[4,5] demonstrate the need for effective policies to increase HPV vaccination.

Scientific Premise

Providers and clinics within healthcare systems are a high-leverage intervention target. Adolescents whose parents receive a recommendation from a HPV vaccine provider to vaccinate their child against HPV are more likely to be vaccinated than those whose parents do not receive a provider recommendation.[6-13] Despite the critical role providers can play in the decision to vaccinate, more parents need to receive a recommendation from a provider.[7,8,12,13] Our team in the proposed P01 Program Project, “Improving Provider Announcement Communication Training (IMPACT),” have demonstrated that Announcement Approach Training (AAT) is effective at improving provider communication and increasing HPV vaccination rates.[14,15] The integrated projects of IMPACT are focusing on healthcare systems because patients increasingly receive care from providers in systems.[16] In addition, systems’ policies (e.g., financial incentives) can create environments that encourage providers to improve HPV vaccine communication.

HPV vaccination is an ideal target for financial incentives. While AAT gives providers the tools to improve HPV vaccine communication, providers need to be motivated to recommend as well. Prior studies, now nearly 20 years old, have shown financial incentives increase delivery of other childhood and adult immunizations.[17-24] This success may be attributable to two features that make immunizations ideal targets for financial incentives. First, financial incentives are most effective when the incentivized behaviors are simple and easy to track.[17,18] Completion of the HPV vaccination series requires decision-making at only two or three time points per patient. These measures can be tracked using electronic health records (EHRs) that are already integrated in healthcare systems. Use of related quality measures, such as the Healthcare Effectiveness Data and Information Set (HEDIS) Immunizations for Adolescents measure, is already pervasive in healthcare systems.[25] Second, financial incentives are most effective when there is room for improvement.[18,26,27] Current rates of HPV vaccinations among adolescents fall well below the Healthy People 2020 goal of 80%.[3,28] Despite these features, the effect of provider financial incentives on *HPV vaccination* has not been evaluated.

Pay-for-performance using financial incentives is becoming widespread as alternative-payment models become more common. The US healthcare system is transitioning from one dominated by fee-for-service payments that reward high volume to a system that rewards providers who provide high-value care.[29,30] The Centers for Medicare and Medicaid Services (CMS) and other payers have begun using alternative payment models, such as pay-for-performance and financial incentives, to more closely link payment for services to quality of care.[29,31,32] Although pay-for-performance is becoming more widespread, its effect on the uptake of HPV vaccinations has not yet been established.

Behavioral nudges can enhance effectiveness of traditional pay-for-performance. Behavioral nudges create choice environments in which desired choices are easier.[33] Nudges combined with financial incentives may provide further motivation for providers to provide high-value preventive care.[34-36] For example, the impact of a financial incentive framed as a loss may be larger than the impact of a financial incentive of the same size that is framed as a gain.[34,37] Although loss aversion has been demonstrated in consumers and patients, our trial will be one of few to integrate it into provider incentive programs.[34] Meeting goals to receive an incentive requires regular feedback, which can also incorporate behavioral nudges.[38-40] Peer comparison feedback, in which providers’ performance is ranked amongst other providers in the clinic, motivates improved performance by engaging professional pride, a desire for social esteem, and establishing social norms. As a component of team-based incentives, peer comparisons can create positive peer effects within a group.[34]

Why is this randomized clinical trial (RCT) needed? We will conduct an RCT to examine whether financial incentives tied to clinic-level improvement in HPV vaccination rates can improve HPV vaccine communication and uptake. The RCT is needed for several reasons. First, this RCT will provide the first estimate of the effect of provider financial incentives on the initiation and completion of HPV vaccination. The evidence from this RCT aligns with current emphasis on value-based payment in the US healthcare system, which increases momentum for adoption of HPV vaccination. Second, this RCT will use behavioral nudges as part of the financial incentives package. Behavioral nudges are one of the few consistently effective strategies for vaccination[41] and have been shown to be cost-effective for consumer and patient behaviors; however, little is known about their effect among healthcare providers. Third, this RCT will examine how the effectiveness of financial incentives could vary by rurality. Clinics that primarily serve patients who live in rural areas are different from non-rural clinics in many dimensions that could affect their ability to respond to the incentives (e.g., lower EHR adoption rates, patient mix). Finally, as healthcare systems choose among interventions to increase HPV vaccine uptake, they consider an intervention's cost-effectiveness; how it will be received (e.g., acceptability, appropriateness); and whether it can be integrated into practice (e.g., feasibility, fidelity, sustainability). Furthermore, they need information about potential implementation facilitators and barriers to ensure the success and longevity of new initiatives. The Intervention Core will synthesize evidence created across research projects in the IMPACT Program into the **AAT Intervention Package**, a resource for healthcare systems and public health agencies to promote better HPV vaccine communication. This much-needed evidence will greatly improve public health by reducing the incidence of HPV and HPV-associated cancers.

INNOVATION

This RCT will provide causal evidence on clinic-level financial incentives for HPV vaccination. Despite the growing body of evidence for pay-for-performance arrangements that tie financial incentives to the quality of care,[17,18,26,27,42] no trial-based evidence exists for the effect of clinic-level financial incentives on increasing HPV vaccination. The existing evidence for clinic-level financial incentives relates to childhood vaccines and is nearly 20 years old.[19,20,23,24] That literature showed that clinic-level financial incentives were effective at increasing childhood vaccination rates. The literature on financial incentives for HPV vaccination has focused on patient-level incentives and has shown small, positive effects on the likelihood of adolescents being vaccinated.[43] For the reasons noted above, we believe that HPV vaccination is an ideal context for evaluating the effectiveness of clinic-level financial incentives. *This RCT will estimate the causal effect of clinic-level financial incentives on HPV vaccination rates, thereby delivering information needed by scientists, payers and healthcare systems looking for strategies to increase HPV vaccination rates.*

This RCT adopts behavioral economic principles to improve effectiveness of pay-for-performance strategies. Behavioral economics has provided several insights into cognitive biases that can be leveraged to "nudge" choices towards socially desirable outcomes.[33] Some of these are beginning to be incorporated into pay-for-performance schemes. For example, Comprehensive Primary Care Plus, a national program from CMS, uses commitment contracts in which quality-based incentives are paid up front and providers are at the risk of losing the payments if quality targets are not met.[44] This approach takes advantage of loss aversion, in which more effort is given to avoid losses than to achieve a similarly sized gain.[34,37] Similarly, many public programs have taken advantage of people's natural proclivity for social comparison to incent pro-social behaviors using positive peer pressure.[45-48] The RCT design will use the concepts of loss aversion and social comparison: peer comparison feedback with clinic-level, pre-paid financial incentives. *This RCT will use behavioral economic strategies to maximize the impact of the tested interventions to increase HPV vaccination.*

This RCT contributes to the scant literature on cost-effectiveness for HPV vaccine-focused interventions. There are relatively few evidence-based interventions to increase HPV vaccination, and the majority of those do not have evidence of their cost-effectiveness. For example, the National Cancer Institute (NCI) lists six programs addressing HPV vaccination in their Research-Tested Intervention Programs.[49] Of those, only one program has published evidence of its cost-effectiveness.[50] Our proposed RCT will collect intervention cost data, report cost per additional adolescent initiating for the tested intervention, and share this information with Project 4 where it will be combined with data from interventions tested in other Projects via simulation modeling. *In doing so, this Project will generate knowledge about the value of HPV vaccination interventions that is needed by public health vaccination programs, payers, and healthcare systems.*

APPROACH

Research Team

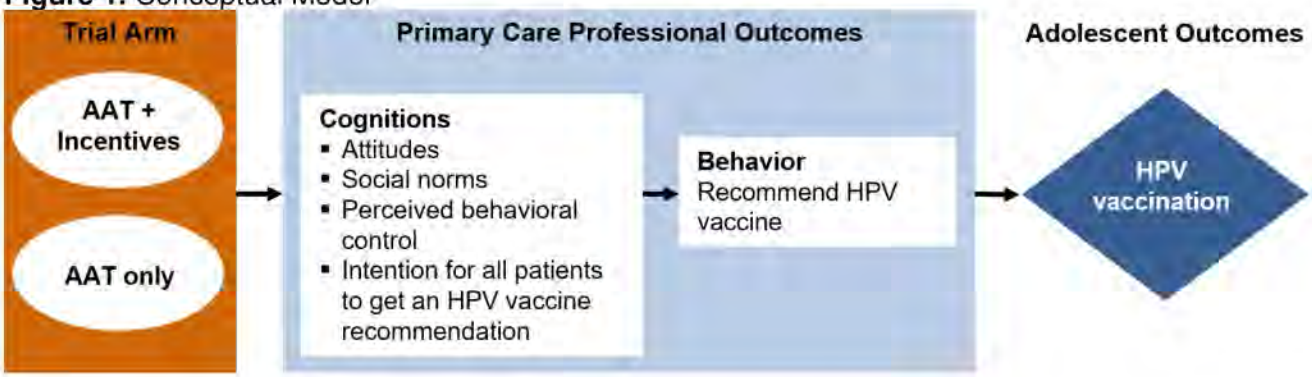
We have assembled a team whose expertise in health economics, behavioral economics, pediatrics, RCTs, implementation science, and health services research is required for a successful trial. **Dr. Justin Trogdon** (Project Lead) is a health economist and Director for Cancer Health Economics Initiatives for the Cancer Outcomes Research Program of the University of North Carolina (UNC) Lineberger Comprehensive Cancer Center. He has been a Principal Investigator on 16 funded research grants and contracts totaling nearly $12 million in total costs, including two R01 awards. His HPV vaccine research includes geospatial analysis of HPV vaccination patterns and vaccine providers, time series estimates of the effects of the release of the latest version of HPV vaccine on vaccination coverage, analysis of claims and survey data to assess the effects of state-level policies on HPV vaccination, and costing and cost-effectiveness modelling of interventions to increase HPV vaccination.[51-56] **Dr. Harsha Thirumurthy** is a health economist and the Associate Director at the University of Pennsylvania Center for Health Incentives & Behavioral Economics. He has been the Principal Investigator on multiple R01 RCTs testing behavioral interventions, including financial incentives and peer referrals, to improve health behaviors. **Dr. Michelle Hernandez** is a pediatrician at UNC Healthcare and an Associate Professor of Pediatrics at UNC School of Medicine. She serves as the Pediatric and Adolescent Director at NCnet, a practice-based research network at UNC (see Setting below), and will lead recruitment. **Dr. Sarah Birken** is an implementation scientist at Wake Forest University and will advise on Aim 3 analyses. Our team will also have access to experts in RCTs (**Drs. Noel Brewer**, **Stephanie Wheeler**, and **Joseph Ibrahim**), biostatisticians (**Dr. Ibrahim**), and implementation scientists (**Dr. Bryan Weiner**) through the Cores.

Connected Health Applications and Interventions (CHAI) Core (www.chaicore.com) is a National Institutes of Health-funded core facility through the UNC Gillings School of Global Public Health and the Lineberger Comprehensive Cancer Center. CHAI Core has extensive experience in qualitative research and graphic design, including designing personalized feedback via text, email, and app notification. CHAI Core has provided research support and design services to over 130 projects, including multiple RCTs. CHAI Core will lead refinement of the peer comparison feedback report (Activity 1c) and qualitative research (Activity 3c).

Conceptual Model

Our RCT is guided by the **Theory of Planned Behavior** as the core model to understand how our intervention works to change provider recommendation behavior (Figure 1).[57] In the context of our intervention, the theory suggests that intervening to improve *cognitions*, through financial incentives that change attitudes, establish new social norms, and increase perceived behavioral control and intentions to recommend will change HPV vaccine recommendation *behavior*. The resulting increase in provider recommendations will lead to increases in HPV vaccination among adolescents.

Figure 1. Conceptual Model



Two theoretical frameworks describe how the *implementation* of the interventions affect outcomes. **Proctor et al.'s Implementation Outcomes Framework**[58] suggests that our intervention should be well received (e.g., acceptable, appropriate) and integrated into practice (e.g., feasible, sustainable). Furthermore, the intervention should be delivered with fidelity, reach most patients with provider recommendations, and be made at a reasonable cost to sustain impact over time. The **Consolidated Framework for Implementation Research**[59] (CFIR) informs our understanding of determinants of AAT and financial incentives implementation (e.g., clinics' structural characteristics; rurality of the patient population served).

Setting

Our primary clinical partner will be the NCnet practice-based research network at UNC. North Carolina has a substantial rural population (34%) and HPV prevention needs typical of the US overall.[3] NCnet includes 159 pediatric and family medicine clinics across North Carolina, such as the UNC Physician's Network with over 90 clinics across the state. Nearly all clinics in NCnet use a common EHR (Epic), which will create efficiencies in implementing the peer comparison feedback report in Aim 1. In addition, our research team can access EHR records for NCnet clinics that are part of the UNC system via the Carolina Data Warehouse for Health, a research ready EHR database. NCnet staff have extensive experience in working with investigators and community-based clinics to conduct pragmatic trials, which will be critical to enhance feasibility and recruitment of clinics.[60,61] If we subsequently need a larger pool of clinics, NCnet is a member of the larger practice-based research network North Carolina Network Consortium. The North Carolina Network Consortium includes 67 additional clinics in North Carolina affiliated with other healthcare systems using Epic and can also serve as a source of clinics.

Preliminary Evidence

We identified 36 family medicine and pediatric clinics in the Carolina Data Warehouse for Health. Using EHR data for adolescent patients who visited each clinic between 2017 and 2018, we calculated the proportions of 11-12 and 13-year-old patients, respectively, who had initiated (at least one dose) and completed (two doses) the HPV vaccine series. Rates of HPV vaccine initiation and completion were low and heterogeneous across clinics, with high-performing clinics initiating the vaccine in over three-quarters of 13-year-old patients and low-performing clinics initiating the vaccine in less than a third (**Table 1**).

We also conducted semi-structured interviews with one provider and one clinic manager from eight clinics affiliated with NCnet (16 interviews). The interviews explored participants' opinions on financial incentives for HPV vaccination. Participants agreed reporting on HPV vaccination was feasible in their EHR, but few currently reported on HPV vaccinations specifically. Epic has recently been integrated with the state immunization information system to provide full vaccination history for all patients. One provider lamented, "*Sadly, because HPV rates are not one of the measures we are incentivized for, we don't have that information handed to us.*" In general, both providers and practices managers felt that publishing and routinely sharing HPV vaccination rates across providers would have a positive impact on increasing HPV vaccination rates at their clinic.

Regarding financial incentives, all participants had experience with pay-for-performance arrangements for other metrics. In general, most participants felt financial incentives had been effective in helping the clinic meet their quality metrics. According to one provider: "*If HPV vaccine became a quality metric with a financial incentive connected to it, then you would see rates go up very quickly.*"

Table 1. Preliminary Evidence on HPV Vaccine Coverage at UNC Clinics

Characteristic, mean ± SD	N=36
# providers per clinic	7.3 ± (5.6)
Min, max	2, 29
11-12 year olds	
# patients per clinic	275 ± (253)
Min, max	51, 823
Initiated (%)	43.7 ± (16.0)
Min, max (IQR)	10.5, 79.2 (18.5)
Completed (%)	20.5 ± (11.3)
Min, max (IQR)	1.9, 49.8 (12.1)
13 year olds	
# per clinic	166 ± (148)
Min, max	27, 507
Initiated (%)	52.1 ± (16.5)
Min, max (IQR)	20.8, 85.3 (26.1)
Completed (%)	32.5 ± (18.1)
Min, max (IQR)	3.2, 81.6 (24.4)

Aim 1. Characterize providers' perceptions of financial incentives with behavioral nudges tied to HPV vaccination.

In **Activity 1a**, we will contribute to the national primary care team survey to understand their current experiences with, and preferred designs for, financial incentives with behavioral nudges (e.g., prepayment contracts, peer comparison feedback). In **Activity 1b**, we will refine a feedback report to assess HPV vaccination rates using EHR data from the clinics participating in the Aim 2 RCT to ensure providers can track progress on incentivized HPV vaccination metrics. ***Aim 1*** *will generate new national findings on opportunities for expanding financial incentives with behavioral nudges for HPV vaccination.*

1a. National survey

The first activity of this aim is to contribute to the development and analysis of the national primary care team survey, which will be shared by three IMPACT projects. The primary goal of the national survey is to fill significant knowledge gaps in implementation of financial incentives for HPV vaccination. For Project 2, we seek to understand providers' experience with, and perceptions of, performance-based incentives and behavioral nudges. The secondary goal of the national survey is to inform refinements to the projects' communication interventions. Together with our pilot qualitative interviews and usability testing with local providers (described below), the national survey will allow us to consider implementation challenges faced by providers in other regions of the country and serving in diverse vaccination roles.

The Data Core will manage the national survey, including the subcontractor WebMD, and IMPACT projects will contribute items to address their own aims. This section will focus on Project 2's contribution to the survey. Overall details about the national survey can be found in the Data Core research strategy.

Participants and recruitment. Survey participants will be a national sample of 2,500 primary care team members, consisting of 1,500 HPV vaccine providers (physicians, physician assistants, and nurse practitioners) and 1,000 registered nurses and medical assistants. Health professionals of all sexes will be included with self-reported sex collected in the survey.

Measures. The national survey will inform six research questions for Project 2 (**Table 2**). It will assess providers' experiences with financial incentives and behavioral nudges, including their perceived effectiveness of each, which will provide valuable information about the prevalence of these strategies in pediatric and family medicine clinics nationwide. The information from the national survey will also help design the feedback report used in the RCT to maximize acceptability and actionability.

Procedures. Project 2 will pilot test each of its own measures. We will first solicit the help of our Clinical Advisory Board to assess our questionnaire's face validity. Next, we will cognitively test the items with eight local providers in NCnet to ensure readability and comprehension. Together with the Data Core and other projects, we will review WebMD's electronic survey for errors and readability. We will also review the results of WebMD's survey pilot to check for appropriate skip patterns and distribution of response items.

Table 2. Project 2 Research Questions Addressed in the National Survey

Question
How are immunization rates shared at the provider level? At the clinic level?
What do providers think of the idea of routinely sharing HPV vaccine rates across providers within their clinic?
Does clinic participate in any "pay-for-performance" initiatives? If so, are vaccinations included? HPV vaccine?
What other kind of clinic-level financial incentives (e.g., bonuses or penalties) exist at the clinic? Do any include HPV vaccination goals?
How have these rewards/recognitions been viewed by providers at the clinic?
How (in)effective have existing financial incentives been?

Analyses. We will describe the types of primary care team members (e.g., physicians, nurse practitioners) likely to have experience with financial incentives and behavioral nudges. We will estimate separate regression models with items for the questions in **Table 2** as the dependent variables. As clinics that primarily serve patients who live in rural areas are different from non-rural clinics in many dimensions that could affect their ability to respond to the incentives (e.g., lower EHR adoption rates, patient mix), the explanatory variables will include provider demographics collected in the national survey (e.g., rurality of clinic). Regression models will use appropriate functional forms for each item scale (e.g., logit for 0/1 outcomes).

1b. Refine feedback report using EHR data to calculate HPV vaccination rates

To ensure that providers can track progress on incentivized HPV vaccination, we will provide a feedback report. The feedback report, based on our team's AAT clinic-level report card and refined by CHAI Core, will incorporate recommendations from four sources: survey responses from the national survey in Activity 1a, IMPACT's Clinical Advisory Board, systematic reviews of feedback in a broad range of healthcare settings,[62-65] and best practices from user-centered design.[66] The report will use the behavioral nudge of peer comparison. Providers' rates will be reported relative to 1) other providers in the clinic (e.g., percentile rank), 2) overall clinic rates, and 3) clinic-level quality improvement targets (e.g., percent improvement from baseline). The report will be delivered via email monthly to providers and discussed during monthly in-person staff meetings. The report will be designed for easy comprehension. Furthermore, we will track the rate at which providers are engaging the report website to measure reach of the feedback.

Data source. For development, we will use the Carolina Data Warehouse, derived from the Epic EHR, which will be used by most participating clinics in the RCT. All patients ages 9 to 17 years of age who visited a participating clinic at least once within the prior two years will be included. Patients will be attributed to providers using a plurality algorithm – patients will be attributed to the most frequently visited provider in the prior two years. In the case of ties, we will attribute the patient to the most recent provider.

Procedures. We will search for HPV vaccinations in procedures and immunization records. HPV vaccination procedures delivered in the healthcare system will be identified using Current Procedural Terminology codes for the nonavalent (90651) vaccine, which is exclusively used in North Carolina. We will then search the EHR for patients' history of immunization records, which have recently been linked to the state's immunization information system, to identify vaccinations administered previously or outside of the healthcare system.

Measures. For each provider, we will calculate up-to-date HPV vaccination, defined by current HEDIS measures[25] as the proportion of the provider's attributed patients who turn 13 years old during the measurement year with at least two HPV vaccines with different dates of service on or between the patient's 9th and 13th birthdays, with at least 146 days between the first and second dose of the HPV vaccine, OR at least three HPV vaccines with different dates of service on or between the patient's 9th and 13th birthdays. This is the primary measure because it is the HPV-related component of the quality metric most healthcare systems are using for quality improvement and reporting standards.[25] We will also include initiation (first dose) rates among ages 11-12 and providers' patient panel size, which is important for metric stability.

Analysis. Once we have an initial draft report, we will interview and conduct a usability test with six to eight providers from our pilot qualitative interviews. CHAI Core will lead this task as well given their subject matter expertise and experience in user-centered design. Suggested changes will be incorporated into the report. **The result of Aim 1 will be an engaging tool to monitor HPV vaccination rates at the provider and clinic levels, which will be incorporated into the Program Project's AAT Intervention Package.**

Aim 2. Demonstrate the impact of clinic-level financial incentives on HPV vaccine communication and uptake in healthcare systems.

In this aim, we will conduct a cluster RCT to compare the effectiveness of AAT with clinic-level financial incentives versus AAT alone. AAT is an NCI-designated Research-Tested Intervention Program that instructs providers to use a presumptive announcement.[14] In **Activity 2a**, we will randomize 34 clinics (17 per arm) in a 1:1 ratio to each arm. In **Activity 2b**, we will assess the impact of each intervention arm on the change in HPV vaccine up-to-date and HPV vaccine initiation rates at 6, 12 and 18 months. Finally, in **Activity 2c** we will examine the change in the intermediate outcomes (cognitions and behavior) attributed to AAT via a survey of providers. ***Aim 2*** *will provide gold-standard, causal evidence for new interventions aimed at improving provider communication and increasing HPV vaccine uptake, which will reduce HPV-associated cancers.*

2a. Recruit and randomize clinics

Participants and recruitment. Thirty-four clinics will be recruited from NCnet. Clinics must meet the following inclusion criteria: 1) specialize in pediatric or family medicine, 2) have 50 or more patients ages 11-12 in the previous two years, and 3) have at least two HPV vaccine providers who provided HPV vaccine in the previous two years. Clinics will be ineligible for the RCT if they had received AAT in the previous six months or planned to do so over the next six months, already have financial incentives *specifically* for HPV vaccination, or are already above 80% up-to-date HPV vaccination coverage on the HEDIS measure.

Following Institutional Review Board (IRB) approval, Dr. Hernandez will lead recruitment efforts using past NCnet relationships and proven processes. The processes include engaging system leadership first, a focus on clinic workflow, on-site visits by Drs. Hernandez and Trogdon, and adequate participation incentives (distinct from financial incentives tied to HPV vaccination coverage in the intervention arm only). Participating clinics will receive $2000 each, $1000 upon completion of baseline data collection and $1000 upon completion of final data collection. Clinics will be recruited in two phases, half in Year 2 and half in Year 3 so that processes can be adapted in the second phase. For each participating clinic, we will identify one or two key contacts for the project with whom the research study has primary communication.

Most NCnet clinics will be part of the same healthcare system. Recruiting and randomizing clinics within a system has several advantages. First, a common EHR will expedite data collection. Second, clinics within a system may have fewer unobserved differences across intervention arms due to shared management. Finally, working with healthcare systems provides a natural audience for implementation of successful interventions.

The challenge of randomizing clinics is the risk of contamination across arms. We believe the risks are minimal for our intervention. The intervention of financial incentives will be restricted to clinics in the intervention arm. Clinics in both arms will receive AAT. It is possible that clinic-level process changes adopted in response to the incentives in the intervention arm could be shared with the control arm. We will ask about this in our qualitative interviews in Activity 3c. To the extent contamination happens, it will only serve to minimize differences between the control and intervention arms and make our estimates conservative.

Randomization. After recruitment, clinics will be randomly assigned to one of two arms. Clinics in the first arm will receive AAT (control).[14] Clinics in the second arm will receive the same AAT and financial incentives with behavioral nudges (intervention). Clinics in the control arm will be waitlisted to transition to the intervention, which will run for an additional 12 months after the RCT. The waitlist control will increase acceptance within healthcare systems and avoid negative reactions in the control clinics. Randomization will be conducted by a biostatistician in the Data Core not affiliated with this trial.

Clinics will be assigned in a 1:1 proportion to the arms, stratified by the rurality of patients served and baseline HPV vaccination rates to ensure balance in these dimensions across arms. Rurality will be determined by Rural-Urban Continuum Codes (RUCC) of patients' home counties using addresses from the EHR.[67] Patients' counties will be defined as either metro counties (RUCC=1, 2 or 3) or nonmetro counties (RUCC greater than 3). Clinics that serve more patients who reside in nonmetro counties than the statewide average (i.e., >40% of patients' counties are nonmetro) will be considered rural clinics for this RCT. At least 25% of participating clinics overall will be rural. Using EHR data, we will calculate baseline clinic-level up-to-date HPV vaccination rates using the HEDIS definition for patients visiting the clinic in the two years ending prior to recruitment. Stratification will target an equal proportion of clinics in each arm above and below the median HPV vaccination rate at baseline. We will register our trial with ClinicalTrials.gov.

Announcement Approach Training. Clinics in both arms will receive AAT, a NCI-designated Research-Tested Intervention Program.[14,15,49,68] AAT instructs providers to use a presumptive announcement, in which the provider begins by stating the child is due for vaccines that prevent three diseases, placing HPV cancers in the middle of the list, assuming the family is ready to vaccinate.[14] If patients have questions or concerns, AAT provides skills for talking with hesitant parents, including research-tested messages for hesitant parents. The AAT workshop is one hour, in-clinic and provides continuing medical education credit for attendees. Intervention delivery will occur in spring to take advantage of summer peaks in adolescent vaccination.[69]

Financial Incentives. Clinics in the intervention arm will be eligible to receive clinic-level financial incentives if they meet pre-determined targets for HPV vaccination rates. The design of the financial incentives will incorporate best practices from the literature (**Table 3**).

Table 3. Best Practices from Financial Incentives Literature

Best Practice	Adaptation for RCT
Specific and easy to track incentive behaviors[17,18]	HPV vaccines delivered are recorded in EHR
Measures are amenable to change[18]	HPV vaccination rates have room to increase dramatically
Process measures rather than outcome measures as targets[18,27]	Vaccine delivery is process measure (rather than cancers avoided)
Room for improvement from baseline[18,26]	Clinics well below Healthy People 2020 targets of 80% (Table 1)
Directed at individuals or small teams[18,27]	Clinic-level incentives rather than at the healthcare system level
Absolute targets rather than relative targets[18]	Healthy People 2020 target (80% completion), with staged incentive the closer clinics come to meeting target
Designed in collaboration with providers and other stakeholders[18,27]	Semi-structured pilot interviews, national survey, Clinical Advisory Board
Incentives are clearly communicated to providers[17,70]	Introduced during AAT and re-iterated in monthly feedback
Positive, rather than competitive, approach[27]	Clinic-level targets provide incentives to cooperate
Uniform structure across different payers[27]	Financial incentives based on patients from all payers
Consider dominant payment structure in place[27]	Clinic-level incentive on top of base fee-for-service reimbursement and any existing provider-level quality bonuses
Estimate long-term effects even after incentive is withdrawn[17]	Analysis of HPV outcomes in the six months following removal of incentives
Support for incentive program among medical leadership[17]	Assess inner context for implementation determinants

Financial incentives that are too small will not be effective but incentives that are too large are inefficient and may crowd out intrinsic motivation to improve.[71] Evidence suggests a dose-response relationship between incentive size and quality of care outcomes.[72] Therefore, our financial incentives can still be effective in the presence of existing pay-for-performance schemes. Our incentive sizes will be guided by formative interviews with providers and clinic managers in North Carolina, the national survey, and prior literature.[19,20,23,72] We propose three sizes of incentives for tiered goals met by the clinic (**Table 4**). The clinic-level incentives will be scaled to equal $1000 per provider, but aggregated and paid to the *clinic*, for reaching the highest tier, an absolute goal of 80% of patients meeting the HEDIS up-to-date measure. Including the Healthy People 2020 goal in the incentive structure ensures clinics know the long-term goal. To keep incentives salient for clinics well below 80%, we will provide smaller bonuses for improvements relative to baseline. Based on our pilot interviews, we will let clinics distribute the incentives as they wish among healthcare professionals and staff.

Our incentives have three key behavioral nudges. First, they are team-based with clinic-level targets. Team-based incentives create additional incentives for physicians and other healthcare providers within a clinic to cooperate and work together to achieve the HPV vaccination goal.[73] Second, our financial incentives will be structured as a commitment contract, in which an up-front payment is made to a study-held account earmarked for the clinic but is at a risk of loss if the improvement targets are not met. The clinic's account balance and projected loss (if any) will be included in the monthly feedback to increase salience. Payments will be made 12 months after the start of the trial. This design is intended to take advantage of the behavioral bias of loss aversion or the endowment effect, in which people exert more effort to avoid a loss than to achieve a similarly-sized gain.[34,37] Finally, providers in the intervention arm will receive monthly, automated provider feedback of each providers' HPV vaccination rates relative to other providers in the clinic. Peer comparison is intended to motivate providers to improve for social esteem.

Table 4. Example Incentives for Average Clinic with Six Providers

Clinic HPV Target	Clinic Bonus
HEDIS ≥ 80%	$6,000
HEDIS < 80% with ≥ 10% improvement	$2,500
HEDIS < 80% with ≥ 5% improvement	$1,500

2b. Assess HPV vaccination uptake

Procedures. Clinics will participate in the RCT for one year. AAT will take place in the first quarter of the intervention year. The provider-level feedback and incentive interventions will be active for 12 months.

Measures. We will measure the HPV vaccination outcomes in the EHR for the 12-month periods ending 0 months (baseline), 6 months (preliminary), 12 months (post-intervention), and 18 months (long-run to assess outcomes after removal of incentives) after the start of the intervention. All measures will be calculated among all patients who visited a participating clinic during the study period. The primary outcome measure will be up-to-date HPV vaccination as defined by current HEDIS measures (i.e., among adolescents who turned 13 in the prior 12 months; Activity 1b). The secondary outcomes will be HPV vaccine initiation (first dose) and completion rates (two doses) among patients who turned 11 and 12 in the prior 12 months (recommended ages for the vaccine according to ACIP) and patients who turned 13 to 17 in the prior 12 months (**Table 5**). We will also measure the following covariates at the clinic-level from the EHR, trial participant survey (Activity 2c), and public sources: sex mix of patients, mix of patients residing in rural and non-rural areas, rural/non-rural location of the clinic, total number of patients ages 11-12 and 13-17, payer mix, number of providers, history of HPV quality improvement activities, ownership structure, and patient-centered medical home status. The trial participant survey will also collect provider specialty and years of experience.

Table 5. Long-Term Outcome Measures from EHR

Measure	Description
Primary: HPV vaccine completion (HEDIS)	Up-to-date at age 13
Secondary: HPV vaccine initiation, 11-12 years and 13-17 years	At least one dose
Secondary: HPV vaccine completion, 11-12 years and 13-17 years	Two doses

Analyses. We hypothesize that the addition of financial incentives to AAT will increase HPV vaccination relative to AAT alone. For all analyses, analysts will be blinded to each clinic's arm.

Inferential Analyses. The main analysis will be intent-to-treat, retaining outcomes for clinics that disenroll from the trial for any reason during the intervention. We will estimate a generalized estimating equation (GEE) model for HPV vaccination using patient-level data from the EHR (0=not up-to-date, 1=up-to-date). Using a sample of patients not yet up-to-date at baseline who visited the clinic during the study period, the GEE model will account for patients clustered by clinic. We will use a binomial link and logit family. The main effect will be

an indicator for intervention arm (at the clinic level). The coefficient represents the difference in the log odds of HPV vaccination at follow-up across the intervention and control arms. We will also adjust for baseline covariates listed above. This analysis will provide an estimate of the effect of financial incentives on HPV vaccination rates. We will repeat these analyses separately for each time point (6-, 12-, and 18-month follow up) and HPV vaccine outcome (**Table 5**). When initiation is the dependent variable, the sample will include patient not yet vaccinated who visited the clinic during the study period.

Exploratory Analyses. Several clinic characteristics could moderate the effect of the intervention. First, clinics that primarily serve patients who live in rural areas are different from clinics that primarily serve patients who live in non-rural areas in many dimensions that could affect their ability to respond to information provided in the feedback and the financial incentives. *Project 4 will provide valuable information from their first aim in the development phase of our project about key differences in rural and non-rural clinics with respect to HPV vaccination.* Second, clinics with higher baseline HPV vaccination rates have less room to improve. Conversely, clinics with higher baseline rates (but not yet at target) may have higher capability to implement quality improvement initiatives. Finally, the interventions can differ in their impact based on the number of providers in the clinic. Providers in smaller clinics may find it easier to cooperate, harder to "free ride" on others, and to share information and tactics. To test for moderating effects of the interventions, we will repeat the GEE models described above adding interactions of the intervention arm variable with each of the following clinic-level variables: rural/non-rural mix of patients, baseline HPV rates, number of providers, and sex as a biological variable.

Statistical Power. Assuming 17 clinics in each arm, 112 13-year old patients per clinic not up-to-date on average (Table 1), a 15 percentage point increase in the control arm (secular trend + AAT),[14] and a intraclass correlation of 0.033 (author calculations from AAT studies), we will have 80% power to detect a minimum of an 8 percentage point difference in our primary outcome in two-sided tests at a 95% confidence level. This effect size is similar to that found in earlier studies of provider incentives for other vaccinations,[19-22] some of which detected effect sizes up to 19 percentage points.[19]

2c. Examine change in provider cognitions and behavior

Procedures. We will survey all providers in participating clinics (n=~204) at baseline (immediately before the AAT workshop, T0), immediately after the AAT workshop (T1), and at the end of the intervention 12 months later (T2). We will use paper surveys for T0 and T1 and web-based RedCap surveys for T2. We will email a link to the survey, sending up to six email and phone reminders. Providers will receive $100 to complete T0 and T1 and $100 to complete T2.

Measures. **Table 6** describes the measures for the intermediate outcomes that will be included in the trial participant survey at all time points (T0, T1 and T2). We will measure each domain from the conceptual model for cognitions and behaviors using a single item with a 5-point Likert scale response. Items for cognitions were developed by IMPACT team members and used in the original evaluation of the AAT.[14] We will also include an item to capture providers' perceptions of the effectiveness of incentives in changing their behavior (T2).

Table 6. Selected Intermediate Outcomes from Trial Participant Survey

Measure	Description
Cognitions	
Attitudes	It is important to me that my patients get a recommendation for HPV vaccine before age 13.
Social norms	It is the norm for our team to routinely recommend HPV vaccine for patients before age 13.
Perceived behavioral control	I feel confident our team can recommend HPV vaccine effectively for our adolescent patients.
Intention to recommend	I intend to make sure all patients get an HPV vaccine recommendation before they turn 13.
Behavior: Use of presumptive announcements	When I first talk about HPV vaccine, I use language that assumes parents are ready to vaccinate.

Analyses. We hypothesize that financial incentives with AAT will improve cognitions and behavior relative to AAT alone. The proposed mechanism is that financial incentives improve *cognitions* through changing attitudes, establishing new social norms, and increasing intentions to recommend, which will change HPV vaccine recommendation *behavior*. We will estimate two-level (provider and clinic) generalized linear mixed-level regression models with a log link and Poisson family. The main effects will be an indicator for time (pre vs post), an indicator for intervention arm (at the clinic level) and an interaction of time and intervention arm. Models will include random effects for clinics and will adjust for baseline covariates listed above.

Integration. Project 4 will provide a spreadsheet to gather these effectiveness data in a standard format to support cost-effectiveness modelling. We will work with the Data Core to complete the spreadsheet and share it with Project 4. **The result of Aim 2 will be an estimate of the impact of clinic-level financial incentives on HPV vaccine communication and HPV vaccine uptake.**

Aim 3. Generate guidance for systems to compare and implement AAT and financial incentives.

In this aim, we will use sequential, explanatory mixed methods to evaluate implementation determinants and outcomes to support healthcare system's adoption and implementation of AAT and financial incentives to increase HPV vaccine uptake. In **Activity 3a,** we will assess the incremental cost of implementing financial incentives, including cost per additional adolescent initiating the HPV vaccine because of financial incentives. In **Activity 3b,** we will examine other implementation outcomes from the Proctor framework to capture how AAT and financial incentives were received (i.e., acceptability, appropriateness) and integrated into practice (i.e., adoption, feasibility, fidelity, reach, sustainability).[58] In **Activity 3c**, we will characterize determinants of AAT and financial incentives implementation from CFIR. Because the financial incentives tested are not prescriptive and allow clinics to tailor their own processes, we will also summarize the strategies clinics used for improving HPV vaccination in response to financial incentives.[59] Finally, in **Activity 3d,** we will use findings from Activities 3a-c to contribute a module to the AAT Intervention Package for improving HPV vaccination in healthcare systems. ***Aim 3*** *will support AAT and financial incentives implementation among clinics and payers.*

Participants. All providers in participating clinics (n~=204) will complete the trial participant survey (see Activity 2c). We will also recruit a purposive sample of two providers and one clinic manager from intervention clinics for semi-structured interviews.

Procedures. Implementation determinants and outcomes will be collected from three sources: study team documentation (intervention expense records, tracking logs and content checklists), participant survey, and semi-structured interviews (**Table 7**).[74] Interviews will be conducted with clinics until we reach theme saturation regarding implementation determinants and outcomes. An experienced interviewer from the CHAI core will conduct 25-30 minute, semi-structured interviews over the phone in a private room. We will develop standardized interview guides with a detailed script regarding implementation determinants and strategies. Open-ended probes will allow stakeholders the opportunity to answer questions in their own way and follow-up probes will clarify answers from stakeholders. All interviews will be digitally audio-recorded and professionally transcribed. Personal identifiers will be removed.

Table 7. Data sources for implementation outcomes

Data source	AAT	Incentives and Use of AA
Intervention expense records Facilitator time, travel, materials	Cost	Cost
Tracking logs of participants 1/clinic, 34 total	Cost, reach	
Checklists of content 1/workshop, 34 total	Cost, fidelity	
Survey of participants ~204 total	Acceptability	All outcomes
Key informant interviews 3/clinic, ~27 total	All outcomes	All outcomes

Note. AA = Announcement Approach. All outcomes = acceptability, adoption, appropriateness, cost, feasibility, fidelity, reach, sustainability.[58]

3a. Assess cost per additional adolescent initiating the HPV vaccine

Measures. Primary measures are the incremental cost of delivering the intervention and incremental cost per additional initiation due to the intervention—from the perspective of a healthcare facility or system. Secondary measures will separate fixed, start-up costs from ongoing variable costs. We will collect micro-cost data for each component of the intervention: AAT, financial incentives, and changes in the use of the announcement approach (AA). We will not assess fixed costs common to both the interventions and the "status quo" (e.g. clinic operation overhead), or costs related to the trial alone (e.g. data collection).

AAT: Facilitators will complete 2-3 minute, online time logs to the nearest quarter hour and travel and intervention materials expense logs. Logs will be completed after each AAT workshop and include practice, planning, preparation, facilitating AAT, and related tasks. Attendance logs will provide the number of provider hours spent in attending the AAT, which will be valued using median salaries by job title for the U.S.[75]
Incentives: Study records will track the amount of incentives paid to clinics. We will also ask clinic leaders about any administrative costs to integrate incentives with existing systems (e.g., EHR modifications) in the semi-structure interviews. **Use of AA:** Providers will report typical HPV vaccine delivery time on the T0 and T2

participant surveys (see Activity 2c). They will report average time spent on HPV vaccine recommendations and documentation for their last five patients ages 11-12.

Analyses. We will calculate mean, median, and standard deviation for cost per arm per clinic and separately for fixed and variable cost per arm per clinic. We will use t-tests to compare mean costs per clinic between intervention arms. We will then calculate the difference in mean costs between intervention arms and divide by the difference in adolescents ages 11-12 initiating the HPV vaccine to estimate cost per additional initiated due to the intervention. In secondary analyses, we will examine potential economies of scale by plotting average cost per clinic against clinic size.

Integration. With the help of the Intervention Core, we will share standardized cost tables with Project 4.

3b. Examine other implementation outcomes

Measures. We will use instruments with established validity and reliability and cognitively test new items with our Clinical Advisory Board.[14,74,76] **AAT**: We will quantitatively assess the following implementation outcomes for the AAT workshops. Participant surveys T0 and T1 will ask about *acceptability* (satisfaction with the intervention activities). We expect acceptability to be above 90%, based on our previous trainings that achieved this goal. A research assistant will complete brief tracking logs (1/workshop, 34 total) that will include the number attending the AAT workshop (*reach*). The research assistant will also complete checklists (1/clinic, 34 total) to assess *fidelity* (whether interventions were delivered as intended). We will calculate the percentage of the intervention curriculum covered as intended. To qualitatively assess *adoption* (AAT use), *appropriateness* (AAT relevance), *feasibility* (ability to facilitate AAT), and *sustainability* (ability to use AAT over time), key informant interviews will use measures and analyses described in Activity 3c.[74]

Incentives and use of AA: We will quantitatively assess all implementation outcomes in the participant surveys (see Activity 2c). For example, Dr. Weiner (Intervention Core) has validated items for *acceptability*, *adoption*, and *feasibility* that we will use with respect to the use of AA and financial incentives.[76] We will measure *fidelity* regarding the use of AA by asking providers about their use of each component (presumptive announcement, connect and counsel, and follow-up) using a single item with a 5-point Likert scale response for each component. We will survey providers regarding *reach* (e.g., did providers use AA for most patients?) and *sustainability* (do providers plan to keep using AA/incentives?). We will also probe all implementation outcomes qualitatively in the key informant interviews (described in Activity 3c).

Analysis. We hypothesize that financial incentives will be associated with favorable implementation outcomes in response to having money at stake. We will use *t*-tests to compare trial arms on quantitative implementation outcomes. We will also repeat the analyses from Activity 2c with the quantitative implementation outcome measures as the dependent variable in separate models. For qualitative data, we will use the analytic methods described in Activity 3c, using a priori codes guided by the Proctor framework.[58] We will integrate quantitative and qualitative results using a joint data display.[77]

Integration. We will share findings with Project 4 for inclusion in the web-based decision support tool.

3c. Characterize determinants of AAT and financial incentives implementation and strategies for improving HPV vaccination that providers and clinics use in response to financial incentives

Measures. We will pilot the interview guide with someone with knowledge of AAT and financial incentives to ensure the interview guide's clarity and comprehensiveness; results will not be included in final analyses. The final interview guide will explore determinants of AAT and financial incentives implementation and other strategies to improve HPV vaccination that clinics use in response to financial incentives (e.g., team huddles). Guided by the Expert Recommendations for Implementing Change (ERIC) strategies compilation, we will ask about how they decided to distribute the incentives within the clinic, why they chose that approach and whether they would make any changes.[78] Guided by the CFIR, will also assess AAT and financial incentives implementation determinants such as leadership engagement and readiness for implementation.[59]

Analysis. Qualitative research experts from CHAI core will use a coding-based thematic analytic approach that identifies main themes within and across the in-depth interviews. We will create a common codebook with coding categories derived a priori from ERIC and the CFIR. We will upload transcripts into a qualitative software management tool (i.e., ATLAS.ti) and at least two team members will independently read and deductively code each transcript. The team will iteratively meet to review the results of the coding and reconcile any discrepancies until they reach consensus. The coding team will generate summary reports of each code across interviews, assessing the degree to which the code emerged in the data. We will generate a key summary report that summarizes each code across the interviews and highlight the key themes with direct participant quotes.

3d. Contribute module to AAT Intervention Package

Project 2's contribution to the AAT Intervention Package will summarize our findings on the effectiveness of financial incentives to boost the impact and implementation of AAT. The module will present Activities 3a-b findings regarding AAT and financial incentives cost-effectiveness, acceptability, appropriateness, and other implementation outcomes to support healthcare system leaders' adoption decision. To inform quality improvement managers' implementation efforts, we will include a context assessment tool based on Activity 3c findings regarding determinants of AAT and financial incentives implementation (e.g., engaging system leadership). We will also compile best practices from the behavioral economics literature regarding incentive size, payment frequency, methods to promote cooperation between providers, and suggestions to align incentives with payment models currently in place. **The results of Aim 3 will provide crucial information on the costs for healthcare systems to facilitate the adoption and implementation of effective interventions to improve HPV vaccine communication and increase HPV vaccination uptake.**

Potential Challenges and Solutions

Covid-19. The Covid-19 pandemic has changed clinic priorities and workflows. We will work with clinics during recruitment and the trial to accommodate to this new environment as needed. For example, we have experience delivering AAT remotely/online (over 50 remote trainings so far). Importantly, the Covid-19 crisis has reduced routine vaccination,[4,5] making the need for increased HPV vaccine uptake even greater.

Generalizability. We acknowledge that our results may not generalize to clinics outside of healthcare systems or using other EHR systems. However, primary care practices are rapidly consolidating in healthcare systems and Epic is one of the most used EHR systems nationwide.

Scalability. For financial incentives to be adopted, payers or healthcare systems would need to adopt them. Many large private insurers, including Blue Cross and Blue Shield of North Carolina, are adopting pay-for-performance contracts with providers. Given this, and our preliminary evidence suggesting providers' support for it, we believe incentives for HPV vaccination can become sustainable and scaled up.

Relevance to Program Project Theme

The **IMPACT Program Project theme** is amplifying the impact of a Research-Tested Intervention Program to improve HPV vaccine communication in healthcare systems. Project 2 addresses this theme via financial incentives to motivate providers to apply what they learn in AAT. Three projects will contribute to the national survey, led by the **Data Core**, which provides each research project access to a higher-quality sample of a more diverse group of health professionals than would be possible if each project conducted a survey independently. With help from the cores, standardized implementation (**Intervention Core**) and impact (**Data Core**) information will be shared with **Project 4** for cost-effectiveness modeling and decision support tool development. The research projects will each contribute a new element to the **AAT Intervention Package**. Project 2 will contribute a module on best strategies for financial incentives for HPV vaccination. We will also work with the **Intervention Core** to disseminate our findings widely to scientific, clinical, and public health audiences through our team's website (hpvIQ.org), scientific publications, conference presentations, and stakeholder engagement. The proposed research can help reduce the incidence of HPV and HPV-associated cancers by increasing adoption of HPV vaccine communication interventions in healthcare systems.

Table 8. Research Timeline

		Year 1				Year 2				Year 3				Year 4				Year 5			
	Quarter	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
Hire staff, IRB application		■																			
Aim 1	1a: Conduct national survey	■	■	■	■																
	1b: Refine feedback report			■	■	■															
Aim 2	2a: Randomize / recruit clinics						■	■			■	■									
	2b: Assess HPV vax							■	■	■	■	■	■	■	■	■	■				
	2c: Examine intrmed outcomes										■	■			■	■					
Aim 3	3a: Assess cost per initiated							■	■	■	■	■	■	■	■	■					
	3b/c: Examine implm outcomes and determinants										■	■			■	■					
	3d: Draft package module																		■	■	■
Disseminate findings						■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■

PHS Human Subjects and Clinical Trials Information

OMB Number: 0925-0001

Expiration Date: 02/28/2023

Use of Human Specimens and/or Data

Does any of the proposed research in the application involve human specimens and/or data *	❍ Yes ● No
Provide an explanation for any use of human specimens and/or data not considered to be human subjects research.	
Are Human Subjects Involved	● Yes ❍ No
Is the Project Exempt from Federal regulations?	❍ Yes ● No
Exemption Number	❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑ 6 ❑ 7 ❑ 8
Other Requested Information	

Human Subject Studies

Study#	Study Title	Clinical Trial?
1	The impact of clinic-level financial incentives on HPV vaccine communication and uptake	Yes

Section 1 - Basic Information (Study 1)

OMB Number: 0925-0001

Expiration Date: 02/28/2023

1.1. Study Title *

The impact of clinic-level financial incentives on HPV vaccine communication and uptake

1.2. Is this study exempt from Federal Regulations * ○ Yes ● No

1.3. Exemption Number ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑ 6 ❑ 7 ❑ 8

1.4. Clinical Trial Questionnaire *

1.4.a. Does the study involve human participants?	● Yes	○ No
1.4.b. Are the participants prospectively assigned to an intervention?	● Yes	○ No
1.4.c. Is the study designed to evaluate the effect of the intervention on the participants?	● Yes	○ No
1.4.d. Is the effect that will be evaluated a health-related biomedical or behavioral outcome?	● Yes	○ No

1.5. Provide the ClinicalTrials.gov Identifier (e.g. NCT87654321) for this trial, if applicable

Section 2 - Study Population Characteristics (Study 1)

2.1. Conditions or Focus of Study

- To examine whether financial incentives tied to clinic-level improvement in HPV vaccination rates can further improve HPV vaccine communication and uptake.

2.2. Eligibility Criteria

Aim 1Activity 1b• Electronic health record (EHR) data will be queried for patients meeting the following criteria:1) Aged 9 to 172) Had at least one visit with a pediatric or family medicine clinic within the UNC system in the prior two years• Usability testing will be conducted with 6-8 providers meeting the following criteria:1) HPV vaccine providers (physicians, physician assistants, and nurse practitioners)2) Provided HPV vaccinations to adolescent patients aged 9-17 in the prior two yearsAim 2Activity 2aClinics will be recruited into the trial that meet the following criteria:1) Specialize in pediatric or family medicine2) Have at least 50 or more patients aged 11 to 12 in the prior two years3) Have at least two HPV vaccine provider who provided HPV vaccine in the prior two years4) No Announcement Approach Training (AAT) in last 6 months or coming 6 months5) No existing financial incentives tied specifically to HPV vaccination6) HEDIS HPV up-to-date measure < 80%.Activity 2bVaccine coverage at the clinic level will be evaluated using EHR data for patients who meet the following criteria:1) Aged 11-12 or 13-172) Had at least one visit with a clinic that was recruited into the trial in Activity 2a during the studyActivity 2cChange in communication cognitions and behaviors will be evaluated based on a survey of providers who meet the following criteria:1) Providers at one of the clinics recruited into the trial in Activity 2aAim 3Activities 3b and 3c1) Providers and clinic managers from the clinics participating in the Aim 2 trial (see clinic inclusion criteria above)

2.3. Age Limits	Min Age:	18 Years	Max Age:	99 Years
2.3.a. Inclusion of Individuals Across the Lifespan	InclusionofLifespanP2r1045595414.pdf			
2.4. Inclusion of Women and Minorities	InclusionWomenMinoritiesP2r1045595415.pdf			
2.5. Recruitment and Retention Plan	RecruitmentP2r1045595416.pdf			
2.6. Recruitment Status	Not yet recruiting			
2.7. Study Timeline	TimelineP2r1045595417.pdf			
2.8. Enrollment of First Participant	12/01/2021	Anticipated		

INCLUSION OF INDIVIDUALS ACROSS THE LIFESPAN – Project 2

The surveys and interventions will focus on primary care professionals, so only adults working in their professional roles in pediatric primary care will be included in the studies. The effectiveness of the planned interventions for the Aim 2 trial will be evaluated using electronic health record data to calculate the proportion of adolescent patients ages 9-17 years who have initiated the HPV vaccine series and the proportion of adolescent patients who are up to date on HPV vaccinations. We will not interact with children as part of the trial or other planned studies.

INCLUSION OF WOMEN AND MINORITIES – Project 2

The proposed research will include women and minorities throughout. Our estimates for inclusion of women and minorities appear in the targeted/planned enrollment tables. We anticipate the inclusion of women and minorities in these calculations to be representative of the distribution of women and minorities providing and receiving HPV vaccines at pediatric and family medicine clinics affiliated with NCnet, our practice-based research network partner.

RECRUITMENT AND RETENTION PLAN – Project 2

We will recruit participants for several data collection strategies to satisfy the specific aims: web-based surveys, cognitive testing, a randomized clinical trial (RCT), and qualitative phone interviews.

Aim 1 Web-based Survey and Cognitive Testing

National primary care team survey

In Aim 1, Activity 1a, we will contribute to the national primary care team survey, jointly with Projects 1 and 4 and the Data Core. Project 2 will add questions to assess providers' perceptions (e.g., acceptability, effectiveness) of HPV vaccine-related financial incentives and behavioral nudges. The Data Core will contract with WebMD Market Research to recruit 2,500 members from its standing, online panel of pediatric primary care professionals. The company will use quota-based sampling to recruit ~500 participants from each of 5 groups: pediatricians; family physicians; nurse practitioners and physician assistants; registered nurses; and medical assistants. WebMD will invite panel members to join the survey via email and targeted ads. Participants will receive up to $45 for participating. Based on the panel's prior performance, we anticipate a response rate of ≥60%.

Cognitive testing

In order to ensure readability and comprehension of the national survey measures for Project 2 and a subset of four to five demographic items, we will employ cognitive testing using "think aloud" exercises with eight local physicians from the NCnet practice-based research network. Recruitment is expected to take 2-3 weeks and interviews will be conducted on a rolling basis. We will offer each participant a $100 gift card for completing the interview. Interviews are expected to take ~30 minutes.

Aim 2 RCT

System and clinic recruitment

In Aim 2, Activity 2a, clinics will be recruited into the RCT. Dr. Hernandez will lead recruitment efforts using past NCnet relationships and proven processes. The processes include engaging system leadership first, a focus on clinic workflow, on-site visits by Drs. Hernandez and Trogdon, and adequate participation incentives. Participating clinics will receive $2000 each, $1000 upon completion of baseline data collection and $1000 upon completion of final data collection. Clinics will be recruited in two phases, half in Year 2 and half in Year 3 so that processes can be adapted in the second phase. For each participating clinic, we will identify one or two key contacts for the project with whom the research study has primary communication. Clinics in the control arm will be waitlisted to transition to the intervention, which will run for an additional 12 months after the RCT, to increase acceptance within the healthcare systems and to avoid negative reactions in the control clinics. Since the data used for the primary and secondary analyses come from electronic health records (EHRs) that are integrated within the clinics, completion and initiation rates can still be calculated for clinics who dropped out of the trial.

Pre- and post-training trial participant surveys

For each Announcement Approach Training (AAT) workshop, pre- (T0) and post-training (T1) surveys will be collected from each participant to assess provider, clinic, and patient-volume characteristics as well as changes in participant knowledge, self-efficacy, and intentions. With a total of 34 clinics recruited, we expect approximately 6 participants in each training from each clinic for a total of approximately 204 participants. Surveys will take 3-5 minutes each. The post-training survey is part of the requirement for earning continuing medical education and continuing education credit. Providers will receive $100 to complete T0 and T1 surveys.

Trial participant follow-up surveys

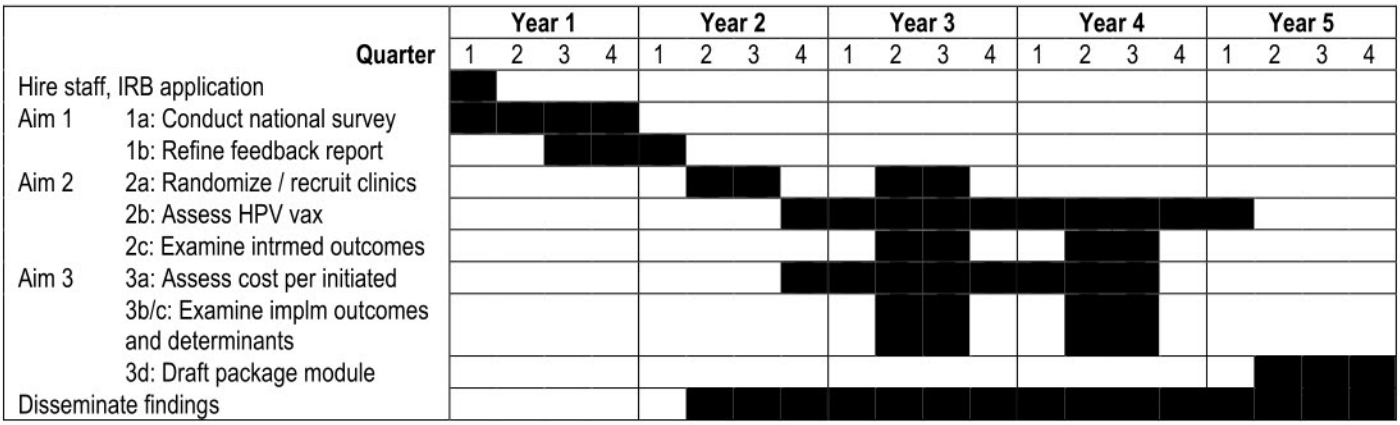
Twelve months after the AAT workshops take place in the clinics, trial participants from each clinic will complete an online follow-up survey (T2). Those who complete the follow-up online surveys will be paid $100. We will use web-based RedCap surveys for T2; to improve response rates, participants will also have the option to complete a paper form of the survey and mail it back to us. We will send up to six email and phone

reminders to improve response rates at T2. The provider survey will also be used in Activity 3c in conjunction with a phone interview (described below) to characterize strategies providers and clinics used in response to financial incentives.

Aim 3 Qualitative Phone Interview

Under Aim 3 (Activity 3c) we will recruit and interview a sample of two providers and one clinic manager from approximately nine clinics who received the intervention. The qualitative interview will be 25-30 minutes long and will be conducted by an experienced interviewer from the CHAI core over the phone. Participants will receive $100 for participating in the interview.

STUDY TIMELINE – Project 2



Aim 1

The timeline for conducting the national primary care team survey (Activity 1a), querying electronic health record (EHR) data to calculate provider-level HPV vaccine coverage and designing the feedback report (Activity 1b) requires quick and nimble implementation. Key to our ability to meet this timeline is having a research team that has worked together in the past on successful projects, having team members work parallel on tasks, and relying on the extensive previous work of our experienced investigators. For Activity 1a, WebMD's existing panel of healthcare providers allows us to quickly access large national samples. In addition, the EHR data queried in Activity 1b are collected at the time of service and can be analyzed within days of data collection over secure servers.

Aim 2

The randomized clinical trial in Aim 2 will be conducted in two waves, in Years 2 and 3, allowing for time to address unexpected challenges that may occur. HPV vaccine outcomes will be measured at 6 months, 12 months, and 18 months post randomization. Trial outcomes will be calculated using EHR data that are collected at the time of service and already integrated within the healthcare systems. We will survey all providers in participating clinics (n=~204) at baseline (immediately before the AAT workshop, T0), immediately after the AAT workshop (T1), and at the end of the intervention 12 months later (T2). Year 4 will allow for some delay in recruitment, but will largely be used to analyze data from the RCT.

Aim 3

Under Activity 3a, we will collect cost data from each AAT workshop, from study records tracking the amount of incentives paid to clinics, from interviews with clinic leaders, and from the trial participant surveys at T0 and T2. Under Activity 3c, we will recruit a sample of two providers and one clinic manager from approximately nine clinics from the intervention arm in the trial. To ensure timeliness of survey data collection, interviews will be conducted by an experienced interviewer from the CHAI core and will take place over the phone.

Dissemination

We will disseminate findings from the proposed research in Year 2-5. In Year 5, the trial team will refine the materials developed for the interventions to determine the best practices to be included in the AAT Intervention Package and disseminated to healthcare systems.

2.9. Inclusion Enrollment Reports

IER ID#	Enrollment Location Type	Enrollment Location
Study 1, IER 1	Domestic	Family medicine and pediatric clinics

Inclusion Enrollment Report 1

1. Inclusion Enrollment Report Title* : The impact of clinic-level financial incentives on HPV vaccine communication and uptake

2. Using an Existing Dataset or Resource* : ❍ Yes ● No

3. Enrollment Location Type* : ● Domestic ❍ Foreign

4. Enrollment Country(ies): USA: UNITED STATES

5. Enrollment Location(s): Family medicine and pediatric clinics

6. Comments: Aim 1: For IER for Activity 1a, please refer to the Data Core. IER below is for Activity 1b. EHR data will be queried for adolescent patients who visit clinics participating in the Aim 2 trial. Numbers below are an estimate and we will not know actual sample sizes until the time of the study.

Planned

Racial Categories	Ethnic Categories				Total
	Not Hispanic or Latino		Hispanic or Latino		
	Female	Male	Female	Male	
American Indian/ Alaska Native	78	75	35	35	223
Asian	448	428	22	22	920
Native Hawaiian or Other Pacific Islander	15	16	21	14	66
Black or African American	3932	3732	182	175	8021
White	10876	10331	1510	1432	24149
More than One Race	615	582	398	382	1977
Total	15964	15164	2168	2060	35356

Cumulative (Actual)

Racial Categories	Ethnic Categories									Total
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			
	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	
American Indian/ Alaska Native	0	0	0	0	0	0	0	0	0	0
Asian	0	0	0	0	0	0	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0	0	0	0	0	0	0
Black or African American	0	0	0	0	0	0	0	0	0	0
White	0	0	0	0	0	0	0	0	0	0
More than One Race	0	0	0	0	0	0	0	0	0	0
Unknown or Not Reported	0	0	0	0	0	0	0	0	0	0
Total	0	0	0	0	0	0	0	0	0	0

Section 3 - Protection and Monitoring Plans (Study 1)

3.1. Protection of Human Subjects	ProtectionHsP2r1045595418.pdf
3.2. Is this a multi-site study that will use the same protocol to conduct non-exempt human subjects research at more than one domestic site?	● Yes ○ No ○ N/A
If yes, describe the single IRB plan	MultisiteStudyP2r1045595419.pdf
3.3. Data and Safety Monitoring Plan	DsmpP2r1045595420.pdf
3.4. Will a Data and Safety Monitoring Board be appointed for this study?	● Yes ○ No
3.5. Overall structure of the study team	StudyTeamP2r1045595421.pdf

PROTECTION OF HUMAN SUBJECTS – Project 2

Risk to subjects

Human subjects involvement

The proposed project "The impact of clinic-level financial incentives on HPV vaccine communication and uptake," will take a multidisciplinary approach to identify the likely impact of financial incentives on HPV vaccine coverage and provider communication. First, we will contribute a web-based national primary care team survey to understand their current experiences with, and preferred designs for, financial incentives with behavioral nudges (e.g., prepayment contracts, peer comparison feedback). Then we will calculate provider-level HPV vaccine up-to-date and initiation rates for the family medicine and pediatric clinics participating in the Aim 2 randomized clinical trial (RCT). Rates for each participating clinic will be calculated based on EHR data for adolescent patients (ages 9-17) who have visited the respective clinics in the prior two years. To assess the impact of financial incentives on HPV vaccine uptake and provider communication, we will conduct an RCT that randomizes clinics to intervention and control arms. Trial outcomes will be calculated using EHR data of adolescent patients (ages 11-17) at the participating clinics. Secondary outcomes will be assessed via surveys of participating providers before and after the intervention. At the end of the RCT, we will interview two providers and one clinic manager at approximately nine participating clinics to characterize the strategies that were used in response to the intervention. Finally, cost data for each participating clinic will be collected through the interviews and time and expense logs completed by Announcement Approach Training (AAT) facilitators.

Source of materials

We will use several data collection strategies to achieve the goals discussed above: web-based national survey of primary care team members, cognitive testing, EHR query, surveys of RCT providers, phone interviews, and web-based cost logs.

National primary care team survey. In collaboration with the Data Core and the Projects, we will conduct a national provider survey with approximately 2,500 primary care team members involved in HPV vaccine provision. Please refer to the Data Core for Inclusion Enrollment Report and other Human Subjects information for the national survey.

Cognitive testing. In order to ensure readability and comprehension of the national survey measures for Project 2 and a subset of four to five demographic items, we will employ cognitive testing using "think aloud" exercises with eight local healthcare professionals from the NCnet practice-based research network. The cognitive testing will consist of asking participants to answer an item that will be included in the web-based survey, asking what they believe the question was trying to ask, and what they intended by their answer. We will temporarily have participants' names and contact information for the purpose of scheduling and conducting the interview and providing incentives. However, identifying information will not be linked to participants' data.

EHR query. In Aim 1 (Activity 1b), we will query EHR data of clinics participating in the RCT to calculate HPV vaccine initiation and up-to-date rates. For each clinic, rates will be calculated based on EHR data for adolescent patients aged 9-17 who visited the respective clinic at least once in the prior two years.

RCT and provider surveys. In Aim 2, we will conduct an RCT to assess the impact of financial incentives on HPV coverage and provider communication. Randomization will occur at the clinic level. EHR data for adolescent patients aged 11-17 who visited the respective clinics at least once during the study will be used to calculate trial outcomes. In Activity 2c, we will survey all providers in participating clinics (n=~204) at baseline (T0), immediately after the AAT workshop (T1) and at the end of the intervention 12 months later (T2). We will use paper surveys for T0 and T1 and web-based RedCap surveys for T2. No survey will request any identifying information or sensitive data from participants. Participants will complete a sign-in sheet that will allow us to distribute continuing medical education credits, but this sign-in sheet will not be kept with survey data.

Phone interviews. Upon completion of the trial, a phone interview will be conducted with two providers and a clinic manager at approximately nine of the clinics in the intervention arm of the trial to characterize the strategies used in response to the intervention (Activity 3c).

Web-based cost logs. AAT facilitators will complete time and expense logs that details the costs associated with each of the AAT workshops (Activity 3a).

Potential risks

We anticipate that risks to participants will be minimal and manageable. There are no biospecimens that will be collected or stored for the purpose of this proposed study. We are not specifically targeting any of the following special classes of people: prisoners, institutionalized individuals, or other special classes of subjects who may be considered vulnerable populations.

No patients will be contacted directly for the proposed study. Adolescents whose EHR data are being used in Aims 1 and 2 will not be contacted directly. Providers participating in our data collection efforts will answer questions about their professional and work beliefs and behaviors. We are not discussing highly personal or sensitive topics with any provider participants.

The main risk is breach of confidentiality. The plan for mitigating this risk is discussed below (under "Adequacy of protections against risk"). All information about human subjects will be maintained by UNC. All members of the study team will abide by applicable laws and regulations regarding the protection of patient privacy and confidentiality in human subjects research.

Adequacy of protection against risks

Recruitment and informed consent

National primary care team survey. Please refer to the Data Core for Inclusion Enrollment Report and other Human Subjects information for the national survey.

Cognitive testing. Cognitive testing will be conducted with eight local providers in NCnet. The informed consent process will occur at the beginning of the testing. The interviewer will read the consent form aloud to the participant to explain the study's purpose, potential risks, expected benefits, protection of confidentiality and time expectations. The interviewer and participant will both sign the informed consent form, and the participant will retain a copy of the form for his or her records. The consent form will include contact information for the IRB and the Principal Investigator in case participants have concerns or questions about the study.

EHR query. EHR data will be stored on a password-protected secure server and all study members who access the EHR data will be bound by a signed Data Use Agreement (DUA) to keep confidential all personal identifiers and information. The data contain information on medical procedures, diagnoses, prescriptions, and patient demographics and will be stripped of names, telephone numbers, addresses, social security numbers, medical record numbers. We anticipate the query to be exempt from the informed consent process since data are collected for administrative purposes at the time of service, no interactions with patients will take place, and direct identifiers are not available in the data.

Surveys with RCT providers. Pre- (T0) and post-training (T1) surveys will take place in the context of the AAT workshops. The UNC IRB has previously considered this activity to be quality improvement rather than human subjects research, and therefore does not require consent. If the IRB deems this activity to be human subjects research, we will use a process of passive consent used in previous trainings in which a consent form is included in the participant materials and is referred to by the facilitator. Participants are given the opportunity to ask questions about the study at that point during the training.

T2 survey participants will read an electronic version of the informed consent form before beginning the survey and will be asked to select a checkbox to confirm their consent. The consent forms for this survey will include information about the study's purpose, that there is minimal risk involved, expected benefits, that survey responses are confidential, time expectations, and that they can stop the survey or not answer any question at any time. The form will also include contact information for the IRB and Principal Investigator in case participants have concerns or questions about the study.

Phone interviews. The consent procedures for the phone interview are identical to "Cognitive testing" with the following modifications for telephone interviews. The study team member will email the consent form in advance, and at the start of the call, they will review the consent form using the process described above and ask for verbal consent to participate before proceeding. We anticipate obtaining informed consent verbally will be appropriate given that participants are adults and the interviews will not cover sensitive information. In-depth interviews will be recorded and transcribed for accuracy. Audio recordings will be destroyed once they have been transcribed and any identifying information will be redacted from the transcriptions.

Web-based cost logs. The consent procedures for the web-based cost logs are identical to "Surveys with RCT providers" above.

Protection against risk

The informed consent process will ensure that participants are aware of the potential risks of participating in the study. If we need to provide informed consent for the pre- and post-trainings surveys, the participant consent form included with the training materials will also outline potential risks of participating in the study. We will also remind participants of their right to drop out of the study at any point without consequence.

We will not share information or data provided by study participants, nor will we share data accessed in the EHRs. All information will be kept confidential, and identification numbers will be used rather than the names of study participants. Survey vendors will provide us with de-identified datasets. All study materials will be kept in a locked file accessible only to key study personnel. All computer files will be stored on a secure, password-protected server and accessed on computers that are password-protected, with IRB-approved personnel having access. Audio recordings from the cognitive testing and phone interviews will be destroyed once data analysis is complete. Staff members must complete an online IRB research ethics training course and other confidentiality certification procedures upon employment. Policies regarding the confidential nature of the data collected, processed, and stored will be explained to all personnel, who must then sign a confidentiality agreement before being allowed access to the confidential information. In addition to this initial training, we will reinforce the need for careful and confidential handling of data at staff meetings.

Potential benefits

By taking part in this study, participants may increase their knowledge of the impact of financial incentives on HPV vaccine uptake and provider communication. Participants may also experience personal satisfaction of knowing they have contributed to a research project aimed at understanding interventions that may improve the provision of the HPV vaccine. They will also receive monetary compensation for the time they invest in the study.

Importance of knowledge to be gained

Given that the risk to participants is minimal and manageable, the knowledge to be gained has the potential to fill an important research gap. Specifically, scientific findings will provide evidence for the value of HPV communication interventions. Ultimately, this work will greatly improve public health by reducing the incidence of HPV-associated cancers.

MULTI-SITE STUDY: SINGLE IRB PLAN – Project 2

The proposed study “The impact of clinic-level financial incentives on HPV vaccine communication and uptake” will implement a single IRB plan. Under Aim 1, UNC will collect data from a web-based national survey subcontracted through WebMed (Activity 1a) and electronic health records (EHRs) at trials participating in the randomized clinical trial (Activity 1b). EHR data and data collected through phone and web-based surveys will also be used to address the Aims 2 and 3. The Project Lead, Dr. Trogdon, will provide oversight of the research at all participating sites.

UNC will exercise authority and responsibility on behalf of our research partners and submit a single IRB application for review of human subjects research, in accordance with NIH policy for research protocols that are carried out at more than one site in the United States. Our research partners have agreed to rely on the proposed single IRB. The Project Lead and Project Manager will communicate directly with our research partners to ensure all study related procedures and documents are approved by UNC’s IRB. Prior to initiating the study, we will sign an authorization/reliance agreement that will clarify the roles and responsibilities of the single IRB and participating sites with our research partners. UNC will maintain records of the authorization/reliance agreements and of the communication plan.

DATA AND SAFETY MONITORING PLAN – Project 2

The Project Lead, Dr. Trogdon, will be responsible for monitoring of the data and safety of the study participants. The proposed studies will be monitored by the UNC IRB. Any unanticipated problems, serious and unexpected adverse events, deviations, or protocol changes will be promptly reported by the Project Lead to the IRB and sponsor agency, if appropriate.

UNC Lineberger Comprehensive Cancer Care Center has an established Data Safety Monitoring Plan in place. The UNC Lineberger's Director and the Associate Director for Clinical Research have the overall responsibility for policy on the data and safety monitoring of clinical trials. The Data Safety Monitoring Subcommittee (DSMS) is the primary agent for the assuring data and safety monitoring. The DSMS meets monthly and has the following responsibilities: 1) Reviewing serious adverse event reports from all active clinical trials and assuring that these have also been reported to the IRB and other appropriate agencies; 2) Reviewing data and safety monitoring reports that are required of all active clinical trials; and 3) Recommending appropriate actions (closure, increased monitoring, etc.) to the IRB based on reviews of serious adverse events and periodic reports.

The DSMS findings, when necessary, will be sent to IRB and to the School of Medicine's Data and Safety Monitoring Board (SOM-DSMB). Following a joint session that will include the SOM-DSMB and a representative of the DSMS, a final report and recommendation regarding continuation or closure of a study will be made to the IRB, reflecting input from both groups. Final responsibility and authority for closing or amending such trials will rest with the IRB.

NIH grant applications require clinical trials to have a data safety and monitoring plan, but some do not require a data safety monitoring board (DSMB) or data monitoring committee (DMC). The NCI in 2001 stated, "there is no longer a blanket requirement for DSMB (DMC) in the cases of low-risk behavioral and nutritional trials... All such trials should include a data…monitoring plan, but this may or may not include a DSMB (DMC)". We believe that our research projects are low risk and do not meet the definition of clinical trials requiring a data safety monitoring board. However, to the ensure maximum protection of human subjects, we will submit our research project information to the SOM-DSMB listed above and allow them to make the final decision regarding risk to participants and whether our studies should receive their supervision. We do not anticipate that our studies will require ongoing supervision by the SOM-DSMB.

OVERALL STRUCTURE OF THE STUDY TEAM – Project 2

The organizational structure of the study team as it pertains to IMPACT Project 2's proposal is below. In addition to the scientists listed below, our team will also have access to biostatisticians with expertise in surveys and randomized clinical trials (RCTs) through the Data Core, who will consult on key design and analysis issues. Our multidisciplinary group has the expertise in health economics, behavioral economics, pediatrics, RCTs, implementation science, and health services research required for a successful study.

UNC Study Team

- *Justin Trogdon*, PhD, will be the Project Lead for the study and will take primary responsibility for the research and administration of this award. He will meet weekly with the full study team to ensure high quality research is conducted on time, within budget, and in compliance with the ethical requirements of the IRB. Dr. Trogdon will lead dissemination including manuscript preparation and conference presentations.
- *Michelle Hernandez*, MD, a Co-Investigator, will lead recruitment of clinics for the RCT and provide mentorship and clinical guidance to the study team. She will attend regular project meetings and contribute to dissemination of study findings.
- *Sarah Birken*, PhD, will advise on the implementation science measures and evaluation in Aim 3.
- *Kathleen Mottus*, the NCnet Project Manager, will assist Dr. Hernandez and the research team with the recruitment of clinics for the trial and will support clinic relationships and communication throughout its duration. She will regularly attend meetings.
- *Project Manager*, to be named, will be responsible for managing daily project operations for the study and will serve as the liaison between the Project Lead, project team, and study contractors. The Project Manager will also coordinate research activities, such as writing research protocols, managing the project budget, submitting IRB protocols and revisions, developing data collection instruments, managing data collection, and preparing reports, conference presentations, and manuscripts to disseminate findings. Dr. Trogdon will supervise the Project Manager.
- *Graduate Research Assistants*, to be named, will help the study team with carrying out administrative and research tasks including supporting data cleaning, data analysis, and interpretation of findings. The Research Assistants will also assist the study team in developing dissemination materials such as conference posters, presentations, and manuscripts. The Project Manager and Dr. Trogdon will jointly manage the Research Assistants.
- *Brian Cass*, the programmer, will assist with data cleaning and data analysis for the electronic health records data. In addition, he will work with the Connected Health Applications and Interventions (CHAI) Core on the development of the feedback report.
- *CHAI Core* will lead refinement of the peer comparison feedback report and qualitative research. CHAI Core has extensive experience in qualitative research graphic design, including designing personalized feedback via text, email, and app notification.

External consultants

- *Harsha Thirumurthy*, PhD, a consultant, will bring expertise regarding the design of the study intervention and clinical trial processes. He will attend regular project meetings and contribute to dissemination of study findings.

Clinical Advisory Board

- We will periodically consult the Clinical Advisory Board convened by the Intervention Core. The Board includes pediatricians, nurses, medical assistants, and other supporting providers and meets quarterly. We will bring questions about the clinical context for Announcement Approach Training workshops and financial incentives.

Section 4 - Protocol Synopsis (Study 1)

4.1. Study Design

4.1.a. Detailed Description

Recruitment: Clinics will be recruited from NCnet, a practice-based research network at UNC. To be eligible to participate, clinics must meet the following inclusion criteria: 1) specialize in pediatric or family medicine, 2) have 50 or more patients aged 11 and 12 years in the previous two years, and 3) have at least 2 HPV vaccine provider who provided HPV vaccine in the previous two years. Clinics will be ineligible for the RCT if they had taken part in Announcement Approach Training (AAT) in the previous six months or planned to do so over the next six months, already have financial incentives specifically for HPV vaccination, or are already meeting the goal of 80% up-to-date on the HEDIS measure. Randomization: After recruitment, clinics will be randomly assigned to one of two arms. Clinics in the first arm will receive AAT (control). Clinics in the second arm will receive the same AAT and a financial incentive via commitment contract tied to clinic-level improvement in HPV vaccine coverage (intervention). Clinics in the control arm will be wait listed to transition to receive the intervention after the end of the RCT to increase acceptance within healthcare systems and to avoid negative reactions in the control clinics. Clinics will be blinded to their assigned arm at recruitment. Randomization will be conducted by a biostatistician in the Data Core not affiliated with this trial. Clinics will be assigned in a 1:1 proportion to the arms, stratified by the rurality of patients served and baseline HPV vaccination coverage rates to ensure balance in these dimensions across arms. Detailed description of intervention: Announcement Approach training (AAT)Clinics in both arms will receive AAT. The AAT instructs providers to use a presumptive recommendation, in which the provider announces the vaccines the child is due for, assuming the family is ready to vaccinate. AAT is one hour, conducted in clinic and provides continuing medical education credit for attendees. Financial Incentives Clinics in the intervention arm will be eligible to receive clinic-level financial incentives if they meet pre-determined targets for HPV vaccination coverage. We propose three sizes of incentives for each tiered goal met by the clinic. The clinic-level incentives will be scaled to equal $1000 per provider, but aggregated and paid to clinic, for reaching highest tier, an absolute goal of 80% of patients meeting the HEDIS up-to-date measure. To keep incentives salient for clinics well below 80%, we will provide smaller bonuses for improvements relative to baseline. These levels were supported as salient by interviews with providers and clinic managers in the pilot phase. Finally, providers in the intervention arm will receive monthly, automated provider feedback of each providers' HPV vaccination rates relative to other providers in the clinic.

4.1.b. Primary Purpose: Prevention

4.1.c. Interventions

Type	Name	Description
Other	AAT and clinic-level financial incentives (intervention)	The Announcement Approach Training (AAT) instructs providers to use a presumptive recommendation, in which the provider announces the vaccines the child is due for, assuming the family is ready to vaccinate. AAT is one hour, conducted in clinic and provides continuing medical education credit for attendees. Providers in the intervention arm will also receive monthly, automated provider feedback of each providers' HPV coverage relative to other providers in the clinic. Clinics in the intervention arm will also be eligible to receive clinic-level financial incentives if they meet pre-determined targets for HPV vaccination coverage. The clinic-level incentives will be scaled to equal $1000 per provider, but aggregated and paid to clinic, for reaching highest tier, an absolute goal of 80% of patients meeting the HEDIS up-to-date measure. To keep incentives salient for clinics well below 80%, we will provide smaller bonuses for improvements relative to baseline.
Other	AAT (control)	The Announcement Approach Training (AAT) instructs providers to use a presumptive recommendation, in which the provider announces the vaccines the child is due for, assuming the family is ready to vaccinate. AAT is one hour, conducted in clinic and provides continuing medical education credit for attendees.

4.1.d. Study Phase: N/A

Is this an NIH-defined Phase III Clinical Trial? ❍ Yes ● No

4.1.e. Intervention Model: Parallel

4.1.f. Masking: ○ Yes ● No

❑ Participant ❑ Care Provider ❑ Investigator ❑ Outcomes Assessor

4.1.g. Allocation: Randomized

4.2. Outcome Measures

Type	Name	Time Frame	Brief Description
Primary	HPV completion rate (HEDIS)	0 months (baseline), 6 months (preliminary), 12 months (post-intervention), and 18 months (long-run)	The primary outcome measure will be HPV vaccine completion rate as defined by current HEDIS measures (i.e., among adolescents who turned 13 in the prior 12 months) assessed at the provider and clinic levels.
Secondary	HPV vaccine initiation rate (11-12 year old patients)	0 months (baseline), 6 months (preliminary), 12 months (post-intervention), and 18 months (long-run)	Proportion of patients who turned 11 and 12 in the prior 12 months who received at least one dose of HPV vaccine at the provider and clinic levels.
Secondary	HPV vaccine initiation rate (13-17 year old patients)	0 months (baseline), 6 months (preliminary), 12 months (post-intervention), and 18 months (long-run)	Proportion of patients who turned 13 to 17 in the prior 12 months who received at least one dose of HPV vaccine at the provider and clinic levels.
Other	Use of presumptive announcements	0 months (baseline) and 12 months (post-intervention)	Provider survey: When I first talk about HPV vaccine, I use language that assumes parents are ready to vaccinate.
Other	Attitudes	0 months (baseline), immediately following AAT, 12 months (post-intervention)	Provider survey: It is important to me that my patients get a recommendation for HPV vaccine before age 13.
Other	Social norms	0 months (baseline), immediately following AAT, 12 months (post-intervention)	Provider survey: It is the norm for our team to routinely recommend HPV vaccine for patients before age 13.
Other	Perceived behavioral control	0 months (baseline), immediately following AAT, 12 months (post-intervention)	Provider survey: I feel confident our team can recommend HPV vaccine effectively for our adolescent patients.
Other	Intention to recommend	0 months (baseline), immediately following AAT, 12 months (post-intervention)	Provider survey: I intend to make sure all patients get an HPV vaccine recommendation before they turn 13.
Other	Acceptability	0 months (baseline), immediately following AAT, 12 months (post-intervention)	Provider survey: satisfaction with the intervention
Other	Adoption	0 months (baseline) and 12 months (post-intervention)	Provider survey: use of the announcement approach
Other	Appropriateness	0 months (baseline), immediately following AAT, 12 months (post-intervention)	Provider survey: relevance of AAT and financial incentives in provider's clinic
Other	Cost	12 months (post-intervention)	The cost per clinic to deliver and use interventions
Other	Feasibility	0 months (baseline), immediately following AAT, 12 months (post-intervention)	Provider survey: ability to facilitate AAT and use AA and financial incentives

Other	Reach	0 months (baseline), immediately following AAT, 12 months (post-intervention)	Attendance logs: number of providers attended AAT. Provider survey: use of announcement approach for most patients
Other	Sustainability	12 months (post-intervention)	Provider survey: plan to keep using AA/incentives
Other	Fidelity	immediately following AAT and 12 months (post-intervention)	Provider survey: whether interventions were delivered as intended and providers used all components of announcement approach
Secondary	HPV vaccine completion rate (11-12 year old patients)	0 months (baseline), 6 months (preliminary), 12 months (post-intervention), and 18 months (long-run)	Proportion of patients who turned 11 and 12 in the prior 12 months who received at two doses of HPV vaccine at the provider and clinic levels.
Secondary	HPV vaccine completion rate (13-17 year old patients)	0 months (baseline), 6 months (preliminary), 12 months (post-intervention), and 18 months (long-run)	Proportion of patients who turned 13 to 17 in the prior 12 months who received at two or three doses of HPV vaccine at the provider and clinic levels.

4.3. Statistical Design and Power — StatDesignPowerP2r1045595422.pdf

4.4. Subject Participation Duration — 12 months

4.5. Will the study use an FDA-regulated intervention? — ❍ Yes ● No

4.5.a. If yes, describe the availability of Investigational Product (IP) and Investigational New Drug (IND)/ Investigational Device Exemption (IDE) status

4.6. Is this an applicable clinical trial under FDAAA? — ❍ Yes ● No

4.7. Dissemination Plan — DissemPlanP2r1045595423.pdf

STATISTICAL DESIGN AND POWER – Project 2

Sample size and power

Aim 1, Activity 1a. National survey

We used a general approach to estimate the minimum sample size required to detect moderately small effects. Specifically, we estimated the sample size required to detect a 10% change in endorsement of a low-prevalence outcome between two groups of unequal size (i.e. 10% endorsement in group 1, containing 75% of the sample, and 20% endorsement in group 2, containing 25% of the sample). With an alpha of .05 and two-tailed tests, an effective sample size of 500 per healthcare professional type (e.g., physicians, nurse practitioners), for a total of 2,500 respondents, is required to obtain 80% power.

Aim 2, Activity 2b. Assess HPV vaccination uptake

Assuming 17 clinics in each arm, 112 13-year old patients per clinic not up-to-date on average, a 15 percentage point increase in the control arm (secular trend + AAT), and a intraclass correlation of 0.033 (author calculations from AAT studies), we will have 80% power to detect a minimum of an 8 percentage point difference in our primary outcome in two-sided tests at a 95% confidence level. This effect size is similar to that found in earlier studies of provider incentives for other vaccinations, some of which detected effect sizes up to 19 percentage points. We tested power varying several of our input assumptions (e.g., patients per clinic, secular trend, ICC). Our results were most sensitive to assumptions about ICC. For example, with an ICC=0.04, we would be powered to detect an effect size of 9 percentage points.

Analytic Plan

Aim 1, Activity 1a. National survey

We will describe the types of primary care team members (e.g., physicians, nurse practitioners) likely to have experience with financial incentives and behavioral nudges. We will estimate separate regression models with items for the research questions as the dependent variables. As clinics that primarily serve patients who live in rural areas are different from non-rural clinics in many dimensions that could affect their ability to respond to the incentives (e.g., lower electronic health record [EHR] adoption rates, patient mix), the explanatory variables will include provider demographics collected in the national survey (e.g., rurality of clinic). Regression models will use appropriate functional forms for each item scale (e.g., logit for 0/1 outcomes).

Aim 2, Activity 2b. Assess HPV vaccination uptake

Inferential analyses. We will consult with our biostatistician on implementation of planned analyses. The main analysis will be intent-to-treat, retaining outcomes for clinics that disenroll from the trial for any reason during the intervention. We will estimate a generalized estimating equation (GEE) model for HPV vaccination using patient-level data from the EHR (0=not up to date, 1=up to date). Using a sample of patients not yet up-to-date at baseline who visited the clinic during the study period, the GEE model will account for patients clustered by clinic. We will use a binomial link and logit family. The main effect will be an indicator for intervention arm (at the clinic level). The coefficient represents the difference in the log odds of HPV vaccination at follow-up across the intervention and control arms. We will also adjust for the following baseline covariates: sex mix of patients, mix of patients residing in rural and non-rural areas, rural/non-rural location of the clinic, total number of patients ages 11-12 and 13-17, payer mix, number of providers, history of HPV quality improvement activities, ownership structure, and patient-centered medical home status. This analysis will provide an estimate of the effect of financial incentives on HPV vaccination rates. The secondary objectives of the Aim 2 analysis will be to test the comparative effectiveness of our intervention for other outcomes. We will repeat these analyses separately for each time point (6-, 12-, and 18-month follow up) and HPV vaccine outcome (HPV initiation ages 11-12 and 13-17 and HPV completion ages 11-12 and 13-17). When initiation is the dependent variable, the sample will include patient not yet vaccinated who visited the clinic during the study period.

Exploratory analyses. Several clinic characteristics could moderate the effect of the intervention. First, clinics that primarily serve patients who live in rural areas are different from clinics that primarily serve patients who live in urban areas in many dimensions that could affect their ability to respond to information provided in the feedback and the financial incentives. *Project 4 will provide valuable information from their first aim in the*

development phase of our project about key differences in rural and urban clinics with respect to HPV vaccination. Second, clinics with higher baseline HPV vaccination rates have less room to improve. Conversely, clinics with higher baseline rates (but not yet at target) may have higher capability to implement quality improvement initiatives. Finally, the interventions can differ in their impact based on the number of providers in the clinic. Providers in smaller clinics may find it easier to cooperate, harder to "free ride" on others, and to share information and tactics. To test for moderating effects of the interventions, we will repeat the GEE models described above adding interactions of the intervention arm variable with each of the following clinic-level variables: urban/rural mix of patients, baseline HPV rates, number of providers, and sex as a biological variable.

Aim 2, Activity 2c. Examine change in provider cognitions and behavior

We hypothesize that the addition of financial incentives to AAT will improve cognitions and behavior relative to AAT alone. The proposed mechanism is that financial incentives improve *cognitions* through changing attitudes, establishing new social norms, and increasing intentions to recommend, which will change HPV vaccine recommendation *behavior*. We will estimate two-level (provider and clinic) generalized linear mixed-level regression models with a log link and Poisson family. The main effects will be an indicator for time (pre vs post), an indicator for intervention arm (at the clinic level) and an interaction of time and intervention arm. Models will include random effects for clinics and will adjust for baseline covariates listed above.

Aim 3, Activity 3a. Assess cost per additional adolescent initiating the HPV vaccine

We will calculate mean, median, and standard deviation for cost per arm per clinic and separately for fixed and variable cost per arm per clinic. We will use t-tests to compare mean costs per clinic between intervention arms. We will then calculate the difference in mean costs between intervention arms and divide by the difference in adolescents ages 11-12 initiating the HPV vaccine to estimate cost per additional initiated due to the intervention. In secondary analyses, we will examine potential economies of scale by plotting average cost per clinic against clinic size. The cost data will be shared with Project 4 using standardized tables developed by the Intervention Core and utilized by Projects 1-3.

Aim 3, Activity 3b. Examine other implementation outcomes

This analysis will compare trial arms on implementation outcomes. We hypothesize that financial incentives will be associated with favorable implementation outcomes in response to having money at stake. We will use t-tests to compare trial arms on quantitative implementation outcomes. We will also repeat the analyses from Activity 2c with the quantitative implementation outcome measures as the dependent variable in separate models. For qualitative data, we will use the analytic methods described in Activity 3c, using a priori codes guided by the Proctor framework. We will integrate quantitative and qualitative results using a joint data display.

Aim 3, Activity 3c. Characterize determinants of AAT and financial incentives implementation and strategies for improving HPV vaccination that providers and clinics use in response to financial incentives

Qualitative research experts from CHAI core will use a coding-based thematic analytic approach that identifies main themes within and across the in-depth interviews. We will create a common codebook with coding categories derived a priori from Expert Recommendations for Implementing Change and the Consolidated Framework for Implementation Research. We will upload transcripts into a qualitative software management tool (i.e., ATLAS.ti) and at least two team members will independently read and deductively code each transcript. The team will iteratively meet to review the results of the coding and reconcile any discrepancies until they reach consensus. The coding team will generate summary reports of each code across interviews, assessing the degree to which the code emerged in the data. We will generate a key summary report that summarizes each code across the interviews and highlight the key themes with direct participant quotes.

DISSEMINATION PLAN – Project 2

A key dissemination activity for Project 2 will be to create an intervention module for the AAT Intervention Package for healthcare systems. The module will describe best strategies for financial incentives for HPV vaccination to a package of interventions. The Intervention Core and Administrative Core will lead efforts to disseminate the Package.

For Aims 1-3, we will publish our findings in peer-reviewed journals, submit docket responses, and present at meetings and national conferences, such as AcademyHealth Annual Research Meeting, American Society of Health Economists, and International Health Economics Association World Congress. As appropriate, we will update materials on hpvIQ.org for others to use. We will produce press releases and other communications to document and share our research findings with the scientific community as well as other key stakeholders and advocates. Dissemination of scientific findings will help advance HPV vaccine provision efforts and reduce the incidence of HPV-associated cancers.

Specific to the Aim 2 RCT, we will register the trial with ClinicalTrials.gov prior to enrollment of the first study participant, and we will submit results and other required information to ClinicalTrials.gov within one year of the conclusion of the study. We will include text in the informed consent information for this study that states that the results of the trial will be available on ClinicalTrials.gov. We will follow the UNC Gillings School of Global Public Health procedures for ensuring the clinical trials registration and results reporting are done in compliance with policy requirements.

Delayed Onset Studies

Delayed Onset Study#	Study Title	Anticipated Clinical Trial?	Justification
The form does not have any delayed onset studies			

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Perelman School of Medicine
University of Pennsylvania

Harsha Thirumurthy, Ph.D.
Associate Professor
Department of Medical Ethics & Health Policy

Associate Director
Center for Health Incentives and Behavioral Economics

August 10, 2020

Noel T. Brewer, PhD
Department of Health Behavior
Gillings School of Global Public Health
University of North Carolina
325 Rosenau Hall CB7440
Chapel Hill, NC 27599

Dear Dr. Brewer:

I am pleased to accept your invitation to collaborate with your research team on your NCI P01 proposal "Improving Provider Announcement Communication Training (IMPACT) Program Project," PAR-20-077. I am very excited to support innovative research regarding how behavioral economic principles can inform efforts to improve provider communication and provision of the HPV vaccine as part of the Project 2 Research Project titled "The impact of clinic-level financial incentives on HPV vaccine communication and uptake" led by Dr. Justin Trogdon.

My research has focused on evaluating interventions that achieve changes in behaviors, including research on disease prevention and child health. Given my expertise in conducting randomized trials of behavioral economic interventions, such as financial incentives, I will advise your research team on scientific issues related to the design of study interventions and trial processes. I will review protocols and preliminary data, provide feedback to the team by email and will attend approximately 12 teleconference meetings per year of the grant. I agree to be paid [$] ([$] per year) for serving approximately [ ] hours per year as an expert advisor.

I eagerly look forward to working with your group on this valuable and innovative research project.

Sincerely,

Harsha Thirumurthy, PhD

423 Guardian Drive, 1111 Blockley Hall | Philadelphia, PA 19104 | Phone: 215-746-0410 | Fax: 215-573-3036 | E-mail: hthirumu@upenn.edu

THE UNIVERSITY of NORTH CAROLINA at CHAPEL HILL

CHAI CORE
Communication for Health Applications and Interventions

GILLINGS SCHOOL OF GLOBAL PUBLIC HEALTH
DEPARTMENT OF NUTRITION
LINEBERGER COMPREHENSIVE CANCER CENTER
CHAPEL HILL NC 27599-7440 T 919.966.7456 dtate@unc.edu

DEBORAH F. TATE, PH.D.
Professor
Faculty Director, CHAI Core

August 5, 2020

Noel T. Brewer, PhD
Department of Health Behavior
Gillings School of Global Public Health
University of North Carolina
325 Rosenau Hall CB7440
Chapel Hill, NC 27599

Dear Dr. Brewer:

The Communication for Health Applications and Interventions (CHAI) Core is pleased to work with you in the NCI P01 proposal "Improving Provider Announcement Communication Training (IMPACT) Program Project," PAR-20-077. As part of the Project 2 Research Project titled *Impact of financial incentives to HPV vaccine providers,* and led by Dr. Justin Trogdon, we will provide graphic design, qualitative user testing, intervention consultation services, related technical support, and conduct qualitative interviews to address factors influencing HPV vaccination rates.

For the proposed work, CHAI Core will be responsible for the creation of logo and color palette, an e-mail template, a data structure, and a separate HTML template. We will also provide ongoing maintenance of these items through the life of the project and needed technical support to the research team. In Years 3 and 4, we will also conduct qualitative interviews with providers. We are excited about your work and are well positioned to fully assist your research team with this project.

CHAI Core (www.chaicore.com), a NIH-funded core facility, has been collaborating with researchers since 2000 to develop and conduct behavioral intervention research, qualitative research and e-health and m-health intervention development. The mission of CHAI Core is to apply state-of-the-art resources and techniques to the development of high quality and rigorously evaluated behavioral science interventions aimed at promoting health and preventing disease in populations at risk. The Core fills a critical gap in existing resources for researchers by facilitating access to and translation of science-based research relevant to communication, health behavior theory, intervention design, and evaluation into strategies and tools that can produce more effective interventions.

CHAI Core has developed a highly collaborative team who are available to provide consultation and assistance with grant submissions, methodology, and intervention development. Specifically, CHAI Core offers consulting and services in behavior change intervention and decision-aid websites and applications; logos and brochures, recruitment and presentation materials; user research, such as usability testing, qualitative interviews

Funding provided by the Gillings School of Global Public Health Nutrition Obesity Research Center (NIDDK: P30 DK56350) and the Lineberger Comprehensive Cancer Center (NCI: P30 CA16086)

and focus groups; tailored messaging and feedback; and responsive design for mobile technology. Our infrastructure and personnel are funded through the Gillings School of Global Public Health Nutrition Obesity Research Center (NIDDK funded; P30 DK56350) and the Lineberger Comprehensive Cancer Center (NCI funded; P30-CA16086).

As director of the Core, I will bring my substantial expertise in technology-based interventions to your project. I have been continuously funded by the NIH either as PI or Co-I on behavioral intervention work involving web and/or mobile technology since 2001 and published some of the earliest RCTs using the web to deliver behavior therapy in top tiered journals such as JAMA and NEJM.

We look forward to working with you on this important and interesting research study.

Sincerely,

Deborah Tate

Deborah F. Tate, PhD
Faculty Director, UNC CHAI Core
Professor,
Department of Health Behavior and Department of Nutrition
Gillings School of Global Public Health

The University of North Carolina at Chapel Hill
Practice Based Research Network

Co-Directors:
Katrina Donahue, MD, MPH
Jacquie Halladay, MD, MPH

Pediatric and Adolescent Director:
Michelle Hernandez, MD

August 13, 2020

Noel T. Brewer, PhD
Department of Health Behavior
Gillings School of Global Public Health
University of North Carolina
325 Rosenau Hall CB 7440
Chapel Hill, NC 27599

Dear Dr. Brewer:

On behalf of NCnet, We are pleased to accept your invitation to serve as your primary clinical partner for your NCI grant proposal "Improving Provider Announcement Communication Training (IMPACT) Program Project," PAR-20-077. We are very excited to support innovative research regarding how behavioral economic principles can inform efforts to improve provider communication and provision of the HPV vaccine.

The NCnet practice-based research network has family medicine and pediatric clinics throughout the state of North Carolina and our team has extensive experience working with investigators and clinics to conduct randomized trials. NCnet was integral in reaching the recruitment goals for the pilot data collection. We successfully recruited providers and practice managers from NCnet practices for 30-45-minute interviews about financial incentives in the context of adolescent HPV vaccinations.

For the proposed project "Impact of financial incentives to HPV vaccine providers," NCnet will assist your research team with the recruitment of clinics for the trial and will support clinic relationships and communication throughout its duration. Our Pediatric and Adolescent Director will communicate with your team by email and will attend approximately 12 teleconference meetings per year of the grant. We understand the Pediatric and Adolescent Director will have [%] salary support in the first and final years of the grant and [%] in years two through four to dedicate for these activities. In addition, our program assistant has [%] salary support in years one through four and [%] in the final year.

We eagerly look forward to working with your group on this valuable and innovative research project.

Sincerely yours,

Katrina Donahue, MD, MPH
Professor of Family Medicine

Jacquie Halladay, MD, MPH
Professor of Family Medicine

UNC PHYSICIANS NETWORK
UNC HEALTH CARE

July 13, 2020

Noel T. Brewer, PhD
Professor of Health Behavior
Gillings School of Global Public Health
University of North Carolina
Campus Box 7440
Chapel Hill, NC 27599

Dear Dr. Brewer:

On behalf of the University of North Carolina Physicians Network, I am pleased to offer our support in recruiting practices for your NCI grant proposal "Improving Provider Announcement Communication Training (IMPACT) Program Project," PAR-20-077. We are very excited to support innovative research regarding how behavioral economic principles can inform efforts to improve provider communication and provision of the HPV vaccine.

I am the President and Chief Executive Officer of the University of North Carolina Physicians Network and Chair of the Primary Care Collaborative of UNC Health. The more than 100 practices and over 300 providers of UNC Physicians Network provide a full range of primary care and specialty services to people in 14 counties throughout North Carolina. As an Internal Medicine-Pediatrics physician who practices primary care, I believe in the importance of HPV vaccination, as it offers protection to adolescents and young adults from future HPV-related cancers. In turn, I support the efforts of the Center and its proposed research studies, which prove essential in achieving this goal of increased HPV vaccination uptake.

For the proposed project "Impact of financial incentives to HPV vaccine providers," UNC Physician Network practices will be encouraged to participate in the randomized trial. As President and Chief Executive Officer, I will communicate the benefits of the trial to our practices and support Drs. Trogdon (Project Lead) and Michelle Hernandez (Pediatric and Adolescent Director of NCnet) with their recruitment.

I eagerly look forward to working with your group on this valuable and innovative research project.

Sincerely,

Lynne Fiscus, MD, MPH
President and Chief Executive Officer
University of North Carolina Physicians Network

UNC Physicians Network
2000 Perimeter Park Drive, Suite 200
Morrisville, NC 27560
(984) 215-4000

uncpn.com

RESOURCE SHARING PLAN – Project 2

We agree with the NIH principle that data sharing is essential for expedited translation of research results into knowledge, products, and procedures to improve human health. All projects and cores will follow the same procedures. We will make data collection instruments available online for public use after data collection and analyses are complete. Leads of the research projects and the Data Core will oversee sharing of de-identified data produced by the Program Project. Dr. Brewer will oversee this process.

One of the key products of the planned research is a shared national primary care team survey conducted with the Data Core who will be the primary contact for requests. The Data Core will contact the Project Lead for approval to share the de-identified dataset with external requestors. For the vaccine outcomes for the trial, the data are owned by the health care system partner. For the provider survey as part of the trial, we will follow the Program's standard procedure for sharing the de-identified dataset and codebooks. See the Program's Overall Resource Sharing Plan for more details. Interview data will not be shared because it would be difficult to protect participants' identities even if we were to remove all identifiers.

OMB Number: 4040-0010
Expiration Date: 12/31/2022

APPLICATION FOR FEDERAL ASSISTANCE

SF 424 (R&R)

5. APPLICANT INFORMATION **Organizational DUNS*:** 608195277

Legal Name*:	The University of North Carolina at Chapel Hill
Department:	Office of Sponsored Research
Division:	Research
Street1*:	104 Airport Drive
Street2:	Campus Box 1350
City*:	Chapel Hill
County:	Orange
State*:	NC: North Carolina
Province:	
Country*:	USA: UNITED STATES
ZIP / Postal Code*:	27599-1350

Person to be contacted on matters involving this application

Prefix:	First Name*:	Middle Name:	Last Name*:	Suffix:
	Andrea		Cogdill	

Position/Title:	Grants Analyst
Street1*:	130 Mason Farm Road
Street2:	CB 9525, Bioinformatics Bldg.
City*:	Chapel Hill
County:	Orange
State*:	NC: North Carolina
Province:	
Country*:	USA: UNITED STATES
ZIP / Postal Code*:	27599-9525

Phone Number*: (919) 962-3950 Fax Number: (919) 843-7094 Email: grants@unc.edu

7. TYPE OF APPLICANT* H: Public/State Controlled Institution of Higher Education

Other (Specify):

Small Business Organization Type ❍ Women Owned ❍ Socially and Economically Disadvantaged

11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT*

IMPACT Project 3 – Engaging clinical champions to improve HPV vaccine communication and uptake in healthcare systems

12. PROPOSED PROJECT

Start Date*	Ending Date*
07/01/2021	06/30/2026

OMB Number: 4040-0010
Expiration Date: 12/31/2022

Project/Performance Site Location(s)

Project/Performance Site Primary Location

❍ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name:	The University of North Carolina at Chapel Hill
Duns Number:	608195277
Street1*:	104 Airport Drive
Street2:	Campus Box 1350
City*:	Chapel Hill
County:	Orange
State*:	NC: North Carolina
Province:	
Country*:	USA: UNITED STATES
Zip / Postal Code*:	27599-1350
Project/Performance Site Congressional District*:	NC-004

Project/Performance Site Location 1

❍ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name:	The Board of Regents of the University of Wisconsin System
DUNS Number:	161202122
Street1*:	Department of Pediatrics
Street2:	21 N. Park Street, Suite 6401
City*:	Madison
County:	
State*:	WI: Wisconsin
Province:	
Country*:	USA: UNITED STATES
Zip / Postal Code*:	53715-1218
Project/Performance Site Congressional District*:	WI-002

Additional Location(s) File Name:

Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED Other Project Information

1. Are Human Subjects Involved?* ● **Yes** ○ **No**

1.a. If YES to Human Subjects

Is the Project Exempt from Federal regulations? ○ Yes ● No

If YES, check appropriate exemption number: _ 1 _ 2 _ 3 _ 4 _ 5 _ 6 _ 7 _ 8

If NO, is the IRB review Pending? ○ **Yes** ○ **No**

IRB Approval Date:

Human Subject Assurance Number 00004801

2. Are Vertebrate Animals Used?* ○ **Yes** ● **No**

2.a. If YES to Vertebrate Animals

Is the IACUC review Pending? ○ Yes ○ No

IACUC Approval Date:

Animal Welfare Assurance Number

3. Is proprietary/privileged information included in the application?* ○ **Yes** ● **No**

4.a. Does this project have an actual or potential impact - positive or negative - on the environment?* ○ **Yes** ● **No**

4.b. If yes, please explain:

4.c. If this project has an actual or potential impact on the environment, has an exemption been authorized or an environmental assessment (EA) or environmental impact statement (EIS) been performed? ○ Yes ○ No

4.d. If yes, please explain:

5. Is the research performance site designated, or eligible to be designated, as a historic place?* ○ **Yes** ● **No**

5.a. If yes, please explain:

6. Does this project involve activities outside the United States or partnership with international collaborators?* ○ **Yes** ● **No**

6.a. If yes, identify countries:

6.b. Optional Explanation:

	Filename
7. Project Summary/Abstract*	AbstractP3r1045594839.pdf
8. Project Narrative*	NarrativeP3r1045594840.pdf
9. Bibliography & References Cited	ReferencesP3r1045594841.pdf
10.Facilities & Other Resources	FacilitiesP3r1045594842.pdf
11.Equipment	EquipmentP3r1045594843.pdf
12. Other Attachments	AcronymsP3r1045594844.pdf

Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

ABSTRACT – Project 3

Widespread HPV vaccination could prevent most HPV cancers, but uptake among US adolescents remains far below national goals. To increase uptake, we developed Announcement Approach Training (AAT). AAT is a 1-hour communication workshop in which our physician facilitators train primary care teams to address the most critical barrier to HPV vaccination: infrequent and ineffective recommendations. AAT is effective for increasing HPV vaccine uptake among adolescents and is certified as an NCI Research-Tested Intervention Program. One of the most promising opportunities for scaling up AAT is to implement the intervention in healthcare systems, where most US pediatricians and family physicians now work. However, new approaches to delivering AAT will be needed to bring the intervention to scale effectively in these settings. Thus, as part of the P01 Program Project, "Improving Provider Announcement Communication Training (IMPACT)," Project 3 will enhance AAT to train systems' own clinical champions to deliver AAT, thereby building capacity for HPV vaccine communication training. **In Aim 1, we will identify opportunities to engage clinical champions in delivering AAT within their own healthcare systems.** Working with 6 partnering healthcare systems, we will interview 24 champions to understand: anticipated barriers and facilitators to AAT delivery; opportunities to extend AAT activities to increase reach and sustainability; and preferences for receiving training on how to deliver AAT. **In Aim 2, we will compare the impact of Champion AAT to Traditional AAT on HPV vaccine uptake and communication.** Using Aim 1 findings, we will adapt our existing intervention package to train champions to deliver AAT to clinics in their own systems. In a 2-arm non-inferiority trial, we will randomize 40 clinics in our 6 systems to receive Champion AAT or Traditional AAT. We will compare interventions on the primary outcome of HPV vaccine initiation, among adolescents ages 11-12, at 12-month follow-up. We hypothesize that Champion AAT will be non-inferior to (i.e., as effective as) Traditional AAT. We will also compare our interventions on intermediate outcomes, including changes in workshop participants' communication, to identify mechanisms that may explain improvements in HPV vaccine uptake. **In Aim 3, we will generate guidance to help healthcare systems compare and implement Champion AAT and Traditional AAT.** We will compare our interventions on implementation measures to understand whether Champion AAT offers advantages, such as higher reach to primary care professionals, compared to Traditional AAT. Lastly, to integrate Project 3 with other IMPACT projects, we will share data to support cost-effectiveness modeling in Project 4 and contribute the Champion AAT module to the P01-wide AAT Intervention Package. In this way, we will prepare our highly scalable intervention for national dissemination. Project 3 addresses the **IMPACT Program Project theme** by engaging clinical champions to build capacity for HPV vaccine communication interventions among primary care teams in healthcare systems.

NARRATIVE – Project 3

The proposed trial will test a new way to help healthcare systems improve HPV vaccination. We will train clinical champions to deliver HPV vaccine communication workshops to primary care teams in their own systems. We expect that this champion-delivered intervention will improve HPV vaccination and build capacity for communication training in healthcare systems.

FACILITIES AND OTHER RESOURCES – Project 3

Refer to Overall Component for both Project 3 and the University of Wisconsin Facilities and Other Resources.

EQUIPMENT – Project 3

None.

LIST OF ACRONYMS – Project 3

AA	Announcement Approach
AAT	Announcement Approach Training
CFIR	Consolidated Framework for Implementation Research
Covid-19	Coronavirus disease 2019
CE	Continuing education
EHR	Electronic health record
HEDIS	Healthcare Effectiveness Data and Information Set
HPV	Human papillomavirus
ICC	Intraclass correlation
IMPACT	Improving Provider Announcement Communication Training
NCI	National Cancer Institute
PROKids	Program of Research on Outcomes for Kids
RA	Research assistant
RCT	Randomized clinical trial
RUCC	Rural-urban continuum code
TPB	Theory of Planned Behavior
UNC	University of North Carolina
US	United States
WI	Wisconsin
WV	West Virginia
WVPBRN	West Virginia Practice-Based Research Network

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED Senior/Key Person Profile (Expanded)

PROFILE - Project Director/Principal Investigator

Prefix: First Name*: Melissa Middle Name Last Name*: Gilkey Suffix:

Position/Title*: Associate Professor
Organization Name*: The University of North Carolina at Chapel Hill
Department: Health Behavior
Division: Gillings Sch. of Public Hlth
Street1*: 317 Rosenau Hall
Street2: CB 7440
City*: Chapel Hill
County: Orange
State*: NC: North Carolina
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 27599-7440

Phone Number*: (919) 966-8650 Fax Number:

E-Mail*: gilkey@email.unc.edu

Credential, e.g., agency login: eRA COMMONS USER NAME

Project Role*: Other (Specify) Other Project Role Category: Project Lead

Degree Type: PhD Degree Year: 2011

Attach Biographical Sketch*: File Name: BioGilkeyP3rV21045663958.pdf

Attach Current & Pending Support: File Name:

Tracking Number: GRANT13205496 Funding Opportunity Number: PAR-20-077 . Received Date: 2020-09-18T11:41:16.000-04:00

PROFILE - Senior/Key Person

Prefix: First Name*: Sarah Middle Name A. Last Name*: Birken Suffix:

Position/Title*: Associate Professor
Organization Name*: Wake Forest University Health Science
Department: Implementation Science
Division: School of Medicine
Street1*: Medical Center Boulevard
Street2:
City*: Winston-Salem
County: Forsyth
State*: NC: North Carolina
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 27157-0000

Phone Number*: (336) 713-4231 Fax Number:

E-Mail*: sbirken@wakehealth.edu

Credential, e.g., agency login: eRA COMMONS USER NAME

Project Role*: Co-Investigator Other Project Role Category:

Degree Type: PhD Degree Year: 2011

Attach Biographical Sketch*: File Name:

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Elizabeth Middle Name D. Last Name*: Cox Suffix: MD, PhD

Position/Title*: Professor
Organization Name*: The Board of Regents of the University of Wisconsin System
Department: Pediatrics
Division: Population Health Sciences
Street1*: H4 / 442 Clinical Science Center
Street2: 600 Highland Avenue
City*: Madison
County:
State*: WI: Wisconsin
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 53792-4108

Phone Number*: (608) 263-9104 Fax Number:

E-Mail*: ecox@wisc.edu

Credential, e.g., agency login: eRA COMMONS USER NAME

Project Role*: Co-Investigator Other Project Role Category:

Degree Type: MD Degree Year: 1991

Attach Biographical Sketch*: File Name: BioCoxP3r1045594862.pdf

Attach Current & Pending Support: File Name:

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 1

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2021 **End Date*:** 06-30-2022 **Budget Period: 1**

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.		Melissa		Gilkey		Project Lead	CAL. MONTHS, INST. BASE SALARY				41,928.00	13,134.00	55,062.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **55,062.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
1	Post Doctoral Associates	12			51,504.00	9,696.00	61,200.00
1	Graduate Students	2.4			5,112.00	1,313.00	6,425.00
	Undergraduate Students						
	Secretarial/Clerical						
1	Project Manager	9			52,530.00	20,111.00	72,641.00
1	Biostatistician	0.6			5,007.00	1,622.00	6,629.00
2	AAT Facilitators	0.96			11,405.00	4,205.00	15,610.00
1	Research Assistant	1.44			5,623.00	2,237.00	7,860.00
7	**Total Number Other Personnel**					**Total Other Personnel**	**170,365.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**225,427.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 1

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2021 **End Date*:** 06-30-2022 **Budget Period: 1**

C. Equipment Description	
List items and dollar amount for each item exceeding $5,000	
Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	
Additional Equipment: File Name:	

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	4,500.00
2. Foreign Travel Costs	
Total Travel Cost	**4,500.00**

E. Participant/Trainee Support Costs	**Funds Requested ($)***
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant Trainee Support Costs**	

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 1

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2021 **End Date*:** 06-30-2022 **Budget Period: 1**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	7,550.00
2. Publication Costs	1,500.00
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	129,502.00
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8. Tuition	3,773.00
9. Other Costs	18,775.00
Total Other Direct Costs	**161,100.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**391,027.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. Organized Research_On Campus	55.5	282,752.00	156,927.00
		Total Indirect Costs	**156,927.00**

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number): DHHS, Darryl Mayes, 202-401-2808

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**547,954.00**

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	547,954.00

L. Budget Justification* File Name: BudgetJustificationP3rV21045663959.pdf

(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 2

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2022 **End Date*:** 06-30-2023 **Budget Period: 2**

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.		Melissa		Gilkey		Project Lead	CAL. MONTHS, INST. BASE SALARY				41,928.00	13,134.00	55,062.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **55,062.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
1	Graduate Students	0.91			1,943.00	499.00	2,442.00
	Undergraduate Students						
	Secretarial/Clerical						
1	Project Manager	9			52,530.00	20,111.00	72,641.00
2	AAT Facilitators	1.92			22,810.00	8,410.00	31,220.00
1	Research Assistant	1.2			4,686.00	1,864.00	6,550.00
5	**Total Number Other Personnel**					**Total Other Personnel**	**112,853.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**167,915.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 2

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2022 **End Date*:** 06-30-2023 **Budget Period: 2**

C. Equipment Description	
List items and dollar amount for each item exceeding $5,000	
Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	
Additional Equipment: File Name:	

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	13,000.00
2. Foreign Travel Costs	
Total Travel Cost	**13,000.00**

E. Participant/Trainee Support Costs	**Funds Requested ($)***
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant Trainee Support Costs**	

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 2

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2022 **End Date*:** 06-30-2023 **Budget Period: 2**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	3,550.00
2. Publication Costs	1,500.00
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	222,471.00
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8. Tuition	1,477.00
9. Other Costs	19,143.00
Total Other Direct Costs	**248,141.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**429,056.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. Organized Research_On Campus	55.5	205,108.00	113,835.00
		Total Indirect Costs	**113,835.00**

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number): DHHS, Darryl Mayes, 202-401-2808

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**542,891.00**

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	542,891.00

L. Budget Justification* File Name: BudgetJustificationP3rV21045663959.pdf

(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 3

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2023 **End Date*:** 06-30-2024 **Budget Period: 3**

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.		Melissa		Gilkey		Project Lead	CAL. MONTHS, INST. BASE SALARY				41,928.00	13,134.00	55,062.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **55,062.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
1	Project Manager	9			52,530.00	20,111.00	72,641.00
2	AAT Facilitators	1.92			22,810.00	8,410.00	31,220.00
1	Research Assistant	0.66			2,577.00	1,025.00	3,602.00
4	**Total Number Other Personnel**					**Total Other Personnel**	**107,463.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**162,525.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 3

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2023 **End Date*:** 06-30-2024 **Budget Period: 3**

C. Equipment Description	
List items and dollar amount for each item exceeding $5,000	
Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	
Additional Equipment: File Name:	

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	13,000.00
2. Foreign Travel Costs	
Total Travel Cost	**13,000.00**

E. Participant/Trainee Support Costs	**Funds Requested ($)***
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant Trainee Support Costs**	

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 3

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2023 **End Date*:** 06-30-2024 **Budget Period: 3**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	1,750.00
2. Publication Costs	1,500.00
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	222,471.00
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8. Other Costs	20,344.00
Total Other Direct Costs	**246,065.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**421,590.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. Organized Research_On Campus	55.5	199,119.00	110,511.00
		Total Indirect Costs	**110,511.00**

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number): DHHS, Darryl Mayes, 202-401-2808

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**532,101.00**

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	532,101.00

L. Budget Justification* File Name: BudgetJustificationP3rV21045663959.pdf

(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

Tracking Number: GRANT13205496 Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 4

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2024 **End Date*:** 06-30-2025 **Budget Period: 4**

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.		Melissa		Gilkey		Project Lead	CAL. MONTHS, INST. BASE SALARY				41,928.00	13,134.00	55,062.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **55,062.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
1	Post Doctoral Associates	6			25,752.00	4,848.00	30,600.00
1	Graduate Students	2.78			5,930.00	1,523.00	7,453.00
	Undergraduate Students						
	Secretarial/Clerical						
1	Project Manager	9			52,530.00	20,111.00	72,641.00
1	Biostatistician	1.8			15,021.00	4,866.00	19,887.00
1	Research Assistant	1.8			7,029.00	2,797.00	9,826.00
5	**Total Number Other Personnel**					**Total Other Personnel**	**140,407.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**195,469.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 4

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2024 **End Date*:** 06-30-2025 **Budget Period: 4**

C. Equipment Description	
List items and dollar amount for each item exceeding $5,000	
Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	
Additional Equipment: File Name:	

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	7,500.00
2. Foreign Travel Costs	
Total Travel Cost	**7,500.00**

E. Participant/Trainee Support Costs		**Funds Requested ($)***
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other:		
Number of Participants/Trainees	**Total Participant Trainee Support Costs**	

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 4

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2024 **End Date*:** 06-30-2025 **Budget Period: 4**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	6,300.00
2. Publication Costs	4,500.00
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	123,175.00
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8. Tuition	4,783.00
9. Other Costs	24,656.00
Total Other Direct Costs	**163,414.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**366,383.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. Organized Research_On Campus	55.5	238,425.00	132,326.00
		Total Indirect Costs	**132,326.00**

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number): DHHS, Darryl Mayes, 202-401-2808

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**498,709.00**

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	498,709.00

L. Budget Justification* File Name: BudgetJustificationP3rV21045663959.pdf

(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 5

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2025 **End Date*:** 06-30-2026 **Budget Period: 5**

A. Senior/Key Person

Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.	Melissa		Gilkey		Project Lead	CAL. MONTHS, INST. BASE SALARY				41,928.00	13,134.00	55,062.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **55,062.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
1	Post Doctoral Associates	9			38,628.00	7,272.00	45,900.00
1	Graduate Students	2.52			5,378.00	1,381.00	6,759.00
	Undergraduate Students						
	Secretarial/Clerical						
1	Project Manager	9			52,530.00	20,111.00	72,641.00
1	Biostatistician	1.8			15,021.00	4,866.00	19,887.00
1	Research Assistant	3			11,715.00	4,661.00	16,376.00
5	**Total Number Other Personnel**					**Total Other Personnel**	**161,563.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**216,625.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 5

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2025 **End Date*:** 06-30-2026 **Budget Period: 5**

C. Equipment Description	
List items and dollar amount for each item exceeding $5,000	
Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	
Additional Equipment: File Name:	

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	6,000.00
2. Foreign Travel Costs	
Total Travel Cost	**6,000.00**

E. Participant/Trainee Support Costs	**Funds Requested ($)***
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant Trainee Support Costs**	

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 5

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2025 **End Date*:** 06-30-2026 **Budget Period: 5**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	3,300.00
2. Publication Costs	4,500.00
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	72,191.00
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8. Tuition	4,468.00
9. Other Costs	23,270.00
Total Other Direct Costs	**107,729.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**330,354.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. Organized Research_On Campus	55.5	253,695.00	140,801.00
		Total Indirect Costs	**140,801.00**

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number): DHHS, Darryl Mayes, 202-401-2808

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**471,155.00**

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	471,155.00

L. Budget Justification* File Name: BudgetJustificationP3rV21045663959.pdf

(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

BUDGET JUSTIFICATION – Project 3

Key Personnel

Melissa Gilkey, PhD, Project Lead

Year 1	Year 2	Year 3	Year 4	Year 5
CAL. MONTHS				

Dr. Gilkey is Associate Professor in the Department of Health Behavior in the University of North Carolina at Chapel Hill (UNC-CH) Gillings School of Global Public Health. She will serve as the Project Lead (PL) for Project 3. Trained in public health and the social and behavioral sciences, Dr. Gilkey studies individual, interpersonal, and organizational approaches to improving the delivery of HPV vaccine in primary care. To conduct the proposed research, she will draw on her expertise in patient-provider communication and her experience conducting large-scale randomized clinical trials (RCTs) to evaluate interventions to improve HPV vaccination. This experience includes: 1) an RCT with 25 clinics that successfully engaged clinical champions to deliver HPV vaccine-related training; 2) an RCT with 91 clinics that used assessment and feedback to improve HPV vaccination; and 3) an ongoing RCT that has successfully recruited and intervened with >250 clinics to evaluate the impact of physician communication training and assessment and feedback on HPV vaccination. As Project Lead, Dr. Gilkey will have overall responsibility for the design and implementation of the research, as well as dissemination of findings. Specifically, she will have overall budgetary, administrative and scientific responsibility and will coordinate and implement activities essential to carrying out the research aims and achieving the project's goals. These activities include maintaining scientific integrity throughout the project, developing instruments and protocols, meeting with co-investigators, supervising project staff, overseeing data collection, and analyzing data. In conjunction with the study team, Dr. Gilkey will develop reports, papers, presentations, and other materials for dissemination.

Sarah A. Birken, PhD, Co-Investigator (CM, Years 1-5 charged to Intervention Core)
Dr. Birken is Associate Professor in the Department of Implementation Science in the Division of Health Sciences at Wake Forest University School of Medicine. Dr. Birken is an implementation scientist and health services researcher with over 15 years of experience in quality improvement, innovations in cancer care, and translating evidence-based interventions into practice. She has been the Principal Investigator or Co-Investigator on numerous grants that have examined the optimization of cancer care and preventive health services, especially for rural patients. Dr. Birken will work collaborate closely with the Project Lead, Melissa Gilkey, at the University of North Carolina and colleagues on Project 3. In Years 1-4 of the Program Project, Dr. Birken will consult on developing and carrying out strategies for effective implementation of intervention components and enhancing the Announcement Approach Training for use with clinical champions. Additionally, in all five years of the Program Project, Dr. Birken will coordinate the Clinical Advisory Board and will consult on harmonization of implementation measures across projects. Finally, in Years 4-5 of the Program Project, she will advise the team on how to meaningfully translate evidence from the research projects into tools that can be disseminated and implemented in a variety of settings. In Year 5, Dr. Birken will also contribute to manuscript preparation. The cost for her effort is kept administratively in the Intervention Core to simplify subcontracts to her home institution.

Other Personnel

Jennifer Heisler-MacKinnon, MPH, Project Manager

Year 1	Year 2	Year 3	Year 4	Year 5
CAL. MONTHS				

Ms. Heisler-MacKinnon will serve as the Project Manager on the proposed study. Ms. Heisler-MacKinnon will draw on her extensive experience managing large-scale, multi-site RCTs to improve HPV vaccine delivery. Specifically, working with Dr. Gilkey, she managed a study with 91 clinics across three states to evaluate the impact of assessment and feedback to increase HPV vaccination. She also manages an ongoing study that has recruited over 250 clinics across three states to evaluate the impact of physician communication and assessment and feedback on HPV vaccination. She will work closely with Dr. Gilkey to

ensure integrity and completion of intervention development, study protocol adherence, and data collection activities. She will manage the study processes in all years including developing study protocols and materials and implementation and standardization of procedures. Throughout the study she will be responsible for maintaining communication among all study team members, the sub-contractor, and vendors. She will also have day-to-day responsibility for the project's management, including budget tracking and monitoring, Institutional Review Board processes, and meeting organization.

TBN, Biostatistician

Year 1	Year 2	Year 3	Year 4	Year 5
0.6 CM	-	-	1.8 CM	1.8 CM

The TBN Biostatistician will be a master's level Principal Statistician in the Biostatistics and Survey Methods Core at the University of North Carolina Lineberger Comprehensive Cancer Center. (S)he will support the study by helping establish databases in Year 1. Additionally, the statistician will clean data, conduct analyses, and archive outcomes data in Years 4 and 5 of the study. (S)he will also assist with manuscript preparation in Years 4 and 5. The statistician will also work closely with the Data Core of the Program Project, which will provide other statistical support.

TBN, Two Announcement Approach Training (AAT) Facilitators, MD

Year 1	Year 2	Year 3	Year 4	Year 5
0.96 CM	1.92 CM	1.92 CM	-	-

The AAT Facilitators will be practicing primary care physicians (*i.e.*, pediatricians or family physicians). The AAT Facilitators will support the study by assisting with protocol development and pilot testing of the intervention in Years 1 and 2. They will also deliver the AAT workshops to primary care clinics participating in the "Traditional AAT" arm of our RCT in Years 2 and 3. In this capacity, the AAT Facilitators will deliver 1-hour communication workshops, including didactic instruction in HPV vaccination and communication skills building activities as "external facilitators". The AAT Facilitators will be responsible for delivering Announcement Approach Trainings, collecting relevant data, and documenting key components of the intervention.

TBN, Postdoctoral Research Associate

Year 1	Year 2	Year 3	Year 4	Year 5
12 CM	-	-	6.0 CM	9.0 CM

In Year 1, the Postdoctoral Research Associate will support the study by assisting with the development of intervention protocols and materials and data collection instruments. (S)he will schedule and help conduct key informant interviews and will assist the study leads in conducting qualitative coding of interview data. In Years 4-5, (s)he will support the research by assisting with data collection and analysis activities. (S)he will analyze intermediate and implementation outcomes in coordination with the study leads and will help support the study team in manuscript preparation.

TBN, Graduate Research Assistant

Year 1	Year 2	Year 3	Year 4	Year 5
2.4 CM	0.91 CM	-	2.78 CM	2.52 CM

In Years 1 and 2 the TBN Graduate Research Assistant will support the study by assisting with development of materials and evaluation instruments and will assist the Project Manager in administrative responsibilities related to the conduct of the study. (S)he will also conduct cognitive testing and pilot testing for provider surveys and program online surveys in Qualtrics or a similar online platform. Additionally, in Years 4-5, the Graduate Research Assistant will assist with data preparation and support the study team in manuscript preparation.

TBN, Research Assistant

Year 1	Year 2	Year 3	Year 4	Year 5
1.44 CM	1.2	0.66 CM	1.8 CM	3.0 CM

In Year 1, the Research Assistant will support the study team in developing intervention materials. In Years 2-4, the TBN Research Assistant will support the study by assisting the Project Manager and Biostatistician with data management activities. (S)he will also send provider survey invitations, reminders, and incentives during Years 2 and 3. In Year 5, the Research Assistant will support the Project Manager and study team in manuscript preparation, preparation of the Intervention Module, and other dissemination activities.

Total Expenses for Personnel=$967,961

Fringe Benefits

Fringe benefits associated with the salary request for this budget has been calculated in accordance with our Institution's DHHS Rate Agreement. The University of North Carolina at Chapel Hill applies appropriate fringe benefit rates to the personnel on this proposal: Basic permanent employee benefits are **25.889%** of annual salary plus **$6,512/FTE/YR** for fixed health insurance. Post-Doctoral Appointee employee benefits are **9.490%** of annual salary plus **$4,808.76/FTE/YR** for fixed health insurance. Graduate Student employee benefits are **9.490%** of annual salary plus **$4,137.60/FTE/YR** for fixed health insurance. P&A Practice Plan member benefits calculate at **30.796%** of annual salary plus **$8,652.80/FTE/YR** for fixed health insurance.

Travel

Travel for Conferences

Year 1	Year 2	Year 3	Year 4	Year 5	Total
-	-	-	$4,500	$6,000	$10,500

The Project Lead and members of the study team, including the Postdoctoral Research Associate and the Project Manager, will attend a total of three national conferences in Year 4 and four national conferences in Year 5 (each trip is budgeted at $1,500). Attending national conferences, such as the annual meetings of the *Society for Behavioral Medicin*e and the *American Society of Preventive Oncology,* and NIH's conference, *Increasing HPV Vaccination in the United States: A Collaboration of NCI-funded Cancer Centers*, will allow the study team to disseminate the Project's findings to a broad audience including public health practitioners, researchers, and policymakers. Additionally, attending conferences will expose the study team to the latest research in the field which will inform the Program's research activities.

Travel for Collaborative Meetings with Partners

Year 1	Year 2	Year 3	Year 4	Year 5	Total
-	$3,000	$3,000	$3,000	-	$9,000

In Years 2-4 the study Project Lead and Project Manager will travel to meet with research partners in Wisconsin (Years 2-3) and West Virginia (Year 4). The purpose of these trips will be to collaborate with partners to finalize materials and assure adherence to study protocols. The study team will also use these trips to ensure that site staff are fully briefed and trained to use materials and study protocols. Each trip is budgeted at $1,500 per trip, per person.

AAT Facilitator Travel

Year 1	Year 2	Year 3	Year 4	Year 5	Total
$4,500	$9,000	$9,000	-	-	$22,500

In Year 1, one AAT Facilitator from the University of North Carolina will travel to Wisconsin to implement the train-the-trainer pilot protocol in participating healthcare systems in Wisconsin. The AAT Facilitator will make one trip per health care system (3 X $1,500 = $4,500). The AAT Facilitators will make six trips to Wisconsin in both Year 2 and Year 3 to implement the RCT protocol. There will be two trips per recruited health system each year. One trip will be to train the clinical champions in each health system, and the other trip will be to provide external facilitation for the Traditional AAT (6 X $1,500 = $9,000, Years 2-3). Each trip is budgeted at $1,500.

Champion Travel

Year 1	Year 2	Year 3	Year 4	Year 5	Total
-	$1,000	$1,000	-	-	$2,000

Travel reimbursements for clinical champions to deliver the Champion AAT is budgeted at $1,000 in Year 2 and Year 3. In each intervention year, clinical champions will travel to 10 clinics within their own healthcare system to deliver the intervention. Because travel is anticipated to be local for clinical champions, each trip is budgeted at $100 ($100 X 10 = $1,000 in Years 2 and 3).

Total Expenses for Travel=$44,000

Supplies

Data Storage

Year 1	Year 2	Year 3	Year 4	Year 5	Total
$3,000	-	-	$3,000	-	$6,000

In Year 1, two computers will be purchased for project staff use and for AAT Facilitators to use for presenting the Announcement Approach Training in study clinics ($1,500 X 2 = $3,000). In Year 4, after warranties expire on staff computers, additional laptops will be purchased ($1,500 X 2 = $3,000).

Software

Year 1	Year 2	Year 3	Year 4	Year 5	Total
$1,800	$1,800	-	$1,800	$1,800	$7,200

Statistical and reference management software will be purchased for up to 3 computers as necessary in Years 1, 2, 4 and 5. The software will be used to perform data analyses as described in Aims 1-3, as well as to manage references to aid in dissemination of study findings. Software to be purchased will include programs such as NVivo, Stata, EndNote, Adobe Acrobat Pro, and SAS. ($600 per license x 3 computers = $1,800 per year in Years 1, 2, 4 and 5).

Printers

Year 1	Year 2	Year 3	Year 4	Year 5	Total
$1,000	-	-	-	-	$1,000

Two color laser jet printers will be purchased in Year 1 ($500 X 2 = $1,000) for project staff use and for printing of intervention materials for the study.

Project Supplies

Year 1	Year 2	Year 3	Year 4	Year 5	Total
$1,000	$1,000	$1,000	$1,000	$1,000	$5,000

Each year, $1,000 will be used for project supplies needed to carry out research activities including office supplies and printing of data collection instruments, protocols, meeting materials, posters to present study findings, and other documents as necessary. Study related supplies include pens, notebooks, folders, stationary file folders, binders, notebooks, markers, and other supplies needed to conduct the study.

Printing services

Year 1	Year 2	Year 3	Year 4	Year 5	Total
$500	$500	$500	$500	$500	$2,500

Printing services are budgeted at $500 each year of the study. This will cover the cost of printing intervention materials to be used in the Announcement Approach Training and other study related materials. Materials that we will send for professional printing services include items that cannot be printed in-house such as Announcement Approach training materials that are printed on card stock and

laminated pocket guides.

Mailing

Year 1	Year 2	Year 3	Year 4	Year 5	Total
$250	$250	$250	-	-	$750

Mailing costs are budgeted at $250 in Years 1-3. This will cover the cost of mailing training materials, including binders, thumb drives and printed Announcement Approach Training materials to all participating clinics.

Total Expenses for Supplies=$22,450

Journal Publication Charges

Year 1	Year 2	Year 3	Year 4	Year 5	Total
$1,500	$1,500	$1,500	$4,500	$4,500	$13,500

It is increasingly common for top journals to charge publication fees. Thus, we have budgeted for 1 article in Years 1-3 and 3 articles in Years 4-5 (at a rate of $1,500 per article).

Total Expenses for Journal Publication Charges=$13,500

Tuition

Year 1	Year 2	Year 3	Year 4	Year 5	Total
$3,773	$1,477	-	$4,783	$4,468	$14,500

We will provide tuition support as compensation for the TBN Graduate Research Assistant's work on the project. We will provide annual in-state tuition at the UNC Gillings School of Global Public Health to the Graduate Research Assistant. Tuition support is calculated by multiplying the graduate student's predicted percent effort on the project times the tuition cost of his/her graduate program.

Total Expenses for Tuition=$14,500

Other Expenses

Honorarium, Jason Terk, MD

Year 1	Year 2	Year 3	Year 4	Year 5	Total
CONSULTANT(S) FEES					

Dr. Terk is a general pediatrician with over 20 years of experience delivering pediatric primary care in a large healthcare system. In a prior study, Dr. Terk worked with the Project Lead to develop the train-the-trainer strategy of engaging primary care providers in efforts to improve HPV vaccination. He will support the research team by advising on the development of the protocol for identifying clinical champions in health care systems and on the enhancement of the train-the-trainer curriculum. Additionally, Dr. Terk will advise the study team on adapting the training and modules based on the findings in the intervention years. He will participate in quarterly study team meetings each year. Dr. Terk will be paid an honorarium of [$] per year.

The West Virginia Practice Based Research Network

Year 1	Year 2	Year 3	Year 4	Year 5	Total
-	-	-	$12,000	$15,510	$27,510

The West Virginia Practice Based Research Network (WVPBRN) is a network of primary care providers and

practices that work with research organizations to improve the health and well-being of the citizens of West Virginia. The WVPBRN will support the project by recruiting two healthcare systems to pilot test the revised intervention materials for their feasibility for use in West Virginia healthcare systems. The WVPBRN will also help adapt materials for contribution to the P01-wide Intervention Package. They are budgeted at $12,000 in Year 4 and $15,510 in Year 5. These costs are based on the WBPBRN's own estimates of cost for salary support for staff to assist with pilot testing and materials review and travel to clinics participating in pilot testing.

The North Carolina Institute for Public Health

Year 1	Year 2	Year 3	Year 4	Year 5	Total
$12,000	-	-	$9,000	$6,000	$27,000

The North Carolina Institute for Public Health (NCIPH) will provide technical and content support to the development of the train-the-trainer curriculum. The NCIPH serves as a bridge between academia and public health practice partners and specializes in continuing education, training development and workforce training and education. Their staff come from a wide array of backgrounds and have specific content expertise in numerous public health, medicine, and technology topics. In Year 1, they are budgeted at $12,000, which includes the development of a train-the-trainer curriculum with notes, scripts and slides and activities such as role playing, hand-outs and pre- and post-tests. In Year 4, they are budgeted at $9,000 to support updates to the train-the-trainer curriculum based on the outcomes of the study and in Year 5 they are budgeted at $6,000 to support further updates based on pilot testing the intervention module in West Virginia. Updated materials will be used in the P01-wide AAT Intervention Package. This work will include content development, graphic design and other dissemination materials.

Participant Incentives

Year 1	Year 2	Year 3	Year 4	Year 5	Total
$2,700	$17,000	$18,200	$1,200	$400	$39,500

Incentives are budgeted at $2,700 in Year 1, $18,000 in Year 2, $19,200 in Year 3, $1,200 in Year 4 and $400 in Year 5. The Year 1 budget includes $100 incentives for in-depth telephone interviews with 24 clinical champions to characterize the role and experiences of clinical champions in healthcare systems ($100 X 24 = $2,400) and $100 incentives for exit phone interviews with clinical champions who participate in the pilot study ($100 X 3 = $300) ($2,400 + $300 = $2,700 in Y1). The Year 2 budget includes $200 honoraria for clinical champions to deliver the Announcement Approach Training in 10 clinics (10 X $200 = $2,000) and $100 gift card incentives for 150 AAT workshop participants for completing surveys (150 X $100 = $15,000) (we anticipate a 75% response rate for completing all three surveys) ($2,000 + $15,000 = $17,000 in Y2). The Year 3 budget includes $200 honoraria for clinical champions to deliver the Announcement Approach Training in 10 clinics (10 X $200= $2,000), $100 incentives for 150 AAT workshop participants for completing surveys (150 X $100 = $15,000) and $100 incentives for in-depth interviews at six-month follow-up with 6 clinical champions who participated in the intervention the previous budget year (6 X $100 = $1,200) ($2,000 + $15,000 + $1,200 = $18,200 in Y3). The Year 4 budget includes $100 incentives for in-depth interviews at six-month follow-up with 6 clinical champions who participated in the intervention the previous budget year (6 X $100 = $1,200). The Year 5 budget includes $100 incentives for in-depth interviews with four clinical champions who participate in the West Virginia pilot of intervention materials (4 X $100 = $400).

Transcription

Year 1	Year 2	Year 3	Year 4	Year 5	Total
$3,075	$1,143	$1,144	$1,456	$360	$7,178

Transcription services are budgeted at $3,075 in Year 1, $1,143 In Year 2, $1,144 in Year 3, $1,456 in Year 4 and $360 in Year 5. This cost will cover the transcription of in-depth interviews with clinical champions across all years of the study. These interviews will assess the characteristics and experiences of clinical champions, champions' experiences with the pilot test and intervention, and champions' plans for future HPV vaccine quality improvement within their healthcare systems. We will use an online transcription service, such as Production Transcripts, that charges $1.95 per minute for recorded phone

interviews.

Total Expenses for Other Expenses=$106,188

Indirect Costs

At UNC-Chapel Hill, F&A costs are calculated on a Modified Total Direct Costs (MTDC) base. This base consists of all direct salaries and wages, applicable fringe benefits, materials and supplies, services, travel and up to the first $25,000 of each subaward (regardless of the period of performance of the subawards under the award). Modified total direct costs shall exclude equipment, capital expenditures, charges for patient care, rental costs, tuition remission, scholarships and fellowships, participant support costs and the portion of each subaward in excess of $25,000.

Per UNC-Chapel Hill's current federally negotiated rate agreement (dated 11/23/2016), F&A costs associated with the proposed research project are calculated at the approved on-campus research rate of 55.5% of MTDC in all years. The cognizant agency for UNC-Chapel Hill is the U.S. Department of Health and Human Services. The cognizant agency point of contact is Darryl Mayes, (202) 401-2808.

Consortium/Contractual Costs

The University of Wisconsin

Year 1	Year 2	Year 3	Year 4	Year 5	Total
$129,502	$222,471	$222,471	$123,175	$72,191	$769,809

The budget includes one domestic subcontract with the University of Wisconsin. A detailed budget and a budget justification for the proposed subcontract is included in this application. Under this subcontract, Dr. Elizabeth Cox, MD (Co-Investigator) will collaborate with the study team and provide expertise on all aspects of the project. The subcontract also includes support for a Research Associate who will assist with facilitating trainings, including process management, on site data collection and consenting participants in Wisconsin. The subcontract also includes travel funds for the Research Associate to travel to health systems recruited in Wisconsin. The Research Associate will also provide administrative support for the subcontract and other reporting requirements. Further, the subcontract includes funds for The Wisconsin Collaborative for Healthcare Quality to facilitate health system recruitment and data retrieval and management services and for the Health Innovations Program at the University of Wisconsin to provide data management and cleaning services. The University of Wisconsin subcontract budget provides more details on their work.

Total Expenses for Consortium/Contractual Costs=$769,809

RESEARCH & RELATED BUDGET - Cumulative Budget

	Totals ($)	
Section A, Senior/Key Person		275,310.00
Section B, Other Personnel		692,651.00
Total Number Other Personnel	26	
Total Salary, Wages and Fringe Benefits (A+B)		967,961.00
Section C, Equipment		
Section D, Travel		44,000.00
1. Domestic	44,000.00	
2. Foreign		
Section E, Participant/Trainee Support Costs		
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other		
6. Number of Participants/Trainees		
Section F, Other Direct Costs		926,449.00
1. Materials and Supplies	22,450.00	
2. Publication Costs	13,500.00	
3. Consultant Services		
4. ADP/Computer Services		
5. Subawards/Consortium/Contractual Costs	769,810.00	
6. Equipment or Facility Rental/User Fees		
7. Alterations and Renovations		
8. Other 1	34,845.00	
9. Other 2	85,844.00	
10. Other 3		
Section G, Direct Costs (A thru F)		1,938,410.00
Section H, Indirect Costs		654,400.00
Section I, Total Direct and Indirect Costs (G + H)		2,592,810.00
Section J, Fee		
Section K, Total Direct and Fee (I + J)		2,592,810.00

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 1

ORGANIZATIONAL DUNS*: 161202122

Budget Type*: ○ Project ● Subaward/Consortium

Enter name of Organization: The Board of Regents of the University of Wisconsin System

Start Date*: 07-01-2021 **End Date*:** 06-30-2022 **Budget Period: 1**

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.		Elizabeth	D.	Cox	MD, PhD	Co-Investigator	CAL. MONTHS, INST. BASE SALARY				25,868.00	9,468.00	35,336.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name: **Total Senior/Key Person** **35,336.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
1	Associate Researcher	6			35,099.00	12,846.00	47,945.00
1	**Total Number Other Personnel**					**Total Other Personnel**	**47,945.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**83,281.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 1

ORGANIZATIONAL DUNS*: 161202122

Budget Type*: ❍ Project ● Subaward/Consortium

Enter name of Organization: The Board of Regents of the University of Wisconsin System

Start Date*: 07-01-2021 **End Date*:** 06-30-2022 **Budget Period: 1**

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	

Additional Equipment: File Name:

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	
2. Foreign Travel Costs	
Total Travel Cost	

E. Participant/Trainee Support Costs	**Funds Requested ($)***
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant Trainee Support Costs**	

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 1

ORGANIZATIONAL DUNS*: 161202122

Budget Type*: ❍ Project ● Subaward/Consortium

Enter name of Organization: The Board of Regents of the University of Wisconsin System

Start Date*: 07-01-2021 **End Date*:** 06-30-2022 **Budget Period: 1**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
Total Other Direct Costs	**0.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**83,281.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. MTDC	55.5	83,281.00	46,221.00
		Total Indirect Costs	**46,221.00**

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number): DHHS, Arif Karim, 214-767-3261

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**129,502.00**

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	129,502.00

L. Budget Justification* File Name: BudJustWisconsinP3rV21045663960.pdf

(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

Tracking Number: GRANT13205496 Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 2

ORGANIZATIONAL DUNS*: 161202122

Budget Type*: ○ Project ● Subaward/Consortium

Enter name of Organization: The Board of Regents of the University of Wisconsin System

Start Date*: 07-01-2022 **End Date*:** 06-30-2023 **Budget Period: 2**

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.		Elizabeth	D.	Cox	MD, PhD	Co-Investigator	CAL. MONTHS, INST. BASE SALARY				25,868.00	9,468.00	35,336.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **35,336.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
1	Associate Researcher	6			35,099.00	12,846.00	47,945.00
1	Programmer Analyst	2.4			17,038.00	6,236.00	23,274.00
1	Outreach Specialist	0.6			3,304.00	1,209.00	4,513.00
3	**Total Number Other Personnel**					**Total Other Personnel**	**75,732.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**111,068.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 2

ORGANIZATIONAL DUNS*: 161202122

Budget Type*: ❍ Project ● Subaward/Consortium

Enter name of Organization: The Board of Regents of the University of Wisconsin System

Start Date*: 07-01-2022 **End Date*:** 06-30-2023 **Budget Period: 2**

C. Equipment Description	
List items and dollar amount for each item exceeding $5,000	
Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	
Additional Equipment: File Name:	

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	2,000.00
2. Foreign Travel Costs	
Total Travel Cost	**2,000.00**

E. Participant/Trainee Support Costs		**Funds Requested ($)***
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other:		
Number of Participants/Trainees	**Total Participant Trainee Support Costs**	

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 2

ORGANIZATIONAL DUNS*: 161202122

Budget Type*: ❍ Project ● Subaward/Consortium

Enter name of Organization: The Board of Regents of the University of Wisconsin System

Start Date*: 07-01-2022 **End Date*:** 06-30-2023 **Budget Period: 2**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8. Data fees and service fees	30,000.00
Total Other Direct Costs	**30,000.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**143,068.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. MTDC	55.5	143,068.00	79,403.00
		Total Indirect Costs	**79,403.00**

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number): DHHS, Arif Karim, 214-767-3261

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**222,471.00**

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	222,471.00

L. Budget Justification* File Name: BudJustWisconsinP3rV21045663960.pdf

(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 3

ORGANIZATIONAL DUNS*: 161202122

Budget Type*: ○ Project ● Subaward/Consortium

Enter name of Organization: The Board of Regents of the University of Wisconsin System

Start Date*: 07-01-2023 **End Date*:** 06-30-2024 **Budget Period: 3**

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.		Elizabeth	D.	Cox	MD, PhD	Co-Investigator	CAL. MONTHS, INST. BASE SALARY				25,868.00	9,468.00	35,336.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **35,336.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
1	Associate Researcher	6			35,099.00	12,846.00	47,945.00
1	Programmer Analyst	2.4			17,038.00	6,236.00	23,274.00
1	Outreach Specialist	0.6			3,304.00	1,209.00	4,513.00
3	**Total Number Other Personnel**					**Total Other Personnel**	**75,732.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**111,068.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 3

ORGANIZATIONAL DUNS*: 161202122

Budget Type*: ❍ Project ● Subaward/Consortium

Enter name of Organization: The Board of Regents of the University of Wisconsin System

Start Date*: 07-01-2023 **End Date*:** 06-30-2024 **Budget Period: 3**

C. Equipment Description	
List items and dollar amount for each item exceeding $5,000	
Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	
Additional Equipment: File Name:	

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	2,000.00
2. Foreign Travel Costs	
Total Travel Cost	**2,000.00**

E. Participant/Trainee Support Costs		**Funds Requested ($)***
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other:		
Number of Participants/Trainees	**Total Participant Trainee Support Costs**	

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 3

ORGANIZATIONAL DUNS*: 161202122

Budget Type*: ❍ Project ● Subaward/Consortium

Enter name of Organization: The Board of Regents of the University of Wisconsin System

Start Date*: 07-01-2023 **End Date*:** 06-30-2024 **Budget Period: 3**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8. Data fees and service fees	30,000.00
Total Other Direct Costs	**30,000.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**143,068.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. MTDC	55.5	143,068.00	79,403.00
		Total Indirect Costs	**79,403.00**

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number): DHHS, Arif Karim, 214-767-3261

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**222,471.00**

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	222,471.00

L. Budget Justification* File Name: BudJustWisconsinP3rV21045663960.pdf

(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 4

ORGANIZATIONAL DUNS*: 161202122

Budget Type*: ○ Project ● Subaward/Consortium

Enter name of Organization: The Board of Regents of the University of Wisconsin System

Start Date*: 07-01-2024 **End Date*:** 06-30-2025 **Budget Period: 4**

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.		Elizabeth	D.	Cox	MD, PhD	Co-Investigator	CAL. MONTHS, INST. BASE SALARY				25,868.00	9,468.00	35,336.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name: **Total Senior/Key Person** **35,336.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
1	Associate Researcher	1.2			7,020.00	2,569.00	9,589.00
1	Programmer Analyst	2.4			17,038.00	6,236.00	23,274.00
1	Outreach Specialist	0.6			3,304.00	1,209.00	4,513.00
3	**Total Number Other Personnel**					**Total Other Personnel**	**37,376.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**72,712.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 4

ORGANIZATIONAL DUNS*: 161202122

Budget Type*: ❍ Project ● Subaward/Consortium

Enter name of Organization: The Board of Regents of the University of Wisconsin System

Start Date*: 07-01-2024 **End Date*:** 06-30-2025 **Budget Period: 4**

C. Equipment Description	
List items and dollar amount for each item exceeding $5,000	
Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	
Additional Equipment: File Name:	

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	1,500.00
2. Foreign Travel Costs	
Total Travel Cost	**1,500.00**

E. Participant/Trainee Support Costs	**Funds Requested ($)***
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant Trainee Support Costs**	

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 4

ORGANIZATIONAL DUNS*: 161202122

Budget Type*: ❍ Project ● Subaward/Consortium

Enter name of Organization: The Board of Regents of the University of Wisconsin System

Start Date*: 07-01-2024 **End Date*:** 06-30-2025 **Budget Period: 4**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8. Data fees and service fees	5,000.00
Total Other Direct Costs	**5,000.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**79,212.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. MTDC	55.5	79,212.00	43,963.00
		Total Indirect Costs	**43,963.00**

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number): DHHS, Arif Karim, 214-767-3261

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**123,175.00**

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	123,175.00

L. Budget Justification* File Name: BudJustWisconsinP3rV21045663960.pdf

(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 5

ORGANIZATIONAL DUNS*: 161202122

Budget Type*: ○ Project ● Subaward/Consortium

Enter name of Organization: The Board of Regents of the University of Wisconsin System

Start Date*: 07-01-2025 **End Date*:** 06-30-2026 **Budget Period: 5**

A. Senior/Key Person

Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.	Elizabeth	D.	Cox	MD, PhD	Co-Investigator	CAL. MONTHS, INST. BASE SALARY				25,868.00	9,468.00	35,336.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name: **Total Senior/Key Person** **35,336.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
1	Associate Researcher	1.2			7,020.00	2,569.00	9,589.00
1	**Total Number Other Personnel**					**Total Other Personnel**	**9,589.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**44,925.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 5

ORGANIZATIONAL DUNS*: 161202122

Budget Type*: ❍ Project ● Subaward/Consortium

Enter name of Organization: The Board of Regents of the University of Wisconsin System

Start Date*: 07-01-2025 **End Date*:** 06-30-2026 **Budget Period: 5**

C. Equipment Description	
List items and dollar amount for each item exceeding $5,000	
Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	
Additional Equipment: File Name:	

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	1,500.00
2. Foreign Travel Costs	
Total Travel Cost	**1,500.00**

E. Participant/Trainee Support Costs	**Funds Requested ($)***
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant Trainee Support Costs**	

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 5

ORGANIZATIONAL DUNS*: 161202122

Budget Type*: ❍ Project ● Subaward/Consortium

Enter name of Organization: The Board of Regents of the University of Wisconsin System

Start Date*: 07-01-2025 **End Date*:** 06-30-2026 **Budget Period: 5**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
Total Other Direct Costs	**0.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**46,425.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. MTDC	55.5	46,425.00	25,766.00
		Total Indirect Costs	**25,766.00**

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number): DHHS, Arif Karim, 214-767-3261

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**72,191.00**

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	72,191.00

L. Budget Justification* File Name: BudJustWisconsinP3rV21045663960.pdf

(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

Tracking Number: GRANT13205496 Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

BUDGET JUSTIFICATION – University of Wisconsin-Madison

Key Personnel

Elizabeth Cox, MD, PhD, Co-Investigator

Year 1	Year 2	Year 3	Year 4	Year 5
CAL. MONTHS				

Dr. Cox is Professor in the Department of Pediatrics at the University of Wisconsin School of Medicine and Public Health, and Director of the Program of Research on Outcomes for Kids. Dr. Cox's research interests include developing, implementing, and evaluating system-level interventions to improve health outcomes for children and adolescents. Dr. Cox will be responsible for communication with clinical practice sites as well as with the Wisconsin Collaborative for Healthcare Quality and the Health Innovation Program. She will ensure timely intervention delivery and data collection, as well as oversee the data handling and management activities. She will also collaborate with Dr. Gilkey and the West Virginia Practice Based Research Network to disseminate products from the research, including refinement of the intervention for use across diverse rural settings. Dr. Cox will also collaborate and contribute to the development of intervention and data collection materials, as well as reports, papers, and publications.

Other Personnel

Harald Kliems, MA, Research Associate

Year 1	Year 2	Year 3	Year 4	Year 5
CAL. MONTHS				

Mr. Kliems is Associate Researcher in the Department of Pediatrics at the University of Wisconsin School of Medicine and Public Health. Under the guidance of Dr. Cox, Mr. Kliems will provide project management. He will be responsible for all aspects of health system recruitment; scheduling and facilitating intervention delivery; and collecting data from providers at the intervention trainings. He will perform administrative duties related to this project including organizing meetings, developing meeting agendas and task lists, and assisting with drafting and revising documents. Mr. Kliems has previously performed similar duties successfully as a member of Dr. Cox's research team.

Allie DeLonay, MS, Programmer

Year 1	Year 2	Year 3	Year 4	Year 5
CAL. MONTHS				

Ms. DeLonay will be the primary University of Wisconsin programming contact with the Wisconsin Collaborative for Healthcare Quality. She will participate in the development of, and be responsible for, implementing any standards for data and variable definitions. She will ensure that all derived variables are fully documented.

Lauren Bednarz, MPH, Outreach Specialist

Year 1	Year 2	Year 3	Year 4	Year 5
CAL. MONTHS				

Ms. Bednarz leads community partnership efforts at the University of Wisconsin Health Innovation Program. She will be responsible for the coordination and management of all activities with Wisconsin Collaborative for Healthcare Quality and the Health Innovation Program.

Total Expenses for Personnel=$423,054

Travel

Travel for data collection

Year 1	Year 2	Year 3	Year 4	Year 5	Total
-	$2,000	$2,000	-	-	$4,000

Travel is budgeted at $2,000 in Years 2 and 3. This will cover the cost of the Research Associate's travel to the clinic sites for data collection activities.

Conference travel

Year 1	Year 2	Year 3	Year 4	Year 5	Total
-	-	-	$1,500	$1,500	$3,000

Travel is budgeted at $1,500 in Years 4 and 5. Dr. Cox will travel to one national conference in Year 4 and one conference in Year 5 to disseminate the Project's findings to a broad audience of public health and medical practitioners and policy makers.

Total Expenses for Travel=$7,000

Other Expenses

Wisconsin Collaborative for Healthcare Quality: $25,000 in Year 2 and 3 – The Wisconsin Collaborative for Healthcare Quality will introduce the project to the health systems and facilitate system and clinic recruitment into the study. They will provide ongoing assistance as needed to manage relationships with the participating systems. They will also provide patient-level data, including HPV vaccination information and demographics, as well as provider and clinic characteristics. Data will be provided at baseline and after intervention to evaluate intervention impact. The data use access fee ($25,000/year) will be provided to Wisconsin Collaborative for Healthcare Quality for access to their statewide data repository. Total cost for the Wisconsin Collaborative for Healthcare Quality is $50,000.

Health Innovative Program data services: $5,000 in Years 2-4 – The Health Innovation Program Data Services team will assist with transfer of data and/or secure transfer setup from the Wisconsin Collaborative for Healthcare Quality data repository to the Health Innovation Program servers for processing and transfer of the final data product to the University of North Carolina team. The Health Information Program Data Services team will also assure regulatory compliance including review of Institutional Review Board applications and data use agreements; and ensure setup of security and privacy controls for accessing the Wisconsin Collaborative for Healthcare Quality data including HIPAA-compliant access and audit controls (including de-identification), transmission security, and designation of security responsibility and awareness. The total cost for the Health Innovation Program data services is $15,000.

Total Expenses for Other Expenses=$65,000

F&A

UW-Madison's negotiated F&A rate agreement is 55.5% of Modified Total Direct Costs.

RESEARCH & RELATED BUDGET - Cumulative Budget

	Totals ($)	
Section A, Senior/Key Person		176,680.00
Section B, Other Personnel		246,374.00
Total Number Other Personnel	11	
Total Salary, Wages and Fringe Benefits (A+B)		423,054.00
Section C, Equipment		
Section D, Travel		7,000.00
1. Domestic	7,000.00	
2. Foreign		
Section E, Participant/Trainee Support Costs		
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other		
6. Number of Participants/Trainees		
Section F, Other Direct Costs		65,000.00
1. Materials and Supplies		
2. Publication Costs		
3. Consultant Services		
4. ADP/Computer Services		
5. Subawards/Consortium/Contractual Costs		
6. Equipment or Facility Rental/User Fees		
7. Alterations and Renovations		
8. Other 1	65,000.00	
9. Other 2		
10. Other 3		
Section G, Direct Costs (A thru F)		495,054.00
Section H, Indirect Costs		274,756.00
Section I, Total Direct and Indirect Costs (G + H)		769,810.00
Section J, Fee		
Section K, Total Direct and Fee (I + J)		769,810.00

PHS 398 Cover Page Supplement

OMB Number: 0925-0001

Expiration Date: 02/28/2023

1. Vertebrate Animals Section

Are vertebrate animals euthanized? ○ Yes ○ No

If "Yes" to euthanasia

Is the method consistent with American Veterinary Medical Association (AVMA) guidelines?

○ Yes ○ No

If "No" to AVMA guidelines, describe method and provide scientific justification

2. *Program Income Section

*Is program income anticipated during the periods for which the grant support is requested?

○ Yes ● No

If you checked "yes" above (indicating that program income is anticipated), then use the format below to reflect the amount and source(s). Otherwise, leave this section blank.

*Budget Period *Anticipated Amount ($) *Source(s)

Tracking Number: GRANT13205496 Funding Opportunity Number: PAR-20-077 . Received Date: 2020-09-18T11:41:16.000-04:00

PHS 398 Cover Page Supplement

3. Human Embryonic Stem Cells Section

*Does the proposed project involve human embryonic stem cells? ○ Yes ● No

If the proposed project involves human embryonic stem cells, list below the registration number of the specific cell line(s) from the following list: http://grants.nih.gov/stem_cells/registry/current.htm. Or, if a specific stem cell line cannot be referenced at this time, check the box indicating that one from the registry will be used:

Specific stem cell line cannot be referenced at this time. One from the registry will be used.

Cell Line(s) (Example: 0004):

4. Human Fetal Tissue Section

*Does the proposed project involve human fetal tissue obtained from elective abortions? ○ Yes ● No

If "yes" then provide the HFT Compliance Assurance

If "yes" then provide the HFT Sample IRB Consent Form

5. Inventions and Patents Section (Renewal applications)

*Inventions and Patents: ○ Yes ○ No

If the answer is "Yes" then please answer the following:

*Previously Reported: ○ Yes ○ No

6. Change of Investigator/Change of Institution Section

❑ Change of Project Director/Principal Investigator

Name of former Project Director/Principal Investigator

Prefix:

*First Name:

Middle Name:

*Last Name:

Suffix:

❑ Change of Grantee Institution

*Name of former institution:

PHS 398 Research Plan

OMB Number: 0925-0001
Expiration Date: 02/28/2023

Introduction	
1. Introduction to Application (for Resubmission and Revision applications)	IntroApplicationP3rV21045663961.pdf
Research Plan Section	
2. Specific Aims	SpecificAimsP3r1045594859.pdf
3. Research Strategy*	ResearchStrategyP3rV21045663962.pdf
4. Progress Report Publication List	
Other Research Plan Section	
5. Vertebrate Animals	
6. Select Agent Research	
7. Multiple PD/PI Leadership Plan	
8. Consortium/Contractual Arrangements	ConsortWisconsinP3r1045594868.pdf
9. Letters of Support	LOSP3Combinedr1045594867.pdf
10. Resource Sharing Plan(s)	ResourceSharingP3r1045594865.pdf
11. Authentication of Key Biological and/or Chemical Resources	
Appendix	
12. Appendix	

Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

INTRODUCTION TO APPLICATION – Project 3

CRITIQUE, RESPONSE TO CRITIQUE

SPECIFIC AIMS – Project 3

Widespread HPV vaccination could prevent 32,100 HPV cancers in the US each year. However, only about half of US adolescents (54%) complete the HPV vaccine series, and uptake is persistently lower in rural areas. We developed Announcement Approach Training (AAT) to improve uptake. AAT is a 1-hour communication workshop in which our physician facilitators train primary care teams to address the most critical barrier to HPV vaccination: infrequent and ineffective recommendations. In a randomized clinical trial, AAT increased HPV vaccine initiation among adolescents by 5 percentage points in just 3 months. If brought to scale, this NCI-certified Research-Tested Intervention Program could quickly increase HPV vaccine uptake nationally.

A promising way to scale up AAT involves training clinical champions to deliver it within their own healthcare systems. Most primary care physicians (>80%) now work in healthcare systems, and training systems' own champions to deliver AAT could dramatically increase capacity for our intervention beyond that of our own team. Furthermore, champions offer local knowledge and networks and an ongoing presence in their systems that could increase AAT reach and sustainability. On the other hand, champions may face unique challenges to AAT delivery, and their impact on HPV vaccine uptake and communication is unknown.

As part of the P01 Program Project, "Improving Provider Announcement Communication Training (IMPACT)," Project 3 will **enhance AAT to engage clinical champions in intervention delivery**. We will first conduct qualitative research with champions to inform adaptations of the traditional AAT intervention package ("Traditional AAT"). We will use the revised intervention package ("Champion AAT") to train champions to deliver our intervention, comparing the effectiveness of Champion AAT to Traditional AAT in a cluster randomized non-inferiority trial. We will use findings to further refine our intervention. Our specific aims are to:

Aim 1. Identify opportunities to engage clinical champions in delivering AAT within their own healthcare systems. *Activities to reach this aim:*

a. Partner with 6 healthcare systems in Wisconsin, a state with a high proportion of rural residents.
b. Interview 4 champions per system (or 24 total) to understand: barriers and facilitators to AAT delivery; opportunities to extend AAT to increase reach and sustainability; and champions' training preferences.

Aim 2. Compare the impact of Champion AAT to Traditional AAT on HPV vaccine uptake and communication in healthcare systems. *Activities to reach this aim:*

a. Use Aim 1 findings to adapt and pilot Champion AAT in partnering healthcare systems.
b. Conduct a cluster randomized non-inferiority trial with 40 clinics across our 6 partnering systems. Within each system, randomize participating clinics to receive Champion AAT or Traditional AAT.
c. Compare interventions on vaccination outcomes, including *HPV vaccine initiation* (i.e., receipt of first dose) at 12-month follow-up, among adolescents ages 11-12, using electronic health record data. Explore whether impact varies for clinics serving a high proportion (>40%) of rural adolescents.
d. Compare interventions on changes in intermediate outcomes, including HPV vaccine communication, via surveys of primary care professionals who attended AAT workshops.

Hypothesis: Champion AAT is non-inferior to Traditional AAT for improving HPV vaccine uptake.

Aim 3. Generate guidance to help healthcare systems compare and implement Champion AAT and Traditional AAT. *Activities to achieve this aim:*

a. Establish cost per additional adolescent initiating HPV vaccine due to Champion AAT or Traditional AAT. Share data with Project 4 team, who will compare cost-effectiveness to other interventions.
b. Assess other implementation outcomes, including *reach* (i.e., proportion of primary care professionals trained), *fidelity* to AAT protocol, and *sustainability* of communication behavior.
c. Examine determinants (i.e., facilitators and barriers) of implementation via key stakeholder interviews.
d. Refine Champion AAT based on Aim 3 findings and implement in 2 West Virginia healthcare systems to enhance generalizability. Contribute Champion module to the P01-wide AAT Intervention Package.

Hypothesis: Champion AAT has higher reach and sustainability, but lower fidelity than Traditional AAT.

Project 3 advances the **IMPACT Program Project theme** by engaging clinical champions to build capacity for HPV vaccine communication interventions among primary care teams in healthcare systems. This research is **significant** in evaluating highly scalable solutions to low HPV vaccine uptake. This study is **innovative** in seeking to leverage the influence of existing clinical champions. With Project 4, we will model our intervention's cost-effectiveness and **disseminate** research findings and intervention packages to US healthcare systems.

RESEARCH STRATEGY – Project 3

SIGNIFICANCE

Widespread HPV vaccination could greatly reduce the burden of HPV cancers in the US. HPV is a highly prevalent infection associated with more than 34,000 cancers in the US each year.[1,2] The annual cost of screening and treatment for HPV-related disease totals over $8 billion.[3] HPV vaccination could prevent the infections that lead to most of these diseases, making the vaccine a powerful tool for cancer prevention.[4–8]

HPV vaccine coverage remains far below national goals. National recommendations are for adolescents to receive 2 doses of HPV vaccine at ages 11-12.[9,10] On-time vaccination is critical for conferring protection before HPV exposure and also enhances immune response, which may increase effectiveness.[10] Those who initiate HPV vaccination on time require fewer doses than older adolescents (≥age 15) who need 3 doses.[10] Unfortunately, only 54% of adolescents were fully vaccinated by 2019, which is far below the Healthy People goal of 80%.[11,12] Furthermore, persistent geographic disparities mean that rural areas have lower HPV vaccine coverage than urban ones (47% vs 57%).[11] This disparity is concerning given that HPV cancers disproportionately affect rural populations.[13–15] Interventions are urgently needed to improve coverage.[16,17]

Scientific Premise

Improving provider communication about HPV vaccination is critical to increasing coverage. A provider's recommendation is the strongest and most consistent predictor of HPV vaccination.[18–23] Adolescents who receive a recommendation have ~10 times higher odds of initiating the series.[18–23] Provider recommendations correlate more strongly with HPV vaccination than other commonly studied factors, including parents' HPV vaccination beliefs.[20,22] Unfortunately, many providers report recommending HPV vaccine weakly, inconsistently, behind schedule, or not at all.[23–34] Suboptimal recommendations are especially common among providers who report discomfort talking with parents about HPV vaccine.[24] In addition to recommending HPV vaccine, providers must feel confident that they can address parents' HPV vaccine concerns.

Announcement Approach Training (AAT) is an effective communication intervention. AAT is a manualized, evidence-based intervention that we developed to improve primary care teams' HPV vaccine communication.[35–38] In our 1-hour, in-clinic workshops, physicians from our study team teach primary care teams to: 1) introduce HPV and other adolescent vaccines with "presumptive announcements" that assume parents are ready to vaccinate; 2) use a structured communication approach known as "connect and counsel" to address parents' concerns with research-tested messages; and 3) recommend HPV vaccine again at a later visit if parents decline. In a randomized clinical trial (RCT) with 29 primary care clinics, AAT raised coverage for HPV vaccine initiation among patients, ages 11-12, by 5 percentage points over control in 3 months.[35] Based on this evidence, the National Cancer Institute has certified AAT as a Research-Tested Intervention Program.[37]

Healthcare systems are key partners for implementing evidence-based interventions, like AAT, to improve HPV vaccination. Primary care is rapidly consolidating in the US, such that relatively few pediatricians work in small private practices, and larger, consolidated healthcare systems now predominate.[39] Similar trends are occurring in family medicine.[40,41] Systems are, thus, uniquely positioned to reach providers with interventions to improve HPV vaccination, including AAT. Systems may also be motivated to improve HPV vaccination, given that vaccine-related quality metrics, such as Healthcare Effectiveness Data and Information Set (HEDIS) measures, are increasingly reported publicly and used by payers to set reimbursement rates.[42]

Healthcare systems need strategies for scaling up evidence-based interventions effectively. Despite their reach to providers and external motivations to improve, systems may also face challenges to implementing HPV vaccine interventions. Systems are responsible for a wide array of quality metrics and must be judicious in allocating resources to any single health service.[43] In the case of AAT, hiring professional trainers to deliver in-clinic workshops would not be feasible for many systems. Not-for-profit organizations, such as professional associations, and research teams, like our own, can volunteer valuable short-term support, but are unlikely to provide consistent, long-term solutions to workforce training. Strategies for training systems' own providers to conduct evidence-based HPV vaccine communication interventions like AAT could increase the reach and sustainability of such training, but would require evaluation to ensure effectiveness.

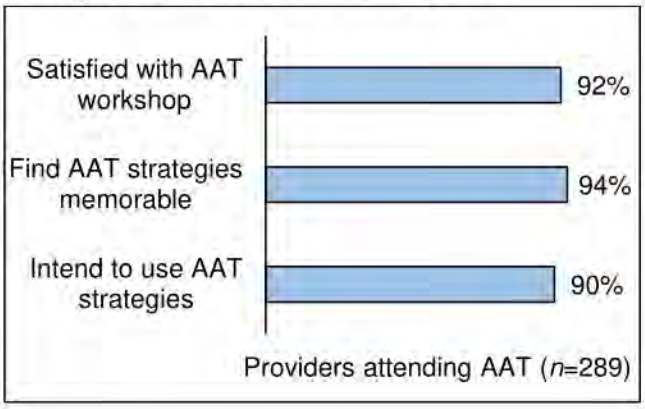
Engaging clinical champions to deliver HPV vaccine communication training could be especially impactful. Clinical champions are healthcare professionals who are committed to improving a clinical practice, and are often identified in the implementation science literature as being integral to the success of change efforts.[44,45] Champions are commonly conceptualized as respected peers whose insider knowledge of their organization facilitates change.[44,45] Champions work with frontline providers and staff to deliver education, overcome barriers, and communicate enthusiasm.[44,45] Given their influence and existing networks, engaging champions to deliver effective and sustainable HPV vaccine communication training is highly promising.

Preliminary Studies

Our preliminary research suggests that clinical champions who deliver HPV vaccine training can reach nearly all potential clinical sites and providers. In a prior study, we partnered with a large healthcare system in Texas to engage clinical champions in an intervention to improve HPV vaccination. Using the system's electronic health record (EHR), we identified physicians whose patients had high HPV vaccine coverage. We recruited these high performers to develop and lead an intervention, including HPV vaccine-related training, with other physicians in their system.[46] This team of clinical champions succeeded in scheduling and delivering trainings in all (100%) clinics in the system, reaching almost all (95%) physicians within those clinics.[46] This reach is far higher than typically observed in HPV vaccine intervention studies, which often enroll <50% of invited clinics. *This study demonstrates that: 1) we have piloted a way to identify clinical champions using EHR data; and 2) clinical champions can be highly successful at reaching their peers.*

Our existing AAT train-the-trainer curriculum is highly acceptable and shows promise for improving HPV vaccine communication. In a second preliminary study, our team developed a train-the-trainer curriculum for AAT. Train-the-trainer is a strategy that spreads knowledge and skills by preparing intervention facilitators to train others.[47] In partnership with the American Academy of Pediatrics, we used the curriculum to train 9 physicians, who then delivered AAT workshops to 289 pediatric providers in 8 US states. Pre-/post-workshop surveys indicated that workshops increased providers' intention to routinely recommend HPV vaccine, as well as their confidence to address parents' concerns (both $p<0.001$). Satisfaction among providers attending the AAT workshops was high (**Figure 1**). *This pilot study demonstrates that our existing train-the-trainer curriculum provides a highly promising foundation for training clinical champions to deliver AAT.*

Figure 1. Satisfaction and intention to use AAT strategies delivered with train-the-trainer



Research Gaps and Significance of Expected Research Contribution

Research is needed to elucidate the role of clinical champions and harness their influence to improve HPV vaccination. As noted above, our preliminary research supports assertions often made in the implementation science literature that champions are influential.[45] Nevertheless, existing studies say surprisingly little about who champions are or how to identify or train them.[45] To our knowledge, only 4 studies have used randomized designs to compare clinical interventions with and without champions.[48–51] This research has generally found in favor of champions, as have observational studies assessing associations between champions and clinical practice improvements.[52–59] However, few studies characterized champions beyond noting their presence or absence.[45] Mechanisms by which champions exert influence are largely unexplored.[48–55] If systems are to leverage champions to improve the delivery of preventive services like HPV vaccination, research is needed to understand their role and develop tools to support their work.

Research is also needed to test the effectiveness of using a train-the-trainer model to implement AAT in healthcare systems. The pilot of our existing train-the-trainer curriculum suggests promise, but the impact on primary care teams' communication or adolescents' HPV vaccine uptake is unknown. Before broad dissemination, it is critical to test the effectiveness of train-the-trainer-delivered AAT. Given rural disparities in HPV vaccination and the diversity of rural areas,[11] exploring impact and acceptability of our train-the-trainer model in a variety of rural contexts would be especially valuable for extending the current evidence for AAT.[17]

The proposed study will build the evidence base for engaging clinical champions to improve HPV vaccine communication and uptake. Based on interviews with champions in 6 healthcare systems, we will identify opportunities to adapt and extend AAT to leverage champions' influence. We will use findings to adapt our existing AAT intervention package, identify champions, and train them to deliver AAT workshops and other activities to improve HPV vaccination within their own systems. In a cluster randomized non-inferiority trial with 40 clinics, we will compare the effectiveness of AAT delivered by champions to traditional AAT delivered by external facilitators for increasing HPV vaccine uptake. We will also compare the interventions on intermediate outcomes, such as communication, and implementation outcomes, such as cost, reach, and sustainability. This study is significant in evaluating the impact of a highly scalable communication intervention to improve HPV vaccination, while also elucidating mechanisms by which champions may work to improve clinical practice.

INNOVATION

Our trial will be the first to compare the effectiveness of engaging clinical champions versus external facilitators to improve HPV vaccination. Several existing HPV vaccine interventions include champions, along with other components.[60,61] To our knowledge, our study will be the first to use a randomized design to assess champions' specific impact. Thus, our trial will offer more targeted guidance to healthcare systems than trials of multi-component interventions that cannot isolate the impact of any single component.

This study is novel in its focus on healthcare systems. To date, studies of provider-focused interventions to improve HPV vaccination have most often taken place in individual clinics, single healthcare systems, single cities, or Federally Qualified Health Centers.[61–66] In contrast, our study will engage multiple systems that include commercially-insured patients. Such systems are important because they serve large numbers of adolescents. Furthermore, HPV vaccine coverage is lower among adolescents with commercial insurance versus Medicaid.[11] Finally, by working in multiple systems versus a single system, we will gain insight into how the implementation of our intervention varies across organizational contexts.

Our study will include clinics serving adolescents in rural areas. Given geographic disparities in HPV vaccination,[11] interventions that support clinics serving rural areas are especially important. We will conduct our trial in a rural state (Wisconsin), and oversample clinics serving rural adolescents to ensure representation of this high-priority, but under-studied population. After the trial, we will work with healthcare systems in a second rural state (West Virginia) to optimize our intervention package for use in other rural contexts.

Champion AAT is designed for dissemination. Implementation scientists emphasize the need to design highly scalable interventions for sustained use in real-world settings.[67,68] We seek to achieve this goal by leveraging a resource—clinical champions—that many systems already have. We will compare key features of Champion AAT and Traditional AAT, including delivery cost, to provide novel data on each intervention. If successful, our approach may be adapted to improve communication for other preventive services.

APPROACH

Study Team and Setting

Our multidisciplinary team offers extensive experience in parent-provider communication, pediatric health services research, and implementation science. **Melissa Gilkey**, PhD, is Associate Professor of Health Behavior at the University of North Carolina (UNC). As project lead, Dr. Gilkey will lead intervention development and evaluation, drawing from her content expertise in HPV vaccination and experience conducting RCTs to evaluate clinical interventions to improve vaccine delivery. **Elizabeth Cox**, MD, PhD, is a practicing pediatrician, Professor of Pediatrics, and Director of the Program of Research on Outcomes for Kids (PROKids) at the University of Wisconsin. Leading healthcare system recruitment and engagement, Dr. Cox will draw from her clinical expertise and experience conducting multi-site clinical trials. **Sarah Birken**, PhD, is Associate Professor of Implementation Science at Wake Forest University. Dr. Birken is an expert in the implementation of cancer care interventions and will lead the evaluation of implementation outcomes.

Our **prior research** lays the groundwork for the present study. This work includes research on HPV vaccine recommendations and the evaluation of strategies to improve HPV vaccine communication via provider training.[23,24,35,36,46] We have successfully recruited healthcare providers to multiple studies, including RCTs.[35,46,69–72] In terms of methods, we have expertise conducting surveys and in-depth interviews with providers,[24,69,70,73–76] evaluating clinical trials using immunization data from EHRs,[46] and developing and validating measures to assess HPV vaccine communication.[23,24] Notably, Drs. Gilkey and Cox are currently collaborating on a study to assess HPV vaccine uptake among rural youth in Wisconsin healthcare systems.

The study team will draw additional expertise from shared resources (see letters). UNC's **North Carolina Institute for Public Health** specializes in professional development for health professionals and will provide technical support to develop Champion AAT. The P01's **Intervention Core** will support the project by convening a **Clinical Advisory Board** representing the perspectives of primary care physicians, nurse practitioners, physician assistants, nurses, medical assistants, and patient and family advocates. The P01's **Data Core** will provide analytic support, including the expertise of a senior biostatistician (Dr. Ibrahim).

We will partner with organizations in two states, Wisconsin and West Virginia, to complete our aims. Compared to the US as a whole, these states offer large proportions of rural residents, which will facilitate comparisons between rural and nonrural populations. These states have middling to low HPV vaccine coverage (**Table 1**).[11,77] We will work with one organization in each state (see letters).

Table 1. State versus US characteristics

	WI	WV	US
Rural residents [77]	30%	51%	19%
HPV vaccination, 1st dose, age 13-17[11]	72%	65%	72%

WI: Wisconsin; WV: West Virginia

First, we will partner with the **Wisconsin Collaborative for Healthcare Quality** (or "the Collaborative") to conduct our non-inferiority trial comparing Champion AAT to Traditional AAT. The Collaborative is a voluntary quality improvement network of 35 healthcare systems representing over 65% of primary care physicians in the state.[78] Participating systems submit data on quality metrics, including HPV vaccine coverage, that are derived from EHRs and include all payers and patients; this dataset is the largest aggregation of patient-level data from non-academic healthcare systems in the US.[79] The Collaborative validates these data, and also works to coordinate improvement efforts across systems. The Collaborative's role in the present study will be to support recruitment and retention of healthcare systems and to provide standardized and validated vaccination data.

Second, we will partner with the **West Virginia Practice-Based Research Network** (WVPBRN) to prepare Champion AAT for dissemination.[80] WVPBRN is a network of >100 primary care sites, including 30 healthcare systems, coordinated by the West Virginia Clinical and Translational Science Institute.[81] Following our Wisconsin-based trial, WVPBRN will collaborate with the study team to refine Champion AAT and implement it in West Virginia systems with the goal of optimizing our intervention in another rural context. Such work is a priority, given that Appalachian states have low HPV vaccine uptake, but high rates of HPV cancers.[11,82]

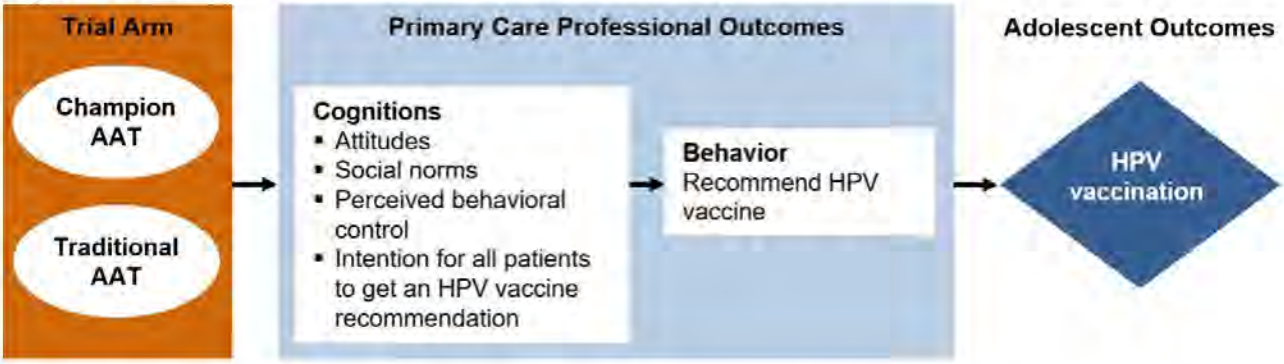
Study Overview

We will compare the effectiveness of 2 interventions for improving HPV vaccination in healthcare systems: **Champion AAT** and **Traditional AAT**. In **Aim 1**, we will conduct a qualitative interview study in Wisconsin healthcare systems to identify ways of adapting Traditional AAT to leverage the influence of clinical champions. Findings will inform the development of Champion AAT, which will engage champions in delivering AAT and related activities within their own systems. In **Aim 2**, we will conduct a cluster randomized non-inferiority trial with 40 clinics from 6 Wisconsin systems. Within each system, we will randomize clinics to receive Champion AAT or Traditional AAT. Our primary outcome will be the proportion of HPV vaccine-naïve patients, ages 11-12, who initiate HPV vaccination between baseline and 12-month follow-up. To understand mechanisms by which our interventions change vaccine uptake, we will also assess intermediate outcomes, including HPV vaccine communication. In **Aim 3**, we will compare Champion AAT to Traditional AAT on implementation measures, including reach, fidelity, sustainability, and cost. We will use findings to refine Champion AAT and conduct focused implementation in West Virginia healthcare systems to prepare for broader dissemination.

Conceptual Model

Our P01's shared conceptual model (**Figure 2**) is guided by the **Theory of Planned Behavior** (TPB).[83] TPB suggests that improving HPV vaccination first requires champions to improve primary care professionals' cognitions, including *intention* to recommend HPV vaccine. Changes in cognitions will lead to improvements in communication behavior, with a focus on HPV vaccine recommendations. Improved behavior will lead to increased HPV vaccine initiation. Using this model, we will compare the mechanisms by which champions and external facilitators may improve HPV vaccine uptake. We have used TPB successfully in prior studies to design and evaluate clinical interventions to improve HPV vaccine uptake, including AAT.[35,36]

Figure 2. Conceptual model



Description of Traditional AAT

In prior studies, we developed the AAT Intervention Package, including the workshop and a train-the-trainer curriculum.[35,36,84] The **Traditional AAT workshop** is a physician-led, in-clinic communication training that uses didactic instruction and role play to teach primary care teams to:

1. **Use presumptive announcements**. Participants learn to introduce adolescent vaccines with brief statements that assume parents are ready to vaccinate. For example, "Now that Michael is 11, he's due for 3 vaccines that will protect him against meningitis, HPV cancers, and whooping cough."

2. **Connect and counsel**. For parents who have concerns, participants learn to "connect and counsel." Connecting involves clarifying the concern and encouraging communication. Counseling involves addressing the concern with research-tested messages to give parents accurate and family-centered information. For example, a participant can address safety concerns by saying, "HPV vaccine is one of the most studied medications on the market. It's safe, just like the other vaccines given at this age."
3. **Recommend again if needed.** If parents decline HPV vaccination, AAT teaches participants to recommend HPV vaccine again at the next visit. This advice is based on our research indicating that about two-thirds of parents who decline HPV vaccine get the vaccine at a later visit or intend to do so.[85]

During the training, participants practice these approaches with a pocket guide of key messages that they keep for future reference. They receive 1.0 hour of continuing education (CE) credit for participating.

The **Traditional AAT train-the-trainer curriculum** is an existing curriculum that prepares physicians to serve as the AAT facilitators who deliver the workshops to primary care teams. First, facilitators-in-training participate in an AAT workshop led by an existing facilitator to experience the intervention firsthand. Next, they attend a 1-hour didactic session that provides more in-depth information on HPV vaccination and builds facilitation skills. Finally, they practice delivering the AAT workshop 3 times: twice on their own and once with study staff who evaluate their performance and provide feedback using a structured evaluation form. Facilitators receive a resource binder, including a "frequently asked questions" guide. Once facilitators complete the curriculum, study staff offer them monthly technical assistance calls for the next 6 months. Using interview data collected in Aim 1, we will adapt and extend this existing train-the-trainer curriculum to engage clinical champions and attend to barriers and facilitators that may affect their ability to serve as AAT facilitators.

Aim 1. Identify opportunities to engage champions in delivering AAT in their own healthcare systems.

In Aim 1 we will collect data to inform adaptations of the Traditional AAT intervention package to engage clinical champions. In **Activity 1a**, we will partner with 6 Wisconsin healthcare systems. In **Activity 1b**, we will identify champions in each system using peer nominations and EHR data. We will interview champions to identify opportunities to leverage their influence to improve the reach and sustainability of AAT.

- The **purpose of Aim 1** is to advance cancer prevention science by characterizing clinical champions' role, while also providing data to inform how we will recruit, train, and engage champions for the Aim 2 trial.

1a. Partner with 6 healthcare systems in Wisconsin.

Participants. In Year 1, we will work with the **Wisconsin Collaborative for Healthcare Quality** to recruit 6 systems with a combined total of 40 eligible clinics (see letter). **Eligible clinics** will be those that: 1) provide primary care to ≥100 patients, ages 11-12, according to EHR data; and 2) provide pediatric or family medicine services. We focus our study on medium- to high-volume clinics to increase the impact of our intervention on adolescents and to ensure sufficient power for our analyses. We prioritize pediatrics and family medicine because in the US most HPV vaccine doses are delivered in these settings.[86] We will **exclude clinics** that: 1) have high HPV vaccine coverage at baseline (defined as >85% for 1 dose, among ages 11-12); or 2) have recently (i.e., in the last 6 months) implemented an HPV vaccine quality improvement program. At least one-quarter of clinics in our sample will serve a substantial proportion (>40%) of rural patients to ensure our intervention meets the needs of this high priority population. We define rural patients as those who reside in a non-metropolitan county (i.e., Rural-Urban Continuum Codes [RUCCs] >3), as indicated by EHR data.[87]

A total of 24 healthcare systems currently participate in the Collaborative's data reporting initiative for HPV vaccination. Our preliminary recruitment efforts have already identified 3 systems with a total of 29 eligible clinics to participate: Ascension (9 clinics), Aurora Health Care (15 clinics), and Mayo Clinic Health System (5 clinics). In the event of funding, we will work closely with the Collaborative's Director of Performance Measurement and Analysis, Matt Gigot, to recruit 3 more systems with at least 11 additional eligible clinics through phone and in-person outreach. Dr. Cox will lead these efforts, drawing from her experience conducting research with the Collaborative and recruiting for pragmatic clinical trials in Wisconsin.

1b. Conduct in-depth interviews with 4 champions per system (or 24 champions total).

Participants. We will identify 4 champions in each participating system (or 24 champions total). **Eligible champions** will be pediatricians and family medicine physicians who have at least two years of clinical experience recommending vaccines for adolescents, ages 11-12, and: 1) are nominated by their peers; or 2) have achieved high HPV vaccination rates for adolescent patients. We prioritize physicians because they served as the facilitators for the original AAT trial and their HPV vaccination rates can be assessed via EHRs.

First, within each system, we will solicit peer nominations for physicians who champion the cause of

adolescent vaccination and work to help others improve vaccination services. We will work with system leaders to solicit nominations at the system level (e.g., during quality improvement meetings) and the clinic level (e.g., during team huddles). We will also invite nominations via system newsletters and email lists. Second, we will use EHR data to identify physicians who are high performers in HPV vaccine delivery, defined as being in the top 10% of their peers for HPV vaccine completion among patients, ages 11-12. Because systems report physician-specific data to the Collaborative, assessing physician-level vaccination rates is highly feasible. We have successfully used EHR data in a prior study to recruit champions in this manner.[46]

Once we have identified potential champions, we will recruit a purposive sample using a maximum variation sampling approach designed to capture a wide range of perspectives. In particular, we will seek diversity in terms of specialty (pediatrics/family medicine) and patient mix (high/low proportion of rural patients).

Procedures and measures. Dr. Gilkey, Dr. Cox, and a trained research assistant (RA) will conduct in-depth telephone interviews. We will audio record and transcribe these interviews, which will last ~45 minutes. Participants will provide oral informed consent and receive $100 incentives (if allowed by their system).

Our semi-structured interview guide will evaluate: champions' clinical role; barriers and facilitators they anticipate encountering during AAT delivery; opportunities to extend AAT activities to increase reach and sustainability; and their preferences for receiving training on how to deliver AAT. Our guide will include prompts for probing how barriers and facilitators, like travel time or staff support, may differ in rural versus nonrural areas. We will pilot our interview guide with 2 members of our Clinical Advisory Board prior to fielding, and iteratively refine the guide as needed during data collection.

Analysis. We will analyze interview data qualitatively via thematic content analysis in the manner described by Patton.[88] First, Drs. Gilkey and Cox will independently conduct open coding of several transcripts to identify topic areas within the data. Through a process of consultation, we will synthesize codes into a codebook. Our team will then apply codes systematically to the transcripts using NVivo. Next, we will work code-by-code to describe the areas of agreement and disagreement in the data.[88,89] We will qualitatively assess differences in participants' responses for those working with high versus low proportions of rural patients. We will also qualitatively compare peer nominations and EHR data as strategies for identifying champions willing to deliver AAT. After completing preliminary analyses, we will reread transcripts in their entirety to test findings and check for dissenting views, or "negative cases," that may require additional analysis.[88] We will also conduct "member checking" by presenting preliminary findings to our Clinical Advisory Board for their feedback.[88]

The **main products from Aim 1** will be an understanding of champions' role in improving HPV vaccination. Findings will inform how we recruit, train and engage champions in Aim 2.

Aim 2. Compare the impact of Champion AAT to Traditional AAT on HPV vaccine uptake and communication in healthcare systems.

In Aim 2, we will conduct a cluster randomized non-inferiority trial, comparing Champion AAT to Traditional AAT. In **Activity 2a**, we will use Aim 1 findings to adapt and pilot the AAT intervention to engage clinical champions. In **Activity 2b**, we will conduct the trial, randomizing 40 primary care clinics to receive Champion AAT or Traditional AAT. In **Activity 2c**, we will compare the interventions on vaccination outcomes, including our primary outcome of HPV vaccine initiation, among adolescents ages 11-12, at 12-month follow-up. In **Activity 2d**, we will compare interventions on intermediate outcomes, including HPV vaccine communication.

- The **purpose of Aim 2** is to build the evidence base for communication training to improve HPV vaccination. We will compare the impact of Champion AAT to Traditional AAT on HPV vaccine uptake, while also examining communication and other mechanisms by which AAT may increase uptake.

2a. Enhance and pilot the AAT Intervention Package to engage clinical champions.

Participants. We will adapt and pilot Champion AAT in the 3 healthcare systems that we have recruited to the study: Ascension, Aurora, and Mayo. In each system, we will identify and train 1 champion to pilot the Champion AAT intervention in 1 clinic (or 3 clinics total). Recruitment procedures and eligibility criteria are as described in Aim 1. We will include at least 1 clinic serving a high proportion (>40%) of adolescents living in rural counties (RUCC>3). Clinics that participate in piloting will be ineligible for further participation in the study.

Procedures. We will first **use Aim 1 findings to adapt Traditional AAT to engage clinical champions**. Our goal will be to build on the unique strengths that champions offer, including their local knowledge and professional networks, as well as their ongoing presence in the healthcare system. These strengths may allow champions to support AAT trainings in ways that external facilitators cannot. Specifically, champions are likely better positioned than external facilitators to: 1) use their professional networks to encourage primary care teams to attend AAT workshops; 2) follow up with teams after trainings to provide technical assistance and

reinforce key messages; 3) periodically offer AAT workshops after the initial intervention period to train new staff members; and 4) engage system leadership to ensure an ongoing commitment to improving HPV vaccination. In these ways, champions may offer continuity and peer support that are not possible in the context of Traditional AAT. Based on Aim 1 findings, we will revise and add to these activities as needed.

We anticipate adapting the Traditional AAT intervention package in at least 3 ways:

1. **Protocol for identifying champions.** Tools for identifying clinical champions are not currently available to healthcare systems.[45] Thus, using Aim 1 findings, we will develop a protocol for identifying champions using peer nominations and EHR data. For example, we will create a brief nomination form with procedures that systems can use to collect peer nominations.
2. **System-specific content.** Champions are theorized to influence clinical practice by publicly supporting change efforts.[44-45] To maximize champions' ability to leverage their local knowledge and networks, we will adapt Traditional AAT with structured opportunities for promoting workshops. For example, we will format slides and other materials so that champions can easily brand AAT materials with system-specific logos and photos. We will also provide guidance for helping champions identify and address system-specific challenges, such as competing quality improvement initiatives, that emerge from Aim 1.
3. **Ongoing outreach and technical assistance.** Champions are conceptualized as coaches who offer encouragement and help others overcome barriers to change, and their ongoing outreach may help to improve the sustainability of AAT, which has traditionally consisted of a single workshop. Thus, we will extend Traditional AAT to support champions in creating an action plan for offering ongoing outreach to clinics (e.g., via periodic visits or phone calls). Champions will also offer workshops for new employees on an ongoing basis to address clinical staff turnover.

After completing adaptations, we will present a draft of Champion AAT to our Clinical Advisory Board, who will offer feedback via facilitated discussion. We will refine materials and procedures based on their feedback.

We will next **pilot Champion AAT** with our 3 partnering healthcare systems. In collaboration with the Intervention Core, we will identify and train 1 champion in each system (or 3 total) to deliver Champion AAT to a clinic within their own system. AAT workshops will be open for all primary care professionals in the clinic to attend, including physicians and other prescribers, nurses, and staff. Eligible participants, including physicians and nurses, will receive 1 hour of continuing education (CE) credit, as is provided for Traditional AAT.

Measures. We will evaluate our pilot to assess our intervention on:

1. **Fidelity.** We will evaluate champions' fidelity to the AAT protocol using an existing intervention fidelity checklist. A trained RA will observe each workshop, using the checklist to document whether champions communicate 8 key training messages and complete the training role play activity.
2. **Acceptability of Champion AAT to participants.** We will administer brief (<5 minute) online surveys to participants after the workshop to assess 3 dimensions of acceptability: convenience, helpfulness, and quality of facilitation.[36] Surveys will be required for conferral of CE credit.
3. **Champions' perceptions.** After the pilot, we will conduct 30-minute telephone interviews with each champion. Using a semi-structured interview guide, we will assess champions' views on the strengths and weaknesses of Champion AAT, their experiences delivering workshops, and suggestions for improvement. We will audio-record and transcribe interviews, and offer a $100 incentive for completion.

Analysis. The goal of the pilot analysis will be to identify opportunities to refine Champion AAT. For each pilot session, we will evaluate **fidelity** by calculating the proportion of key training content covered. We will evaluate **acceptability to participants** by calculating the mean of each satisfaction item, with averages of 4.0/5.0 or higher considered acceptable. Finally, we will analyze data from interviews qualitatively via thematic content analysis (using methods described in Activity 1b) to understand **perceptions of champions**. Using a standardized codebook, Drs. Gilkey and Cox will independently code transcripts using NVivo software to identify opportunities for further strengthening the process and content of our intervention. In consultation with systems leaders and our Clinical Advisory Board, we will use findings to refine Champion AAT as needed.

2b. Conduct a non-inferiority trial to compare Champion AAT to Traditional AAT.

Trial design. We will conduct a cluster randomized non-inferiority trial, randomizing 40 clinics across 6 systems to compare Champion AAT to Traditional AAT. Our trial is pragmatic, given that we will compare two clinically-relevant interventions in a diverse study population.[90-91] To ensure the feasibility of our trial, we will deliver interventions over 2 years, working with 3 systems per year. We will deliver interventions in spring to take advantage of summer peaks in adolescent vaccination.[92] We will register our trial with ClinicalTrials.gov.

Our non-inferiority trial design offers several important advantages over other designs. First, **our design is efficient** in that it directly compares a novel intervention (Champion AAT) to an evidence-based intervention

with established effectiveness for improving HPV vaccine uptake (Traditional AAT). If Champion AAT proves non-inferior, then systems will have more options for implementing AAT; it is not necessary for Champion AAT to outperform Traditional AAT to have value. Second, we have chosen to **randomize clinics within systems**, rather than randomizing whole systems, because systems are extremely diverse. Such diversity can limit between-system comparability in the absence of very large sample sizes. Finally, adolescent vaccination is highly seasonal, with the majority of doses delivered in the summer.[92] Such trends can compromise sequential roll out designs (e.g., stepped wedge), but **seasonality will not negatively affect our study**. In these ways, we believe that our trial design will offer rigorous, real-world evidence of Champion AAT impact.

Participants and procedures. We will work with quality improvement leaders in each of our 6 partnering healthcare systems to confirm which clinics in their system are eligible at baseline (see 1b for eligibility criteria). A biostatistician in the Data Core will randomize clinics within each system to receive Champion or Traditional AAT in a 1:1 ratio. To maximize balance in trial arms, we will use EHR data to yoke randomization based on clinics' baseline HPV vaccine coverage (1st dose, ages 11-12) and rurality (≥40% patients with RUCC>3).

We will next prepare clinical champions and external facilitators to deliver AAT. We will **identify champions** using the protocol described in Activity 2a. Research suggests that engaging multiple champions is more effective than using just one.[45] Thus, we will identify 2 or more champions per system (or ≥12 total). To **prepare champions**, an experienced trainer from the Intervention Core will use the adapted train-the-trainer curriculum to convene champions in groups of 2-4 by video conference. As previously described, this curriculum involves attending an AAT workshop, participating in a 1-hour train-the-trainer session, leading 3 practice workshops, and receiving performance feedback and ongoing technical assistance from study staff. **External facilitators** will be UNC primary care physicians who do not have existing relationships with Wisconsin systems. To **prepare external facilitators**, we will use the Traditional AAT train-the-trainer curriculum. Thus, training for champions and external facilitators will be of comparable intensity.

We will next deliver AAT to clinics in both intervention arms simultaneously. In the **Champion AAT arm**, champions will work within their systems using procedures described in Activity 2a. They will invite primary care teams in each clinic by email and phone to attend a 1-hour, in-person AAT workshop. Champions will deliver 1 workshop per clinic, using materials branded for their system. After the workshop, champions will use their action plan to complete follow-up activities and to offer ongoing workshops for new employees.

A trained RA will attend workshops and coordinate research-specific activities related to informed consent and data collection. As participants arrive to the workshop, the RA will complete an attendance log and obtain written informed consent. We will reimburse champions for travel and, when allowed by their employer, provide an honorarium of $200 for participating in research activities.

In the **Traditional AAT arm**, external facilitators will invite primary care teams by email or phone to participate, travel to the clinic site to deliver trainings in-person, and work with an RA who will facilitate research activities. Given their limited involvement with the healthcare system, external facilitators will not conduct ongoing outreach; rather, they will focus only on delivering communication workshops, as per the Traditional AAT intervention protocol. External facilitators will be remunerated for time and travel.

Throughout the trial, we will work to **prevent contamination** that could occur if primary care teams in the Champion AAT arm receive Traditional AAT content or vice versa. First, prior to randomization, we will assess eligible clinics within each system to flag any that share physicians, staff, or substantial proportions (>10%) of patients; in the case of sharing, we will randomly select one clinic from each cluster and exclude remaining clinics in the cluster from the study. We have used these procedures successfully to prevent contamination in a prior study.[35] Second, external facilitators will be UNC physicians without ties to Wisconsin so that we will not inadvertently introduce local champions into the Traditional AAT arm. Third, we will train champions and external facilitators separately. Fourth, we will limit AAT workshop participation to primary care professionals who practice in the clinic where the workshop is held. Finally, we will instruct champions and external facilitators to limit their activities to clinics assigned to their arm.

2c. Compare Champion AAT to Traditional AAT on vaccination outcomes.

Measures. We will assess the vaccination status of adolescents who are HPV vaccine naïve at baseline, using EHR data routinely collected by the Collaborative. To ensure systems' patient lists are up to date, the Collaborative requires that patients have had ≥2 primary care visits in the past 24 months, including 1 visit in the past 12 months, to be included. Patients are excluded if allergic to vaccine components or on hospice.

Analysis. The **primary objective** of the Aim 2 analysis will be to compare Champion AAT to Traditional AAT on HPV vaccine initiation, among patients ages 11-12, between baseline and 12-month follow-up.

- **Hypothesis.** Champion AAT is non-inferior to Traditional AAT for increasing HPV vaccine initiation.
  Rationale: By engaging highly influential physicians, we anticipate that Champion AAT will be at least as effective as Traditional AAT for increasing HPV vaccine uptake.

Our analyses will be intent-to-treat, including all enrolled clinics. To address our **primary objective**, we will model HPV vaccine uptake using a generalized estimating equation (GEE) for logistic outcomes. GEE models accommodate non-independence due to nesting of patients within clinics by adjusting standard error terms. The outcome of the model will be patient-level HPV vaccine initiation at follow-up (0=no, 1=yes): $\ln(p(vax_{2ij})/1-p(vax_{2ij})) = b_0 + b_1 Champion_j + b_2 RUCC_j + b_3 BaselineVax_j + b_4 Sex_{ij} + b_5 Age_{ij}$. We include the clinic-level (*j*) baseline vaccination rate as a covariate, along with clinic RUCC and treatment assignment (Champion=1; Traditional=0). The model will also include fixed effects for system membership. Tests will be 2-tailed with α=.05. The non-inferiority margin, delta, will be .04, which we have selected to detect any clinically meaningful difference between the effectiveness of our interventions. To test for non-inferiority with a margin of .04, we will translate the lower and upper 95% confidence interval limits into predicted probability units and conclude that Champion AAT is inferior if the transformed upper confidence limit falls below .04.

The **secondary objectives** of the Aim 2 analysis will be to test the effectiveness of our interventions for other outcomes. We will conduct these analyses separately for each time point (6-, 12-, 24-month follow-up) and HPV vaccine outcome (1st dose, 2nd dose). In **exploratory analyses,** we will assess interactions between study arm and other variables, such as patient rurality and sex as a biological variable. We will add each variable as a main effect and its interaction with trial arm. Analysts will be blinded to study arm assignment.

Power. With 20 clinics per study arm, we will have **≥80% power to conclude non-inferiority** of Champion vs Traditional AAT when Champion AAT increases HPV vaccine uptake ≥8% points over the secular trend. This calculation assumes: 1) a clinic-level ICC of .033 for change in HPV vaccine initiation, as observed in our pilot work; 2) a non-inferiority margin of .04; 3) 100 patients, ages 11-12, per clinic on average; 4) a secular trend of 10% points; and 5) Traditional AAT effect of 5% points, as observed in our prior trial.[35] Achieving an effect size of ≥8% points with Champion AAT is feasible, given that we are modeling HPV vaccination among unvaccinated adolescents, whose uptake will be higher proportionally than the general population.

Integration. Project 4 will provide a spreadsheet to gather vaccination data for cost-effectiveness modelling. We will complete the spreadsheet using the same approach as the other projects and share it with Project 4.

2d. Compare Champion AAT and Traditional AAT on intermediate outcomes.

Participants. We will assess intermediate outcomes related to primary care professionals' cognitions and communication behaviors, according to our conceptual model. We will collect data on intermediate outcomes via surveys administered to AAT workshop participants at 3 time points: immediately pre- and post-workshop and at 3-month follow-up. All members of the clinics will be eligible, and we estimate having 10 participants per clinic on average (or 400 participants total). Based on response rates we have achieved in prior studies,[36,93] we anticipate that almost all participants will complete the pre- and post-workshop survey, and at least 75% will complete follow-up surveys. Participants who complete all 3 surveys will receive $100.

Procedures and measures. Participants will complete our very brief (<5 minute) surveys online. They will access the pre- and post-workshop surveys using a QR code, and complete these surveys as part of CE activities. For follow-up surveys, we will send a survey link by email, sending up to 6 email and mail reminders.

We will use validated measures from prior studies to assess cognitions and communication behaviors.[36] See **Table 2** for constructs, sample items, and the administration timeline. Items will use 5-point Likert-style response options. The pre-workshop survey will also include characteristics of respondents, including their training, sex, clinical role, and number of years in practice.

Table 2. Intermediate outcomes on cognitions and behavior related to HPV vaccine communication

Construct	Sample item	Pre	Post	3m
Attitudes	It is important to me that my patients get a recommendation for HPV vaccine before age 13.	•	•	•
Norms	It is the norm for our team to routinely recommend HPV vaccine for patients before age 13.	•	•	•
Perceived behavioral control	I feel confident our team can recommend HPV vaccine effectively for all patients before age 13.	•	•	•
Intentions	I intend for all our patients to get an HPV vaccine recommendation before age 13.	•	•	•
Recommendation behavior	Our team recommends HPV vaccine to all patients before age 13.	•		•

Analysis. This analysis will compare the effectiveness of Champion AAT and Traditional AAT for improving primary care professionals' cognitions and behavior related to HPV vaccine communication.

- **Hypothesis.** Champion AAT will be non-inferior to traditional AAT for changing primary care professionals' communication-related cognitions and behavior. *Rationale:* As systems insiders, champions are well-positioned to influence their peers.

We will use GEE models for each outcome measure to assess difference by study arm at pre-workshop, post-workshop, and follow-up time points. The repeated intermediate outcomes will be regressed on nominal indicators of time (pre, post, and follow-up), intervention arm, interactions between intervention arm and time indicators, and a fixed effect of healthcare system. Standard errors will be adjusted to account for nesting of observations within participant and participants within clinics. Tests will be 2-tailed with α=.05.

The **main products of Aim 2** will be data on the comparative effectiveness of Champion AAT and Traditional AAT for improving HPV vaccine uptake and communication. Deliverables will include manuscripts on vaccination and intermediate outcomes, as well as the Champion AAT intervention package.

Aim 3. Generate guidance to help systems compare and implement Champion and Traditional AAT.

Aim 3 will use mixed methods to provide the guidance healthcare systems need to compare and successfully implement Champion and Traditional AAT. In **Activity 3a**, we use trial data to assess the delivery cost of each intervention from the perspective of healthcare systems. In **Activity 3b**, we will examine other implementation outcomes, guided by Proctor et al.'s framework,[94] to understand how each intervention is received and integrated into practice. In **Activity 3c**, we will use the Consolidated Framework for Implementation Research (CFIR) to assess implementation determinants (or facilitators and barriers) that may influence implementation.[44] In **Activity 3d**, we will use Aim 3 findings to package our Champion AAT intervention and implement it in 2 West Virginia systems to further enhance its generalizability.

- The **purpose of Aim 3** is to provide data, including cost, that systems need to compare and implement communication interventions to improve HPV vaccination.

3a. Establish the cost of Champion AAT and Traditional AAT.

Participants and procedures. We will collect cost data from champions, external facilitators, and AAT workshop participants to calculate costs from the perspective of healthcare systems. We will include costs related to delivering AAT activities, attending AAT activities, and using Announcement Approach (AA) communication behavior to recommend HPV vaccine to adolescent patients. We will exclude costs for routine clinic operations or for research-related data collection such as participant interviews or surveys.

To assess the **cost of AAT delivery**, champions and external facilitators will complete brief (<2 minute) online expense records each week to report time spent implementing AAT to the nearest quarter hour, as well as travel and material costs (**Table 3**). Logs will include time for training, and for planning and facilitating AAT. We have used these methods in a prior study to achieve response rates of >95%.[93]

To assess **costs related to attending AAT activities**, we will use data from participant tracking logs to calculate the number of primary care professional hours spent in attending AAT workshops. Hours will be valued using median salaries by job title in Wisconsin.

Table 3. Aim 3 data sources for implementation outcomes

Data source		Interventions: AAT workshops	Behavior: Use of AA
	Intervention expense records Facilitator time, travel, materials	Cost	Cost
	Tracking log of participants 1/workshop, 40 total	Cost, reach	
	Checklist of AAT content 1/workshop, 40 total	Cost, fidelity	
	Survey of AAT participants 10/workshop, 400 total	Acceptability	All outcomes[a]
	Key informant interviews 4/system, 24 total	All outcomes[a]	All outcomes[a]

[a] Implementation outcomes are acceptability, appropriateness, adoption, cost, feasibility, fidelity, reach, sustainability.[94]

To assess **costs related to using the Announcement Approach** to recommend HPV vaccine, workshop participants will report average time spent on recommendations for the last 5 patients ages 11-12 years, using an online survey conducted before the workshop and at 3-month follow-up. (See Activity 2d for methods.)

Analysis. We will calculate the total cost of Champion and Traditional AAT, using t-tests to compare mean costs per clinic. We will calculate the difference in costs between arms and divide by the difference in doses initiated to estimate cost per additional adolescent, ages 11-12, initiating HPV vaccine due to the intervention.

3b. Compare Champion and Traditional AAT on other implementation outcomes.

Procedures. Guided by Proctor's framework,[94] we will use sequential, explanatory mixed methods to assess outcomes related to: 1) the implementation of AAT workshops and 2) the use of the Announcement Approach for recommending HPV vaccine to patients (**Table 3**).

1. **Implementation of AAT workshops.** To assess *reach* (who attended AAT workshops), workshop participants will complete brief tracking logs as they sign in (1 log/clinic, 40 total). We will calculate the total attendees per workshop. To assess *fidelity* (whether interventions were delivered as intended), the RA will observe and rate workshops, using an existing checklist (1 checklist/clinic, 40 total). We will calculate the percentage of the intervention curriculum covered as intended. To assess *acceptability* (satisfaction with the intervention activities), intervention participants will complete a 3-month follow-up survey (described in Activity 2d). We will conduct key informant interviews (described further in Activity 3c) to assess *adoption* (intervention use), *appropriateness* (intervention relevance), *feasibility* (ability to use the interventions), and *sustainability* (ability to use interventions over time).
2. **Use of the Announcement Approach**. The 3-month follow-up survey of workshop participants will assess implementation outcomes regarding use of the Announcement Approach to recommend HPV vaccine to adolescent patients (e.g., *acceptability*).

Analysis. Analyses will compare Champion AAT and Traditional AAT on implementation outcomes.

- **Hypothesis.** Compared to Traditional AAT, Champion AAT will reach a higher proportion of primary care professionals and achieve higher ratings on sustainability. Champion AAT will achieve lower fidelity. *Rationale:* Based on our pilot work, we anticipate that champions' local networks and knowledge will help them attract more participants and sustain intervention activities. In contrast, champions' fidelity to the AAT protocol may be lower due to their having less experience with AAT delivery.

To analyze **quantitative data**, we will compare study arms using generalized linear mixed-level regression models with a random effect term to account for clustering by clinic. Tests will be 2-tailed with α=0.05. To analyze **qualitative interview data**, we will use thematic content analysis methods, as described in Activity 1b, using qualitative analyses to probe quantitative findings. We will share findings from Activities 3a and 3b with Project 4 for inclusion in the web-based decision support tool.

3c. Examine determinants of implementation.

Participants and procedures. We will conduct interviews with 4 key informants per system (or 24 total), including participating champions, external facilitators, quality leaders, and AAT workshop participants. In addition to implementation outcomes, interviews will assess "determinants of implementation," or facilitators and barriers to achieving implementation outcomes. We will derive interview questions from CFIR, whose domains include characteristics of the intervention, individuals and organizations implementing the intervention, the implementation process, and the broader environment.[44] In each domain, open-ended questions will allow stakeholders to respond in their own way, and probes will clarify answers. We will record and transcribe interviews, which will last ~45 minutes. Participants will receive a $100 gift card incentive.

Analysis. We will analyze key informant interview data via thematic content analysis, using the methods described in Activity 1b. The goal of the analysis will be to identify contextual factors, such as leadership engagement, that are needed to successfully implement Champion and Traditional AAT interventions.

3d. Contribute Champion AAT module to P01-wide AAT Intervention Package.

Participants and procedures. We will work with our Clinical Advisory Board and the West Virginia Practice-Based Research Network (WVPBRN) to package our champion module. First, we will use trial findings to revise our module, with guidance from our Clinical Advisory Board. Specifically, we will: update data on HPV vaccine coverage, safety, and effectiveness; incorporate lessons learned in stakeholder interviews; and provide data on intervention effectiveness and implementation. Based on 3c findings, we will also create a context assessment tool describing determinants of successful implementation. We will work with the Intervention Core and graphic designers to package our materials into an attractive and accessible module.

Second, we will partner with WVPBRN to implement our revised module in West Virginia healthcare systems. We will work with WVPBRN to recruit two systems, according to the eligibility criteria described in Activity 1a. Using our Champion AAT intervention package and the methods described in Activity 2a, we will work with healthcare system leaders in each system to identify and train 2 clinical champions per system (or 4 total), who will then deliver an AAT workshop to at least one clinic in their system. As in the Aim 2 pilot, we will assess the fidelity of AAT workshops using checklists, the acceptability of workshops using brief surveys, and the perceptions of champions using exit interviews. Our interview guide will elicit participants' perspectives on how the module might be adapted to fit the needs of West Virginia systems. As in Aim 2, interview participants

will receive a $100 gift card incentive. We will incorporate lessons learned into the Champion AAT module.

Third, we will deliver our module to the Intervention Core in Year 5 Quarter 2 for inclusion in the overall AAT Intervention Package. We will work with the Intervention Core to disseminate this package via our professional networks and existing dissemination websites: hpvIQ.org and HIPxchange.org.

The **main products of Aim 3** will be novel data on implementation, including delivery cost, that healthcare systems can use to compare Champion AAT and Traditional AAT, along with the Champion AAT intervention module. To support cost-effectiveness modeling and **integration across IMPACT projects**, we will work with the Intervention Core to share data with Project 4, using standardized tables, in Year 5 Quarter 1.

Potential Challenges and Solutions

Covid-19. The Covid-19 pandemic could disrupt our plans to conduct in-person study activities, such as AAT workshops. If needed, we will transition our intervention and data collection activities to online platforms. We have extensive experience delivering AAT by Zoom, having completed >50 remote workshops to date.

Recruitment challenges. Our team has extensive experience recruiting primary care clinics and healthcare professionals.[35,46,69-70] In the present study, we will work closely with established partners including the Clinical Advisory Board and the Wisconsin Collaborative for Health Care Quality to achieve our recruitment goals. Dr. Cox is well-positioned to lead these efforts, given her established relationships with the Collaborative and WVPBRN, including multiple funded collaborations. In the event of recruitment challenges, we can expand our pool of potential participants by extending our eligibility criteria to include smaller clinics (e.g., to >50 patients).

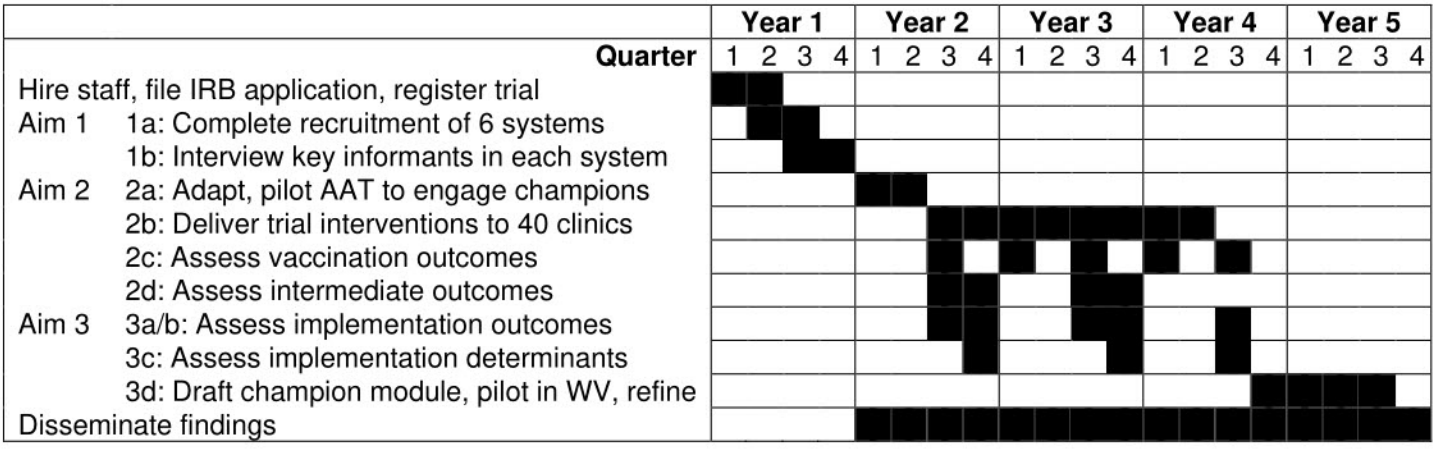
Self-reported data. We assess our primary outcome objectively using EHR data, but some secondary outcomes are assessed via self-report, including communication behavior.[23-24] Though subjective, participants' perceptions are highly salient to improving intentions to recommend HPV vaccine. Furthermore, self-report is less intrusive and more cost effective and acceptable to partnering systems than recording patient encounters. To maximize rigor, we will collect self-reported data using measures that have been validated and/or that we have fielded successfully in prior intervention studies to improve HPV vaccine uptake and communication.

Generalizability of study findings. The proposed trial will offer strong evidence to compare Champion AAT and Traditional AAT on vaccination and implementation outcomes. Our findings will be most generalizable to pediatric and family medicine clinics in healthcare systems; this focus is appropriate given that most HPV vaccine doses are delivered in these settings in the US.[86] We will conduct our trial in a rural state, Wisconsin, to ensure that our intervention serves the needs of rural patients, who have lower HPV vaccine coverage than the general population. In addition, we will follow up by implementing Champion AAT in a second rural state, West Virginia, to optimize our intervention for use in other rural contexts.

Relevance to Program Project Theme

The **IMPACT Program Project's shared theme** is to build capacity for HPV vaccine communication interventions in healthcare systems. Project 3 addresses this theme by engaging clinical champions to bring AAT to scale. If Champion AAT proves non-inferior to Traditional AAT, this study will meaningfully expand the research evidence and intervention tools that healthcare systems have available for improving HPV vaccine uptake and communication to protect youth from future HPV cancers. More broadly, this study's examination of key intervention mechanisms and implementation outcomes will provide crucial information to inform next steps to advance scalable interventions to increase HPV vaccination in healthcare systems.

Timeline



PHS Human Subjects and Clinical Trials Information

OMB Number: 0925-0001

Expiration Date: 02/28/2023

Use of Human Specimens and/or Data

Does any of the proposed research in the application involve human specimens and/or data *	❍ Yes ● No
Provide an explanation for any use of human specimens and/or data not considered to be human subjects research.	
Are Human Subjects Involved	● Yes ❍ No
Is the Project Exempt from Federal regulations?	❍ Yes ● No
Exemption Number	❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑ 6 ❑ 7 ❑ 8
Other Requested Information	

Human Subject Studies

Study#	Study Title	Clinical Trial?
1	Engaging Clinical Champions to Improve HPV Vaccine Communication and Uptake in Healthcare Systems	Yes

Section 1 - Basic Information (Study 1)

OMB Number: 0925-0001

Expiration Date: 02/28/2023

1.1. Study Title *

Engaging Clinical Champions to Improve HPV Vaccine Communication and Uptake in Healthcare Systems

1.2. Is this study exempt from Federal Regulations * ○ Yes ● No

1.3. Exemption Number ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑ 6 ❑ 7 ❑ 8

1.4. Clinical Trial Questionnaire *

1.4.a. Does the study involve human participants?	● Yes	○ No
1.4.b. Are the participants prospectively assigned to an intervention?	● Yes	○ No
1.4.c. Is the study designed to evaluate the effect of the intervention on the participants?	● Yes	○ No
1.4.d. Is the effect that will be evaluated a health-related biomedical or behavioral outcome?	● Yes	○ No

1.5. Provide the ClinicalTrials.gov Identifier (e.g. NCT87654321) for this trial, if applicable

Section 2 - Study Population Characteristics (Study 1)

2.1. Conditions or Focus of Study

- Papillomavirus vaccines

2.2. Eligibility Criteria

Aim 1a:Healthcare systems are eligible if they:-have clinics that provide primary care to at least 100 patients, ages 11-12, and that specialize in pediatrics or family medicineAim 1b:Primary care team members are eligible to be clinical champions if they:-practice primary care in a participating healthcare system-are primary care physicians (pediatricians and family physicians)with at least two years of experience recommending and prescribing adolescent vaccines and who are nominated by their peers and/or have achieved high HPV vaccine uptake among their adolescent patientsAim 2a-d:Primary care clinics are eligible if they:-provide primary care to at least 100 patients, ages 11-12 and specialize in pediatrics or family medicine in participating healthcare systems in Wisconsin Aim 2 a-d:Primary care team members are eligible to be clinical champions if they:-practice primary care in a participating healthcare system-are primary care physicians (pediatricians or family physicians)with at least two years of experience recommending and prescribing adolescent vaccines and who are nominated by their peers and/or have achieved high HPV vaccine uptake among their adolescent patientsAim 2a and d:Primary care team members are eligible to be training participants if they:-work in a participating clinic-participated in an Announcement Approach Training workshopAim 3a and b:Primary care team members and study staff are eligible if they:-participated in Aim 2 RCT activities in any capacity (as clinical champions, external AAT facilitators, participants in AAT trainings, or staff involved in intervention delivery)Aim 3c:Healthcare system employees are eligible if they:-are employed by participating healthcare systems-served in any of the following roles during Aim 2 RCT activities: clinical champion, healthcare system leader, and/or Announcement Approach Training participantAim 3d:Healthcare systems are eligible if they:-have clinics that provide primary care to at least 100 patients, ages 11-12, and specialize in pediatrics or family medicine in West VirginiaAim 3d:Primary care team members are eligible to be clinical champions if they:-practice primary care in participating healthcare systems in West Virginia-are primary care physicians (pediatricians or family physicians)with at least two years of experience recommending and prescribing adolescent vaccines and who are nominated by their peers and/or have achieved high HPV vaccine uptake among their adolescent patients Aim 3d:Primary care team members are eligible to be training participants if they:-work in a participating clinic in West Virginia -participate in an Announcement Approach Training workshop

2.3. Age Limits	Min Age: 18 Years	Max Age: 99 Years
2.3.a. Inclusion of Individuals Across the Lifespan	InclusionofLifespanP3r1045594849.pdf	
2.4. Inclusion of Women and Minorities	InclusionWomenMinoritiesP3r1045594850.pdf	
2.5. Recruitment and Retention Plan	RecruitmentP3r1045594851.pdf	
2.6. Recruitment Status	Not yet recruiting	
2.7. Study Timeline	TimelineP3r1045594852.pdf	
2.8. Enrollment of First Participant	11/01/2021	Anticipated

INCLUSION OF INDIVIDUALS ACROSS THE LIFESPAN – Project 3

The interventions and data collection in this study will focus on primary care team members, so only adults working in their professional roles in pediatric primary care will be included. This study will not recruit or have direct contact with children at any time. We will evaluate our intervention to support the guideline-consistent delivery of HPV vaccine using medical records of children, ages 11-12; however, all medical record data will be de-identified.

There will be no upper age limit for inclusion in the study. However, because the study will focus on adults working in their professional capacity, all participants will be currently employed, thus possibly limiting the number of older adults included. We anticipate enrollment of adults in proportion to their representation among currently working primary care professionals in the US.

INCLUSION OF WOMEN AND MINORITIES – Project 3

We will recruit primary care team members (including physicians, nurse practitioners, physician assistants, nurses, and medical assistants) to take part in this study. We anticipate including women and minorities as participants throughout the study in proportion to their representation in the general populations in the United States. Estimates for inclusion of women and minorities appear in the targeted enrollment tables. To arrive at these estimates, we used recent US Census data.

RECRUITMENT AND RETENTION PLAN – Project 3

Aim 1 Engagement of healthcare systems and clinical champions

Healthcare system recruitment

We will recruit six healthcare systems to participate in the study. Eligible systems will be those with clinics that 1) provide primary care to at least 100 patients, ages 11-12, according to EHR records; and 2) have a pediatric or family medicine specialty. We will partner with the Wisconsin Collaborative for Healthcare Quality (WCHQ) to recruit healthcare systems. We will work closely with Matt Gigot and other members of the Collaborative's leadership team to recruit and build partnerships with healthcare systems by phone and in-person outreach. Dr. Elizabeth Cox will lead these efforts, drawing from her experience recruiting for clinical trials, as well as her extensive professional network as a leader in pediatric research and practice at the University of Wisconsin. WCHQ will assist in recruiting healthcare systems from among their member organizations, based on interest in the project, availability and support for their primary care team members to participate as vaccine champions, and agreement to participate. Participating healthcare systems must provide primary care to adolescent patients.

In-depth interviews with clinical champions

We will identify four clinical champions in each participating healthcare system (24 total). Eligible clinical champions will be pediatricians and family medicine physicians who recommend and prescribe vaccines for adolescents, ages 11-12, and: 1) are nominated by their peers; and/or 2) have achieved high HPV vaccination rates for adolescent patients. To recruit clinical champions, we will first solicit peer nominations for physicians who champion adolescent vaccination within the healthcare system. We will solicit nominations through healthcare system-wide newsletters and email lists. We will also recruit potential participants by using EHR data to identify physicians who are in the top 10% of their peers for HPV vaccine completion among their 11-12 year old patients.

After identifying clinical champions, we will recruit a purposive sample of 24 clinical champions using a maximum variation sampling approach designed to capture a wide range of perspectives. In particular, we will seek diversity in terms of specialty (pediatrics/family medicine) and patient mix (high/low proportion of rural patients). Champions will be invited to participate in in-depth interviews and other study activities by email and phone. Email invitations will include study information, including a description of key study activities, and information about how to volunteer to participate. Drs. Gilkey and Cox will conduct in-depth 45 minute phone interviews with recruited clinical champions. Incentives for participating in interviews will be a $100 gift card.

Aim 2 Pilot study and RCT

Healthcare system recruitment (pilot study)

We will work with three of the healthcare systems recruited in Activity 1a to pilot test our Champion Announcement Approach Training (Champion AAT) intervention. Recruitment of healthcare systems is described in Aim 1. We will adapt the Traditional AAT based on findings in Aim 1 to create our Champion AAT for pilot testing.

Clinical champion recruitment (pilot study)

We will recruit three clinical champions identified in Activity 1b who practice in the healthcare systems participating in the pilot study (1 per system) to test the Champion AAT curriculum. Eligibility criteria are as described in Aim 1.

Champions will be trained to deliver the Champion AAT to one clinic in their healthcare system. Clinical champions will be invited to participate in the pilot study by email and phone. Email invitations will include study information, including a description of key study activities and information about how to participate. Incentives for participating will be a $100 gift card for completing pilot study activities and participating in a 30 minute exit interview.

Training Participant recruitment (pilot study)

In the pilot study, champions will invite primary care team members in each pilot clinic by email and phone to attend an in-clinic Champion AAT workshop. Champions will recruit participants within their own clinics for the pilot test, and we will take several steps to support their work. First, we will provide email templates, talking

points, and a study fact sheet to facilitate invitations. Second, we will provide a research assistant (RA) to coordinate research-specific activities related to informed consent and data collection. As participants arrive to the workshop, the RA will complete an attendance log, give an overview of the pilot study, and obtain written informed consent from participants. Training participants will receive 1.0 hour of continuing education (CE) credit.

Primary care clinic recruitment (RCT)

We will work with quality improvement leaders in each of our 6 partnering healthcare systems to determine which clinics in their system are eligible. Eligible clinics will 1) provide primary care to at least 100 patients, ages 11-12, according to EHR records; and 2) have a pediatric or family medicine specialty. Systems will then identify at least 4 clinics each (for a total of 40 clinics overall) from among those eligible to participate.

Clinical champion recruitment (RCT)

We will recruit at least two physicians in each partner healthcare system (or ≥12 total) to participate as clinical champions in the RCT. Participants will be recruited through their healthcare system and identified based on criteria identified in Aim 1. Primary care team members who participated in the pilot study will not be eligible to participate as champions in the RCT.

Physicians will be invited to participate in the RCT by email and phone. Email invitations will include study information, including a description of key study activities and information about how to participate. Incentives for participating will be a $200 honorarium per champion for each training that they deliver (if allowed by their healthcare system). We will also reimburse champions for travel expenses.

AAT workshop participant recruitment (RCT)

In the Champion AAT arm of the study, champions will invite primary care team members in each intervention clinic by email and phone to attend an in-clinic AAT workshop. Champions will work within their own systems, and we will take several steps to support their work. First, we will provide email templates, talking points, and a study fact sheet to facilitate invitations. Second, we will provide an RA to coordinate research-specific activities related to informed consent and data collection. As participants arrive to the workshop, the RA will complete an attendance log, give an overview of the study, obtain written informed consent from participants, and distribute links for primary care team member surveys. Workshop participants will receive 1.0 hour of CE credit.

In the Traditional AAT arm, a physician external to the healthcare system will lead trainings. External facilitators will be study-affiliated physicians who have been trained with the Traditional AAT curriculum. Facilitators in the Traditional AAT arm will invite primary care team members by email or phone, deliver in-clinic trainings, and work with an RA who will facilitate research activities. Workshop participants will receive 1.0 hour of CE credit for attending traditional AAT trainings.

Primary care team member surveys

We will administer surveys to up to 400 primary care team members that participated in Champion and Traditional AAT workshops in Activity 2b of the study. Participants will complete online surveys immediately before and after the trainings. At three-month follow-up, online surveys will be administered to participants using email addresses that they provide during the training. We will email a link to the survey, sending up to 6 email and phone reminders. Participants will receive a gift card incentive of $100 for completing all three surveys.

Aim 3 Generate guidance for healthcare systems

Implementation measures

All primary care team members and study staff who participated in Aim 2 RCT activities will be recruited to participate in data collection on implementation measures, including completing time and expense logs, surveys (see Aim 2), observations, tracking logs, and in-depth interviews.

In-depth interviews

At 12-month follow-up, we will conduct in-depth interviews with four key informants from each healthcare system. Eligible participants will be clinical champions, AAT participants from RCT activities and leaders from participating healthcare systems. Interview participants will be recruited via email and phone. Email invitations

will include study information, including a description of the purpose of the interview, and information about how to volunteer to participate. Participants in in-depth interviews will receive a $100 gift card.

Healthcare system recruitment (module pilot testing)

We will partner with the West Virginia Practice-Based Research Network (WVPBRN) to pilot test our Champion AAT module to refine it for inclusion in the intervention module. Eligible systems will be those that have clinics that 1) provide primary care to at least 100 patients, ages 11-12, according to EHR records; and 2) have a pediatric or family medicine specialty. Dr. Elizabeth Cox will again lead these efforts. The WVPBRN will assist in recruiting healthcare systems from among their member organizations, based on interest in the project, availability and support for their primary care team members to participate as vaccine champions, and agreement to participate. Participating healthcare systems must provide primary care to adolescent patients.

Clinical champion recruitment (module pilot testing)

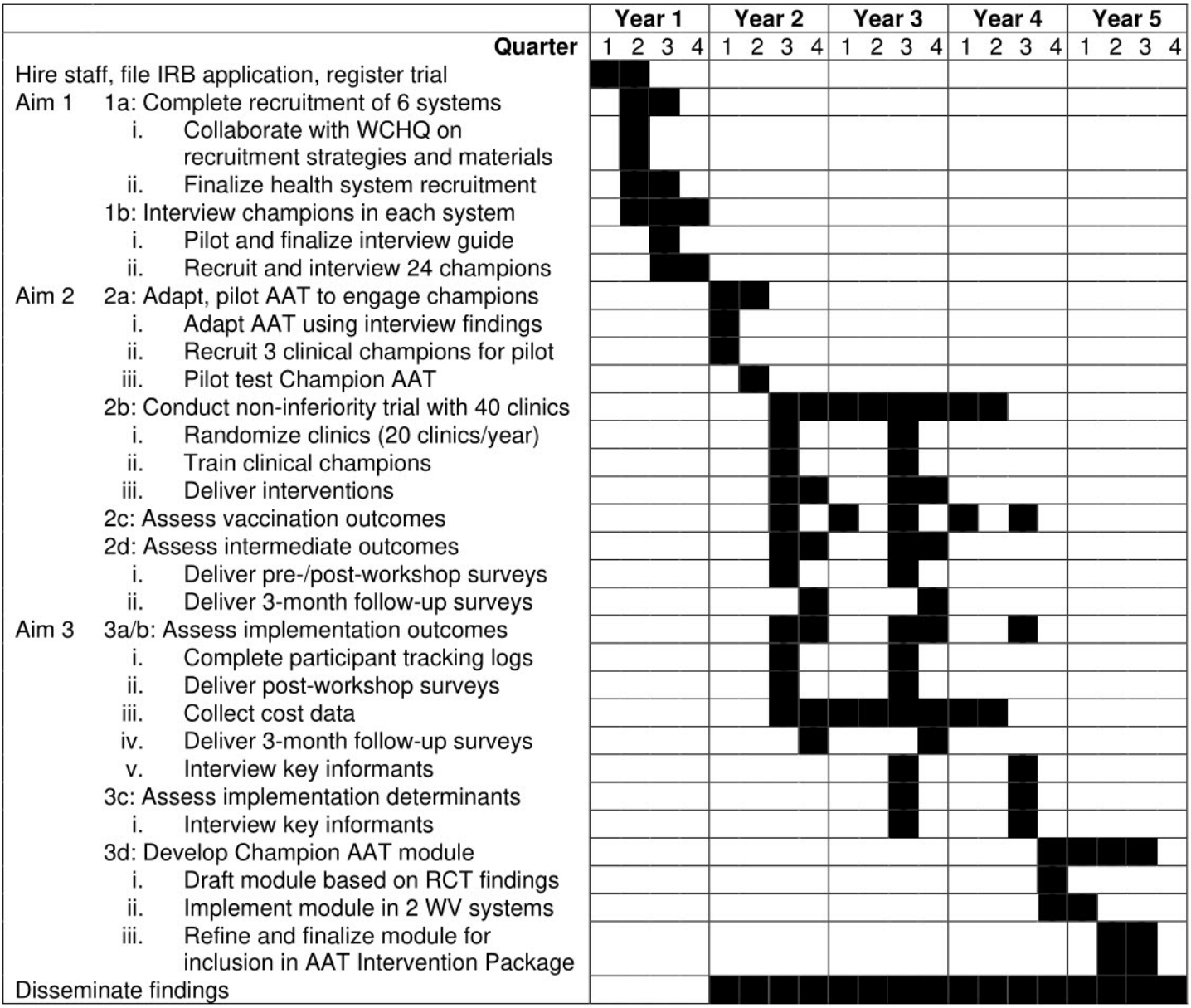
Using the methods described in Aim 1 (in-depth interviews), we will recruit two clinical champions in each of the participating healthcare systems in West Virginia (or 4 total) to pilot test the Champion ATT intervention module. Eligibility criteria are as described in Aim 1.

Champions will be trained to deliver the Champion AAT to one clinic in their healthcare system. Clinical champions will be invited to participate in the module pilot test by email and phone. Email invitations will include study information, including a description of key study activities and information about how to participate. Incentives for participating will be a $100 gift card for completing pilot study activities and participating in a 30 minute exit interview.

AAT workshop participant recruitment (module pilot testing)

In the module pilot test, champions will invite primary care team members in one clinic each by email and phone to attend an in-clinic Champion AAT lunch-and-learn session. Champions will recruit participants within their own clinics for the module pilot test, and we will take several steps to support their work. First, we will provide email templates, talking points, and a study fact sheet to facilitate invitations. Second, we will provide an RA to coordinate research-specific activities related to informed consent and data collection. As participants arrive to the workshop, the RA will complete an attendance log, give an overview of the module pilot test, and obtain written informed consent from participants. Training participants will receive 1.0 hour of continuing CE credit.

STUDY TIMELINE – Project 3



Aim 1

Our ability to implement activities within the timeframe described comes from having an experienced team that has worked extensively on projects with similar components. The team will work simultaneously on multiple tasks, guided by experienced investigators.

In Year 1, we will focus on finalizing recruitment of healthcare systems and clinical champions. We will work with the Wisconsin Collaborative for Healthcare Quality to recruit six healthcare systems that are part of their member network. We will collect formative data by interviewing clinical champions to assess their roles in their healthcare systems and the barriers and facilitators that they anticipate facing as they seek to deliver AAT.

Aim 2

In Year 2, we will adapt the Traditional AAT materials based on our findings from in-depth interviews in the previous year to create our Champion AAT materials and protocol. We will pilot Champion AAT in three healthcare systems and make further refinements to the materials based on findings. We will conduct a 2-arm cluster randomized non-inferiority trial with 40 clinics in six healthcare systems in Years 2-4. Clinics will be randomized to receive either Traditional AAT or Champion AAT. We will assess vaccination outcomes in Years

2-4. Our primary outcome (HPV vaccine initiation at 12-month follow-up) will be assessed in Years 3-4. In Years 2-3, we will also collect data to assess intermediate outcomes of the trial.

Aim 3

In Years 2-4 we will collect data to assess implementation outcomes and implementation determinants of the trial. This includes the cost evaluation that we will contribute to Project 4 modeling. We will also refine our Champion AAT materials based on the outcome of the Aim 2 trial in Year 4. These materials will be used to create the Champion AAT module that will be contributed to the P01-wide intervention package. We will implement the refined Champion AAT module in two healthcare systems in West Virginia in Years 4-5. Based on findings from the pilot test of the module, we will finalize materials in Year 5 and contribute them to the P01-wide AAT Intervention Package.

2.9. Inclusion Enrollment Reports

IER ID#	Enrollment Location Type	Enrollment Location
Study 1, IER 1	Domestic	Wisconsin
Study 1, IER 2	Domestic	Wisconsin
Study 1, IER 3	Domestic	Wisconsin
Study 1, IER 4	Domestic	Wisconsin
Study 1, IER 5	Domestic	West Virginia
Study 1, IER 6	Domestic	West Virginia

Inclusion Enrollment Report 1

1. Inclusion Enrollment Report Title* : Enrollment of Clinical Champions in Key Informant Interviews

2. Using an Existing Dataset or Resource* : ❍ Yes ● No

3. Enrollment Location Type* : ● Domestic ❍ Foreign

4. Enrollment Country(ies): USA: UNITED STATES

5. Enrollment Location(s): Wisconsin

6. Comments: The following enrollment table is for key informant interviews completed as part of Aim 1b. Enrollment of primary care team members will be in proportion to the demographic make up of the US, per recent US Census data. Three of these enrolled participants will be clinical champions in pilot testing as part of Aim 2a.

Planned

Racial Categories	Ethnic Categories				Total
	Not Hispanic or Latino		Hispanic or Latino		
	Female	Male	Female	Male	
American Indian/ Alaska Native	0	0	0	0	0
Asian	1	1	0	0	2
Native Hawaiian or Other Pacific Islander	0	0	0	0	0
Black or African American	2	1	0	0	3
White	7	7	2	2	18
More than One Race	0	1	0	0	1
Total	10	10	2	2	24

Cumulative (Actual)

Racial Categories	Ethnic Categories									Total
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			
	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	
American Indian/ Alaska Native	0	0	0	0	0	0	0	0	0	0
Asian	0	0	0	0	0	0	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0	0	0	0	0	0	0
Black or African American	0	0	0	0	0	0	0	0	0	0
White	0	0	0	0	0	0	0	0	0	0
More than One Race	0	0	0	0	0	0	0	0	0	0
Unknown or Not Reported	0	0	0	0	0	0	0	0	0	0
Total	0	0	0	0	0	0	0	0	0	0

Inclusion Enrollment Report 2

1. Inclusion Enrollment Report Title* : Enrollment of Training Participants for Pilot Study

2. Using an Existing Dataset or Resource* : ❍ Yes ● No

3. Enrollment Location Type* : ● Domestic ❍ Foreign

4. Enrollment Country(ies): USA: UNITED STATES

5. Enrollment Location(s): Wisconsin

6. Comments: The following enrollment table is for training participants as part of Aim 2a. Enrollment of primary care team members who will participate in pilot trainings will be in proportion to the demographic make up of the US, per recent US Census data.

Planned

Racial Categories	Ethnic Categories				Total
	Not Hispanic or Latino		Hispanic or Latino		
	Female	Male	Female	Male	
American Indian/ Alaska Native	0	0	0	0	0
Asian	1	1	0	0	2
Native Hawaiian or Other Pacific Islander	0	0	0	0	0
Black or African American	2	2	0	0	4
White	9	9	3	2	23
More than One Race	1	0	0	0	1
Total	13	12	3	2	30

Cumulative (Actual)

Racial Categories	Ethnic Categories									Total
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			
	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	
American Indian/ Alaska Native	0	0	0	0	0	0	0	0	0	0
Asian	0	0	0	0	0	0	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0	0	0	0	0	0	0
Black or African American	0	0	0	0	0	0	0	0	0	0
White	0	0	0	0	0	0	0	0	0	0
More than One Race	0	0	0	0	0	0	0	0	0	0
Unknown or Not Reported	0	0	0	0	0	0	0	0	0	0
Total	0	0	0	0	0	0	0	0	0	0

Inclusion Enrollment Report 3

1. Inclusion Enrollment Report Title* : Enrollment of Clinical Champions - RCT

2. Using an Existing Dataset or Resource* : ❍ Yes ● No

3. Enrollment Location Type* : ● Domestic ❍ Foreign

4. Enrollment Country(ies): USA: UNITED STATES

5. Enrollment Location(s): Wisconsin

6. Comments: The following enrollment table is for recruitment of clinical champions in the RCT completed as part of Aims 2 and 3. Enrollment of primary care team members to serve as clinical champions will be in proportion to the demographic make up of the US, per recent US Census data.

Planned

Racial Categories	Ethnic Categories				Total
	Not Hispanic or Latino		Hispanic or Latino		
	Female	Male	Female	Male	
American Indian/ Alaska Native	0	0	0	0	0
Asian	0	1	0	0	1
Native Hawaiian or Other Pacific Islander	0	0	0	0	0
Black or African American	1	1	0	0	2
White	4	3	1	1	9
More than One Race	0	0	0	0	0
Total	5	5	1	1	12

Cumulative (Actual)

Racial Categories	Ethnic Categories									Total
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			
	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	
American Indian/ Alaska Native	0	0	0	0	0	0	0	0	0	0
Asian	0	0	0	0	0	0	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0	0	0	0	0	0	0
Black or African American	0	0	0	0	0	0	0	0	0	0
White	0	0	0	0	0	0	0	0	0	0
More than One Race	0	0	0	0	0	0	0	0	0	0
Unknown or Not Reported	0	0	0	0	0	0	0	0	0	0
Total	0	0	0	0	0	0	0	0	0	0

Inclusion Enrollment Report 4

1. Inclusion Enrollment Report Title* : Enrollment of Training Participants - RCT

2. Using an Existing Dataset or Resource* : ❍ Yes ● No

3. Enrollment Location Type* : ● Domestic ❍ Foreign

4. Enrollment Country(ies): USA: UNITED STATES

5. Enrollment Location(s): Wisconsin

6. Comments: The following enrollment table is for enrollment of training participants completed as part of Aims 2 and 3. Enrollment of primary care team members as training participants will be in proportion to the demographic make up of the US, per recent US Census data.

Planned

Racial Categories	Ethnic Categories				Total
	Not Hispanic or Latino		Hispanic or Latino		
	Female	Male	Female	Male	
American Indian/ Alaska Native	2	1	0	0	3
Asian	11	12	0	0	23
Native Hawaiian or Other Pacific Islander	0	0	0	0	0
Black or African American	26	25	0	0	51
White	120	120	36	36	312
More than One Race	6	5	0	0	11
Total	165	163	36	36	400

Cumulative (Actual)

Racial Categories	Ethnic Categories									Total
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			
	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	
American Indian/ Alaska Native	0	0	0	0	0	0	0	0	0	0
Asian	0	0	0	0	0	0	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0	0	0	0	0	0	0
Black or African American	0	0	0	0	0	0	0	0	0	0
White	0	0	0	0	0	0	0	0	0	0
More than One Race	0	0	0	0	0	0	0	0	0	0
Unknown or Not Reported	0	0	0	0	0	0	0	0	0	0
Total	0	0	0	0	0	0	0	0	0	0

Inclusion Enrollment Report 5

1. Inclusion Enrollment Report Title* : Enrollment of Clinical Champions - module pilot test

2. Using an Existing Dataset or Resource* : ❍ Yes ● No

3. Enrollment Location Type* : ● Domestic ❍ Foreign

4. Enrollment Country(ies): USA: UNITED STATES

5. Enrollment Location(s): West Virginia

6. Comments: The following enrollment table is for pilot testing of the Champion AAT module completed as part of Aim 3d. Enrollment of primary care team members as clinical champions will be in proportion to the demographic make up of the US, per recent US Census data.

Planned

Racial Categories	Ethnic Categories				Total
	Not Hispanic or Latino		Hispanic or Latino		
	Female	Male	Female	Male	
American Indian/ Alaska Native	0	0	0	0	0
Asian	0	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0	0
Black or African American	0	1	0	0	1
White	1	1	1	0	3
More than One Race	0	0	0	0	0
Total	1	2	1	0	4

Cumulative (Actual)

Racial Categories	Ethnic Categories									Total
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			
	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	
American Indian/ Alaska Native	0	0	0	0	0	0	0	0	0	0
Asian	0	0	0	0	0	0	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0	0	0	0	0	0	0
Black or African American	0	0	0	0	0	0	0	0	0	0
White	0	0	0	0	0	0	0	0	0	0
More than One Race	0	0	0	0	0	0	0	0	0	0
Unknown or Not Reported	0	0	0	0	0	0	0	0	0	0
Total	0	0	0	0	0	0	0	0	0	0

Inclusion Enrollment Report 6

1. Inclusion Enrollment Report Title* : Enrollment of Training Participants for Module Pilot

2. Using an Existing Dataset or Resource* : ❍ Yes ● No

3. Enrollment Location Type* : ● Domestic ❍ Foreign

4. Enrollment Country(ies): USA: UNITED STATES

5. Enrollment Location(s): West Virginia

6. Comments: The following enrollment table is for training participants as part of Aim 3d. Enrollmentof primary care team members who will participate in pilot testing the Intervention Module will be in proportion to the demographic make up of the US, per recent US Census data.

Planned

Racial Categories	Ethnic Categories				Total
	Not Hispanic or Latino		Hispanic or Latino		
	Female	Male	Female	Male	
American Indian/ Alaska Native	0	0	0	0	0
Asian	1	1	0	0	2
Native Hawaiian or Other Pacific Islander	0	0	0	0	0
Black or African American	3	2	0	0	5
White	12	12	3	4	31
More than One Race	1	1	0	0	2
Total	17	16	3	4	40

Cumulative (Actual)

Racial Categories	Ethnic Categories									Total
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			
	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	
American Indian/ Alaska Native	0	0	0	0	0	0	0	0	0	0
Asian	0	0	0	0	0	0	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0	0	0	0	0	0	0
Black or African American	0	0	0	0	0	0	0	0	0	0
White	0	0	0	0	0	0	0	0	0	0
More than One Race	0	0	0	0	0	0	0	0	0	0
Unknown or Not Reported	0	0	0	0	0	0	0	0	0	0
Total	0	0	0	0	0	0	0	0	0	0

Section 3 - Protection and Monitoring Plans (Study 1)

3.1. Protection of Human Subjects	ProtectionHsP3r1045594853.pdf
3.2. Is this a multi-site study that will use the same protocol to conduct non-exempt human subjects research at more than one domestic site?	● Yes ○ No ○ N/A
If yes, describe the single IRB plan	MultisiteStudyP3r1045594854.pdf
3.3. Data and Safety Monitoring Plan	DsmpP3r1045594855.pdf
3.4. Will a Data and Safety Monitoring Board be appointed for this study?	○ Yes ● No
3.5. Overall structure of the study team	StudyTeamP3r1045594856.pdf

PROTECTION OF HUMAN SUBJECTS – Project 3

Risk to Human Subjects

We acknowledge that our study involves populations that could be considered vulnerable: adolescents and primary care professionals trained in their places of work. We have worked closely with our IRB to successfully conduct multiple similar studies with similar data sources (anonymized health records of adolescent vaccination and anonymized participant surveys). We will again work closely with the IRB to ensure the protection of all study participants.

Human subjects involvement

The proposed study will compare the standard Announcement Approach Training ("Traditional AAT") to a training adapted to be delivered by clinical champions ("Champion AAT"). We will collect formative data to adapt Traditional AAT for delivery by clinical champions and then pilot the resulting Champion AAT in three healthcare systems. After further refining our materials, we will conduct a two arm non-inferiority trial of Traditional AAT and Champion AAT. The trial will compare the impact of Traditional AAT and Champion AAT using electronic health records (EHR) data, AAT participant surveys (conducted before and after AAT workshops and at 3 month follow-up), and micro-costing data.

In-depth interviews. We will recruit 24 primary care physicians (pediatricians and family physicians) to participate in in-depth interviews to explore clinical champions' roles in healthcare systems, anticipated barriers and facilitators to delivering Announcement Approach Training (AAT), opportunities to extend AAT activities to increase reach and sustainability, and training preferences. Eligible participants will be primary care physicians who prescribe and administer HPV vaccine to patients, ages 11-12, and who are either nominated by their peers or have achieved high HPV vaccine uptake among their patients.

Pilot test. We will pilot test our Champion AAT curriculum in three healthcare systems. One clinical champion will be recruited in each participating healthcare system in Wisconsin. Clinical champions will complete the train-the-trainer curriculum, as per the Champion AAT protocol. Each clinical champion will then deliver an AAT workshop to one primary care clinic in their own healthcare system. The initial train-the-trainer curriculum will take approximately two hours to complete. The subsequent Champion AAT workshops will take one hour to deliver. Approximately 30 primary care team members will be invited to attend the pilot workshops and complete a brief (<5 minute) online survey. After the clinical champions deliver the Champion AAT workshop, champions will be asked to participate in an exit interview so that we can collect feedback on how to further refine our study materials and procedures. Clinical champions will receive a $100 gift card for participating in exit interviews.

RCT. In each healthcare system, we will recruit at least two clinical champions (or ≥12 total) who will be trained to deliver the Champion AAT via the train-the-trainer curriculum. Eligible participants will be primary care physicians (pediatricians or family physicians) who prescribe or deliver HPV vaccination to patients, ages 11-12 in participating healthcare systems, and who are either nominated by their peers or have achieved high HPV vaccine uptake among their patients. The train-the-trainer curriculum will take approximately two hours to complete and will be led by an experienced leader from the Intervention Core. After the session, clinical champions will be asked to deliver the Champion AAT in two to three primary care clinics in their healthcare systems. Clinical champions will receive a $200 honorarium for each AAT they deliver and will be reimbursed for any travel expenses.

We will work with quality improvement leaders in participating healthcare systems to identify clinics in their systems that are eligible to participate in the study. Systems will then identify at least four clinics to participate. About 400 primary care team members (or 10/clinic) will then attend Announcement Approach Training (AAT) workshops delivered by either the system's own clinical champion or an external facilitator. Workshop participants will include physicians, other prescribers, nurses, and other staff who work in participating clinics. Workshop participants will receive 1.0 hour of continuing education (CE) credit for attending the training.

Intermediate and implementation outcomes assessment. Primary care team members who participate in either Champion or Traditional AAT trainings will be eligible to participate in assessments of intermediate and implementation outcomes.

Module pilot testing. We will partner with two healthcare systems in West Virginia to pilot the Champion AAT module that we will contribute to the Program Project's Intervention Package. In each healthcare system, we will recruit two primary care physicians (pediatricians or family physicians), or four in total, to participate as clinical champions. Champions will be trained to deliver the Champion AAT by completing the train-the-trainer curriculum. Eligible participants will be those who prescribe or deliver HPV vaccination to patients, ages 11-12,

who provide primary care in participating healthcare systems, and who are either nominated by their peers or have achieved high HPV vaccine uptake among their patients. The train-the-trainer curriculum will take approximately two hours to complete and will be led by an experienced leader from the Intervention Core. After the session, clinical champions will deliver the Champion AAT intervention in at least one primary care clinic in their healthcare systems. About 40 primary care team members from participating clinics will attend the Champion AAT workshops and complete a brief survey. Workshop participants will include physicians, other prescribers, nurses, and other staff who work in participating clinics. After the clinical champions deliver the Champion AAT, they will participate in an exit interview so that we can collect feedback on how to further refine our dissemination materials. Clinical champions will receive a $100 gift card for participating in exit interviews.

Source of materials

In-depth interviews (n=24). (Activity 1b) We will conduct ~45-minute telephone interviews with 24 champions who practice in participating healthcare systems in Wisconsin. Trained interviewers will use a semi-structured interview guide. Interviews will be audio recorded and transcribed with participants' consent. We will temporarily have participants' names and contact information for the purpose of scheduling and conducting the interview and providing incentives. However, identifying information will not be linked to participants' data.

Observation of pilot AAT trainings (n=3). (Activity 2a) We will evaluate champions' fidelity to AAT using an existing intervention checklist. A trained research assistant (RA) will observe each workshop, using the checklist to document whether champions communicate 8 key training messages and complete the training role play activity. The RA will also note questions that participants raise, including any points of confusion.

Primary care team pilot surveys (n=30). (Activity 2a) We will administer brief (<5 minute) online surveys to participating primary care team members immediately after the workshop to assess acceptability to participants. We will use previously developed closed-ended items on the training's convenience, helpfulness, and quality of instruction. We will obtain a written consent waiver and distribute an information sheet to participants with the other training materials. The post-training survey is part of the requirement for earning continuing education credit (CE). Surveys will not request any identifying information or sensitive data from participants. Participants will complete a sign-in sheet that will allow us to distribute CE credits, but this sign-in sheet will not be kept with survey data.

Pilot exit interviews (n=3). (Activity 2a) We will conduct 30-minute exit interviews with each champion by phone upon completion of the pilot in order to understand the perceptions of champions. Using a semi-structured interview guide, we will ask champions to reflect on the strengths and weaknesses of our curriculum, their experience delivering workshops, and their suggestions for improvement. With champions' consent, we will audio-record interviews and transcribe them verbatim.

Electronic health record (EHR) data. (Activity 2c) We will assess adolescents' HPV vaccination status using de-identified vaccination data obtained from EHRs. Our primary outcome is proportion of 11- to 12-year-old patients who have initiated HPV vaccination (≥1 dose) at 12-month follow-up. Our secondary outcomes include other HPV vaccination outcomes (2 doses) and time periods (6- and 24-month follow-up). In addition to measures of vaccination status, we will use EHR data to characterize clinics in terms of size (total number of adolescent patients and primary care team members), specialty (pediatrics, family medicine), and patient demographics, including sex, race/ethnicity, and rurality. We will determine rurality of patients by Rural-Urban Continuum Codes of their addresses with rural counties (sometimes called nonmetropolitan areas) being those with codes >3. We will comply with UNC IRB requirements, which do not call for HIPAA authorization or consent for anonymized electronic health record (EHR) data.

Primary care team surveys (n=400). (Activities 2d and 3b) We will administer a brief (<5 minute) self-administered online survey to primary care team members immediately pre- and post-training and at 3-month follow-up. Surveys will use closed-ended, validated measures to assess cognitions and behaviors as well as characteristics of participants and the settings in which they practice. Consent procedures will be as described for primary care team pilot surveys.

Time and expense logs (n=15)**.** (Activity 3a) Champions, external facilitators, and staff involved in intervention delivery will complete weekly online expense logs to collect micro-costing data used to calculate delivery cost per clinic. These very brief (<2 minute) weekly surveys will assess the hours spent on key activities (e.g., traveling to clinics, delivering trainings) to the nearest quarter hour, and any material expenses incurred.

Checklists (n=40). (Activity 3b) We will observe AAT workshops to assess fidelity. A trained RA attending each workshop will use an existing 8-item checklist to assess whether facilitators cover AAT content.

Tracking logs (n= 40). (Activity 3b) The RA will also track the number and clinical role of primary care team members attending each AAT workshop. These tracking logs will not include participants' names, only their roles within the clinic.

Key informant interviews (n=24). (Activity 3c) At 12-month follow-up we will conduct in-depth interviews with four key informants from each healthcare system, including the clinical champion, a healthcare system leader, and two training participants. We will use a semi-structured interview guide to conduct ~30 minute interviews to explore AAT acceptability, appropriateness, reach and fidelity to enhance quantitative survey findings. Interviews will be audio-recorded and transcribed with participants' consent. We will have participants' names and contact information for the purpose of scheduling and conducting the interview and providing incentives. However, identifying information will not be linked to participants' data.

Observation of module pilot AAT trainings (n=4). (Activity 3d) We will evaluate champions' fidelity to AAT using an existing intervention checklist. An RA will observe each workshop, using the checklist to document whether champions communicate 8 key training messages and complete the training role play activity. The RA will also note questions that participants raise, including any points of confusion.

Module pilot primary care team surveys (n=40). (Activity 3d) We will administer brief (<5 minute) written surveys to participating primary care team members immediately after the workshop to assess acceptability to participants. We will use previously developed closed-ended items on the training's convenience, helpfulness, and quality of instruction. Consent procedures will be as described above for primary care team pilot surveys.

Module pilot exit interviews (n=4). (Activity 3d) We will conduct 30-minute exit interviews with each champion by phone upon completion of the module pilot in order to understand champions' perspectives on how the module might be adapted to meet the needs of West Virginia healthcare systems. With participants' consent, we will audio-record interviews and transcribe them verbatim.

Potential Risks

We anticipate that the risks to participants will be minimal. However, the primary risk is potential risk of breach of confidentiality. The risk of such a breach will be minimized through appropriate training of all study personnel regarding confidentiality. All study personnel will complete training and obtain certification in human-subjects protection. They also agree not to divulge, publish, or otherwise make known to unauthorized persons or to the public any information obtained during this study that could identify the persons who participated in the study.

Study activities will not collect personal or sensitive information. Rather, we are asking primary care physicians to share knowledge and opinions they have developed in their professional practice. We will not share the identities of participants with their employers, professional societies to which they belong, or with other participants in the study. In this way, we will seek to limit the potential for their decision to participate to affect their professional relationships.

All EHR data obtained for the study will be anonymized before being given to the research team. Additionally, electronic copies of data will be stored in password-protected files on secure computer servers, access to which also is network password protected. Hard copies of data will be stored in locked filing cabinets in locked offices. All records in EHR data will be assigned a unique identification number. Access to electronic data and hard copies of the data will be restricted to project members only. Oral presentations and written reports drawing on the data will contain no identifying information linking individuals to specific comments.

Adequacy of protection against risks

Recruitment and informed consent

Six healthcare systems will be recruited to participate in the trial. We will arrange a meeting with system quality improvement leaders to discuss the two interventions involved in the study. Health system leaders will identify individual clinics to participate in the study. The system and clinic leadership will consent on behalf of the clinics. We will apply for a waiver of written consent, and we will comply with all UNC IRB requirements, which do not call for HIPAA authorization for anonymized EHR data.

We will work with recruited healthcare systems to identify and recruit participating primary care team members, based on interest and availability and overall agreement to participate. Participants will receive a fact sheet about the study. The fact sheet will include a statement that participation is voluntary, that there is minimal risk involved, that they can discontinue participation at any time, that responses are confidential, and

information on how to contact someone if they have any questions. Primary care team members will have time to review the consent form and will then provide written informed consent prior to participation.

For all in-depth interviews, study staff will explain the purpose of the study and interview. At the start of the interview, the study team member conducting the interview will welcome the participant and review and obtain consent from participants. During this process, the study team member will point out that participation is voluntary, that there is minimal risk involved, that they can stop the interview or not answer any question at any time, that responses are confidential, and how to contact someone if they have any questions. If the participant gives verbal consent, the study team member will then proceed with the interview. We anticipate obtaining informed consent verbally will be appropriate given that participants are adults and the interviews will not cover sensitive information. These interviews will be recorded and transcribed for accuracy. Audio recordings will be destroyed once they have been transcribed and any identifying information will be redacted from the transcriptions.

Protection against risk

The primary risk to subjects participating in this research project is a breach of confidentiality. The risk of such a breach will be minimized through appropriate training of all study personnel regarding confidentiality. All study personnel will complete training and obtain certification in human-subjects protection. They also agree not to divulge, publish, or otherwise make known to unauthorized persons or to the public any information obtained during this study that could identify the persons who participated in the study. Electronic copies of data will be stored in password-protected files on secure computer servers, access to which also is network password protected. Hard copies of data will be stored in locked filing cabinets in locked offices. Each study participant will be assigned a unique identification number. A master list linking names and identification numbers will be stored separately from project data. Only study staff will have access to the master list. Access to electronic data and hard copies of the completed surveys will be restricted to project members only. Oral presentations and written reports drawing on the data will contain no identifying information linking individuals to specific comments.

Vulnerable Subjects

Not applicable

Potential Benefits

By taking part in this study, primary care team members may increase their knowledge about HPV vaccination and increase their skills in recommending the vaccine. Participants may also experience personal and professional satisfaction from contributing to efforts to improve communication about HPV vaccination.

Importance of Knowledge to Be Gained

HPV vaccination could significantly reduce the HPV-attributable cancer burden in the United States, but only a minority of US adolescents completes the vaccine series before age 13 as recommended. This research is intended to develop a sustainable approach to integrating evidence-based strategies to improve HPV vaccination into clinical practice. The overall goal is to improve primary care teams' communication and, in turn, the delivery of HPV vaccine to adolescents.

MULTI-SITE STUDY: SINGLE IRB PLAN – Project 3

The proposed study will implement a single IRB plan. UNC will serve as the single IRB of record in accordance with NIH policy for research protocols that are carried out at more than one site in the United States and will submit all materials on behalf of our research partners. Our subcontractor will implement the same protocol as the UNC team and has agreed to rely on the IRB submitted by the University of North Carolina. Any domestic sites added after the award will be required to agree to this arrangement unless they meet the criteria for exception to the policy.

The Project Lead, Dr. Gilkey, will provide oversight of the research for all studies. The Project Lead and Project Manager at UNC will communicate directly with our research partners to ensure all study related procedures and documents are approved by UNC's IRB. Prior to initiating the study, we will sign an authorization/reliance agreement that will clarify the roles and responsibilities of the single IRB and participating sites with our research partners. UNC will maintain records of the authorization/reliance agreements and of the communication plan.

DATA AND SAFETY MONITORING PLAN – Project 3

The proposed study involves human subjects. No contact of study participants or data collection will be started until full review and approval by the University of North Carolina-Chapel Hill (UNC-CH) Institutional Review Board (IRB). The IRB will review study protocols, informed consent procedures, data safety, and relevant study materials and will determine risk/benefit of study procedures.

Congruent with NIH regulations for clinical trials, this study does not require a DSMB, as it is not a Phase III clinical trial. However, data management at Wisconsin sites will be overseen by subcontract co-Investigator Dr. Cox and the staff of the Wisconsin Collaborative for Healthcare Quality and the Health Innovation Program at the University of Wisconsin-Madison. Dr. Gilkey and Dr. Cox will retain responsibility for maintaining all study databases for quality and integrity.

Additionally, Drs. Gilkey and Cox, along with the Project Manager, Jennifer Heisler-MacKinnon, will conduct routine protocol compliance checks to ensure that safety procedures, such as ensuring participant confidentiality and maintaining approved standards for data transport, are strictly followed. All study files will be maintained in a centralized location on secured servers. Access to this data will be password protected and subject to the same security protections as other confidential data. Access must be granted by the UNC Gillings School of Global Public Health IT Department and will be limited to the research team working on this study. All study files containing participant data will use study IDs to ensure no identifying information is linked to participant data.

We do not anticipate adverse events (AEs) for study participants due to the nature of this study. The research team, all of whom have met IRB training requirements, will be trained to identify potential AEs and instructed to report them immediately to Dr. Gilkey. Dr. Gilkey will distinguish serious adverse events (SAEs) from non-serious AEs. Although neither are anticipated, all SAEs must (and will) be reported to the UNC-CH IRB and NIH project officer within 48 hours. An annual report will be submitted to the NIH and IRB summarizing all adverse events, including SAEs.

OVERALL STRUCTURE OF THE STUDY TEAM – Project 3

The organizational structure of the study team as it pertains to the proposed grant application is described below. Our multi-disciplinary group has tremendous experience related to HPV vaccine communication, health services delivery, and cancer prevention and control research.

UNC Study Team (Aims 1-3)

- *Melissa Gilkey, PhD,* will be the Project Lead for the study and will have overall responsibility for the design and implementation of the study as well as the dissemination of findings. Specifically, she will have overall budgetary, administrative and scientific responsibility and will coordinate and implement activities essential to carrying out the research aims and achieving the project's goals.
- *Sarah Birken, PhD,* will be Co-Investigator on the study and will collaborate with the Project Lead on developing and carrying out effective strategies for implementation of intervention components and enhancing the Announcement Approach Training for use with clinical champions. Additionally, she will collaborate on dissemination activities, including advising on how to translate evidence from the study into tools that can be used in clinical settings and contributing to manuscript preparation.
- *Jennifer Heisler-MacKinnon* will be the Project Manager and will be responsible for managing daily project operations for the study and will serve as the liaison between the Project Lead, project team, and study subcontractor. She will also coordinate research activities, such as writing research protocols, managing the project budget, submitting IRB protocols and revisions, developing data collection instruments, and preparing reports, presentations and manuscripts to disseminate findings.
- *The Biostatistician*, to be named, will provide analytical support to the team by running continuous data quality checks, and conducting data analyses to evaluate the outcomes of the study.
- *The two Announcement Approach Training Facilitators*, to be named, will serve as external facilitators who will deliver communication trainings to participating primary care clinics. They will also be responsible for collecting relevant data and documenting key components of the intervention in clinical sites.
- *The Postdoctoral Research Associate*, to be named, will assist with study design, survey development, study implementation, data analysis and dissemination of study findings. (S)he will also help support the Project Manager and Project Lead in manuscript preparation.
- *The Graduate Research Assistant*, to be named, will assist the study team with carrying out administrative and research tasks supporting materials development, data cleaning, and interpretation of findings. (S)he will also support the study team in manuscript preparation and other dissemination activities.
- *The Research Assistant*, to be named, will assist the study team with developing intervention materials and will support the Project Manager and Biostatistician with data management and manuscript preparation.

University of Wisconsin subcontract team (Aims 1-3)

- *Elizabeth Cox, MD, PhD*, will be Co-Investigator for the study and will manage the relationships with clinical partners in Wisconsin, oversee intervention delivery and data collection for Wisconsin based clinical sites, oversee University of Wisconsin staff, and have responsibility for study protocol adherence, scientific integrity and data collection activities in Wisconsin sites. Dr. Cox will also facilitate the relationship with the West Virginia Practice-Based Research Network and West Virginia clinical sites. She will collaborate with Dr. Gilkey on intervention material and protocol development and research products.
- *Harald Kliems*, Associate Researcher, will be responsible for supporting AAT trainings, including process management, on site data collection, and consenting participants in Wisconsin clinical sites.
- *Allie DeLonay,* Programmer with the Health Innovation Program at the University of Wisconsin, will assist with the development of, and be responsible for, implementing data quality checks and variable development.

- *Lauren Bednarz,* Outreach Specialist with the Health Innovation Program at the University of Wisconsin, will lead community partnership efforts in Wisconsin and will be responsible for the coordination and management of all activities with the Wisconsin Collaborative for Healthcare Quality.

The Wisconsin Collaborative for Healthcare Quality (WCHQ) (Aims 2-3)

- *The WCHQ*, a voluntary consortium of healthcare systems and medical clinics in Wisconsin will facilitate relationships between the study team and the collaborative's member organizations, thus supporting recruitment of Wisconsin clinical sites. WCHQ will also work with the Health Innovation Program at the University of Wisconsin to provide data for evaluating the intervention.

The West Virginia Practice Based Research Network (WVPBRN) (Aim 3d)

- *The WVPBRN*, a network of over 100 clinical sites and 13 educational and organizational partners across West Virginia, will facilitate relationships between the study team and the network's member organizations, thus supporting the pilot testing of the Champion AAT module to be added to the Program-wide intervention package following the trial.

Clinical Advisors

- We will periodically consult the study's Clinical Advisor, Jason Terk, MD, and the Clinical Advisory Board convened by the Intervention Core. The Board includes pediatricians, nurses, medical assistants and other supporting providers and meets quarterly. We will bring questions about the clinical context for AAT workshops and the identification of clinical champions to our advisors. Our clinical advisors will also consult on the refinement and dissemination of intervention materials via the overall P01-wide intervention package.

Section 4 - Protocol Synopsis (Study 1)

4.1. Study Design

4.1.a. Detailed Description

Recruitment:We will recruit six healthcare systems in Wisconsin to participate in the study. Eligible systems will be those that have clinics that 1) provide primary care to at least 100 patients, ages 11-12, according to EHR records; and 2) have a pediatric or family medicine specialty. We will partner with The Wisconsin Collaborative for Healthcare Quality (WCHQ). We will work closely with members of the Collaborative's leadership team to recruit and build partnerships with healthcare systems by phone and in-person outreach. WCHQ will assist in recruiting healthcare systems from among their member organizations, based on interest in the project, availability and support for their healthcare providers and other primary care team members to participate as clinical champions, and agreement to participate.We will work with quality improvement leaders in each of our 6 partnering healthcare systems to determine which clinics in their system meet the aforementioned eligibility criteria. Systems will then identify 4 or more clinics each (or 40 clinics total) from among those eligible to participate. At least 25% of clinics in our sample will serve a substantial proportion (>40%) of rural patients to ensure our intervention is responsive to the needs of this high priority population.Participants in this study will be primary care team members, including physicians, nurse practitioners, physician assistants, nurses, and medical assistants. To pilot test our intervention, we will recruit three primary care physicians from participating healthcare systems to participate as champions. To test our intervention in a non-inferiority trial, we will recruit at least 12 primary care physicians to participate as clinical champions. All participants will be recruited through their healthcare system. AAT workshop participants will be recruited from clinics that participate in the study. In the Champion AAT arm of the study, champions will invite primary care teams in each intervention clinic by email and phone to attend an in-clinic Announcement Approach Training (AAT) workshop. Champions will work within their own systems, and we will take several steps to support their work. First, we will provide email templates, talking points, and a study fact sheet to facilitate invitations. Second, we will provide a research assistant (RA) to coordinate research-specific activities related to informed consent and data collection. In the Traditional AAT arm, external facilitators who will be practicing pediatric or family medicine physicians, will invite primary care teams by email or phone, deliver in-clinic trainings, and work with an RA who will facilitate research activities. Randomization: For our RCT, we will randomize 40 clinics to one of two study arms. In each healthcare system, half of the recruited clinics will be randomized to receive AAT delivered by a clinical champion ("Champion AAT") and half will be randomized to receive AAT delivered by an external facilitator ("Traditional AAT").Detailed description of study procedures:Aim 1Activities 1a-b:1. We will collaborate with the WCHQ to recruit six healthcare systems. We will identify four clinical champions in each partner healthcare system (24 total). We will conduct 45-minute in-depth interviews with champions to explore the roles and characteristics of clinical champions, barriers and facilitators to their work, and their interest in participating in an HPV vaccine improvement project. Information from these interviews will be used to develop our Champion AAT intervention. Aim 2Activity 2a:1. We will refine the existing Traditional AAT train-the-trainer curriculum based on the findings of the in-depth interviews in Aim 1 to develop a Champion AAT curriculum. The Champion AAT curriculum will include a protocol for identifying champions, system-specific content, and ideas for ongoing outreach.2. We will pilot test the Champion AAT materials and protocol with three Wisconsin health system partners. In collaboration with the Intervention Core, we will identify and train one clinical champion in each system. Upon completion of training, our 3 champions will each deliver the Champion AAT in one clinic in their healthcare systems.3. A trained RA will observe ATT sessions to assess champions' fidelity to the protocol. We will also administer a brief written survey to primary care team members attending AAT pilot sessions to assess their satisfaction with the workshop. 4. We will conduct 30-minute exit interviews with clinical champions to assess the strengths and weaknesses of our curriculum.Activity 2b:1. Based on the findings of the pilot, we will refine our intervention materials and protocol in preparation for a 2-arm non-inferiority trial. 2. We will conduct a 2-arm non-inferiority trial with our six partner health systems in Wisconsin. Quality improvement leaders in each system will identify at least 4 eligible clinics in their healthcare systems, for a total of 40 eligible clinics. In each healthcare system, half of the recruited clinics will be randomized to receive AAT delivered by a clinical champion and half will be randomized to receive AAT delivered by an external facilitator.3. We will identify at least two clinical champions in each healthcare system to take part in the train-the-trainer session. External facilitators will be practicing pediatric or family medicine providers from the University of North Carolina.4. Next we will deliver AAT to clinics in both intervention arms simultaneously. In the Champion AAT arm, champions will invite primary care professionals in each intervention clinic by email and phone to attend an in-clinic AAT lunch-and-learn session. Champions will deliver 1 AAT workshop per clinic. Participating providers will receive 1.0 hour of continuing education (CE) credit. The external facilitation arm will use the Traditional AAT intervention package. Facilitators in the Traditional AAT arm will invite primary care professionals to participate by email or phone and will deliver in-clinic trainings. Participating providers in this arm will also receive 1.0 hour of CE credit. Activity 2c:1. We will assess adolescents' HPV vaccination status using de-identified data from health systems' electronic health records (EHR) to compare changes in vaccination coverage across study arms. Activity 2d:1. Up to 400 primary care team members who attended either Champion or Traditional AAT workshops will complete brief (<5 minute) online surveys before the training, immediately after the training, and at 3-month follow-up.2. We will compare Champion AAT and Traditional AAT on intermediate outcomes, including attitudes, norms, perceived behavioral control, intentions, recommendation behavior, and participant characteristics.Aim 3Activity 3a1. Clinical champions, external facilitators,

and other study staff involved in intervention delivery will complete time and expense logs to collect data on costs for delivery of the interventions.Activities 3b-c1. Using observational data, tracking logs, participant surveys, and in-depth interviews, we will compare the Champion AAT to the Traditional AAT on implementation outcomes.2. Using primary care provider surveys described in Activity 2d, we will assess participants' satisfaction with AAT components and fit with their clinics' culture.3. At 12-month follow-up we will conduct interviews with 4 key informants from each healthcare system, including the champion facilitator, a healthcare system leader, and two AAT workshop participants. Activity 3d1. Working with the Intervention Core, we will refine our materials and procedures to contribute to the Program Project's package of intervention modules.2. Partnering with the West Virginia Practice-Based Research Network, we will partner with two healthcare systems in West Virginia.3. Using methods described in Activity 2a, we will identify four clinical champions to pilot test the Champion AAT module in four clinics in West Virginia.4. We will refine module materials based on feedback from clinical champions and AAT participants in West Virginia and deliver the module to the Intervention Core for inclusion in the Program Project's dissemination package. Outcomes:Our primary outcome is the number of HPV vaccine-naive (i.e., unvaccinated) patients, ages 11-12, who have initiated HPV vaccination (≥1 dose) at 12-month follow-up. We will also examine implementation determinants and implementation outcomes such as cost-effectiveness, fidelity to the intervention protocols, reach to participants, and sustainability of interventions. Finally, we will examine intermediate outcomes such as participant cognitions and recommendation behaviors.

4.1.b. Primary Purpose: Prevention

4.1.c. Interventions

Type	Name	Description
Behavioral (e.g., Psychotherapy, Lifestyle Counseling)	Champion Announcement Approach Training	Our Champion Announcement Approach Training intervention uses clinical champions in healthcare systems. The intervention consists of a train-the-trainer curriculum where clinical champions are instructed on how to lead in-clinic Announcement Approach Trainings for other primary care teams in their system. Clinical champions will use slides, a script and pocket cards to lead an interactive communication workshop. Clinical champions also will receive performance feedback and ongoing technical assistance for supporting their communication trainings.
Behavioral (e.g., Psychotherapy, Lifestyle Counseling)	Traditional Announcement Approach Training	Our traditional Announcement Approach Training uses external facilitators who are pediatric and family medicine physicians at the University of North Carolina. The trained, external facilitators lead in-clinic Announcement Approach Trainings for primary care teams. External facilitators will use slides, a script and pocket cards to lead an interactive communication workshop.

4.1.d. Study Phase: N/A

Is this an NIH-defined Phase III Clinical Trial? ❍ Yes ● No

4.1.e. Intervention Model: Parallel

4.1.f. Masking ❍ Yes ● No

❑ Participant ❑ Care Provider ❑ Investigator ❑ Outcomes Assessor

4.1.g. Allocation: Randomized

4.2. Outcome Measures

Type	Name	Time Frame	Brief Description
Primary	HPV vaccine initiation	12 months	Proportion of 11- to 12-year-old patients who have initiated HPV vaccination (≥1 dose) at 12-month follow-up
Secondary	HPV vaccine initiation	Six months	Proportion of 11- to 12-year-old patients who have initiated HPV vaccination (≥1 dose) at 6-month follow-up

Secondary	HPV vaccine initiation	24 months	Proportion of 11- to 12-year-old patients who have initiated HPV vaccination (≥1 dose) at 24-month follow-up
Secondary	HPV vaccine completion	12 months	Proportion of 11- to 12-year-old patients who have completed HPV vaccination (2 doses) at 12-month follow-up
Secondary	HPV vaccine completion	Six months	Proportion of 11- to 12-year-old patients who have completed HPV vaccination (2 doses) at 6-month follow-up
Secondary	HPV vaccine completion	24 months	Proportion of 11- to 12-year-old patients who have completed HPV vaccination (2 doses) at 24-month follow-up
Other	Cost of intervention delivery	3 months	The cost per clinic to deliver the interventions
Other	Acceptability	3 months	Satisfaction with the AAT workshops, including content, convenience, and facilitation for participants attending trainings
Other	Reach	3 months	Percentage of eligible primary care team members in each clinic who attend AAT workshops
Other	Fidelity	3 months	Percentage of key AAT workshop content delivered
Other	Sustainability	12 months	Description of efforts to promote HPV vaccination after AAT workshops
Other	Change in normative beliefs	3 months	The change in primary care team members' belief that their team prioritizes on-time HPV vaccination at three months post intervention
Other	Change in Attitudes	3 months	The change in primary care team members' perception that a provider's recommendation for HPV vaccine is important
Other	Change in intentions	3 months	The change in primary care team members' intention to recommend HPV vaccine to their 11-12 year old patients
Other	Change in recommendation behavior	3 months	The change in participants' use of high-quality practices to recommend HPV vaccine

4.3. Statistical Design and Power

StatDesignPowerP3r1045594857.pdf

4.4. Subject Participation Duration

Clinical champions participate for ≤ 12 months, including train-the-trainer protocol, delivering AAT workshops, and exit interviews. Primary care team members who attend workshops will participate for ≤3 months, including workshops and follow-up surveys.

4.5. Will the study use an FDA-regulated intervention?

❍ Yes ● No

4.5.a. If yes, describe the availability of Investigational Product (IP) and Investigational New Drug (IND)/ Investigational Device Exemption (IDE) status

4.6. Is this an applicable clinical trial under FDAAA?

❍ Yes ● No

4.7. Dissemination Plan

DissemPlanP3r1045594858.pdf

STATISTICAL DESIGN AND POWER – Project 3

Cluster randomized non-inferiority trial

Trial vaccination outcomes

Analyses will examine our hypothesis that Champion AAT is non-inferior to Traditional AAT for increasing HPV vaccine uptake among adolescents, ages 11-12. Our analyses will be intent-to-treat, including all enrolled clinics. For our **primary objective**, we will model HPV vaccine uptake using a generalized estimating equation (GEE) for logistic outcomes. GEE models accommodate non-independence due to nesting of patients within clinics by adjusting standard error terms. The outcome will be patient-level HPV vaccine initiation at 12 months (0=no, 1=yes): $\ln(p(vax_{2ij})/1-p(vax_{2ij})) = b_0 + b_1 Champion_j + b_2 RUCC_j + b_3 BaselineVax_j + b_4 Sex_{ij} + b_5 Age_{ij}$. We include the clinic-level (*j*) baseline vaccination rate as a covariate, along with clinic RUCC and treatment assignment (Champion=1; Traditional=0). The model will also include fixed effects for system membership. Tests will be 2-tailed with α=.05. The non-inferiority margin, delta, will be .04, which we have selected to detect any clinically meaningful difference between the effectiveness of our interventions. To test for non-inferiority with a margin of .04, we will translate the lower and upper 95% confidence interval limits into predicted probability units and conclude that Champion AAT is inferior if the transformed upper confidence limit falls below .04.

The **secondary objectives** of the Aim 2 analysis will be to test the effectiveness of our interventions for other outcomes. We will conduct these analyses separately for each time point (6-, 12-, 24-month follow-up) and HPV vaccine outcome (1st dose, 2nd dose). In **exploratory analyses,** we will assess interactions between study arm and other variables, such as patient rurality and sex as a biological variable. We will add each variable as a main effect and its interaction with trial arm. Analysts will be blinded to study arm assignment.

Power. Power analyses relied on estimates from our previous research and pilot work delivering AAT in healthcare systems. With 20 clinics per study arm, we will have **≥80% power to conclude non-inferiority** of Champion vs Traditional AAT when Champion AAT increases HPV vaccine uptake ≥8% points over the secular trend. This calculation assumes: 1) a clinic-level ICC of .033 for change in HPV vaccine initiation, as observed in our pilot work; 2) a non-inferiority margin of .04; 3) 100 patients, ages 11-12, per clinic on average; 4) a secular trend of 10% points; and 5) Traditional AAT effect of 5% points, as observed in our prior trial. Achieving an effect size of ≥8% points with Champion AAT is feasible, given that we are modeling HPV vaccination among unvaccinated adolescents, whose uptake will be higher proportionally than the general population.

In sensitivity analyses, we examined other scenarios to understand the number of clinics and Champion AAT effect needed to conclude non-inferiority (**Figure**).

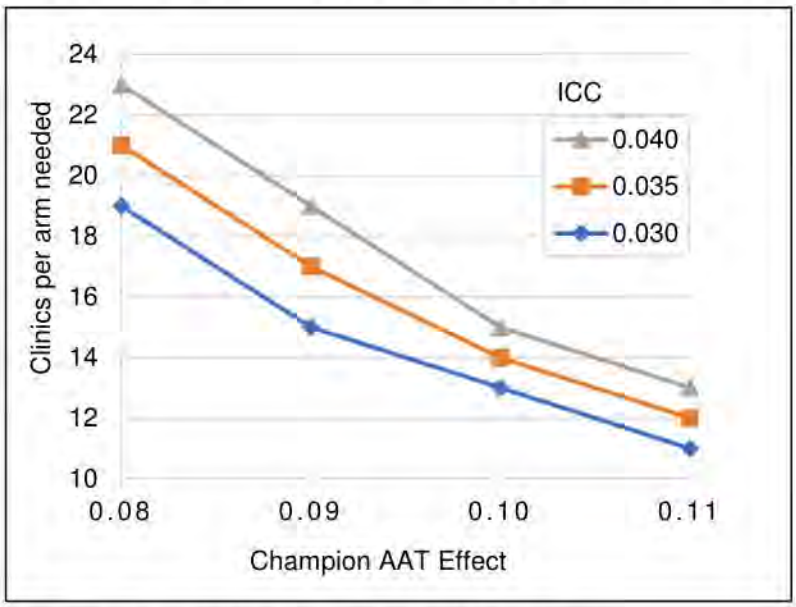


Figure. Sensitivity analyses for ≥80% power

Intermediate outcomes

Analyses will compare Champion AAT to Traditional AAT for improving primary care professionals' HPV vaccine-related cognitions and recommendation behavior. We will use GEE models for each outcome measure to assess difference by study arm at pre-workshop, post-workshop, and follow-up time points. The repeated intermediate outcomes will be regressed on nominal indicators of time (pre, post, and follow-up), intervention arm, interactions between intervention arm and time indicators, and a fixed effect of healthcare system. Standard errors will be adjusted to account for nesting of observations within participant and participants within clinics. Tests will be 2-tailed with α=.05.

Cost analysis

Analyses will compare Champion AAT to Traditional AAT on delivery cost. We will calculate the total cost of Champion AAT and Traditional AAT, using t-tests to compare mean costs per clinic. We will calculate the difference in costs between arms and divide by the difference in doses initiated to estimate cost per additional adolescent, ages 11-12, initiating HPV vaccine due to the intervention.

Implementation outcomes

Analyses will compare Champion AAT to Traditional AAT on implementation outcomes. For each measure, we will compare study arms using generalized linear mixed-level regression models with a random effect term to account for clustering by clinic. Tests will be 2-tailed with α=0.05.

DISSEMINATION PLAN – Project 3

After the study period, deidentified data will be stored in the University of North Carolina Dataverse, managed by the Odum Institute at UNC. The Dataverse project is an open-source software platform for archiving, searching, and sharing data. Data will be made available in a high-quality, nonproprietary format within 30 months of the end of data collection. Data will be accompanied by a data dictionary that includes a description of data collection methods, variable names and descriptions, and a description of data strengths and limitations.

We will disseminate our findings to the diverse audience of stakeholders working to raise HPV vaccination coverage in the US. We will present the findings of our study at professional conferences, including the annual meeting of the NCI-*funded Cancer Center Collaborative for Increasing HPV Vaccination in the United States* and through our professional networks. This dissemination will be facilitated by our leadership roles in professional organizations including the National HPV Vaccination Roundtable. We will also disseminate findings through peer-reviewed journals, such as *Implementation Science*. Further, we will keep our clinical partners in Wisconsin and West Virginia appraised of our findings through regular written reports and virtual meetings. Finally, we will make intervention materials and open-access publications freely available on our existing website, hpvIQ.org, which is designed to disseminate our research to support clinical practice improvements for HPV vaccination.

Specific to Aim 2, we will register the study with ClinicalTrials.gov prior to enrollment of the first study participant, and we will submit results and other required information to ClinicalTrials.gov within 1 year of the conclusion of the study. We will include text in the informed consent information for this study that states that the results of the trial will be available on ClinicalTrials.gov. We will follow the UNC Gillings School of Global Public Health procedures for ensuring the clinical trials registration and results reporting are completed in compliance with policy requirements.

Delayed Onset Studies

Delayed Onset Study#	Study Title	Anticipated Clinical Trial?	Justification
The form does not have any delayed onset studies			

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CONSORTIUM/CONTRACTUAL ARRANGEMENTS – Project 3

The Project 3 proposal includes a collaborative effort between UNC and the University of Wisconsin-Madison (UW). UNC will serve as the prime institution for Project 3, and UW will serve as the subrecipient. The proposed activities include a subcontract with UW to involve Dr. Elizabeth Cox in all proposed specific aims as a Co-Investigator. The appropriate programmatic and administrative personnel of each organization involved in this grant application are aware of the NIH consortium agreement policy and are prepared to establish the necessary inter-organizational agreement(s) consistent with that policy.

Dr. Melissa Gilkey is the Project Lead responsible for ensuring proper conduct of the project at the consortium site of UNC. Dr. Elizabeth Cox is the Consortium Lead responsible for ensuring proper conduct of the project at UW. UNC will manage the programmatic, fiscal, and administrative tasks necessary to ensure the overall success of this subcontract. Dr. Melissa Gilkey will lead weekly meetings in all years of the project. Dr. Cox will attend these meetings by phone. Dr. Gilkey and the study Project Manager will also travel to the University of Wisconsin in Years 2 and 3 to meet in person with the UW team and clinical partners in Wisconsin.

As a Co-Investigator on this research project, Dr. Cox will be responsible for communication with clinical practice sites as well as with the Wisconsin Collaborative for Healthcare Quality (WCHQ), the Health Innovation Program (HIP), and the West Virginia Practice-based Research Network (WVPBRN). She will ensure timely intervention delivery and data collection, as well as oversee the data handling and management activities. Dr. Cox will also collaborate and contribute to the development of intervention and data collection materials, as well as reports, papers, and publications.

The grantee and subrecipient organizations are prepared to make a formal consortium agreement with terms and conditions stipulating ownership of all data, reports, materials, inventions and if applicable, future use. This agreement will be developed in accordance with NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards Subpart B: Terms and Conditions for Specific Types of Grants, Grantees, and Activities (15 Consortium Agreements).

RESEARCH

University of North Carolina at Chapel Hill
Subrecipient Letter of Intent

To be completed by Subrecipient

SUBRECIPIENT	SPONSOR
Legal Name: The Board of Regents of the University of Wisconsin System	Legal Name: The University of North Carolina at Chapel Hill
DUNS: 161202122	DUNS: 608195277
Lead PI: Elizabeth D. Cox, MD, PhD	Lead PI: Melissa Gilkey, PhD

Subrecipient Administrative Contact:	*Sponsor Administrative Contact:*
Name/Title: Jeffrey Nytes	Name/Title: David Paul/Assistant Vice Chancellor
Address: 21 N. Park St., Suite 6401, Madison, WI 53715-1218	Address: 104 Airport Drive, Suite 2200 Chapel Hill, NC, 27599
Phone: 608-262-3822	Phone: 919-966-3411
Email: preaward@rsp.wisc.edu	Email: ResAdminOSR@unc.edu

Project Title: Program Project- Improving Provider Announcement Communication Training (IMPACT)

Prime Awarding Agency: NIH/NCI

RFA/RFP: PA-20-077

Project Period: Start 07/01/2021 End 06/30/2026

UNC-CH Proposal Number: (Enter UNC IPF Number)

BUDGET INFORMATION

Choose as appropriate below:

(•) Federal Rate ( ) Sponsor Rate ( ) Other

Applicable F&A Rate: 55.5 %

Direct Costs: $495,054.00

Indirect Costs: $274,756.00

Total Request: $769,810.00

COMPLIANCE INFORMATION

Human Subjects: (•) Yes ( ) No

Animal Subjects: ( ) Yes (•) No

Is your institution a participant of Federal Demonstration Partnership (FDP) Clearing House? (•) Yes ( ) No

This LETTER OF INTENT confirms the appropriate program and administrative personnel have reviewed and approve the above referenced Solicitation/ RFP/RFA. Further, the institution and its Principal Investigator certify that:

Information submitted within this application is true, complete, and accurate to the best of the institution's and PI's knowledge; any false, fictitious, or fraudulent statements or claims may subject the institution and PI to criminal, civil, or administrative penalties; PI agrees to accept responsibility for the scientific conduct of the project and to provide the required progress reports if an award is made, and a mutually agreeable subcontract is executed as a result thereof.

Included: • Statement of Work • Budget • Budget Justification Other:

Subrecipent Principal Investigator: Elizabeth D Cox MD PhD

Date: 8/5/2020

Subrecipient Authorized Official: Brenda Egan

Date: 08/05/2020

Form Approved Through 02/28/2023 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Application

Do not exceed character length restrictions indicated.

LEAVE BLANK—FOR PHS USE ONLY.		
Type	Activity	Number
Review Group		Formerly
Council/Board (Month, Year)		Date Received

1. TITLE OF PROJECT *(Do not exceed 81 characters, including spaces and punctuation.)*
Program Project- Improving Provider Announcement Communication Training (IMPACT)

2. RESPONSE TO SPECIFIC REQUEST FOR APPLICATIONS OR PROGRAM ANNOUNCEMENT OR SOLICITATION ☐ NO ☒ YES
(If "Yes," state number and title)
Number: PA-20-077 Title: National Cancer Institute Program Project Applications

3. PROGRAM DIRECTOR/PRINCIPAL INVESTIGATOR

3a. NAME (Last, first, middle)	3b. DEGREE(S)	3h. eRA Commons User Name
Cox, Elizabeth D.	MD PhD	eRA COMMONS USER NAME

3c. POSITION TITLE
Professor

3d. MAILING ADDRESS *(Street, city, state, zip code)*
H4/442 Clinical Science Center 600 Highland Avenue Madison, WI 53792-4108

3e. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Department of Pediatrics

3f. MAJOR SUBDIVISION
Medicine and Public Health

3g. TELEPHONE AND FAX *(Area code, number and extension)*
TEL: 608-263-8558 FAX: 608-263-0722

E-MAIL ADDRESS:
ecox@wisc.edu

4. HUMAN SUBJECTS RESEARCH	4a. Research Exempt	If "Yes," Exemption No.
☐ No ☒ Yes	☒ No ☐ Yes	

4b. Federal-Wide Assurance No.	4c. Clinical Trial	4d. NIH-defined Phase III Clinical Trial
FwA000005399	☒ No ☐ Yes	☐ No ☐ Yes

5. VERTEBRATE ANIMALS ☒ No ☐ Yes — 5a. Animal Welfare Assurance No.

6. DATES OF PROPOSED PERIOD OF SUPPORT *(month, day, year—MM/DD/YY)*		7. COSTS REQUESTED FOR INITIAL BUDGET PERIOD		8. COSTS REQUESTED FOR PROPOSED PERIOD OF SUPPORT	
From / Through		7a. Direct Costs ($)	7b. Total Costs ($)	8a. Direct Costs ($)	8b. Total Costs ($)
8/01/2021	07/31/2026	$83,281	$129,502	$495,054	$769,810

9. APPLICANT ORGANIZATION
Name: Board of Regents of the UW System
Address: 21 N. Park Street, Suite 6401
Madison, WI 53715-1218

10. TYPE OF ORGANIZATION
Public: → ☐ Federal ☒ State ☐ Local
Private: → ☐ Private Nonprofit
For-profit: → ☐ General ☐ Small Business
☐ Woman-owned ☐ Socially and Economically Disadvantaged

11. ENTITY IDENTIFICATION NUMBER
396006492
DUNS NO. 161202122 Cong. District WI-002

12. ADMINISTRATIVE OFFICIAL TO BE NOTIFIED IF AWARD IS MADE
Name: Brenda Egan
Title: Managing Officer
Address: Research & Sponsored Programs
21 N. Park St., Suite 6401
Madison, WI 53715-1218
Tel: 608-262-3822 FAX: 608-262-5111
E-Mail: preaward@rsp.wisc.edu

13. OFFICIAL SIGNING FOR APPLICANT ORGANIZATION
Name: Brenda Egan
Title: Managing Officer
Address: Research & Sponsored Programs
21 N. Park St., Suite 6401
Madison, WI 53715-1218
Tel: 608-262-3822 FAX: 608-262-5111
E-Mail: preaward@rsp.wisc.edu

14. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

SIGNATURE OF OFFICIAL NAMED IN 13. *(In ink. "Per" signature not acceptable.)* Brenda Egan

DATE 08/05/2020

Program Director/Principal Investigator (Last, First, Middle): Cox, Elizabeth D.

SCOPE OF WORK

Dr. Elizabeth Cox will serve as subcontract principal investigator for this project and will dedicate ☐ calendar months effort on the project for all study years. Dr. Cox will serve in a variety of roles in the project.

First, Dr. Cox will manage the relationships with clinical partners to ensure recruitment and retention of health systems. This includes working with the Wisconsin Collaborative for Healthcare Quality to recruit interested and eligible healthcare systems and facilitating active communication between clinical and research stakeholders (Years 1-3).

Second, Dr. Cox will oversee intervention delivery and data collection for Wisconsin-based sites, in partnership with the Health Innovation Program. Dr. Cox will supervise the site Research Associate, who will be responsible for facilitating trainings, including process management, on-site data collection and consenting participants. Further, Dr. Cox will oversee data handling and management activities by the Wisconsin Collaborative for Healthcare Quality and the Health Innovation Program at the University of Wisconsin, Madison. She will have responsibility for study protocol adherence, scientific integrity and data collection activities at Wisconsin sites (Years 1-4).

Third, Dr. Cox will collaborate closely with the lead PI, Melissa Gilkey, on intervention and protocol development, including contributions to intervention materials, data collection instruments, and research products. In the dissemination phase (Years 4-5), Dr. Cox will work with Dr. Gilkey and the West Virginia Practice-Based Research Network to disseminate products from the research, including refinement of the intervention across diverse rural settings. She will work with the study team to help develop reports, papers and presentations. This will include being an author on publications and presenting at scientific conferences (Years 1-5).

RELEVANCE (See instructions):

PROJECT/PERFORMANCE SITE(S) (if additional space is needed, use Project/Performance Site Format Page)

Project/Performance Site Primary Location			
Organizational Name: The Board of Regents of the University of Wisconsin System			
DUNS: 161202122			
Street 1: 21 N Park Street		Street 2: Suite 6401	
City: Madison	County: Dane		State: WI
Province:	Country:		Zip/Postal Code: 53715-1218
Project/Performance Site Congressional Districts: WI-002			

Additional Project/Performance Site Location			
Organizational Name:			
DUNS:			
Street 1:		Street 2:	
City:	County:		State:
Province:	Country:		Zip/Postal Code:
Project/Performance Site Congressional Districts:			

WISCONSIN COLLABORATIVE for HEALTHCARE QUALITY

July 16, 2020

Elizabeth Cox, MD PHD
Professor, Department of Pediatrics
University of Wisconsin School of Medicine and Public Health
H6/558 Clinical Science Center
600 Highland Ave.
Madison, WI 53792

Melissa B. Gilkey, PhD
Associate Professor of Health Behavior
Gillings School of Global Public Health
University of North Carolina, Campus Box 7440
Chapel Hill, NC 27599

Dear Drs. Cox and Gilkey:

I am writing to express enthusiastic support for your NCI P01 Proposal "Improving Provider Announcement Communication Training (IMPACT)" Program Project. We would be pleased to collaborate with your team as part of the study, "Engaging Clinical Champions to Improve HPV Vaccine Communication and Uptake." I am CEO and president of the Wisconsin Collaborative for Healthcare Quality (WCHQ), a nationally recognized organization devoted to quality measurement and reporting. Your team's goal to support primary care providers in the delivery of HPV vaccine directly aligns with our organization's mission to improve the quality of preventive services in Wisconsin, and we would look forward to the opportunity to partner with you in this important work.

The Collaborative is a voluntary statewide consortium of 35 healthcare organizations in Wisconsin that has led the nation in measuring and reporting the quality of care in physician groups. One of our major strengths is the use of standardized reporting metrics across our members, which cover more than 65% of Wisconsin's primary care physicians. We have a refined measurement development process that involves assessing potential concepts and indicators, examining the completeness and quality of needed data elements, proposing selected measures to the WCHQ Measurement Advisory Committee for approval, developing technical specifications, and, most importantly, collecting, validating, and reporting these measures. We have extensive experience assessing immunization metrics, and in recent years have chosen HPV vaccination as a special focus, given room for clinically meaningful improvement in many of our systems.

In the event of funding, we will support your study in several ways. We will facilitate relationships between the study team and The Collaborative's member organizations. We have already identified three healthcare systems with interest in participating that have five, nine, and fifteen primary care clinics respectively, reporting HPV vaccination coverage to our database. I am confident in the ability of our partnership to support the proposed study and our staff will work closely with your team to maintain these relationships to ensure retention. We will also provide standardized HPV vaccination data for evaluating your intervention, with our standard cost for data pulls being $25,000. As previously mentioned, The Collaborative's validated measures are standardized across participating systems and offer unparalleled data quality.

I will play a lead role in data sharing, project communication with the WCHQ community, as well as assume fiscal and administrative management for the collaboration. The staff of the Collaborative who will

contribute to this project bring over 40 years of experience in the field with expertise in data, measurement, system improvement, and software development that contribute to our reporting on more than 40 existing quality metrics. We have a strong commitment to increasing HPV vaccination and to HPV vaccination quality improvement and believe that working with your project has the potential to significantly impact both of those areas in Wisconsin and across the nation.

Sincerely,

Christopher Queram
President/CEO
Wisconsin Collaborative for Healthcare Quality

August 4, 2020

Elizabeth Cox, MD PhD
Professor, Department of Pediatrics
University of Wisconsin School of Medicine and Public Health

Melissa Gilkey, PhD
Associate Professor, Department of Health Behavior
University of North Carolina at Chapel Hill

Dear Drs. Cox and Gilkey:

We offer our enthusiastic support for your NCI P01 Proposal "Improving Provider Announcement Communication Training (IMPACT)" Program Project. We would be pleased to collaborate with Project 3, "Engaging Clinical Champions to Improve HPV Vaccine Communication and Uptake." The West Virginia Practice-Based Research Network (WVPBRN) is comprised of primary care practices that work with researchers to improve the health and well-being of the citizens of West Virginia. As I shared in our recent conversations, our members are very concerned about the decline in immunization rates in their practices, so your project is well matched to their interests.

Our Network currently has 107 primary care clinics among 30 health systems in West Virginia and has a rich history of collaboration with clinic staff and providers. The Network includes 338 providers serving over 395,000 patients. Our clinical partners are in almost every county across the state, assuring that we have a wide reach to primary care providers and patients across West Virginia. West Virginia ranks 3rd in the nation for high rates of HPV-associated cancers such as cervical cancer and head/neck cancers. This proposal fits the mission of the Network by providing communication training to increase HPV vaccination coverage and save providers time.

Should your project be funded, the WVPBRN will offer a variety of support services, including recruitment strategies, organizational resources, and translation and dissemination of research tools and practices to improve patient outcomes. We will work closely with your team to recruit two healthcare systems serving adolescent patients, including adolescents in rural areas. We will facilitate relationships between the study team and health system leaders to ensure the timely completion of activities. We will also support you in disseminating study findings to health systems and other community partners.

Robert C. Byrd Health Sciences Center • PO Box 9102 • Morgantown, WV 26506
Phone: 304.293.7015 • www.wvctsi.org

The WVPBRN welcomes the opportunity to work with your project. Improving provider communication for HPV vaccine recommendations by engaging clinical vaccine champions has the potential to increase HPV vaccination rates across West Virginia, thus preventing many future HPV-related cancers. We gladly offer our support to this important public health project.

Yours truly,

William Lewis (Aug 11, 2020 16:19 EDT)

William Lewis, MD
West Virginia University
Harpers Ferry Family Medicine
Co-Director, WVPBRN

Jennifer Boyd, PA-C (Aug 11, 2020 17:24 EDT)

Jennifer Boyd, PA-C
WV Primary Care Association
New River Health Association
Co-Director, WVPBRN

UNC | GILLINGS SCHOOL OF GLOBAL PUBLIC HEALTH

THE UNIVERSITY OF NORTH CAROLINA AT CHAPEL HILL
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North Carolina Institute for Public Health

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July 28, 2020

Melissa B. Gilkey
Department of Health Behavior
Gillings School of Global Public Health
University of North Carolina at Chapel Hill
317 Rosenau Hall CB 7440
Chapel Hill, NC 27599

Dear Dr. Gilkey:

I am writing to offer our services to support your NCI P01 proposal "Improving Provider Announcement Communication Training (IMPACT)" Program Project. As part of Project 3 titled "Engaging Clinical Champions to Improve HPV Vaccine Communication and Uptake," the North Carolina Institute for Public Health (NCIPH) will provide technical support for the development and implementation of the project's train-the-trainer materials and protocol.

To support the project, the NCIPH will work with the research team to develop the train-the-trainer curriculum, including notes, scripts, slides, accompanying activities, and written materials. Additionally, we will support the adaptation of the curriculum for further use and dissemination based on the results of pilot testing and the outcomes of the study. We estimate the cost of this work at $12,000 for the initial development of the curriculum and training protocol and $15,000 for the adaptation of the materials for dissemination.

The NCIPH has extensive experience providing technical assistance to research and evaluation projects and conducting trainings with public health and health care practitioners. We have a wealth of experience in a range of public health topics areas, improvement planning, and population health. We have prepared train-the-trainer/champion curriculums for many organizations, including The Centers for Disease Control and Prevention, The Pan American Health Organization, numerous local health departments, and a variety of research teams in the UNC Gillings School of Global Public Health.

We look forward to working with your team and supporting this important public health topic. As part of the UNC Gillings School of Global Public Health, we are committed to improving the health and well-being of people in North Carolina, across the US, and around the world. We enthusiastically support your proposal and wish you the best of luck.

Sincerely,

Douglas W. Urland, MPA
Director
North Carolina Institute for Public Health

Cook Children's
Health Care System

August 6, 2020

Melissa B. Gilkey, PhD
Department of Health Behavior
UNC Gillings School of Global Public Health
Campus Box 7440
Chapel Hill, NC 27599

Dear Dr. Gilkey:

I'm pleased to confirm my commitment to serve as a clinical advisor to the proposed NCI P01 proposal "Improving Provider Announcement Communication Training (IMPACT)" and specifically to Project 3 "Engaging Clinical Champions to Improve HPV Vaccine Communication and Uptake." This research offers a unique opportunity to develop strategies for increasing HPV vaccination rates in healthcare systems. As a practicing pediatrician with a strong commitment to adolescent immunization, I would welcome the opportunity to contribute to this important work.

In the event of funding, I will support the study team in several ways. Most importantly, I will review and provide feedback on intervention materials and procedures, including the content of the train-the-trainer curriculum for clinical champions. I will also review data collection instruments, help the team interpret preliminary findings, and offer ideas for disseminating those findings. My goal will be to offer the perspective of a practicing pediatrician, and to help the team understand HPV vaccination within the broader policy and practice contexts of pediatric care.

My qualifications for this role include over twenty years of experience as a pediatrician and immunization advocate. Most recently, I led a system-wide quality improvement effort to improve HPV vaccination coverage among adolescents served by the 27 pediatric ambulatory care clinics in Cook Children's Health Care System. I enjoyed working with you and your team to evaluate this effort, which successfully engaged 95% of the pediatricians in our system. In addition to quality improvement, I have experience delivering grand rounds and other presentations related to HPV vaccination, both nationally and internationally. I am also active in professional organizations, including the American Academy of Pediatrics and the Texas Medical Association.

I understand that my involvement in the project will include quarterly meetings with the study team by webinar. I am also available to review materials "offline" and to provide feedback by phone or email on an ad hoc basis. Given that we have successfully collaborated across institutions in the past, I am confident that these communication strategies will be effective. I understand that I will receive an honorarium of $ per year for the five-year study period.

801 Seventh Avenue
Fort Worth, TX 76104-2796
682-885-4000
www.cookchildrens.org

In closing, I wish you the best of luck with your proposal, and I look forward to our continued collaboration.

Yours truly,

Jason V. Terk, MD, FAAP

801 Seventh Avenue
Fort Worth, TX 76104-2796
682-885-4000
www.cookchildrens.org

University of Wisconsin
SCHOOL OF MEDICINE
AND PUBLIC HEALTH

Department of Pediatrics

August 4, 2020

Melissa B. Gilkey, PhD
Associate Professor of Health Behavior
Gillings School of Global Public Health
University of North Carolina, Campus Box 7440
Chapel Hill, NC 27599

Dear Melissa:

I am pleased to provide my support for your NCI P01 Proposal "Improving Provider Announcement Communication Training" (IMPACT) Program Project. I will serve as co-investigator on Project 3, "Engaging Clinical Champions to Improve HPV Vaccine Communication and Coverage." It has been a pleasure to work with you on this proposal that aims to evaluate new ways to scale up healthcare system-wide delivery of an evidence-based intervention to increase HPV vaccination rates.

As a pediatrician and health services researcher, my work has focused on redesigning healthcare processes and systems to deliver high quality, patient-centered care for children and adolescents. Much of my research revolves around implementation and evaluation of evidence-based interventions within healthcare settings, as in your study. I have collaborated or led multiple federally-funded projects that engage clinical and healthcare system stakeholders, as well as vulnerable populations (e.g., rural populations or chronically ill children), in redesigning care delivery.

For your project, my team will manage the relationships with healthcare system partners, including the Wisconsin Collaborative for Healthcare Quality, to ensure successful recruitment and retention. We will also oversee intervention delivery and data collection in Wisconsin-based healthcare systems. We will facilitate timely delivery of data from the Wisconsin Collaborative for Healthcare Quality and the Health Innovation Program. In the latter years of the award, my team will collaborate with you and the West Virginia Practice-Based Research Network to disseminate findings.

Importantly, I am able to leverage my existing relationships as we implement, evaluate and disseminate the intervention. For over a decade, I have worked collaboratively with the Health Innovation Program, the source of data to evaluate the intervention's implementation. I also have a faculty appointment at West Virginia University and multiple ongoing, extramurally funded collaborations with investigators there that will support dissemination of the project.

Your track record in developing and evaluating interventions to improve HPV vaccination in various clinical settings makes you the ideal leader for this project. Together with the multidisciplinary team you have organized, you have the experience, commitment, and collaborative spirit needed to make this effort successful, significantly contributing to health of the future generations.

I look forward to working on this project.

Sincerely,

Elizabeth D Cox MD PhD

Elizabeth Cox, MD PhD
Professor

H4/442 Clinical Science Center
608/263-8558
600 Highland Avenue
Madison, WI 53792-4108
FAX 608/263-0722

RESOURCE SHARING PLAN – Project 3

We agree with the NIH principle that data sharing is essential for expedited translation of research results into knowledge, products, and procedures to improve human health. All projects and cores will follow the same procedures. We will make data collection instruments available online for public use after data collection and analyses are complete. Leads of the research projects and the Data Core will coordinate sharing of de-identified data produced by the Program Project. Dr. Brewer will oversee this process.

For the vaccine outcomes for the trial, the data are owned by the healthcare system partner. For the provider surveys conducted as part of the trial, we will follow the Program's standard procedure for sharing the de-identified dataset and codebooks. See the Program's Overall Resource Sharing Plan for more details. Interview data will not be shared because it would be difficult to protect participants' identities even if we were to remove all identifiers.

OMB Number: 4040-0010
Expiration Date: 12/31/2022

APPLICATION FOR FEDERAL ASSISTANCE

SF 424 (R&R)

5. APPLICANT INFORMATION **Organizational DUNS*:** 608195277

Legal Name*:	The University of North Carolina at Chapel Hill
Department:	Office of Sponsored Research
Division:	Research
Street1*:	104 Airport Drive
Street2:	Campus Box 1350
City*:	Chapel Hill
County:	Orange
State*:	NC: North Carolina
Province:	
Country*:	USA: UNITED STATES
ZIP / Postal Code*:	27599-1350

Person to be contacted on matters involving this application

Prefix:	First Name*:	Middle Name:	Last Name*:	Suffix:
	Andrea		Cogdill	

Position/Title:	Grants Analyst
Street1*:	130 Mason Farm Road
Street2:	CB 9525, Bioinformatics Bldg.
City*:	Chapel Hill
County:	Orange
State*:	NC: North Carolina
Province:	
Country*:	USA: UNITED STATES
ZIP / Postal Code*:	27599-1350

Phone Number*: (919) 962-3950 Fax Number: (919) 843-7094 Email: grants@unc.edu

7. TYPE OF APPLICANT* H: Public/State Controlled Institution of Higher Education

Other (Specify):

Small Business Organization Type ❍ Women Owned ❍ Socially and Economically Disadvantaged

11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT*

IMPACT Project 4 – Budget impact, cost-effectiveness, and population outcomes of interventions to improve HPV vaccine communication and uptake in rural and nonrural communities

12. PROPOSED PROJECT

Start Date*	Ending Date*
07/01/2021	06/30/2026

OMB Number: 4040-0010
Expiration Date: 12/31/2022

Project/Performance Site Location(s)

Project/Performance Site Primary Location

❍ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name:	The University of North Carolina at Chapel Hill
Duns Number:	608195277
Street1*:	104 Airport Drive
Street2:	Campus Box 1350
City*:	Chapel Hill
County:	Orange
State*:	NC: North Carolina
Province:	
Country*:	USA: UNITED STATES
Zip / Postal Code*:	27599-1350
Project/Performance Site Congressional District*:	NC-004

Additional Location(s) File Name:

Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED Other Project Information

1. Are Human Subjects Involved?* ● **Yes** ○ **No**

1.a. If YES to Human Subjects

Is the Project Exempt from Federal regulations? ○ Yes ● No

If YES, check appropriate exemption number: _ 1 _ 2 _ 3 _ 4 _ 5 _ 6 _ 7 _ 8

If NO, is the IRB review Pending? ○ **Yes** ○ **No**

IRB Approval Date:

Human Subject Assurance Number 00004801

2. Are Vertebrate Animals Used?* ○ **Yes** ● **No**

2.a. If YES to Vertebrate Animals

Is the IACUC review Pending? ○ Yes ○ No

IACUC Approval Date:

Animal Welfare Assurance Number

3. Is proprietary/privileged information included in the application?* ○ **Yes** ● **No**

4.a. Does this project have an actual or potential impact - positive or negative - on the environment?* ○ **Yes** ● **No**

4.b. If yes, please explain:

4.c. If this project has an actual or potential impact on the environment, has an exemption been authorized or an environmental assessment (EA) or environmental impact statement (EIS) been performed? ○ Yes ○ No

4.d. If yes, please explain:

5. Is the research performance site designated, or eligible to be designated, as a historic place?* ○ **Yes** ● **No**

5.a. If yes, please explain:

6. Does this project involve activities outside the United States or partnership with international collaborators?* ● **Yes** ○ **No**

6.a. If yes, identify countries: Germany

6.b. Optional Explanation:

	Filename
7. Project Summary/Abstract*	AbstractP4r1045594869.pdf
8. Project Narrative*	NarrativeP4r1045594870.pdf
9. Bibliography & References Cited	ReferencesP4r1045594871.pdf
10.Facilities & Other Resources	FacilitiesP4r1045594872.pdf
11.Equipment	EquipmentP4r1045594873.pdf
12. Other Attachments	AcronymsP4r1045663973.pdf Foreign Justification.pdf

Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

ABSTRACT – Project 4

Human papillomavirus (HPV) cancers are preventable through vaccination. Yet HPV vaccine coverage is well below the national goal of 80%, especially in rural areas where HPV cancers are more common. HPV vaccine communication interventions are a promising approach to address low uptake. As part of the P01 Program Project, "Improving Provider Announcement Communication Training (IMPACT)," Projects 1-3 will test novel enhancements of the Announcement Approach Training (AAT) intervention in healthcare systems to improve primary care team members' HPV vaccine communication. **The overall objective of Project 4 is to facilitate decision makers' selection and adoption of AAT and other effective HPV vaccination interventions,** by quantifying tradeoffs in their comparative cost and health impact in rural and nonrural areas. **Aim 1 is to identify differences in contextual factors in rural and nonrural clinical settings that may influence the implementation and effectiveness of enhanced AAT interventions**. Using a mixed-methods approach, we will conduct semi-structured interviews in rural (*n*=20) and nonrural areas (*n*=20) among primary care team members, quality improvement decision makers, and health administrators, as well as survey a national sample of primary care team members (*n*=2,500) to examine contextual differences across rural and nonrural clinical settings. **Aim 2 is to evaluate the budget impact, cost-effectiveness, and population outcomes of HPV vaccine communication and other evidence-based interventions** in rural and nonrural clinical settings, including the enhanced AAT interventions studied in Projects 1-3, to facilitate comparisons for decision making. We will develop a national county-specific HPV microsimulation model that overlays interventions onto populations reflecting patterns of baseline HPV vaccination, HPV transmission, and progression to HPV cancers to project the anticipated budget impact, cost-effectiveness, and population outcomes of HPV vaccine interventions in rural and nonrural clinical settings. **Aim 3 is to aid stakeholder implementation planning by developing a web-based interactive decision support tool** illustrating the value and implementation outcomes of HPV vaccine interventions in rural and nonrural clinical settings. We will engage stakeholders to evaluate the usability of the decision support tool for decision making and add to the AAT Intervention Package. Project 4 addresses the **IMPACT Program Project theme** of amplifying HPV vaccine communication interventions' impact in healthcare systems. Our project findings will translate the health impact and cost of interventions tested in Projects 1-3 in rural and nonrural areas into a dissemination format well-suited to the needs of decision makers in healthcare systems to accelerate the adoption of promising HPV vaccine communication interventions to prevent cancer in diverse geographic contexts.

NARRATIVE – Project 4

Our goal is to facilitate the adoption of promising HPV vaccine communication interventions. This study will examine the budget impact, cost-effectiveness, and population outcomes of HPV vaccine communication interventions in rural and nonrural communities, and aid decision makers with a decision support tool. We expect generated evidence to accelerate the uptake of promising interventions to improve HPV vaccination.

FACILITIES AND OTHER RESOURCES – Project 4

Refer to Overall Component for Project 4 Facilities and Other Resources.

EQUIPMENT – Project 4

None.

LIST OF ACRONYMS – Project 4

AAT	Announcement Approach Training
AMGA	American Medical Group Association
CDC	Centers for Disease Control and Prevention
CFIR	Consolidated Framework for Implementation Research
CHAI	Communication for Health Applications and Interventions
CPCRN	Cancer Prevention and Control Research Network
Covid-19	Coronavirus disease 2019
HPV	Human papillomavirus
ICER	Incremental cost-effectiveness ratio
IMPACT	Improving Provider Announcement Communication Training
NC	North Carolina
NCI	National Cancer Institute
NHANES	National Health and Nutrition Examination Survey
NIH	National Institutes of Health
NIS-Teen	National Immunization Survey—Teen
NPCR	National Program of Cancer Registries
QALY	Quality-adjusted life year
QI	Quality improvement
RCT	Randomized clinical trial
RUCC	Rural-Urban Continuum Codes
SEER	Surveillance, Epidemiology, and End Results Program
SEIR	Susceptible-exposed-infected-recovered
TOPS	Training in Oncology Population Sciences
UNC	University of North Carolina
VACs	Vaccinate Adolescents against Cancers
WI	Wisconsin

FOREIGN JUSTIFICATION – Project 4

This proposal includes one foreign external advisor whose expertise is integral to the proposed project's success. Ms. Colleen Higgins, MSPH, is a mathematical modeler skilled at coding and building computer simulations on public health topics. Ms. Higgins is an American citizen living in Germany. Ms. Higgins has worked with Dr. Ozawa for over two years to build an agent-based model that assesses the impact of substandard and falsified antimalarials (SAFARI model) in five different countries. Ms. Higgins holds a Masters of Science in Public Health from the Department of Health Policy and Management at UNC Gillings School of Global Public Health and has programming expertise in Java Script, AnyLogic, Python, and NetLogo. Ms. Higgins is uniquely suited to advise this project due to her extensive experience coding and building computer simulations for agent-based models. She will work with the project team on Aim 2 to build an agent-based model to assess the cost-effectiveness of HPV provider communication intervention strategies. She will help to conceptualize the structure of the model, write and audit code, perform sensitivity analyses, interpret and present output data, and conduct searches and/or data analyses to gather relevant data inputs.The US does not have scholars with Ms. Higgins's unique combination of skills and expertise that perfectly apply to this proposal.

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED Senior/Key Person Profile (Expanded)

PROFILE - Project Director/Principal Investigator

Prefix: First Name*: Sachiko Middle Name Last Name*: Ozawa Suffix:

Position/Title*: Associate Professor
Organization Name*: The University of North Carolina at Chapel Hill
Department: SOP - Practice Advancement
Division: UNC Eshelman School of Pharmac
Street1*: Beard Hall 115H
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Phone Number*: (919) 966-2626 Fax Number:

E-Mail*: ozawa@unc.edu

Credential, e.g., agency login: eRA COMMONS USER NAME

Project Role*: Other (Specify) Other Project Role Category: Project Lead

Degree Type: PhD Degree Year: 2010

Attach Biographical Sketch*: File Name: BioOzawaP4rV21045663965.pdf

Attach Current & Pending Support: File Name:

Tracking Number: GRANT13205496 Funding Opportunity Number: PAR-20-077 . Received Date: 2020-09-18T11:41:16.000-04:00

PROFILE - Senior/Key Person

Prefix: First Name*: Stephanie Middle Name B Last Name*: Wheeler Suffix:

Position/Title*: Professor
Organization Name*: The University of North Carolina at Chapel Hill
Department: Health Policy and Management
Division: Gillings Sch. of Public Hlth
Street1*: 1104E McGavran-Greenberg
Street2: CB 7411
City*: Chapel Hill
County: Orange
State*: NC: North Carolina
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 27599-7411

Phone Number*: (919) 966-7374 Fax Number:

E-Mail*: stephanie_wheeler@unc.edu

Credential, e.g., agency login: eRA COMMONS USER NAME

Project Role*: Co-Investigator Other Project Role Category:

Degree Type: PhD Degree Year: 2010

Attach Biographical Sketch*: File Name: BioWheelerP4r1045594876.pdf

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Sarah Middle Name Denton Last Name*: Mills Suffix:

Position/Title*: Research Assistant Professor
Organization Name*: The University of North Carolina at Chapel Hill
Department: Health Policy and Management
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Province:
Country*: USA: UNITED STATES
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Phone Number*: (919) 966-0246 Fax Number:

E-Mail*: sarahmills@unc.edu

Credential, e.g., agency login: eRA COMMONS USER NAME

Project Role*: Co-Investigator Other Project Role Category:

Degree Type: PhD Degree Year: 2017

Attach Biographical Sketch*: File Name: BioMillsP4rV21045663964.pdf

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Lisa Middle Name Last Name*: Spees Suffix:

Position/Title*: Assistant Professor
Organization Name*: The University of North Carolina at Chapel Hill
Department: Health Policy and Management
Division: Gillings Sch. of Public Hlth
Street1*: 1002 G McGavran Greenberg
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Country*: USA: UNITED STATES
Zip / Postal Code*: 27599-7411

Phone Number*: (919) 966-6609 Fax Number:

E-Mail*: lspees21@email.unc.edu

Credential, e.g., agency login: eRA COMMONS USER NAME

Project Role*: Co-Investigator Other Project Role Category:

Degree Type: PhD Degree Year: 2016

Attach Biographical Sketch*: File Name: BioSpeesP4rV21045663967.pdf

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Kristen Middle Name Last Name*: Hassmiller Lich Suffix:

Position/Title*: Associate Professor
Organization Name*: The University of North Carolina at Chapel Hill
Department: Health Policy and Management
Division: Gillings Sch. of Public Hlth
Street1*: 1140D McGavran Greenberg
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Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 27599-7411

Phone Number*: (919) 843-9932 Fax Number:

E-Mail*: klich@unc.edu

Credential, e.g., agency login: eRA COMMONS USER NAME

Project Role*: Co-Investigator Other Project Role Category:

Degree Type: PhD Degree Year: 2007

Attach Biographical Sketch*: File Name: BioHassmillerP4r1045594879.pdf

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Evan Middle Name Last Name*: Myers Suffix:

Position/Title*:
Organization Name*: N/A
Department:
Division:
Street1*: 6617 Turkey Farm Road
Street2:
City*: Chapel Hill
County:
State*: NC: North Carolina
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 27514-0000

Phone Number*: (919)201-4884 Fax Number:

E-Mail*: evan.r.myers@gmail.com

Credential, e.g., agency login: eRA COMMONS USER NAME

Project Role*: Consultant Other Project Role Category:

Degree Type: MD Degree Year: 1988

Attach Biographical Sketch*: File Name: BioMyersP4r1045594880.pdf

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Jane Middle Name Last Name*: Kim Suffix:

Position/Title*:
Organization Name*: N/A
Department:
Division:
Street1*: 656 Main Street
Street2:
City*: Medfield
County:
State*: MA: Massachusetts
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 02052-0000

Phone Number*: (617) 6974384 Fax Number:

E-Mail*: jane.resch@gmail.com

Credential, e.g., agency login: eRA COMMONS USER NAME

Project Role*: Consultant Other Project Role Category:

Degree Type: PhD Degree Year: 2005

Attach Biographical Sketch*: File Name: BioKimP4r1045594881.pdf

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Colleen Middle Name Last Name*: Higgins Suffix:

Position/Title*:
Organization Name*: N/A
Department:
Division:
Street1*: Jonasstrabe 22
Street2:
City*: Berlin
County:
State*:
Province:
Country*: DEU: GERMANY
Zip / Postal Code*: 12053-0000

Phone Number*: +49017682942054 Fax Number:

E-Mail*: colleenrosehiggins@gmail.com

Credential, e.g., agency login:

Project Role*: Consultant Other Project Role Category:

Degree Type: MSPH Degree Year: 2018

Attach Biographical Sketch*: File Name: BioHigginsP4rV21045663963.pdf

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Jennifer Middle Name Last Name*: Spencer Suffix:

Position/Title*:
Organization Name*: N/A
Department:
Division:
Street1*: 48 A Harvard Avenue
Street2: Apt. 3
City*: Brookline
County:
State*: MA: Massachusetts
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 02446-0000

Phone Number*: (919) 633-1912 Fax Number:

E-Mail*: jenny.c.spence@gmail.com

Credential, e.g., agency login: eRA COMMONS USER NAME

Project Role*: Consultant Other Project Role Category:

Degree Type: PhD Degree Year: 2019

Attach Biographical Sketch*: File Name: BioSpencerP4r1045594893.pdf

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Sarah Middle Name A. Last Name*: Birken Suffix:

Position/Title*: Associate Professor
Organization Name*: Wake Forest University Health Sciences
Department: Implementation Science
Division: School of Medicine
Street1*: Medical Center Boulevard
Street2:
City*: Winston-Salem
County: Forsyth
State*: NC: North Carolina
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 27157-0000

Phone Number*: (336) 713-4231 Fax Number:

E-Mail*: sbirken@wakehealth.edu

Credential, e.g., agency login: eRA COMMONS USER NAME

Project Role*: Co-Investigator Other Project Role Category:

Degree Type: PhD Degree Year: 2011

Attach Biographical Sketch*: File Name:

Attach Current & Pending Support: File Name:

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 1

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2021 **End Date*:** 06-30-2022 **Budget Period: 1**

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.		Sachiko		Ozawa		Project Lead					29,525.00	9,011.00	38,536.00
2.		Stephanie	B	Wheeler		Co-Investigator					40,520.00	11,858.00	52,378.00
3.		Sarah	Denton	Mills		Co-Investigator	CAL. MONTHS, INST. BASE SALARY				0.00	0.00	0.00
4.		Lisa		Spees		Co-Investigator					30,385.00	9,494.00	39,879.00
5.		Kristen		Hassmiller Lich		Co-Investigator					10,559.00	3,189.00	13,748.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **144,541.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
1	Graduate Students	6			12,780.00	3,282.00	16,062.00
	Undergraduate Students						
	Secretarial/Clerical						
1	**Total Number Other Personnel**					**Total Other Personnel**	**16,062.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**160,603.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 1

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2021 **End Date*:** 06-30-2022 **Budget Period: 1**

C. Equipment Description	
List items and dollar amount for each item exceeding $5,000	
Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	
Additional Equipment: File Name:	

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	1,000.00
2. Foreign Travel Costs	
Total Travel Cost	**1,000.00**

E. Participant/Trainee Support Costs	**Funds Requested ($)***
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant Trainee Support Costs**	

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 1

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2021 **End Date*:** 06-30-2022 **Budget Period: 1**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	1,200.00
2. Publication Costs	
3. Consultant Services	14,000.00
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8. Tuition	6,688.00
9. Other Costs	34,137.00
Total Other Direct Costs	**56,025.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**217,628.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. Organized Research_On Campus	55.5	210,940.00	117,072.00
		Total Indirect Costs	**117,072.00**

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number): DHHS, Darryl Mayes, 202-401-2808

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**334,700.00**

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	334,700.00

L. Budget Justification* File Name: BudgetJustificationP4rV31045711761.pdf

(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

Tracking Number: GRANT13205496 Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 2

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2022 **End Date*:** 06-30-2023 **Budget Period: 2**

A. Senior/Key Person

Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.	Sachiko		Ozawa		Project Lead	CAL. MONTHS, INST. BASE SALARY				29,525.00	9,011.00	38,536.00
2.	Stephanie	B	Wheeler		Co-Investigator					40,520.00	11,858.00	52,378.00
3.	Sarah	Denton	Mills		Co-Investigator					2,184.00	696.00	2,880.00
4.	Lisa		Spees		Co-Investigator					30,385.00	9,494.00	39,879.00
5.	Kristen		Hassmiller Lich		Co-Investigator					10,559.00	3,189.00	13,748.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **147,421.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
1	Graduate Students	6			12,780.00	3,282.00	16,062.00
	Undergraduate Students						
	Secretarial/Clerical						
1	Programmer	3			20,600.00	6,961.00	27,561.00
2	**Total Number Other Personnel**					**Total Other Personnel**	**43,623.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**191,044.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 2

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2022 **End Date*:** 06-30-2023 **Budget Period: 2**

C. Equipment Description	
List items and dollar amount for each item exceeding $5,000	
Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	
Additional Equipment: File Name:	

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	4,000.00
2. Foreign Travel Costs	
Total Travel Cost	**4,000.00**

E. Participant/Trainee Support Costs	**Funds Requested ($)***
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant Trainee Support Costs**	

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 2

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2022 **End Date*:** 06-30-2023 **Budget Period: 2**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	1,000.00
2. Publication Costs	
3. Consultant Services	44,000.00
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8. Tuition	6,889.00
Total Other Direct Costs	**51,889.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**246,933.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. Organized Research_On Campus	55.5	240,044.00	133,224.00
		Total Indirect Costs	**133,224.00**

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number): DHHS, Darryl Mayes, 202-401-2808

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**380,157.00**

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	380,157.00

L. Budget Justification* File Name: BudgetJustificationP4rV31045711761.pdf

(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

Tracking Number: GRANT13205496 Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 3

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2023 **End Date*:** 06-30-2024 **Budget Period: 3**

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.		Sachiko		Ozawa		Project Lead	CAL. MONTHS, INST. BASE SALARY				29,525.00	9,011.00	38,536.00
2.		Stephanie	B	Wheeler		Co-Investigator					40,520.00	11,858.00	52,378.00
3.		Sarah	Denton	Mills		Co-Investigator					2,184.00	696.00	2,880.00
4.		Lisa		Spees		Co-Investigator					30,385.00	9,494.00	39,879.00
5.		Kristen		Hassmiller Lich		Co-Investigator					10,559.00	3,189.00	13,748.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **147,421.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
1	Graduate Students	6			12,780.00	3,282.00	16,062.00
	Undergraduate Students						
	Secretarial/Clerical						
1	Programmer	3			20,600.00	6,961.00	27,561.00
2	**Total Number Other Personnel**					**Total Other Personnel**	**43,623.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**191,044.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 3

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2023 **End Date*:** 06-30-2024 **Budget Period: 3**

C. Equipment Description	
List items and dollar amount for each item exceeding $5,000	
Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	
Additional Equipment: File Name:	

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	4,000.00
2. Foreign Travel Costs	
Total Travel Cost	**4,000.00**

E. Participant/Trainee Support Costs	**Funds Requested ($)***
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant Trainee Support Costs**	

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 3

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2023 **End Date*:** 06-30-2024 **Budget Period: 3**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	1,000.00
2. Publication Costs	
3. Consultant Services	44,000.00
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8. Tuition	7,095.00
9. Other Costs	8,875.00
Total Other Direct Costs	**60,970.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**256,014.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. Organized Research_On Campus	55.5	248,919.00	138,150.00
		Total Indirect Costs	**138,150.00**

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number): DHHS, Darryl Mayes, 202-401-2808

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**394,164.00**

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	394,164.00

L. Budget Justification* File Name: BudgetJustificationP4rV31045711761.pdf

(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

Tracking Number: GRANT13205496 Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 4

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2024 **End Date*:** 06-30-2025 **Budget Period: 4**

A. Senior/Key Person

Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.	Sachiko		Ozawa		Project Lead	CAL. MONTHS, INST. BASE SALARY				29,525.00	9,011.00	38,536.00
2.	Stephanie	B	Wheeler		Co-Investigator					40,520.00	11,858.00	52,378.00
3.	Sarah	Denton	Mills		Co-Investigator					2,184.00	696.00	2,880.00
4.	Lisa		Spees		Co-Investigator					30,385.00	9,494.00	39,879.00
5.	Kristen		Hassmiller Lich		Co-Investigator					22,627.00	6,835.00	29,462.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **163,135.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
1	Graduate Students	3			12,780.00	3,282.00	16,062.00
	Undergraduate Students						
	Secretarial/Clerical						
1	Programmer	3			20,600.00	6,961.00	27,561.00
2	**Total Number Other Personnel**					**Total Other Personnel**	**43,623.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**206,758.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 4

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2024 **End Date*:** 06-30-2025 **Budget Period: 4**

C. Equipment Description	
List items and dollar amount for each item exceeding $5,000	
Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	
Additional Equipment: File Name:	

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	6,000.00
2. Foreign Travel Costs	
Total Travel Cost	**6,000.00**

E. Participant/Trainee Support Costs	**Funds Requested ($)***
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant Trainee Support Costs**	

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 4

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2024 **End Date*:** 06-30-2025 **Budget Period: 4**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	1,000.00
2. Publication Costs	
3. Consultant Services	44,000.00
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8. Tuition	7,308.00
9. Other Costs	17,758.00
Total Other Direct Costs	**70,066.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**282,824.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. Organized Research_On Campus	55.5	275,516.00	152,911.00
		Total Indirect Costs	**152,911.00**

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number): DHHS, Darryl Mayes, 202-401-2808

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**435,735.00**

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	435,735.00

L. Budget Justification* File Name: BudgetJustificationP4rV31045711761.pdf

(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

Tracking Number: GRANT13205496 Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 5

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2025 **End Date*:** 06-30-2026 **Budget Period: 5**

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.		Sachiko		Ozawa		Project Lead	CAL. MONTHS, INST. BASE SALARY				29,525.00	9,011.00	38,536.00
2.		Stephanie	B	Wheeler		Co-Investigator					40,520.00	11,858.00	52,378.00
3.		Sarah	Denton	Mills		Co-Investigator					2,184.00	696.00	2,880.00
4.		Lisa		Spees		Co-Investigator					30,385.00	9,494.00	39,879.00
5.		Kristen		Hassmiller Lich		Co-Investigator					22,627.00	6,835.00	29,462.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name: **Total Senior/Key Person** **163,135.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
1	Graduate Students	12			25,560.00	6,563.00	32,123.00
	Undergraduate Students						
	Secretarial/Clerical						
1	Programmer	3			20,600.00	6,961.00	27,561.00
2	**Total Number Other Personnel**					**Total Other Personnel**	**59,684.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**222,819.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 5

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2025 **End Date*:** 06-30-2026 **Budget Period: 5**

C. Equipment Description	
List items and dollar amount for each item exceeding $5,000	
Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	
Additional Equipment: File Name:	

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	7,000.00
2. Foreign Travel Costs	
Total Travel Cost	**7,000.00**

E. Participant/Trainee Support Costs	**Funds Requested ($)***
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant Trainee Support Costs**	

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 5

ORGANIZATIONAL DUNS*: 608195277

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: The University of North Carolina at Chapel Hill

Start Date*: 07-01-2025 **End Date*:** 06-30-2026 **Budget Period: 5**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	1,000.00
2. Publication Costs	1,500.00
3. Consultant Services	44,000.00
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8. Tuition	15,055.00
9. Other Costs	23,623.00
Total Other Direct Costs	**85,178.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**314,997.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. Organized Research_On Campus	55.5	299,942.00	166,468.00
		Total Indirect Costs	**166,468.00**

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number): DHHS, Darryl Mayes, 202-401-2808

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**481,465.00**

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	481,465.00

L. Budget Justification* File Name: BudgetJustificationP4rV31045711761.pdf

(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

Tracking Number: GRANT13205496 Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

BUDGET JUSTIFICATION – Project 4

Key Personnel

Sachiko Ozawa, PhD, Project Co-Lead

Year 1	Year 2	Year 3	Year 4	Year 5
CAL. MONTHS				

Dr. Sachiko Ozawa will join Dr. Wheeler as Project Co-Lead for Project 4. Dr. Ozawa is Associate Professor in the Practice Advancement and Clinical Education Division of UNC Eshelman School of Pharmacy, and Adjunct Associate Professor in Maternal and Child Health in the UNC Gillings School of Global Public Health. She brings nearly 10 years of experience in infectious disease and value of vaccination research. Dr. Ozawa has previously led large-scale vaccine impact analyses, such as estimating the economic impact of vaccinations in 73 low- and middle-income countries from 2001-2020, and assessing the return on investment of childhood immunization. Her work has been cited by the Bill and Melinda Gates Foundation, UNICEF, the World Health Organization and Gavi, the Vaccine Alliance. Dr. Ozawa has over 60 peer-reviewed publications, the majority of which are focused on vaccine economics or modeling applications. She serves on the WHO Strategic Advisory Group of Experts Global Vaccine Action Plan Working Group, and leads the Global Health Economics for Pharmacy team at UNC. In partnership with Dr. Wheeler, Dr. Ozawa will lead Project 4 and will be responsible for the scientific integrity and study activities carried out in Aims 1-3, as well as the overall direction and supervision of the study team. Dr. Ozawa in particular will lead the quantitative and qualitative work in Aim 1 to understand contextual factors influencing intervention implementation for rural and nonrural primary care team members. Dr. Ozawa will serve as the contact Project Lead for Project 4, and will be responsible for communications with the funding agency and for the overall administrative functions of the project. Together, Drs. Ozawa and Wheeler will lead the preparation of reports and manuscripts, achievement of milestones, and budget and management for Project 4. Dr. Ozawa will oversee the work of Modeling Consultant Colleen Higgins.

Stephanie Wheeler, PhD, Project Co-Lead

Year 1	Year 2	Year 3	Year 4	Year 5
CAL. MONTHS				

Dr. Wheeler will serve as Project Co-Lead for Project 4, in partnership with Dr. Sachiko Ozawa. Dr. Wheeler is Professor of Health Policy and Management and Associate Director of Community Outreach and Engagement at the UNC Lineberger Comprehensive Cancer Center. With over 120 publications, she has expertise in health services and health disparities research, particularly in decision analytic modeling and the use of registry-linked-claims data to examine quality of cancer care and cancer care delivery. Dr. Wheeler has led numerous grants focused on the quality of, and access to, cancer care and cancer-prevention services. Dr. Wheeler is PI of the national Cancer Prevention and Control Research Network (CPCRN) Coordinating Center, which focuses on the dissemination and implementation of cancer prevention and control interventions in underserved communities. Dr. Wheeler will build on extensive previous work within CPCRN to develop a complex microsimulation model to estimate cost and potential impacts of cancer prevention efforts on cancer control in diverse populations. Dr. Wheeler will work closely with Dr. Ozawa (Co-Lead) to develop and re-specify a microsimulation model with HPV intervention cost and effectiveness data collected by Projects 1-3, and to develop a decision support tool to educate key stakeholders and decisionmakers on HPV vaccine communication interventions and implementation. Drs. Wheeler and Ozawa will co-lead Project 4 data analyses, cost effectiveness model design and analyses, development and testing of the online decision support tool, and preparation of manuscripts and presentations of the results. Drs. Wheeler and Ozawa will collaborate on all Aims, and Dr. Wheeler will take the lead on the Aim 3 work to develop, test for usability, and disseminate the web-based decision support tool. In partnership with Dr. Ozawa, Dr. Wheeler will oversee administrative, fiscal, and scientific roles in the proposed project, including leading study team meetings, overseeing data capture and analysis, and developing reports, manuscripts, presentations and other dissemination products to share with NCI and other partners. Dr. Wheeler will oversee the work of Assistant Professor Dr. Lisa Spees and Modeling Consultant Dr. Jennifer Spencer.

Kristen Hassmiller Lich, PhD, Co-Investigator

Year 1	Year 2	Year 3	Year 4	Year 5
CAL. MONTHS				

Dr. Lich is Associate Professor in the Department of Health Policy and Management in the Gillings School of Global Public Health. She specializes in the application of systems thinking, operations research, and systems science simulation modeling techniques for health policy, public health delivery, and medical decision making, including co-leading with Dr. Wheeler the statewide colorectal cancer screening modeling project developed through CPCRN. Her research is focused on advancing the way models (both quantitative and qualitative) and local data are used to improve decision making by engaging system stakeholders in the process. Dr. Lich will consult on the development of the cost-effectiveness analysis model in Years 1-3, the user testing and development of the web-based decision support tool in Years 4-5, and the evaluation and dissemination of the decision support tool with decision-makers in Years 4-5.

Sarah Birken, PhD, Co-Investigator (CM, Years 1-5 charged to Intervention Core).

Dr. Birken is Associate Professor of Implementation Science in the Division of Public Health Sciences at Wake Forest University Health Sciences. Dr. Birken is an implementation scientist and health services researcher with over 15 years of experience in quality improvement, innovations in cancer care, and translating evidence-based interventions into practice. She has been the principal investigator or co-investigator on numerous studies that have examined the optimization of cancer care and preventive health services, especially for rural patients. In the current project, Dr. Birken's primary responsibilities will be to ensure that determinants of implementation are appropriately assessed in the national provider survey and our qualitative work, and that the cost-effectiveness model and web-based decision support tool are developed for implementation in practice. As described in the Intervention Core, Dr. Birken will contribute her expertise to quantitative and qualitative work in Years 1-2, model development in Year 3, and decision support tool testing and dissemination in Years 4-5. The cost for her effort is kept administratively in the Intervention Core to simplify subcontracts to her home institution.

Lisa Spees, PhD, Program Director

Year 1	Year 2	Year 3	Year 4	Year 5
CAL. MONTHS				

Dr. Spees is Assistant Professor in the Department of Health Policy and Management at UNC Chapel Hill, As the Program Director, Dr. Spees will manage day-to-day project administration and operations, stakeholder engagement communications, and the budget across all five years of the project. Dr. Spees will take a major role in conducting and analyzing the qualitative interviews, as well as the development and testing of the web-based decision support tool. She has extensive experience in using the Consolidated Framework for Implementation Research for qualitative analyses and has previously worked with both Dr. Birken and Dr Wheeler. She will assist Drs. Wheeler and Ozawa with literature reviews, preparation of survey and interview materials to assess rural and nonrural contextual differences influencing implementation, and analysis of the decision support tool usability testing data. Dr. Spees will lead and contribute to manuscripts, presentations and reports to disseminate project results.

Sarah Mills, PhD, Co-Investigator

Year 1	Year 2	Year 3	Year 4	Year 5
CAL. MONTHS				

Dr. Mills is Assistant Professor of Health Behavior at UNC and expert in health disparities and mathematical modeling. Dr. Mills currently has funding to develop a microsimulation model that estimates the public health impact of a federal tobacco control policy on tobacco use and tobacco-related diseases, including cardiovascular disease and cancer. Similar to the model in the proposed project, Dr. Mills' microsimulation model distinguishes inputs based on racial/ethnic background as well as other sociodemographic characteristics. Her current active engagement in trainings on recommendations for simulation modeling methods will ensure that our model meets the highest analytic standards. Dr. Mills will play an important role as an Advisor on the part of the Expert Modeling Advisory Committee.

Other Personnel

TBN, Programmer

Year 1	Year 2	Year 3	Year 4	Year 5
-	3.0 CM	3.0 CM	3.0 CM	3.0 CM

The Programmer will be responsible for analyzing existing data to be used as input parameters for the simulation model and for operationalizing the team's modeling decisions. The Programmer will contribute to writing and auditing code in Python for the development of the agent-based model in collaboration with Ms. Higgins. Model development by the Programmer will involve coding, parameterizing and calibrating the models for rural and nonrural settings utilizing data from Projects 1-3, in addition to analysis of data outputs. The Programmer will be jointly supervised by Drs. Wheeler and Ozawa and will work closely with Ms. Higgins and the Expert Modeling Advisory Committee to ensure that the model is representative of the team's modeling decisions.

TBD, Graduate Research Assistant

Year 1	Year 2	Year 3	Year 4	Year 5
6.0 CM	6.0 CM	6.0 CM	6.0 CM	12.0 CM

The Graduate Research Assistant will work with the Project Co-Leads and study team to carry out both administrative and research tasks across all 5 years of the grant. Activities will include assisting Dr. Spees with literature reviews, conducting and planning qualitative interviews, contributing to survey development, assisting the Programmer with data cleaning and analysis, and assisting with the development, testing, and dissemination of the web-based decision support tool. In Year 5, the Graduate Research Assistant will transition to full-time work to support the writing of manuscripts, conference presentations, and progress reports to disseminate project findings.

Total Expenses for Personnel=$972,268

Fringe Benefits

Fringe benefits associated with the salary request for this budget has been calculated in accordance with our Institution's DHHS Rate Agreement. The University of North Carolina at Chapel Hill applies appropriate fringe benefit rates to the personnel on this proposal: Basic permanent employee benefits are **25.889%** of annual salary plus **$6,512/FTE/YR** for fixed health insurance. Graduate Student employee benefits are **9.490%** of annual salary plus **$4,137.60/FTE/YR** for fixed health insurance.

Travel

Travel for Meetings with Rural and Nonrural Providers & Decision-Makers

Year 1	Year 2	Year 3	Year 4	Year 5	Total
$1,000	$4,000	$4,000	$6,000	$6,000	$21,000

Members of the study team will travel to meet with rural and nonrural providers, decision-makers, and key stakeholders in North Carolina and Wisconsin to understand their barriers and facilitators to implementing the Announcement Approach Training intervention, inform the development of the cost effectiveness modeling technique, and receive input on the development, testing, and dissemination of the web-based decision support tool. We have budgeted for 1 team member (Co-Lead) to take 1 trip in Year 1 ($1,000), 2 study team members (Co-Lead and Project Manager) to take two trips per year in Years 2-3 ($1,000 x 2 people x 2 trips = $4,000), and 3 study team members (Co-Lead, Co-I, and Project Manager) to take two trips per year in Years 4-5 ($1,000 x 3 people x 2 trips = $6,000). In the event that Covid-19 prevents travel, we will transition to phone and Zoom interviews.

Travel for Conferences

Year 1	Year 2	Year 3	Year 4	Year 5	Total
-	-	-	-	$1,000	$1,000

Members of the project team will attend a national conference in year 5 ($1,000 x 1 person x 1 conference in year 5). Attending a national conference such as the Society for Medical Decision Making annual research meetings will allow Drs. Wheeler, Ozawa, and colleagues to disseminate project findings to a broad audience including public health practitioners, researchers, and policymakers. Additionally, attending conferences will expose Drs. Wheeler, Ozawa, and colleagues to the latest research in the field, which will inform the Program's research activities.

Total Expenses for Travel=$22,000

Supplies

Software

Year 1	Year 2	Year 3	Year 4	Year 5	Total
$200	-	-	-	-	$200

Reference management software such as Endnote will be purchased for up to 3 computers as necessary in Year 1 to manage references to aid in dissemination of study findings throughout the 5 years of the study. ($65 per license x 3 computers = $200 per year).

Project Supplies

Year 1	Year 2	Year 3	Year 4	Year 5	Total
$1,000	$1,000	$1,000	$1,000	$1,000	$5,000

Each year, $1,000 will be used for project supplies needed to carry out research activities including office supplies and printing of data collection instruments, protocols, meeting materials, posters to present study findings, and other documents as necessary.

Total Expenses for Supplies=$5,200

Journal Publication Charges

Year 1	Year 2	Year 3	Year 4	Year 5	Total
-	-	-	-	$1,500	$1,500

It is increasingly common for top journals to charge publication fees. We have budgeted for at least 1 article in Year 5 (at a rate of $1,500 per article) to be included in a journal with publication fees

Total Expenses for Journal Publication Charges=$1,500

Consultants / Expert Modeling Advisory Committee

Jennifer Spencer, PhD

Year 1	Year 2	Year 3	Year 4	Year 5	Total
CONSULTANT(S) FEES					

Dr. Spencer is an HPV modeling expert and a post-doctoral fellow in the Training in Oncology Population Sciences (TOPS) program at Dana Farber/Harvard Cancer Center under the mentorship of Dr. Jane Kim. In her dissertation work with Dr. Wheeler at UNC, Dr. Spencer developed a dynamic model of HPV transmission and vaccination to simulate current and future HPV cancer disparities between low-poverty and high-poverty US counties. Through this model, Dr. Spencer evaluated the potential effect of current vaccination rates, assessed the cost-effectiveness of vaccination in both low- and high-poverty settings, and identified cost-effective strategies for increasing HPV vaccine uptake. Dr. Spencer will serve as an Advisor on the Expert Modeling Advisory Committee. In the current project, Dr. Spencer will provide modeling expertise on the

development, testing, and visualization of the dynamic HPV model in Aim 2. She will devote approximately [ ] hours per year to this work in Years 2-5 of the project, and will communicate with the team through conference calls and email. She will be compensated [$] per year ([$] per hour) for her effort.

Jane Kim, PhD

Year 1	Year 2	Year 3	Year 4	Year 5	Total
CONSULTANT(S) FEES					

Dr. Kim is Professor of Health Decision Science at Harvard University. Her research focuses on the development and application of mathematical modeling methods to evaluate health policy issues related to women's health. In addition to extensively modeling and evaluating cervical cancer screening strategies, she has modeled the effect of vaccinating boys against HPV in the United States, and has contributed to a systematic review and meta-analysis of existing HPV transmission dynamic models. Dr. Kim will serve as an Advisor on the Expert Modeling Advisory Committee. Dr. Kim will provide insight and expertise on the development of the agent-based HPV transmission model in Aim 2, specifically its development, parameterization, and testing. She will also provide mentorship and oversight to the work of Jennifer Spencer, Post-doctoral Fellow at Harvard University and consultant on this project. She will work with the study team through video conferences and email communication as needed. Dr. Kim will contribute [ ] hours per year in Years 2-5 of the project, and will be compensated at a rate of [$] per hour ([$] per year).

Evan Myers, PhD

Year 1	Year 2	Year 3	Year 4	Year 5	Total
CONSULTANT(S) FEES					

Dr. Myers is a trained Ob/Gyn clinician and Professor of Obstetrics and Gynecology at the Duke University School of Medicine. Dr. Myers is an expert in the application of quantitative methods, especially mathematical modeling and decision analysis, to problems in women's health. Dr. Myers will serve as an Advisor on the Expert Modeling Advisory Committee. In his role as Consultant, Dr. Myers will provide a clinical perspective to the research team to inform the development of the agent-based HPV transmission model in Aim 2. He will communicate with the research team by email and conference calls as needed. In Years 2-5, Dr. Myers will provide [ ] hours per year to the project, and will be compensated [$] per year ([$] per hour).

Colleen Higgins, MSPH

Year 1	Year 2	Year 3	Year 4	Year 5	Total
CONSULTANT(S) FEES					

Ms. Higgins is a mathematical modeler skilled at coding and building computer simulations on public health topics. She worked with Dr. Ozawa for over two years to build agent-based models that assess the impact of substandard and falsified antimalarials (SAFARI model) in five different countries. She has also developed agent-based models to assess the return on investment of post-market surveillance to improve medicine quality. Ms. Higgins holds a Masters of Science in Public Health from the Department of Health Policy and Management at UNC Gillings School of Global Public Health and has programming expertise in Java Script, AnyLogic, Python, and NetLogo. Ms. Higgins will work with the project team on Aim 2 to build an agent-based model to assess the cost-effectiveness of HPV provider communication intervention strategies. She will help to conceptualize the structure of the model, write and audit code, perform sensitivity analyses, and interpret and present output data. Ms. Higgins will also conduct searches and/or data analyses to gather relevant data inputs. Her efforts are estimated at [$] in year 1 and [$] in years 2 through 5 of the project ([$] per hour).

Total Expenses for Consultants=$190,000

Tuition

Year 1	Year 2	Year 3	Year 4	Year 5	Total
$6,688	$6,889	$7,095	$7,308	$15,055	$43,035

We will provide half of the annual in-state tuition and fees at the UNC Gillings School of Global Public Health to the Graduate Research Assistant as compensation for his or her part-time work in Years 1-4. We will provide full annual in-state tuition in Year 5, as the Graduate Research Assistant transitions to a full-time position to support dissemination of study findings. Tuition cost is based on the Department of Health Policy and Management tuition rate for doctoral students.

Total Expenses for Tuition=$43,035

Other Expenses

CHAI Core

Year 1	Year 2	Year 3	Year 4	Year 5	Total
$26,555	-	$8,875	$17,758	$19,623	$72,811

In concert with the research team, the Communications for Health Applications and Interventions (CHAI) Core at UNC will conduct key informant interviews with quality improvement decision makers, health administrators, and primary care team members practicing in rural (*n*=20) and nonrural (*n*=20) clinics for Aim 1 in Year 1. CHAI Core will assist the study team with interview guide development and will implement all interview activities, including screening, scheduling, conduct, incentive delivery, transcript analyses, and drafting the final report to deliver to the study team. CHAI Core will also contribute to publications from the interviews. In addition to Aim 1 qualitative work, CHAI Core will work with the Project team in Years 3-5 to design, build, and test the web-based decision support tool outlined in Aim 3 of the Project. CHAI Core will work with the Project team to conduct user testing during the development of the tool, support logo and color palette creation, and assist in simulated experimental evaluation of the tool. They will also provide ongoing maintenance of the decision support tool through the life of the Program, and provide any needed technical support to the research team during the tool's development and dissemination. We have included CHAI Core's cost estimate for this work in our budget.

Participant Incentives

Year 1	Year 2	Year 3	Year 4	Year 5	Total
$4,000	-	-	-	$4,000	$8,000

In Year 1, CHAI Core, in partnership with the study team, will conduct interviews with quality improvement decision makers, health administrators, and primary care team members practicing in rural (*n*=20) and nonrural (*n*=20) clinics. We have budgeted for participants in the Aim 1 interviews to receive a $100 gift card incentive at the completion of the interviews (40 participants x $100 gift card = $4,000). In Year 5, the study team will implement a survey with health system leaders and decision-makers to evaluate the web-based decision support tool. The survey will reach up to 40 participations, and each participant will be offered a $100 gift card at the conclusion of the survey (40 participants x $100 gift card = $4,000).

Transcription Services

Year 1	Year 2	Year 3	Year 4	Year 5	Total
$3,582	-	-	-	-	$3,582

In Year 1, $3,582 is requested for professional transcription services for the 40 qualitative interviews conducted by CHAI Core. Each interview will be 45 minutes. Landmark Associates, Inc. (LAI) has been providing transcription services for NIH-funded studies since 1987 (www.thelai.com) and provides discounted rates for UNC-CH research. Their competitive rate for 2 speakers per audio minute is $1.99 per minute (or $1.99 x 45 minutes = $89.55 per interview recording). The total cost for transcription services will be ($89.55 x 40 interviews = $3,582).

Total Expenses for Other Expenses=$84,393

Indirect Costs

At UNC-Chapel Hill, F&A costs are calculated on a Modified Total Direct Costs (MTDC) base. This base consists of all direct salaries and wages, applicable fringe benefits, materials and supplies, services, travel and up to the first $25,000 of each subaward (regardless of the period of performance of the subawards under the award). Modified total direct costs shall exclude equipment, capital expenditures, charges for patient care, rental costs, tuition remission, scholarships and fellowships, participant support costs and the portion of each subaward in excess of $25,000.

Per UNC-Chapel Hill's current federally negotiated rate agreement (dated 11/23/2016), F&A costs associated with the proposed research project are calculated at the approved on-campus research rate of 55.5% of MTDC in all years. The cognizant agency for UNC-Chapel Hill is the U.S. Department of Health and Human Services. The cognizant agency point of contact is Darryl Mayes, (202) 401-2808.

RESEARCH & RELATED BUDGET - Cumulative Budget

	Totals ($)	
Section A, Senior/Key Person		765,653.00
Section B, Other Personnel		206,615.00
Total Number Other Personnel	9	
Total Salary, Wages and Fringe Benefits (A+B)		972,268.00
Section C, Equipment		
Section D, Travel		22,000.00
1. Domestic	22,000.00	
2. Foreign		
Section E, Participant/Trainee Support Costs		
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other		
6. Number of Participants/Trainees		
Section F, Other Direct Costs		324,128.00
1. Materials and Supplies	5,200.00	
2. Publication Costs	1,500.00	
3. Consultant Services	190,000.00	
4. ADP/Computer Services		
5. Subawards/Consortium/Contractual Costs		
6. Equipment or Facility Rental/User Fees		
7. Alterations and Renovations		
8. Other 1	43,035.00	
9. Other 2	84,393.00	
10. Other 3		
Section G, Direct Costs (A thru F)		1,318,396.00
Section H, Indirect Costs		707,825.00
Section I, Total Direct and Indirect Costs (G + H)		2,026,221.00
Section J, Fee		
Section K, Total Direct and Fee (I + J)		2,026,221.00

PHS 398 Cover Page Supplement

OMB Number: 0925-0001

Expiration Date: 02/28/2023

1. Vertebrate Animals Section

Are vertebrate animals euthanized? ○ Yes ○ No

If "Yes" to euthanasia

Is the method consistent with American Veterinary Medical Association (AVMA) guidelines?

○ Yes ○ No

If "No" to AVMA guidelines, describe method and provide scientific justification

2. *Program Income Section

*Is program income anticipated during the periods for which the grant support is requested?

○ Yes ● No

If you checked "yes" above (indicating that program income is anticipated), then use the format below to reflect the amount and source(s). Otherwise, leave this section blank.

*Budget Period *Anticipated Amount ($) *Source(s)

Tracking Number: GRANT13205496 Funding Opportunity Number: PAR-20-077 . Received Date: 2020-09-18T11:41:16.000-04:00

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3. Human Embryonic Stem Cells Section

*Does the proposed project involve human embryonic stem cells? ○ Yes ● No

If the proposed project involves human embryonic stem cells, list below the registration number of the specific cell line(s) from the following list: http://grants.nih.gov/stem_cells/registry/current.htm. Or, if a specific stem cell line cannot be referenced at this time, check the box indicating that one from the registry will be used:

Specific stem cell line cannot be referenced at this time. One from the registry will be used.

Cell Line(s) (Example: 0004):

4. Human Fetal Tissue Section

*Does the proposed project involve human fetal tissue obtained from elective abortions? ○ Yes ● No

If "yes" then provide the HFT Compliance Assurance

If "yes" then provide the HFT Sample IRB Consent Form

5. Inventions and Patents Section (Renewal applications)

*Inventions and Patents: ○ Yes ○ No

If the answer is "Yes" then please answer the following:

*Previously Reported: ○ Yes ○ No

6. Change of Investigator/Change of Institution Section

❑ Change of Project Director/Principal Investigator

Name of former Project Director/Principal Investigator

Prefix:

*First Name:

Middle Name:

*Last Name:

Suffix:

❑ Change of Grantee Institution

*Name of former institution:

PHS 398 Research Plan

OMB Number: 0925-0001
Expiration Date: 02/28/2023

Introduction	
1. Introduction to Application (for Resubmission and Revision applications)	IntroApplicationP4rV21045663969.pdf
Research Plan Section	
2. Specific Aims	SpecificAimsP4rV21045663970.pdf
3. Research Strategy*	ResearchStrategyP4rV21045663971.pdf
4. Progress Report Publication List	
Other Research Plan Section	
5. Vertebrate Animals	
6. Select Agent Research	
7. Multiple PD/PI Leadership Plan	MultiplePIplanP4r1045663976.pdf
8. Consortium/Contractual Arrangements	
9. Letters of Support	LOSP4Combined1045594905.pdf
10. Resource Sharing Plan(s)	ResourceSharingP4r1045594906.pdf
11. Authentication of Key Biological and/or Chemical Resources	
Appendix	
12. Appendix	

Tracking Number: GRANT13205496
Funding Opportunity Number: PAR-20-077. Received Date: 2020-09-18T11:41:16.000-04:00

INTRODUCTION TO APPLICATION – Project 4

CRITIQUE, RESPONSE TO CRITIQUE

SPECIFIC AIMS – Project 4

Human papillomavirus (HPV) cancers are preventable through vaccination. Yet HPV vaccine coverage is well below the national goal of 80%, especially in rural areas where HPV cancers are more common. HPV vaccine communication interventions are an evidence-based approach to address low uptake. Announcement Approach Training (AAT) has been shown to increase HPV vaccine initiation and is recognized as an NCI-designated Research-Tested Intervention Program. As part of the P01 Program Project "Improving Provider Announcement Communication Training (IMPACT)," Projects 1-3 will test novel enhancements of AAT interventions in healthcare systems to improve primary care team members' HPV vaccine communication. Project 4 builds on this work by facilitating the selection and adoption of promising HPV vaccination interventions in rural and nonrural clinical settings to improve HPV vaccination.

The overall goal of Project 4 is to facilitate health system leaders' selection and adoption of AAT and other effective HPV vaccination interventions, by quantifying tradeoffs in their comparative cost and health impact in rural and nonrural areas. We will develop HPV microsimulation models that overlay interventions onto simulated populations reflecting patterns of baseline HPV vaccination, HPV transmission, and progression to HPV cancer to project the anticipated budget impact, cost-effectiveness, and population health outcomes of HPV vaccination interventions in rural and nonrural settings. We will also aid stakeholder implementation planning by developing a web-based interactive decision support tool illustrating the value of HPV vaccination interventions in rural and nonrural clinical settings. Demonstrating the trade-offs in cost and health impact to decision makers can accelerate the adoption of successful HPV vaccination interventions.

Rural areas have a distinct clinical and social context. Thus, we propose to identify contextual differences in rural and nonrural areas that may affect AAT intervention implementation, cost, and effectiveness, and examine the value of HPV vaccination interventions across geographic settings. This enables health system leaders to make evidence-based decisions that support increasing HPV vaccine coverage in rural settings.

Aim 1. Identify differences in contextual factors in rural and nonrural clinical settings that may influence the implementation and effectiveness of enhanced AAT interventions.

a. Interview 20 rural and 20 nonrural primary care team members, quality improvement decision makers, and health administrators from the healthcare systems in North Carolina (NC) and Wisconsin (WI), to develop a deeper understanding of the contextual differences and decision support needs as related to AAT intervention implementation across rural and nonrural clinical settings.
b. Survey a national sample of primary care team members (n=2,500) to characterize the implementation context for AAT interventions across rural and nonrural clinical settings.

Aim 2. Evaluate the budget impact, cost-effectiveness, and population outcomes of HPV vaccine communication and other evidence-based interventions in rural and nonrural clinical settings.

a. Develop, parameterize, and calibrate a national county-specific HPV microsimulation model reflecting patterns of HPV vaccination, transmission, and progression to HPV cancers using secondary data.
b. Overlay interventions onto the model to compare the budget impact, cost-effectiveness, and population health outcomes of HPV vaccine communication interventions, including enhanced AAT interventions from Projects 1-3 as well as other evidence-based interventions (e.g., IQIP and motivational interviewing training to improve provider communication).

Aim 3. Aid stakeholder implementation planning with a decision support tool illustrating the value of HPV vaccine communication interventions in rural and nonrural clinical settings.

a. Develop a decision support tool to visualize results from Aim 2 and summarize implementation outcomes from Projects 1-3, in coordination with the Intervention Core.
b. Engage rural and nonrural primary care team members, quality improvement decision makers, and health administrators in NC and WI to evaluate the usability of the decision support tool for enhanced AAT implementation support and ability to facilitate intervention selection and adoption decisions; incorporate feedback and disseminate the tool via IMPACT's website and AAT Intervention Package.

Project 4 advances the **IMPACT Program Project theme** of amplifying an HPV vaccine communication intervention's uptake in healthcare systems. Our project is **significant** in advancing cancer prevention science in rural and nonrural areas. It is **innovative** in translating the value of interventions tested in Projects 1-3 into a format well-suited to decision makers in healthcare systems. This will enhance our **dissemination** by accelerating the adoption of HPV vaccine interventions to prevent cancer in diverse geographic contexts.

RESEARCH STRATEGY – Project 4

SIGNIFICANCE

Uptake of human papillomavirus (HPV) vaccination remains low overall, and even lower in rural areas, despite demonstrated effectiveness. Compared with nonrural populations, rural women face significantly higher rates of cervical, vaginal, vulvar, oropharyngeal, and anal cancer, while rural men have higher rates of penile cancer.[1-3] HPV vaccination offers protection against 7 oncogenic HPV types.[4] However, only 72% of adolescents ages 13-17 have initiated the HPV vaccine, and only 54% have received all recommended doses.[5] Furthermore, studies consistently report large and persistent geographic disparities in HPV vaccine coverage.[6-14] HPV vaccine up-to-date coverage among adolescents aged 13-17 is only 47% in rural areas, as compared to 53% in suburban or transitional areas and 57% in urban areas.[5] Effective and cost-effective interventions are urgently needed to improve HPV vaccine uptake, especially in rural areas, to reduce disparities in cancer outcomes.

Scientific Premise

Rural areas have a distinct clinical context, which may influence the reach, cost and cost-effectiveness, and adoption of HPV vaccination interventions. Rural populations are fundamentally different from nonrural areas in community structures, health resource availability and sociodemographic composition (e.g., educational attainment, average income, employment, health insurance status).[15-21] These differences suggest that interventions that are successful in nonrural settings may need adaptation to achieve similar success in rural communities. No studies have examined whether implementation determinants for clinics and healthcare systems differ between rural and nonrural areas for HPV vaccine interventions.[22-27] Understanding how to increase HPV vaccination in rural areas has been identified as a research priority by the National HPV Vaccination Roundtable and also by the President's Cancer Panel.[28,29] The 2018 report to the US President by the Chair of the President's Cancer Panel specifically notes that "research is needed to elucidate factors that contribute to lower HPV vaccination rates among rural populations with disproportionately high rates of HPV cancers."[29]

The Announcement Approach Training (AAT) increases HPV vaccine initiation, but it is critical to also assess the budget impact, cost-effectiveness, and population outcomes of AAT implementation to inform decision making. AAT has successfully demonstrated increases in HPV vaccine initiation in a randomized clinical trial (RCT),[30,31] and NCI has designated AAT as a Research-Tested Intervention Program for increasing HPV vaccination coverage. Our proposed P01 Program Project "Improving Provider Announcement Communication Training (IMPACT)" will test approaches to enhance AAT by optimizing standing orders (Project 1), offering financial incentives (Project 2), and engaging clinical champions (Project 3) in healthcare systems. However, in the context of limited budgets and competing health and non-health spending priorities, it is important for health system leaders to have information about the relative value of these enhanced AAT interventions to make informed public health planning decisions.[32,33] As HPV cancer incidence is far downstream from administration of HPV vaccine, and because the counterfactual of no vaccination is difficult to observe, mathematical modeling can be used to predict interventions' budget impact, cost-effectiveness, and population health outcomes in both the short-term (i.e., additional individuals vaccinated, extra budget needed) and in the long-term (i.e., number of HPV-related cancers averted).[34-36] Project 4 will generate the needed scientific evidence to compare HPV vaccine interventions – including enhanced AAT interventions from Projects 1-3 and other evidence-based interventions, such as quality improvement visits from state health departments – to help health system leaders compare and prioritize among multiple interventions for improving HPV vaccination in rural and nonrural contexts.

Dissemination of user-friendly cost-effectiveness findings could help decision makers compare interventions to improve HPV vaccination in healthcare systems. Simulation models are increasingly used to provide cost-effectiveness information, and growing numbers of organizations rely on simulation modeling to forecast the health and economic consequences of intervention alternatives.[37-39] However, few simulation models make their results available to decision makers in an accessible format that allows manipulation or hypothetical testing of model inputs by the user.[40] In addition, cost-effectiveness data must be institutionally and contextually relevant for these tools and their projections to be fully accepted and used.[41-43] Decision support tools can aid stakeholder implementation planning by helping decision makers visualize and compare relevant data. Among the few decision support tools that have been developed, which have primarily focused on estimating the population outcomes from alternative breast and colorectal cancer screening and treatment options, usability was high, with 94% of users finding the tool helpful and reporting they would recommend the

tool to a colleague.[44,45] Project 4 proposes to develop and disseminate a web-based interactive decision support tool that will illustrate the value of HPV vaccine interventions and account for distinct implementation differences in rural and nonrural contexts. This project integrates findings across the IMPACT Program Project and presents user-friendly results to health system leaders, so that they can make informed, evidence-based decisions to improve HPV cancer outcomes by increasing HPV vaccine uptake in diverse settings.

Significance of Expected Research Contribution

The proposed study will advance cancer prevention science by building the evidence base on the value and impact of enhanced AAT interventions in rural and nonrural areas and accelerate their uptake to improve HPV vaccination. Using data from qualitative interviews and a national survey of primary care team members, we will assess how rural clinics' context may differ from nonrural clinics' context in ways that may influence the implementation and effectiveness of enhanced AAT interventions. We will then model and evaluate the comparative value of different HPV vaccine interventions, including enhanced AAT interventions tested in Projects 1-3, as well as other HPV vaccine interventions such as quality improvement visits from state health departments. We will estimate the budget impact, cost-effectiveness, and population health outcomes to assess the value of these interventions across all counties in the U.S. To accelerate dissemination and uptake of promising interventions, we will develop a decision support tool leveraging simulation model results and implementation outcomes findings from Projects 1-3 for health system leaders' use in implementation planning. This study will demonstrate the extent to which our enhanced AAT interventions are cost-effective on a population scale and provide value in rural and nonrural clinical settings, while also facilitating the use of this evidence by decision makers in diverse healthcare systems.

INNOVATION

We will provide novel guidance for decision makers to make evidence-based decisions to improve HPV vaccine uptake in the face of constrained health budgets. Simulation modeling methods have been used to compare multiple HPV prevention strategies, such as assessing whether to include boys in HPV vaccination programs,[46-51] what age ranges should be targeted,[52-54] and how cervical cancer screening protocols should change as a result of the vaccine.[34,55-57] However, none have compared enhanced HPV vaccine communication interventions — such as standing orders, financial incentives, and vaccine champions in AAT — to increase HPV vaccine uptake. By comparing the budget impact, cost-effectiveness, and population health outcomes of multiple enhanced AAT interventions alongside other HPV vaccine interventions, such as quality improvement visits by state health departments, we will aid health system leaders in their use of evidence to improve HPV vaccine uptake. Budget impact and cost-effectiveness analyses will integrate data across the P01 IMPACT Program Project to facilitate the adoption of enhanced AAT intervention approaches (from Projects 1-3) focused on increasing HPV vaccine uptake.

We will provide a new and comprehensive evaluation of HPV vaccine interventions in both rural and nonrural settings. No studies to date have examined the implications of differences in HPV vaccination rates in rural versus nonrural areas on HPV-associated cancer burden. Moreover, rural primary care team members may have different priorities, concerns, workflows, and processes, potentially requiring HPV vaccination interventions to be specifically modified for rural settings (for example, Project 1's focus on optimizing standing orders for non-physician vaccine delivery may be especially potent in rural areas, given physician shortages).[58,59] Assessing ways to increase HPV vaccine coverage in rural areas is a research priority.[28,29] Meanwhile, intervening in nonrural areas is also important to increase HPV vaccine coverage, since most Americans (~80%) live in nonrural areas.[60] Therefore, we will collect data on both rural and nonrural primary care teams' context-specific implementation needs with regard to HPV vaccine interventions. We will first qualitatively examine rural/nonrural implementation barriers and facilitators in two states, North Carolina (NC) and Wisconsin (WI) where Projects 2 and 3 will conduct RCTs, because rural contexts and the value of HPV vaccination interventions may differ by state. These states face low to average HPV vaccine coverage, have large proportions of rural residents, and cover different regions (Midwest and South).[60] We will subsequently incorporate emerging themes into a national survey of primary care team members to assess broader generalizability. We are expanding upon previous HPV vaccination analyses by assessing factors expected to influence intervention implementation in diverse geographic settings.

We will develop the first decision support tool to help decision makers in healthcare systems easily compare the budget impact, cost-effectiveness, and population health and implementation outcomes of enhanced AAT intervention strategies. Our proposed study is innovative in that it facilitates scale-up and dissemination of HPV vaccine communication interventions beyond the research setting through the

development of a user-friendly decision support tool. Decision makers in healthcare systems, as well as payers, state health departments, and the Centers for Disease Control and Prevention (CDC) need to weigh tradeoffs and implementation outcomes related to potential interventions' immediate budget impact, as well as long-term costs and effectiveness. This study is novel in providing such decision support for clinics, healthcare systems and beyond. Our decision support tool will allow health system leaders to compare how implementation outcomes vary across interventions. It will also allow users to change model inputs, including contextual factors that may influence the value of interventions specific to their setting, enabling more relevant and actionable dissemination of results. This step will help ensure that the enhanced AAT intervention results are not solely an academic product but presented in a manner that can be tailored and used by decision makers to prioritize and implement interventions to increase HPV vaccine uptake and prevent cancer.

APPROACH

Research Team and Preliminary Studies

This study brings together a diverse research team with expertise in simulation modeling, economic evaluation, implementation science, and health disparities. The team will be co-led by **Sachiko Ozawa**, PhD, Associate Professor of Maternal Child Health and Practice Advancement and Clinical Education in Pharmacy, and **Stephanie Wheeler**, PhD, Professor of Health Policy and Management, both at the University of North Carolina (UNC). Dr. Ozawa is an internationally recognized expert on the value of vaccines, vaccine demand and simulation model development with over $4 million in research support. Dr. Wheeler is an expert in decision science, cost-effectiveness analysis, and rural cancer care delivery to support cancer-related decision making and implementation planning, with over $20 million in cancer-related research funding. Drs. Ozawa and Wheeler have written over 52 papers combined on model simulations, 51 papers on disparities, 44 papers on economic evaluations, and 27 papers on vaccines.

Dr. Ozawa will serve as Contact Lead and be responsible for Project 4's overall administration and reporting to the funding agency. Dr. Ozawa will lead the interviews and survey in rural and nonrural areas (Aim 1). Drs. Ozawa and Wheeler will work collaboratively on model building (Aim 2), and Dr. Wheeler will lead the development and dissemination of the decision support tool (Aim 3). Both Drs. Ozawa and Wheeler will interface with IMPACT research projects and cores [See Multiple PD Plan]. **Sarah Birken**, PhD, Associate Professor of Implementation Science at Wake Forest School of Medicine, will advise on qualitative methods, as well as the study of AAT implementation in rural and nonrural settings. **Kristen Hassmiller Lich**, PhD, Associate Professor of Health Policy and Management at UNC and expert on systems science methods, will advise on the involvement of stakeholders in decision support tool development and testing. **Lisa Spees**, PhD, Assistant Professor of Health Policy at UNC, will act as Program Director, managing day-to-day operations, stakeholder engagement communications, and the budget. **Colleen Higgins**, MSPH, Independent Modeling Consultant, will perform HPV transmission model programming and simulation analyses.

Drs. Jane Kim, Jennifer Spencer, Evan Myers, and **Sarah Mills** will be part of an Expert Modeling Advisory Committee, which will meet quarterly and provide technical and conceptual input on the model development, parameterization, and debugging process. **Jane Kim**, PhD, Professor of Health Decision Science at Harvard University, will consult on HPV transmission model development. **Jennifer Spencer**, PhD, Postdoctoral Fellow in the Training in Oncology Population Sciences (TOPS) program at Dana Farber/Harvard Cancer Center, will consult on parameterization of evidence-based interventions during model development. **Evan Myers**, PhD, Walter L. Thomas Professor of Obstetrics and Gynecology at Duke University, will provide clinical decision making expertise. **Sarah Mills**, PhD, Assistant Professor of Health Behavior at UNC and expert in health disparities and mathematical modeling, will consult on parameterizing rural/nonrural and race-specific model inputs.

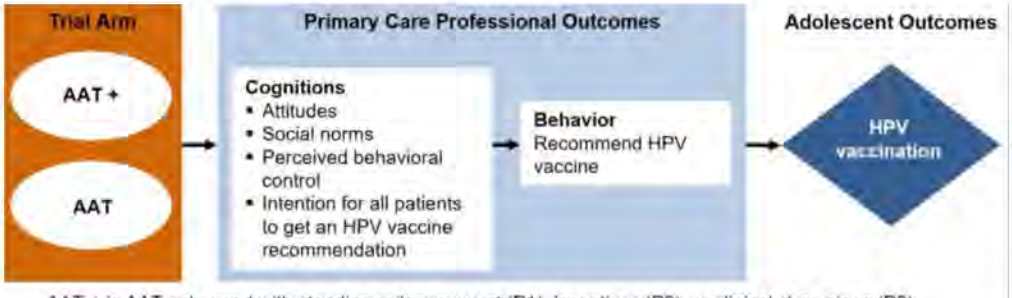
The team offers substantial experience conducting **cost-effectiveness analyses and vaccine-related modeling** in collaboration. Drs. Wheeler and Spencer have collaborated on several decision modeling studies,[61-63] including Dr. Spencer's work developing a dynamic HPV vaccination model exploring socioeconomic disparities and implementation of hypothetical interventions.[64] Dr. Ozawa is known for her cost-effectiveness review and modeling of the return on investment of vaccines, including the HPV vaccine,[65-69] and has led the development of various microsimulation models, working closely with Ms. Higgins.[70,71] Drs. Wheeler and Lich have used microsimulation modeling to evaluate the cost-effectiveness of alternate interventions to increase preventive service use across populations.[72-76] The team also has expertise in **health disparities** research. Dr. Wheeler has worked with Dr. Spees, Dr. Spencer, Dr. Mills, and others on numerous studies examining rural and racial/ethnic disparities and understanding the role of health system organization and structure in shaping such disparities.[18,22,77-82] Dr. Ozawa has studied global vaccination disparities extensively,

including estimating the differential burden of vaccine preventable diseases,[83] the economic value of targeting hard-to-reach populations for vaccination,[84,85] and the geospatial impact of improving HPV vaccine access.[86,87] The team also has expertise in the rapidly evolving field of **implementation science**. Dr. Birken is an expert in the application of implementation science using qualitative methods.[88,89] Both Drs. Birken and Wheeler are prior Fellows in the prestigious Mentored Training for Dissemination and Implementation Research in Cancer program. Additionally, Dr. Wheeler has studied the implementation of cancer-related preventive services and worked with decision makers to integrate simulation modeling methods into evidence-based intervention implementation planning.[22,74,90] The team has also worked closely with the Communications for Health Applications and Interventions (CHAI) Core, which brings extensive expertise in qualitative methods and translating research into web-enabled tools.

Conceptual Model

As shown in **Figure 1**, the P01 IMPACT Program Project shares a conceptual model guided by the Theory of Planned Behavior (TPB).[91] TPB suggests that improving primary care professionals' cognitions can change recommendation behavior, leading to HPV vaccination. Projects 1-3 affect primary care professionals' cognitions through enhanced AAT interventions (standing orders, financial incentives, and clinical champions). Project 4 proposes to present the results of Projects 1-3 side-by-side by modeling the interventions' impact and cost-effectiveness as a function of population demographics (Aim 2), and translating evidence into a user-friendly, modifiable decision support tool (Aim 3). Moreover, Project 4 proposes to provide Projects 1-3 with contextual information on rural/nonrural differences by identifying factors that are expected to affect implementation processes and outcomes, as well as effectiveness of AAT in different contexts (Aim 1). Project 4 proposes to not only produce rigorous impact estimates of value associated with enhanced AAT interventions, but to also facilitate dissemination and implementation by creating a user-friendly, dynamic, web-based, interactive tool with estimates relevant to specific stakeholder rural/nonrural contexts and perspectives. Summaries of outputs from this tool, guidance for its use, and descriptions of rural/non-rural implementation determinants and outcomes will be included in the AAT Intervention Package with guidance relevant to specific stakeholder rural/nonrural contexts.

Figure 1. Conceptual Model

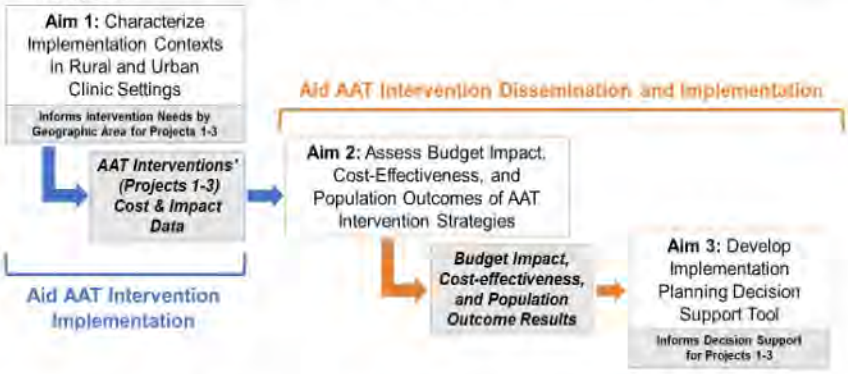


AAT + is AAT enhanced with standing orders support (P1), incentives (P2), or clinical champions (P3)

Integration

Through integration and data sharing with Projects 1-3, alongside the Data and Intervention Cores, Project 4 will aid AAT intervention implementation and dissemination. Prior to AAT intervention implementation, Project 4 will characterize implementation contexts in rural and nonrural settings to inform intervention needs by geographic area for Projects 1-3 (Aim 1). We will collaborate with Projects 2, 3, and the Intervention Core to conduct interviews (Activity 1a), and also work with Projects 1, 2, and the Data Core on the national primary care team survey (Activity 1b). During the RCTs run by Projects 1-3, Project 4 will develop model simulations so that the population-level impact of AAT interventions can be immediately estimated at the conclusion of the trials. Project 4 will receive cost and impact data from Projects 1-3 to estimate the budget impact, cost-effectiveness, and population outcomes of each enhanced AAT intervention (Aim 2). Project 4 will also aid decision makers' use of simulation model results by developing a decision support tool and conduct usability testing (Aim 3). This integrative approach is outlined in **Figure 2.**

Figure 2. Integration of Project 4 into the P01 IMPACT Program Project



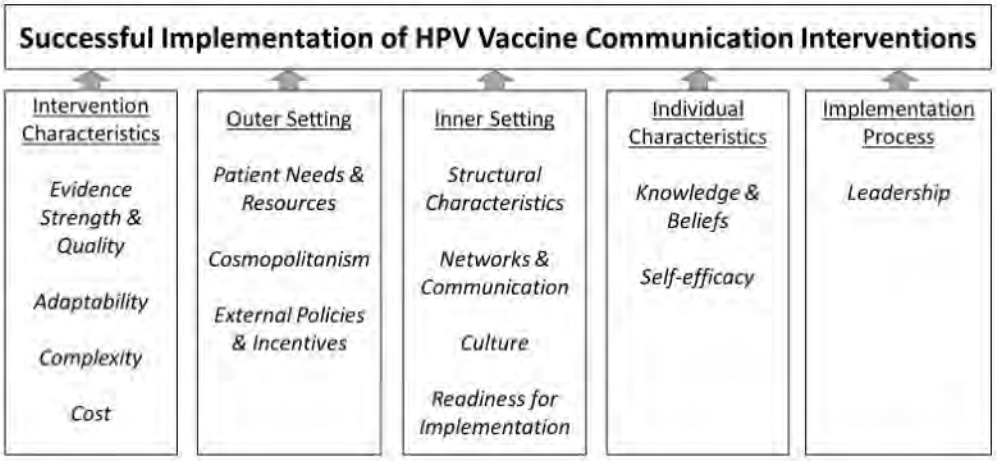
Aim 1. Identify differences in contextual factors in rural and nonrural clinical settings that may influence the implementation and effectiveness of enhanced AAT interventions.

Prior to implementing enhanced AAT interventions in diverse rural and nonrural settings, it is critical to understand organizational factors that may aid or impede this process. We will employ a mixed methods approach to conduct detailed assessments of the context of rural and nonrural clinics and healthcare system settings. Specifically, this Aim will involve 2 phases: (1) conducting semi-structured interviews with 20 rural and 20 nonrural primary care team members, quality improvement decision makers, and health administrators identified from NC and WI in coordination with Projects 2 and 3 to develop an in-depth, nuanced understanding of the contextual differences and decision support needs across rural and nonrural clinical settings; and (2) surveying a national sample of 2500 primary care team members, in conjunction with Projects 1, 2 and Data Core, to further characterize the implementation contexts of rural and nonrural clinics and healthcare systems.

Conceptual Framework for Aim 1

We will use the Consolidated Framework for Implementation Research (CFIR)[92] as a comprehensive implementation determinants framework to examine factors expected to affect successful implementation of HPV vaccination interventions. We will explore perceptions of key healthcare informants and providers about the extent to which the domains of *Intervention Characteristics, Outer Setting, Inner Setting, Individual Characteristics*, and *Implementation Process* influence how HPV vaccine communication interventions diffuse through healthcare clinics and health systems. Our interview guide will probe on potentially relevant sub-constructs of each domain such as: (1) evidence strength and quality, adaptability, complexity and cost under *Intervention Characteristics;* (2) patient needs and resources, cosmopolitanism (i.e. degree of external networking), and external policies and incentives under *Outer Setting*; (3) structural characteristics, networks and communication, culture, and readiness for implementation under *Inner Setting;* (4) knowledge and beliefs, and self-efficacy under *Individual Characteristics*; and (5) leadership under *Implementation Process* in rural and nonrural settings (see **Figure 3**). We expect that these sub-constructs, a priori, may affect HPV vaccine communication intervention implementation success and health outcomes.[93]

Figure 3. Application of the Consolidated Framework for Implementation Research to Aim 1



1a. Conduct interviews with rural and nonrural primary care team members.

Participants and Recruitment. We will recruit primary care team members, quality improvement decision makers, and health system administrators in rural and nonrural clinics in NC and WI to further understand differences in their organizational processes and distinct opportunities and challenges to implementation of enhanced AAT interventions. We aim to recruit 40 primary care team members in rural (n=20) and nonrural (n=20) clinics from the healthcare systems in Projects 2 and 3 who agree to be interviewed, in coordination with Projects 2, 3, and the Intervention Core. Rurality will be defined using the Rural-Urban Continuum Codes (RUCC)[94] as nonrural/metropolitan (RUCC=1, 2 or 3), or rural (RUCC>3) based on the clinic address of each primary care team. In-depth interviews will allow us to explore how and the extent to which the context of rural and nonrural clinics is expected to influence AAT implementation.

Procedures. We will use an in-depth, semi-structured interview guide based on CFIR to understand the differences between rural and nonrural contexts that may affect the implementation of AAT interventions. We will also ask about successful prior practices for implementing similar interventions in rural and nonrural areas. For Activity 1a, we will collaborate with CHAI Core, an NCI-funded shared resource at UNC Lineberger Comprehensive Cancer Center that offers qualitative research services, with which Dr. Wheeler has worked

previously. We will work closely with CHAI Core's qualitative research team, to iterate and finalize the interview guide, conduct in-depth 45-60 minute phone interviews, confirm coding consistency, and ensure fidelity in analysis. Interviews will be audio-recorded and transcribed verbatim, removing any identifying information. Participants will be compensated for their time with a gift card of $100.

Measures. We will probe on CFIR constructs that are identified as important to AAT intervention implementation or that differ significantly in rural and nonrural areas. This would include the exploration of rural/nonrural differences in public confidence in HPV vaccine. Drawing upon the experience of Drs. Birken and Spees using similar methods,[95,96] information from these interviews will be used to understand: (1) how implementation **opportunities** might differ between rural and nonrural areas interested in HPV vaccine communication interventions; and (2) how AAT implementation **challenges** might differ between rural and nonrural areas interested in HPV vaccine communication interventions.

Analyses. We will employ template analysis, which involves using a priori codes based on CFIR constructs and allowing additional codes to emerge from the interview data. To maximize rigor of qualitative analyses, we will use multiple trained coders, a standardized codebook, and keep detailed notes of analytic decisions. Interview transcripts will be analyzed using a qualitative software management tool (i.e. Atlas.ti) and follow a coding-based thematic analysis. Two qualitative researchers at CHAI Core will independently code interview transcripts. The initial code book will be pilot tested using a randomly selected group of four transcripts where two coders will discuss any discrepancies in coding, reconcile differences, and refine the code book to ensure reliability. We will examine differences in themes across rural and nonrural clinics, which will be investigated further in Activity 1b.

1b. Survey a national sample of primary care team members.

The P01-wide primary care team survey will be conducted in Year 1 in conjunction with Projects 1, 2, and the Data Core. By leveraging data collection across the P01 Program Projects, we will gain generalizable knowledge that would not be possible in a single-project study. Further details – such as feasibility, methods, and additional subcontractor information – are described in the Data Core proposal.

Participants and procedures. The Data Core will contract with WebMD Market Research, a survey research company affiliated with the online publisher WebMD, to facilitate a national survey of pediatric vaccination primary care team members. The WebMD panel includes ~60% of US pediatricians and other healthcare professionals. The survey, to be used by three of the four P01 IMPACT Program Projects, will include a national sample of 2,500 primary care team members including ~500 participants from 5 disciplines: pediatricians; family physicians; nurse practitioners and physician assistants; nurses; and medical assistants. Eligible individuals include those who: 1) are in pediatrics or family medicine clinics; and 2) whose duties include prescribing, administering, documenting, or counseling parents about adolescent vaccines. To facilitate rural/nonrural comparisons, WebMD will oversample from rural areas, targeting a sample comprised of at least 20% rural. Rurality will be characterized based on the RUCC classification of the county(ies) of the primary care team members' clinic(s) where they practice.[94] This measure is considered more valid than primary care teams' self-report of the proportion of patients who reside in rural areas.[97] The survey will be conducted online and pilot tested with 20 participants. Respondents will receive $45 for their time.

Measures. The survey will include ~75 items, comprised of up to 15 core items for demographics (e.g., medical training, role in HPV vaccine provision, healthcare system, and rurality) and at least 15 items contributed by each P01 IMPACT Program Project. Project 4 will include items based on the specific contextual themes with the potential to affect the implementation of AAT interventions in rural and nonrural clinics emerging from the qualitative interviews in Activity 1a (see **Figure 3**).

Analyses. The primary analyses will assess rural/nonrural differences in implementation determinants expected to inform enhanced AAT implementation in rural and nonrural contexts. We will compare differences in responses, by rural/nonrural clinic locations, using Mann Whitney tests, chi square tests, and multivariable regression analyses to examine whether implementation context measures differ. Statistical tests will be 2-tailed with a critical alpha of 0.05. With our sample size of >500 rural and up to 2,000 nonrural respondents, we will have 80% power to detect differences of >10 percentage points in rural/nonrural contextual differences. Regression models will examine the rural effect controlling for demographic variables. Identified rural/nonrural differences will be shared with Projects 1-3.

The qualitative interview results (Activity 1a) and quantitative survey (Activity 1b) will yield a deeper understanding of how rural/nonrural organizational differences may influence the implementation of enhanced AAT interventions in clinics and healthcare systems than either data source alone could

offer. Promising practices for implementing similar interventions in rural and nonrural areas will be shared with Projects 1-3 to help contextualize and improve enhanced AAT intervention implementation in different settings. We will generate a report and manuscript summarizing main findings for each theme, including a joint display of qualitative and quantitative data, comparing clinics in rural and nonrural settings.

Aim 2. Evaluate the budget impact, cost-effectiveness, and population outcomes of HPV vaccine communication and other evidence-based interventions in rural and nonrural clinical settings.

Budget impact and cost-effectiveness analyses are useful for program planning to determine whether investment in HPV vaccine interventions provides clinical benefit at a reasonable cost and within an organization's budget.[33] Specifically, a simulation model can demonstrate tradeoffs in value between upfront intervention costs, potential savings, and health benefits associated with averting future illness. In Years 2-5, we will build a national county-specific HPV microsimulation model to estimate and compare the budget impact, cost-effectiveness, and population outcomes of HPV vaccine interventions. We will evaluate the value of each enhanced AAT intervention (i.e., standing orders, financial incentives, and clinical champions) conducted by Projects 1-3, separately and in combination, as well as other evidence-based interventions. Enhanced AAT communication interventions that are less effective than AAT alone will not be modeled. We will examine the potential impact of combinations of enhanced AAT interventions through sensitivity analyses, varying assumptions about the costs and combined effectiveness of these interventions. The model will be informed by our work in Aim 1, as well as previously published data on HPV transmission and HPV-related cancer incidence in rural/nonrural counties.[18,22,77-82]

Procedures. In Year 1, to ensure consistency in data inputs, we will develop spreadsheets in coordination with the Intervention Core and Data Core to help Projects 1-3 gather standardized cost and effectiveness data throughout the RCTs. Data collected on these spreadsheets will be incorporated into our modeling as preliminary data, and upon conclusion of the RCTs.

In Years 2-3, we will develop a national county-specific HPV microsimulation model in Python. Specifically, we will develop, parameterize, and calibrate an agent-based model reflecting patterns of baseline HPV vaccination, HPV transmission, and progression to HPV cancer (see **Table 2** for data sources). The modeling steps will involve simulating: (1) population demographic characteristics (Year 2); (2) HPV transmission and behavior (Year 2); (3) HPV cancer risk and progression (Years 2-3); and (4) costs (Year 3). The model will incorporate rural/nonrural contextual differences at the level of county where possible. Rural/nonrural parameterization is important to capture variation in rural contexts and differences in value of HPV vaccine interventions across county populations. The HPV microsimulation model will allow for an understanding of vaccination benefits at the individual and population levels by incorporating sexual transmission dynamics and cancer risk and progression, based upon sex as a biological variable, using a susceptible-exposed-infected-recovered (SEIR) compartmental model.[98] This will allow us to model benefits of individual protection through HPV vaccination as well as herd immunity effects from increasing vaccination rates. The HPV microsimulation model will also facilitate simulation of rural/nonrural population intermingling and the effect of population density and geography on partnerships. Developing these models take time, with model coding and meticulous data calibration. In her earlier 3-year project, Dr. Ozawa has successfully developed other agent-based models[70,99] and has used SEIR models alongside examination of cost-effectiveness of vaccination strategies.[84]

In Year 4, we will overlay interventions onto the model to compare the budget impact, cost-effectiveness, and population outcomes of HPV vaccine interventions, using preliminary data of enhanced AAT interventions from Projects 1-3. We will also simulate other HPV vaccine interventions beyond those evaluated in Projects 1-3 to allow for broader comparisons by decision makers, including quality improvement coaching (e.g., IQIP) and motivational interviewing training. Specifically, we will use the model and data from the literature to simulate implementation and impact of HPV interventions across U.S. counties.[100-102] We will select specific comparators based on evidence of costs and effectiveness available at the time of analysis.

At the beginning of Year 5, after the completion of Project 1-3 RCTs, we will update the model with final cost and effectiveness data from enhanced AAT interventions. The model will be used to estimate a one-time implementation of each HPV vaccine intervention (compared to the status quo). Using the model, we will (1) conduct a budget impact analysis, comparing budgets with immediate intervention cost over 1- year and 3-year time horizons, and (2) conduct a cost-effectiveness analysis, assessing the incidence of HPV-related cancers, anogenital warts averted, and quality-adjusted life years (QALYs) gained over different time horizons (e.g. 1 year, 3 years, and up to 50 years). Examining the budget impact and cost-effectiveness of HPV vaccine interventions over different time horizons will aid decision makers in considering shorter and longer term investments of resources and return on those investments. As the model will already be built and calibrated

prior to RCT completion, we will be able to quickly simulate and disseminate Project 1-3 results once the RCTs are completed, accelerating the adoption and implementation of effective AAT interventions.

Measures. The model will incorporate data available from the literature as well as health impact and cost data from Project 1-3 RCTs. Known model input parameters will come from both existing HPV modeling literature[103] and from high-quality secondary data sources as shown in **Table 2**. To reflect differential HPV cancer risk and death in rural and nonrural settings, county-matched data will be obtained reflecting HPV prevalence (from NHANES),[105] HPV vaccination (from NIS—Teen),[108] and cancer registries.[3,109] These data will be stratified using the RUCC codes to generate rural- and nonrural-specific model inputs.[94] Migration between rural and nonrural areas will also be incorporated. Finally, HPV-related cancer incidence by age, race/ethnicity, and rural/nonrural residence will be obtained from the Surveillance, Epidemiology, and End Results Program (SEER)[106] and CDC-funded National Program of Cancer Registries (NPCR) data.[107] The HPV microsimulation model of HPV transmission, HPV vaccination, and progression to HPV outcomes will be developed following assumptions made by previous models.[103] Inputs specific to rural and nonrural settings will be used to create separate subgroups within the models, representing rural and nonrural counties. Model inputs that are less certain (e.g., sexual behavior, infectivity, and HPV progression variables) will be simultaneously calibrated to fit rural and nonrural HPV cancer incidence data from SEER or NPCR using 10,000 Latin hypercube sampling to identify the parameter set that produces the closest fit to observed incidence.[110]

Table 2. Data sources for HPV vaccination model development

Data	Source
Population age structure, births, deaths	CDC Wonder Database[104]
Sexual behavior, HPV type-specific infectivity rates, and vaccine efficacy	Existing HPV modeling literature
HPV type-specific prevalence by age	Existing HPV modeling literature
Overall HPV prevalence	National Health and Nutrition Examination Survey (NHANES)[105]
Overall HPV cancer incidence	Surveillance, Epidemiology, and End Results Program (SEER)[106] and/or CDC-funded National Program of Cancer Registries (NPCR) Data[107]
HPV vaccine initiation and follow-through	National Immunization Survey—Teen (NIS-Teen)[108]
Cervical cancer screening rates	Existing HPV modeling literature
Identification of rural/nonrural counties	Rural-Urban Continuum Codes (RUCC)[94]
Cost of cancer care	Existing cost literature
Health utilities	Existing health utility literature

In conjunction with the Data Core and Intervention Core, Projects 1-3 will collect data on enhanced AAT intervention effectiveness and costs (both fixed and variable), from the healthcare facility or system perspective. The standardized spreadsheets will gather data specific to clinic rurality, which is defined as having more than 40% of their patient panel residing in nonmetro areas. Intervention effectiveness will be defined as the proportion of unvaccinated 11- and 12-year-olds initiating HPV vaccine in each intervention arm in excess of the control arm. In sensitivity analysis, we will consider a range of intervention hypothetical effectiveness, using 95% confidence intervals of point estimates from Projects 1-3. The projects will gather cost data using tracking logs and online surveys. Variable costs may include intervention materials, financial incentive payments (Project 2), and other costs accrued by each additional training. Fixed costs may include program startup and administration. We will not assess fixed costs common to both the interventions and the "status quo" (e.g., clinic operation overhead), or costs related to the study alone (e.g., data collection). In addition to the costs from the healthcare facility or system perspectives collected by Projects 1-3, we will model the societal perspective to estimate additional costs incurred by patients.

Analyses. Our HPV microsimulation model will be used for two purposes. First, we will conduct a budget impact analysis of the cost in dollars of each intervention. This answers the question of whether the intervention is *affordable* for an organization. Second, we will conduct a cost-effectiveness analysis estimating the incremental cost per additional adolescent initiating HPV vaccine, per QALY gained and per HPV cancer death averted for each intervention. For each HPV vaccine intervention, we will run simulations to estimate the additional costs and additional adolescents vaccinated compared to the status quo. This answers the question of whether the intervention provides *value* relative to the status quo.[111]

We will separately assess the immediate budget impact and long-term cost-effectiveness of each intervention in rural and nonrural settings, similar to Drs. Spencer's and Wheeler's prior work in low- and high-income settings using rural/nonrural-specific input parameters.[64] We will produce population-level estimates of cost, cost-effectiveness, and health impact as in our previous work.[76]

Incremental cost effectiveness ratios (ICERs) will be reported.[64] Interventions that cost less and result in more QALYs gained, deaths averted, and persons vaccinated are cost-saving (or dominant) options. Interventions that cost more and result in more QALYs will be evaluated against standard willingness-to-pay thresholds (i.e., $50,000, $100,000, and $150,000 per QALY gained) to understand decision makers' willingness to absorb those costs to gain additional QALYs.[112,113] For outcomes other than QALYs and for which standard willingness-to-pay thresholds are unavailable, we will plot outcomes on an efficiency frontier and cost-effectiveness acceptability curve to help decision makers visualize benefits gained at different willingness-to-pay levels, as we have done previously.[76] Although we may uncover dominant options, we expect this analysis to demonstrate the tradeoffs among HPV vaccine interventions.

The budget impact analysis will provide decision makers with estimates of the financial feasibility of each intervention to aid in resource allocation.[114] We will estimate the budget impact of a one-time implementation of each enhanced AAT intervention annually and over a 3-year time horizon. We will also estimate the budget impact of implementation at the level of a healthcare system for use by healthcare administrators and primary care team members. Budget impact analysis results will be particularly important for decision makers in healthcare systems, as they may not see the long-term benefits modeled in cost-effectiveness analysis due to individuals moving between clinics and insurance plans over the life course.

Sensitivity analyses will examine the potential impact of varying assumptions about the costs and effectiveness of these interventions, including potential combinations of interventions. Specifically, we will employ deterministic sensitivity analyses to examine model assumptions and key parameter uncertainties, including reporting changes in cost-effectiveness estimates as discount rates change. We will assume that intervention effects would be additive unless cost components are redundant across interventions and vary this assumption. We will conduct probabilistic sensitivity analyses (using Monte Carlo simulation) to account for parameter uncertainty within each modeled intervention. The model will be simulated 5,000 times to capture uncertainty in baseline HPV prevalence, intervention cost, effectiveness, and vaccine characteristics. Results will represent an average across simulated model runs with an estimated uncertainty range. We will depict sensitivity results graphically and with relevant descriptive statistics. We will estimate net monetary benefits of each intervention at a range of willingness-to-pay thresholds,[115-117] presenting a visual graph depicting the probability that each intervention is preferred given the decision maker is willing to pay at least the threshold value for each additional adolescent vaccinated or each additional life year gained, consistent with prior work.[61,62,64]

Aim 2 will yield comparisons of the budget impact, cost-effectiveness, and population outcomes of multiple AAT interventions in both rural and nonrural settings across U.S. counties. Aim 3 will then translate these findings into an accessible, relevant decision support tool.

Aim 3. Aid stakeholder implementation planning with a decision support tool illustrating the value of HPV vaccine communication interventions in rural and nonrural clinical settings.

To be used in real-world settings, budget impact, cost-effectiveness and other implementation findings must be provided to health system leaders in an appropriate usable format. It is therefore critical to develop and evaluate the usability of our decision support tool for implementation support and decision making.

Pilot Study

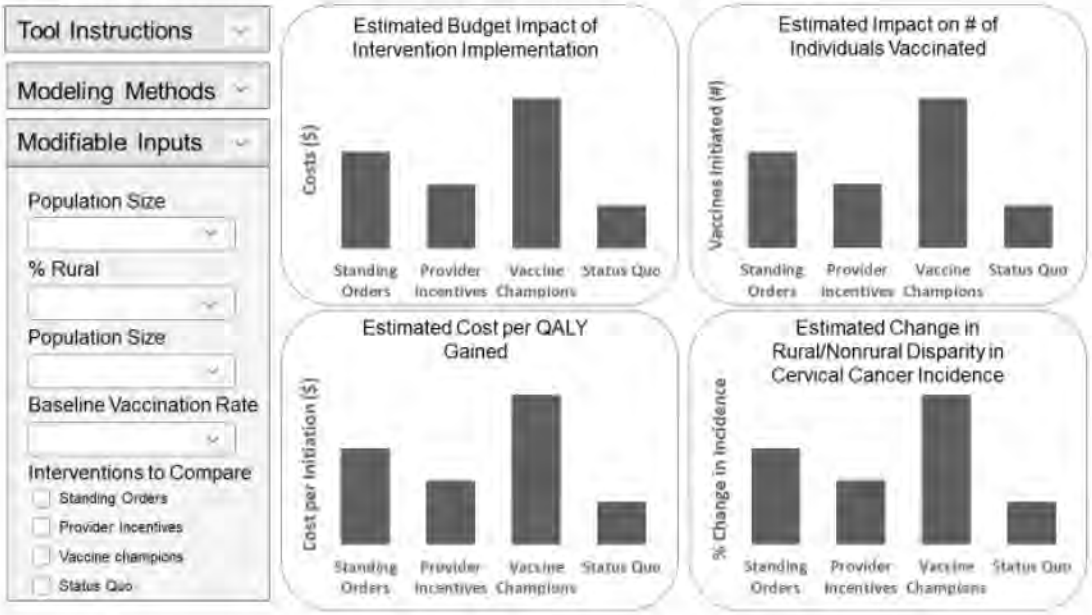
We interviewed ten health system quality improvement (QI) managers to ask whether they use data on cost and effectiveness for vaccination QI activities. Many respondents noted that cost-effectiveness data are not currently being used for decision making because they do not have the matching cost and effectiveness data for their healthcare system. The majority found existing cost-effectiveness data difficult to use. Importantly, **all respondents agreed that it would be useful to have data that is more specific to their healthcare system or local context** to better interpret and utilize cost-effectiveness data. Respondents supported having a web-based tool with data specific to the healthcare system. These preliminary results suggest that **a web-based interactive interface with data customized for healthcare systems could be used by decision makers to select among strategies for improving HPV vaccination rates**.

An interactive interface serves to augment conventional population health modeling data, allowing stakeholders to make informed decisions specific to their population and setting. Moreover, web-based decision support tools have been shown to be an acceptable strategy for decision makers to quantify and visualize complex, multi-faceted outcomes in other contexts.[44,118,119] As many health system leaders must consider outcomes in both rural and nonrural settings, a web-based interface will allow individuals to specify rural/nonrural population composition, among other demographic parameters, when viewing and comparing relevant cost and effectiveness simulation results for various enhanced AAT interventions.

3a. Develop a decision support tool to visualize simulation model results.

Procedures. A web-based interactive decision support tool will be constructed in collaboration with CHAI Core, using results from the Aim 2 simulation model. In addition to providing advanced qualitative research resources, CHAI Core also specializes in translating research into usable, web-enabled tools and is currently supporting Drs. Wheeler's and Lich's efforts to translate results from a similarly structured colorectal cancer screening model into a web-based tool. Housing both web development and graphic design teams, CHAI Core includes programmers with expertise in scripting language such as ASP, ASP.NET, PHP, and JSP.
We will work closely with CHAI Core to ensure that the final interface is relevant, attractive, and accessible on our hpvIQ.org website. Specifically, CHAI Core will provide web and user interface design based on the IMPACT Program Project branding; wireframe and information architecture development; dynamic and static website programming; back-end database functionality for data collection; project management; quality assurance testing to assure site functionality; tracking of website usage using Google Analytics; and ongoing maintenance of the web-enabled tool for the life of the project, as they have also done for Drs. Wheeler's and Lich's related project. By integrating simulation cost-effectiveness and budget impact results from each intervention into a single web-based tool, decision makers will be able to access a side-by-side comparison of cost and impact estimates specific to their context. Examples of modifiable parameters include the following: rural/nonrural proportion, race/ethnicity, population size, baseline vaccination rate, budget size and intervention effectiveness. For computational feasibility and tool loading speed, the interactive interface will house transmission model results for a finite number of modifiable parameter combinations, and the tool will display results based on user inputs. Decision support tool outputs will include: (a) estimated costs of intervention implementation; (b) estimated impact of intervention implementation on number of individuals vaccinated and HPV-related health outcomes; (c) estimated costs per person vaccinated and per QALY gained; (d) estimated reduction in rural/nonrural disparity in HPV-related health outcomes; (e) estimated budget impact; and (f) implementation outcomes summaries. A series of interactive figures will allow users to compare the simulation results of implementing each AAT intervention (see example template in **Figure 4**). Outcomes will also be compared to those expected in the absence of an intervention (status quo). Interventions found not to be effective in RCTs will not be included in the decision support tool modules. Following usability testing (see Activity 3b), the final web tool will be made publicly available on hpvIQ.org and in the AAT Intervention Package.

Figure 4. Hypothetical Web-based Interactive Interface (Example)



3b. Engage stakeholders to evaluate the usability of the decision support tool.

Participants and recruitment. We will work closely with Projects 2, 3 and the Intervention Core to recruit quality improvement decision makers and health system administrators in North Carolina and Wisconsin, including as many as possible who participated in Activity 1a interviews, to evaluate the usability of the decision support tool developed in Activity 3a. Participants also will involve other healthcare system leaders, payers, representatives from state health departments and national advisory groups such as the CDC. To identify these stakeholders, we will use our network of contacts through the P01 IMPACT Program Project's External Advisory Board, the Clinical Advisory Board maintained by the Intervention Core, and health system leaders participating in Projects 2 and 3. We will also use our existing relationships, including contacts with Medicaid and Medicare quality improvement organizations, county and state departments of Health and

Human Services, medical societies, and professional organizations. Up to twenty individuals will be contacted for usability testing. First, a convenience sample of 10 stakeholders will be contacted for initial pilot testing. After incorporating suggestions, up to 10 additional stakeholders will be contacted to conduct a second, iterative round of usability testing to reach feedback saturation.

Procedures. Potential participants will receive a pre-call letter to let them know we will attempt to contact them for a usability testing survey and to describe the topic and participation incentive amount. We will make three call attempts and seek verbal consent. The first sample of 10 stakeholders will receive an initial version of the web-based decision support tool for pilot testing. A link to the preliminary version of the tool will be emailed to consenting participants, along with a unique username and password for tool access, a brief orientation tutorial introducing the tool, and an electronic usability evaluation survey. Interviews will employ the System Usability Scale and other measures to assess the usability of the decision support tool.[120] Users will provide their role in HPV vaccine decision making, record the time they spend using the tool (expected to range anywhere from 20-30 minutes), and complete the associated electronic survey assessing their experience. Participants will be compensated for their time with a gift card of $100. Following data collection and analysis, relevant suggestions will be incorporated to improve the decision support tool. The same protocol will be followed to iteratively recruit up to 10 additional stakeholders to achieve feedback saturation.

Measures. Outcomes assessed during usability testing will include: (a) usability or ease of tool navigation; (b) acceptability of tool appearance; (c) time spent using the tool; (d) likelihood of recommending the tool to a colleague; (e) perceived importance of model outcomes; (f) additional outcomes requested for tool inclusion; and (g) additional suggestions for improvement (open-ended).[44] **Table 3** includes example survey items assessing each outcome. As appropriate, response options will be open-ended, Likert scale, or yes/no items. An open-ended question at the end of the survey will ask users to express any additional comments or general recommendations to inform future tool refinement.

Table 3. Sample decision support tool usability evaluation survey items

Outcome Assessed	Survey Item[44]
Usability of tool	System Usability Scale (rank with one of five responses (from strongly agree to strongly disagree) to 10 statements on usability
Acceptability of tool appearance	What do you like / dislike about the site's appearance? Why?
Time spent using the tool	For approximately how long did you use this tool?
Likelihood of recommending tool to a colleague	Would you recommend this tool to a colleague? Why / why not?
Model outcomes ranked in order of importance	Rank the following outcomes in order of importance to you when making HPV vaccine quality improvement decisions.
Additional outcomes requested for tool inclusion	What additional outcomes do you think the tool should show?

Analyses. The initial round of usability survey results (n=10) will be compiled. Features requiring additional consideration (based on recommendation themes provided in open-ended questions, two or more "no" responses on yes/no questions, and two or more below average ratings on scaled questions) will be addressed in tool revision. Examples of potential areas requiring revision, based on usability testing of prior policy-level web-based tools, include instruction clarity and graphics comprehension.[44] We will assess the saturation of feedback based on continued evaluation of survey results, when we observe agreement on the tool design.

Aim 3 will yield a publicly available decision tool to support decision makers' use of cost-effectiveness and implementation outcomes data for implementation planning. The tool will facilitate side-by-side comparisons of population impact, cost and other implementation outcomes, allowing users to modify key parameters for local relevance and translate IMPACT Program Project findings in real-world terms.

Potential Challenges and Solutions

Impact of Covid-19. The Covid-19 pandemic could disrupt plans for in-person activities. However, we anticipate that this will have a minimal impact on our plans. Qualitative interviews in Activities 1a and 3b will be conducted by telephone and/or Zoom. The national survey in Activity 1b will be delivered virtually. Aim 2 model development will be conducted through virtual collaboration. AAT can be delivered virtually.[121]

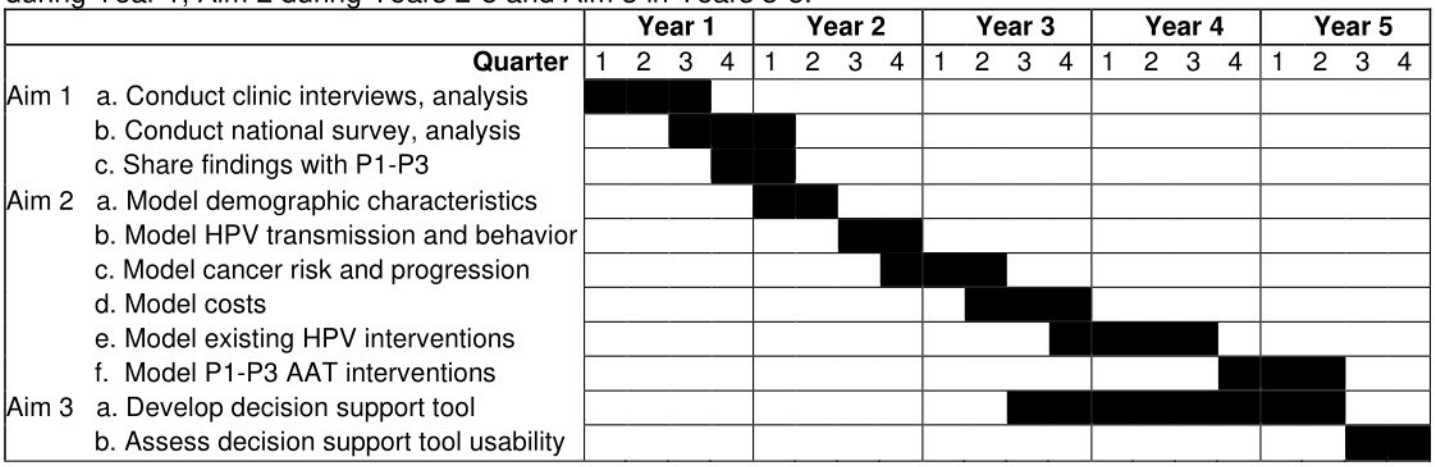
Modeling challenges. All models, by definition, are simplifications of real life and cannot account for every possible source of uncertainty. To maximize rigor and reproducibility of quantitative analyses, we will use high-quality data sources (Table 2) and model vaccination outcomes for both sexes, relying on medical records (versus self-report). We will draw on model inputs from various available sources to best reflect patterns of HPV vaccination, HPV transmission, and progression to HPV cancers across the US, in order to quantify the

budget impact, cost-effectiveness, and population outcomes of HPV vaccine interventions. Moreover, we will conduct sensitivity analyses to examine the potential impact of varying assumptions about the costs and effectiveness of these interventions, including potential combinations of interventions.

Generalizability of study findings. This project can accelerate the dissemination and adoption of HPV vaccine communication interventions in healthcare systems, thus enhancing the potential impact of the program project on increasing HPV vaccination rates. However, generalizability may be limited to medium- to high-volume pediatric and family medicine clinics prioritized by this IMPACT Project Program. This focus is appropriate given that most US adolescents are served in these settings, but additional research would be needed to assess outcomes among practices that are not part of healthcare systems.

Timeline

Below is our study timeline across Aims over the 5-year project timeline. Aim 1 will be conducted primarily during Year 1, Aim 2 during Years 2-5 and Aim 3 in Years 3-5.



Dissemination

We will disseminate our research findings and the decision support tool to academic, practice, and policy audiences in a timely manner to accelerate the translation of evidence to improve HPV vaccine interventions in healthcare systems. We will reach key stakeholders at local, state, and national healthcare and public health agencies primarily through webinars, trainings, peer-reviewed publications, presentations, social media content, and contact with healthcare systems. We will start with the health systems participating in Projects 1-3 who have already demonstrated a willingness to learn about HPV communication interventions. We will also share our findings via the CDC-funded Cancer Prevention and Control Research Network (CPCRN), which is focused on accelerating the implementation of evidence-based interventions in community settings, for which Dr. Wheeler directs the Coordinating Center and the Modeling Evidence-Based Intervention Impact Group.

We will make our results and the decision support tool publicly accessible on the hpvIQ.org website and the AAT Intervention Package led by the Intervention Core. We also will disseminate our findings through groups such as the American Medical Group Association (AMGA), the National HPV Vaccination Roundtable Integrated Delivery Systems Task Group, the HPV Vaccinate Adolescents against Cancers (VACs) Program, Association of State and Territorial Health Officials, National Association of Community Health Centers, Association of Immunization Managers, and Immunization Action Coalition. We will work closely with the Intervention Core and our Clinical Advisory Board to disseminate our research.

Relevance to Program Project Theme

The IMPACT Program Project's shared theme is amplifying the impact of a Research-Tested Intervention Program to improve HPV vaccine communication in healthcare systems. Project 4 addresses this theme by modeling the budget impact, cost-effectiveness, and population outcomes of HPV vaccine interventions and disseminating user-friendly results to health system leaders and other stakeholders. These activities will accelerate the dissemination and implementation of AAT interventions, especially in healthcare systems that are highly sensitive to budget impact, by providing actionable, population-level evidence that can inform and simplify the process of choosing interventions. Our findings will translate the health impact and cost of interventions tested in Projects 1-3 in rural and nonrural areas into a format well-suited to the needs of decision makers in healthcare systems to accelerate the adoption of interventions to prevent cancer.

PHS Human Subjects and Clinical Trials Information

OMB Number: 0925-0001

Expiration Date: 02/28/2023

Use of Human Specimens and/or Data

Does any of the proposed research in the application involve human specimens and/or data *	❍ Yes ● No
Provide an explanation for any use of human specimens and/or data not considered to be human subjects research.	
Are Human Subjects Involved	● Yes ❍ No
Is the Project Exempt from Federal regulations?	❍ Yes ● No
Exemption Number	❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑ 6 ❑ 7 ❑ 8
Other Requested Information	

Human Subject Studies

Study#	Study Title	Clinical Trial?
1	Budget impact, cost-effectiveness, and population outcomes of interventions to improve HPV vaccine communication and uptake in rural and nonrural communities	No

Section 1 - Basic Information (Study 1)

OMB Number: 0925-0001

Expiration Date: 02/28/2023

1.1. Study Title *

Budget impact, cost-effectiveness, and population outcomes of interventions to improve HPV vaccine communication and uptake in rural and nonrural communities

1.2. Is this study exempt from Federal Regulations * ○ Yes ● No

1.3. Exemption Number ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑ 6 ❑ 7 ❑ 8

1.4. Clinical Trial Questionnaire *

1.4.a. Does the study involve human participants?	● Yes	○ No
1.4.b. Are the participants prospectively assigned to an intervention?	○ Yes	● No
1.4.c. Is the study designed to evaluate the effect of the intervention on the participants?	○ Yes	● No
1.4.d. Is the effect that will be evaluated a health-related biomedical or behavioral outcome?	○ Yes	● No

1.5. Provide the ClinicalTrials.gov Identifier (e.g. NCT87654321) for this trial, if applicable

Section 2 - Study Population Characteristics (Study 1)

2.1. Conditions or Focus of Study

- This study is focused on provider communication about HPV vaccine.

2.2. Eligibility Criteria

Aim 1a1) Ages 18+2) Health administrators, physicians, and other primary care team members, such as nurse practitioners (NPs), physician assistants (PAs), registered nurses(RNs), medical assistants (MAs)Aim 1b1) Ages 18+2) Primary care team members (MDs, PAs, NPs, RNs, MAs)Aim 3b1) Ages 18+2) Active role as a health care administrator or vaccine quality improvement decision-maker

2.3. Age Limits	Min Age: 18 Years	Max Age: 99 Years
2.3.a. Inclusion of Individuals Across the Lifespan	InclusionofLifespanP4r1045594895.pdf	
2.4. Inclusion of Women and Minorities	InclusionWomenMinoritiesP4r1045594901.pdf	
2.5. Recruitment and Retention Plan	RecruitmentP4r1045594900.pdf	
2.6. Recruitment Status	Not yet recruiting	
2.7. Study Timeline	TimelineP4r1045594896.pdf	
2.8. Enrollment of First Participant	12/01/2021	Anticipated

INCLUSION OF INDIVIDUALS ACROSS THE LIFESPAN – Project 4

The surveys and interviews will focus on primary care professionals, and so only adults working in their professional roles in pediatric primary care, healthcare administration, or vaccine-related quality improvement decision-making will be included in the studies. The effectiveness of the planned interventions in Projects 1-3 will be evaluated using anonymized adolescent immunization rates provided by the state immunization registries, as well as electronic health record (EHR) data. These rates will represent all adolescents served by the primary care clinics in the health systems included in the implementation of each quality improvement intervention. Although outcomes modeled will include the additional number of adolescent patients vaccinated, the adolescents themselves will not be recruited to the study.

INCLUSION OF WOMEN AND MINORITIES – Project 4

The proposed research will include women and minorities throughout. Our estimates for inclusion of women and minorities appear in the targeted enrollment tables. To arrive at these estimates, we used recent US Census data.

RECRUITMENT AND RETENTION PLAN – Project 4

Aim 1 In-depth interviews and a web-based survey

Interviews

We will conduct one-on-one interviews with 20 rural and 20 nonrural primary care professionals, health administrators, and quality improvement decision makers in North Carolina and Wisconsin. The research team from Projects 2 and 3, along with the Intervention Core, will ask participants if they would be willing to be contacted for an interview. If the participant agrees, their contact information will be provided to the Project 4 research team. Among providers and clinic leaders who a) indicate that they would be willing to be contacted and b) provide reliable contact information, we will work with UNC's Communication for Health Applications and Interventions (CHAI) Core to recruit qualitative interview participants via email and phone (depending on the information provided). Providers and clinic leaders who complete an interview will be compensated for their time with a gift certificate of $100. Interviews are expected to take approximately 45-60 minutes.

National primary care team survey

Project 4 will work with the Data Core and Projects 1 and 2 to conduct a national online survey of primary care professionals. Project 4 will add questions to assess contextual differences in rural and nonrural clinical settings that may influence the implementation and effectiveness of HPV vaccine communication interventions. The Data Core will contract with WebMD Market Research to recruit 2,500 members from its standing, online panel of pediatric primary care professionals. The company will use quota-based sampling to recruit ~500 providers from each of the 5 disciplinary groups: pediatricians; family physicians; nurse practitioners and physician assistants; registered nurses; and medical assistants. WebMD will invite panel members to join the survey via email and targeted ads. Participants will receive up to $45 for participating. Based on the panel's prior performance, we anticipate a response rate of ≥60%.

Aim 3 Usability Testing

We will conduct two iterative rounds of usability testing, which consists of asking participants to use the decision support tool created in Aim 3, record the amount of time spent, and answer a series of questions via an online survey about their experience and suggestions for improvement. A convenience sample of 10 rural and nonrural primary care team members, quality improvement decision makers, and health administrators in North Carolina and Wisconsin will be contacted for usability testing. A second round of 10 participants will be contacted iteratively to reach feedback saturation. We will recruit participants by utilizing our network contacts through the Intervention Core, the Clinical Advisory Board, and health system leaders in Project 2 and 3. We will also use our existing relationships, including relationships with Medicaid and Medicare, quality improvement organizations, the County and State Departments of Health and Human Services, the Centers for Disease Control and Prevention, medical societies, and professional organizations.

Potential study participants will receive a pre-call letter to let them know we will attempt to contact them for a usability survey, the topic, and participation incentive amount. We will make three call attempts. Participants who complete the survey will be compensated for their time with a gift certificate of $100. Usability testing is expected to take approximately 30 minutes to an hour to complete.

STUDY TIMELINE – Project 4

		Year 1				Year 2				Year 3				Year 4				Year 5			
	Quarter	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
Aim 1	a. Conduct clinic interviews, analysis	■	■	■																	
	b. Conduct national survey, analysis			■	■	■															
	c. Share findings with P1-P3				■	■															
Aim 2	a. Model demographic characteristics					■	■														
	b. Model HPV transmission and behavior							■	■												
	c. Model cancer risk and progression								■	■	■										
	d. Model costs										■	■	■								
	e. Model existing HPV interventions												■	■	■	■					
	f. Model P1-P3 AAT interventions																■	■	■		
Aim 3	a. Develop decision support tool											■	■	■	■	■	■	■	■		
	b. Assess decision support tool usability																			■	■

Aim 1

During Year 1, Aim 1 will generate qualitative and quantitative data and insights about contextual differences in rural/nonrural clinical settings that may influence AAT intervention implementation and effectiveness. This will involve interviewing 20 rural and 20 nonrural primary care team members, quality improvement decision makers, and health administrators from the healthcare systems in North Carolina (NC) and Wisconsin (WI), to develop a deeper understanding of the contextual differences and decision support needs as related to AAT intervention implementation across rural and nonrural clinical settings. We will also survey a national sample of primary care team members (n=2,500) to characterize the implementation context for AAT interventions across rural and nonrural clinical settings. We will share these insights with Projects 1-3 at the end of Year 1 and beginning of Year 2 to inform RCT implementation. Our ability to implement these activities within the timeframe described comes from having experienced investigators and a multidisciplinary team who will work simultaneously on multiple tasks.

Aim 2

In Years 2-5, we will develop a national county-specific HPV microsimulation model. We will develop, parameterize, and calibrate this model reflecting patterns of baseline HPV vaccination, HPV transmission, and progression to HPV cancer using secondary data. Specifically, the modeling steps will involve simulating: (1) population demographic characteristics (Year 2); (2) HPV transmission and behavior (Year 2); (3) HPV cancer risk and progression (Years 2-3); (4) costs (Year 3); and (5) existing HPV interventions (Years 3-4). Near the end of Year 4, we will overlay interventions tested in Project 1-3 RCT onto the models to compare the budget impact, cost-effectiveness, and population outcomes of HPV vaccine communication interventions. In Year 5, after Project 1-3 RCT completion, we will update the models with final cost and effectiveness data from enhanced AAT interventions. The model will be used to compare the budget impact, cost-effectiveness, and population health outcomes of HPV vaccine communication interventions, including enhanced AAT interventions from Projects 1-3 as well as other evidence-based interventions (e.g., IQIP and motivational interview training to improve provider communication).

Aim 3

In Years 3-5, the team will work with CHAI Core to develop a decision support tool using results from the simulation model developed in Aim 2. At the beginning of Year 5, the decision support tool will be updated with final model estimates, after which the tool will undergo usability testing and iterative modification. The final decision support tool will be made publicly available and disseminated to key stakeholder groups.

2.9. Inclusion Enrollment Reports

IER ID#	Enrollment Location Type	Enrollment Location
Study 1, IER 1	Domestic	

Inclusion Enrollment Report 1

1. Inclusion Enrollment Report Title* : Inclusion Report for Budget impact, cost-effectiveness, and population outcomes of interventions to improve HPV vaccine communication and uptake in rural and nonrural communities

2. Using an Existing Dataset or Resource* : ❍ Yes ● No

3. Enrollment Location Type* : ● Domestic ❍ Foreign

4. Enrollment Country(ies): USA: UNITED STATES

5. Enrollment Location(s):

6. Comments: Qualitative studies from Aim 1: Activity 1a and Aim 3: Activity 3b (interviews, usability testing, n=60)

Planned

Racial Categories	Ethnic Categories				Total
	Not Hispanic or Latino		Hispanic or Latino		
	Female	Male	Female	Male	
American Indian/ Alaska Native	0	0	0	0	0
Asian	2	2	0	0	4
Native Hawaiian or Other Pacific Islander	0	0	0	0	0
Black or African American	3	3	1	1	8
White	19	19	4	4	46
More than One Race	1	1	0	0	2
Total	25	25	5	5	60

Cumulative (Actual)

Racial Categories	Ethnic Categories									Total
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			
	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	
American Indian/ Alaska Native	0	0	0	0	0	0	0	0	0	0
Asian	0	0	0	0	0	0	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0	0	0	0	0	0	0
Black or African American	0	0	0	0	0	0	0	0	0	0
White	0	0	0	0	0	0	0	0	0	0
More than One Race	0	0	0	0	0	0	0	0	0	0
Unknown or Not Reported	0	0	0	0	0	0	0	0	0	0
Total	0	0	0	0	0	0	0	0	0	0

Section 3 - Protection and Monitoring Plans (Study 1)

3.1. Protection of Human Subjects	ProtectionsHsP4r1045594897.pdf
3.2. Is this a multi-site study that will use the same protocol to conduct non-exempt human subjects research at more than one domestic site?	● Yes ○ No ○ N/A
If yes, describe the single IRB plan	MultisiteStudyP4r1045594898.pdf
3.3. Data and Safety Monitoring Plan	
3.4. Will a Data and Safety Monitoring Board be appointed for this study?	○ Yes ● No
3.5. Overall structure of the study team	StudyTeamP4r1045594899.pdf

PROTECTION OF HUMAN SUBJECTS – Project 4

Risk to Subjects

Human Subjects Involvement

The proposed studies in our application, "Budget impact, cost-effectiveness, and population outcomes of interventions to improve HPV vaccine communication and uptake in rural and nonrural communities," will take a multidisciplinary approach to aid the implementation and dissemination of the enhanced Announcement Approach Training (AAT) interventions in diverse healthcare settings. First, we will interview 20 rural and 20 nonrural primary care team members, quality improvement decision makers, and health administrators from the healthcare systems in North Carolina (NC) and Wisconsin (WI), to develop a deeper understanding of the contextual differences and decision support needs as related to AAT intervention implementation across rural and nonrural clinical settings. Then, we will survey a national sample of primary care team members (n=2,500) to characterize the implementation context for AAT interventions across rural and nonrural clinical settings. Following HPV microsimulation modeling of the budget impact, cost-effectiveness and population outcomes of HPV vaccine interventions, we will also develop a web-based decision support tool to aid the dissemination of these results. We will conduct usability testing among a sample of up to 20 rural and nonrural primary care team members, quality improvement decision makers, and health administrators in NC and WI. Usability testing will be conducted via an electronic survey to facilitate intervention selection and adoption decisions. Feedback from usability testing will be incorporated and the tool will be disseminated via IMPACT's website and the Intervention Package.

Source of Materials

We will use several data collection strategies to achieve the goals discussed above: interviews, a national primary care team survey, and usability testing.

Interviews. In Aim 1, we will conduct 1-on-1 phone interviews with 20 rural and 20 nonrural primary care team members, quality improvement decision makers, and health administrators participating in Projects 2 and 3. The research team from Projects 2 and 3 along with the Intervention Core will ask participants if they would be willing to be contacted for an interview. If the participant agrees, their contact information will be provided to the Project 4 research team. Among primary care professionals and clinic leaders who a) indicate that they would be willing to be contacted and b) provide reliable contact information, we will work with UNC's Communication for Health Applications and Interventions (CHAI) Core to recruit qualitative interview participants via email and phone (depending on the information provided). Interview questions will focus on answering two questions: 1) how might implementation *opportunities* differ between rural and nonrural areas interested in HPV vaccine interventions, and 2) how might AAT implementation *challenges* differ between rural and nonrural areas interested in HPV vaccine interventions. We will temporarily have participants' names and contact information for the purpose of scheduling and conducting the interview and providing incentives. However, identifying information will be discarded once the interviews are completed.

National primary care team survey. Also a part of Aim 1, we will work in collaboration with Project 1 and 2 along with the Data Core to conduct a national survey of 2,500 primary care team members. Please refer to the Data Core Inclusion Enrollment Report and other Human Subjects information for national survey details.

Usability Testing. In Aim 3 we will conduct up to two iterative rounds of usability testing, which consist of asking participants to use the CHAI Core-developed decision support tool, record the amount of time spent, and answer a series of questions via an online survey about their experience and suggestions for improvement. A convenience sample of 10 rural and nonrural primary care team members, quality improvement decision makers, and health administrators in NC and WI will be contacted for pilot usability testing. If needed, a second round of 10 participants will be contacted to reach feedback saturation. We will recruit participants by utilizing our network contacts through the Intervention Core, the Clinical Advisory Board, and health system leaders in Projects 2 and 3. We will also use our existing relationships, including relationships with Medicaid and Medicare, quality improvement organizations, the County and State Departments of Health and Human Services, the Centers for Disease Control and Prevention, medical societies, and professional organizations. We will temporarily have participants' names and contact information for the purpose of scheduling and conducting the interview and providing incentives. However, identifying information will not be linked to participants' data.

Potential Risks

We anticipate that the risks to participants will be minimal and manageable. We are not collecting biological specimens or discussing highly personal or sensitive topics. All study participants will be adults. The main risk is breach of confidentiality. The plan for mitigating this risk is discussed below (under Protections against Risk).

Adequacy of Protection Against Risks

Recruitment and Informed Consent

Interviews. We will recruit primary care team members, quality improvement decision makers, and health administrators in rural (n=20) and nonrural (n=20) counties, as defined by the RUCC classification codes. We will recruit participants in Projects 2 and 3 in NC and WI who indicate willingness to participate and provide valid contact information. All interviews will take place by phone. A study team member will email the consent form to individuals expressing willingness to participate in advance of the interview. At the start of the call, they will review the consent form, pointing out that participation is voluntary, that there is minimal risk involved, and that they can stop the interview or not answer any question at any time. They will also be informed that responses are confidential and given instructions on how to contact the Project Co-Leads if they have any questions or concerns about the study. After also explaining the study's purpose and time expectations, the interviewer will obtain the participant's verbal consent to participate before proceeding. We anticipate obtaining informed consent verbally will be appropriate given that participants are adults and the interviews will not cover sensitive information. In-depth interviews will be recorded and transcribed for accuracy. Audio recordings will be destroyed once they have been transcribed and any identifying information will be redacted from the transcriptions.

National primary care team survey. In collaboration with Project 1 and 2 along with the Data Core, we will recruit 2,500 primary care team members for the national survey through our subcontractor WebMD's existing healthcare professional panel. Please refer to the Data Core Inclusion Enrollment Report and other Human Subjects information for national survey details.

Usability Testing. We will recruit up to 20 rural and nonrural primary care team members, quality improvement decision makers, and health administrators in NC and WI by utilizing our network contacts through the Intervention Core, the Clinical Advisory Board, and health system leaders in Projects 2 and 3. We will also use our existing relationships, including relationships with Medicaid and Medicare, quality improvement organizations, the County and State Departments of Health and Human Services, the Centers for Disease Control and Prevention, medical societies and professional organizations. Participants will be recruited primarily by email, and by phone as appropriate. Adult usability testing participants (ages 21+) will read an electronic version of the informed consent form before beginning the web-based survey, and will be asked to select a checkbox to confirm their consent. The consent forms for these surveys will include information about the study's purpose, potential risks, expected benefits, protection of confidentiality, and time expectations. The form will also emphasize that participation is voluntary, that they can stop the survey or not answer any question at any time, and that there is minimal risk involved. Contact information for the IRB and the Project Co-Leads in case participants have concerns or questions about the study will be included. We anticipate that obtaining informed consent electronically will be appropriate given that participants are adults and the surveys will not cover sensitive information. If the participant consents to the survey, they will click "next" and will advance to the following page to start the survey.

Protections Against Risk

The informed consent process used for the interviews, primary care team survey, and usability testing will ensure that participants are aware of the potential risks of participating in the study. We will also remind participants of their right to drop out of the study at any point, without consequence.

We will not share information or data provided by individual participants with their coworkers, clinic staff, or clinic leadership. All information provided by study participants will be kept confidential, and identification numbers will be used rather than names of study participants. For the national survey, WebMD Market Research will provide us with a deidentified data set. All study materials will be kept in a locked file accessible only to key study personnel. All computer files will be stored on a secure, password-protected server and accessed on computers that are password-protected, with only IRB-approved study personnel having access. The interview audio recordings will be destroyed once we have completed analyses. Staff members must complete an online IRB research ethics training course and other confidentiality certification procedures upon employment. Policies regarding the confidential nature of the data collected, processed, and stored will be explained to all personnel, who must then sign a confidentiality agreement before being allowed access to

confidential information. In addition to this initial training, we will reinforce the need for careful and confidential handling of data at staff meetings.

Potential Benefits

By taking part in this study, participants may increase their knowledge of quality improvement initiatives to increase HPV vaccine uptake in adolescents. Participants may also experience personal satisfaction of knowing they have contributed to a research project aimed at increasing HPV vaccine uptake. They will also receive monetary compensation for the time they invest in the study.

Importance of the Knowledge to be Gained

Given that the risk to participants is minimal and manageable, the knowledge to be gained has the potential to fill an important research gap. Specifically, scientific findings will advance cancer prevention efforts and improve communication efforts around HPV vaccination between primary care professionals and patients.

MULTI-SITE STUDY: SINGLE IRB PLAN – Project 4

The proposed study, “Budget impact, cost-effectiveness, and population outcomes of interventions to improve HPV vaccine communication and uptake in rural and nonrural communities,” will implement a single IRB plan. Our study team at UNC will submit all IRB materials on behalf of our research partners. UNC will collect data in Aim 1 through in-depth interviews with primary care team members, quality improvement decision makers, and health administrators from Project 2 and Project 3 as well as an online national survey subcontracted through WebMD Market Research and conducted in coordination with Project 1 and Project 3 along with the Data Core. Our Aim 2 will not involve the collection of any primary data, other than that received from Project 1-3’s RCT (randomized clinical trial) studies. In Aim 3, UNC, along with CHAI Core, will collect data through a web-based usability testing survey. The Project Co-Leads, Drs. Wheeler and Ozawa, will provide oversight of the research.

UNC will exercise authority and responsibility on behalf of our research partners and will submit a single IRB application for review of human subjects research, in accordance with NIH policy for research protocols that are carried out at more than one site in the United States. Our research partners have agreed to rely on the proposed single IRB. The Project Co-Leads and Program Director at UNC will communicate directly with our research partners to ensure all study related procedures and documents are approved by UNC’s IRB. Prior to initiating the study, we will sign an authorization/reliance agreement that will clarify the roles and responsibilities of the single IRB and participating sites with our research partners. UNC will maintain records of the authorization/reliance agreements and of the communication plan.

OVERALL STRUCTURE OF THE STUDY TEAM – Project 4

The organizational structure of the study team as it pertains to IMPACT Project 4's proposal is below. Members of this multi-disciplinary team have collaborated successfully in the past and are well-versed in cost-effectiveness modeling, cancer disparities research, implementation science, and stakeholder engagement in decision support.

UNC Study Team (Aims 1-3)

- *Sachiko Ozawa, PhD*, will be one of two Project Co-Leads for the study, and will work in conjunction with Dr. Wheeler to take joint responsibility for the research and administration of this award. Dr. Ozawa will collaborate on all Aims and will lead the quantitative and qualitative work in Aim 1 to understand contextual factors influencing intervention implementation for rural and nonrural healthcare organizations. Dr. Ozawa will serve as the contact Project Lead for Project 4, and will be responsible for communications with the funding agency and for the overall administrative functions of the project.
- *Stephanie B. Wheeler, PhD*, will be the other Project Co-Lead for the study who will take joint responsibility for the research and administration of this award. Drs. Wheeler and Ozawa will collaborate on all Aims, and Dr. Wheeler will take the lead on Aim 3 work to develop and disseminate the web-based decision support tool. Both Project Co-Leads will meet bi-weekly with the full study team to ensure high quality research is conducted on time, within budget, and in compliance with the ethical requirements of the Institutional Review Board. Drs. Wheeler and Ozawa will also lead dissemination including manuscript preparation and conference presentations.
- As Co-Investigator, *Kristen Hassmiller Lich, PhD*, will bring expertise in systems thinking, operations research, and systems science simulation modeling techniques for health policy, public health delivery, and medical decision making. Dr. Hassmiller Lich will consult on the development of the cost-effectiveness analysis model in Aim 2 and the development of the web-based decision support tool in Aim 3, specifically the incorporation of stakeholders in user testing and evaluation.
- As Co-Investigator, *Sarah A. Birken, PhD*, will bring expertise in dissemination and implementation, a rapidly growing field in population sciences which seeks to translate research findings regarding high-quality cancer care into practice. Dr. Birken's primary responsibilities will be to ensure that determinants of implementation are appropriately assessed in Aim 1, and that the cost-effectiveness model and web-based decision support tool are developed for implementation in practice in Aims 2 and 3.
- As Program Director, *Lisa P. Spees, PhD,* will be responsible for managing daily project operations and will serve as the liaison between the Project Co-Leads, project team, and study contractors. She will take a major role in the application of the agent-based model for decision making in Aim 2, as well as the development and testing of the web-based decision support tool in Aim 3. She will also assist Drs. Wheeler and Ozawa with literature reviews informing the preparation of survey and interview materials to assess rural and nonrural contextual differences influencing implementation in Aim 1.
- *The Programmer*, to be named, will be responsible for analyzing existing data to be used as input parameters for the simulation model and for operationalizing the team's modeling decisions in Aim 2. The Programmer will contribute to writing and auditing code in Python for the development of the agent-based transmission model.
- *The Research Assistant*, to be named, will help the study team with carrying out administrative and research tasks including supporting literature reviews, data cleaning, data analysis, and interpretation of findings. The Research Assistant will also assist the study team in developing dissemination materials such as conference posters, presentations, and manuscripts. Dr. Spees, Dr. Wheeler, and Dr. Ozawa will jointly oversee the Research Assistant.

Expert Modeling Advisory Committee (Aim 2)

- As Co-Investigator, *Sarah Mills PhD*, will play an important role as an Advisor on the part of the Expert Modeling Advisory Committee. She will provide modeling expertise on development, parameterization, and debugging of the agent-based HPV transmission model in Aim 2, as well as lend her expertise in health disparities. She will provide expertise via conference call and email.
- *Jennifer Spencer, PhD*, will provide modeling expertise on the development, testing, and visualization of the agent-based HPV transmission model in Aim 2, based on her prior HPV modeling work. She will

provide expertise via conference call and email. Dr. Spencer will serve as an Advisor on the Expert Modeling Advisory Committee.

- *Jane Kim, PhD,* will provide insight and expertise on the development of the agent-based HPV transmission model in Aim 2, specifically its development, parameterization, and testing. She will also provide mentorship and oversight to the work of Jennifer Spencer, Postdoctoral Fellow at Harvard University and consultant on this project. She will provide expertise via conference call and email. Dr. Kim will serve as an Advisor on the Expert Modeling Advisory Committee.
- *Evan Meyers, PhD,* will provide a clinical perspective to the research team to inform the development of the agent-based HPV transmission model in Aim 2. He will communicate with the research team by conference calls and email as needed. Dr. Meyers will serve as an Advisor on the Expert Modeling Advisory Committee.

Other Consultants

- *Colleen Higgins, MSPH,* will be primarily responsible for coding the agent-based HPV transmission model in Aim 2. She will help to conceptualize the structure of the model, write and audit code, perform sensitivity analyses, and interpret and present output data. Ms. Higgins will also conduct searches and/or data analyses to gather relevant data inputs. She will work remotely and provide expertise via conference call and email. Dr. Ozawa will oversee the work of Ms. Higgins.

Communication for Health Applications and Interventions (CHAI) Core (Activities 1a, 3a)

- *CHAI Core*, an NCI-funded shared resource at UNC that offers techniques and resources for the development of behavioral science interventions, will conduct 1-on-1 phone interviews in Activity 1a. CHAI Core will assume responsibility for recruitment and data collection efforts. Additionally, CHAI Core will develop the web-based decision support tool in Activity 3a. CHAI core will assume responsibility for web and user interface design, wireframe and information architecture development, website programming, quality assurance testing, and ongoing maintenance.

Clinical Advisory Board

- We will periodically consult the Clinical Advisory Board convened by the Intervention Core. The Board includes primary care professionals and meets quarterly. We will bring questions about the organizational context for HPV communication interventions and the interpretation of cost-effectiveness results.

Section 4 - Protocol Synopsis (Study 1)

4.1. Study Design

4.1.a. Detailed Description

4.1.b. Primary Purpose

4.1.c. Interventions

Type	Name	Description

4.1.d. Study Phase

Is this an NIH-defined Phase III Clinical Trial? ❍ Yes ❍ No

4.1.e. Intervention Model

4.1.f. Masking ❍ Yes ❍ No

❑ Participant ❑ Care Provider ❑ Investigator ❑ Outcomes Assessor

4.1.g. Allocation

4.2. Outcome Measures

Type	Name	Time Frame	Brief Description

4.3. Statistical Design and Power

4.4. Subject Participation Duration

4.5. Will the study use an FDA-regulated intervention? ❍ Yes ❍ No

4.5.a. If yes, describe the availability of Investigational Product (IP) and Investigational New Drug (IND)/ Investigational Device Exemption (IDE) status

4.6. Is this an applicable clinical trial under FDAAA? ❍ Yes ❍ No

4.7. Dissemination Plan

Delayed Onset Studies

Delayed Onset Study#	Study Title	Anticipated Clinical Trial?	Justification
The form does not have any delayed onset studies			

MULTIPLE PD/PI LEADERSHIP PLAN – Project 4

Rationale

Dr. Sachiko Ozawa (UNC-Pharmacy) and Dr. Stephanie Wheeler (UNC-Health Policy and Management), the proposed Project Co-Leads, chose the multiple lead leadership model because their respective training, background, and expertise, used in collaboration, are necessary for the success of the proposed project. The proposed interdisciplinary project requires bringing together an in-depth understanding of decision sciences modeling, implementation science, and disparities research with complex vaccine simulation modeling to assess the population impact, budget impact, and cost-effectiveness of implementing enhanced Announcement Approach Training (AAT) and other HPV vaccine interventions in rural and nonrural settings.

Dr. Ozawa is an expert in vaccine economics, mathematical modeling, and reaching hard-to-reach populations for vaccination. Dr. Ozawa currently leads the Global Health Economics for Pharmacy (GHEP) team at UNC, where her research has estimated the global impact of vaccines, the differential geographic burden of vaccine preventable diseases, and the economic value of childhood vaccination, including the HPV vaccine. Dr. Ozawa's research findings have been cited by Bill Gates, and used by the CDC, Bill & Melinda Gates Foundation, World Health Organization, UNICEF and Gavi (the Vaccine Alliance) to advocate for vaccine introduction and coverage globally. Dr. Ozawa has led the development of various agent-based models, working closely with Ms. Higgins. Dr. Ozawa has also sought to understand and intervene on the problem of low immunization coverage among hard-to-reach populations including in rural areas. This work has included reviews of definitions of hard-to-reach populations for vaccination, examining costs of interventions to increase immunization coverage, and estimating the economic value of targeting hard-to-reach populations in remote and rural areas for vaccination.

Dr. Wheeler is a health services researcher and decision scientist in the School of Public Health with 10 years of experience conducting mixed methods research focused on cancer care quality, access, cost, and value, with an emphasis on cancer disparities and vulnerable populations. Dr. Wheeler is an expert in cost-effectiveness analyses and has, for many years, taught the primary methods course in cost-effectiveness analysis in the School of Public Health, supervised and mentored trainees in cost-effectiveness research, and led multiple studies focused on cost-effectiveness in healthcare. In much of her work, Dr. Wheeler has focused on improving access to cancer care in rural populations and co-leads the CDC- and NCI-funded Geographic Management of Cancer Health Disparities Program (GMaP) Region 1 South hub. Additionally, she has experience in directing a large national thematic research network focused on EBI dissemination and implementation in cancer and heads the Coordinating Center and Modeling Evidence-Based Intervention Impact workgroup of the CDC- and NCI-funded Cancer Prevention and Control Research Network (CPCRN).

Drs. Ozawa and Wheeler have complementary skills and considerable experience participating in large multi-center research projects that span domestic and international institutions, often in positions of leadership, ensuring that they both have the management skills necessary to successfully conduct the proposed research.

Table. Roles and Responsibilities of the Multiple Project Leads

Leadership by Research Aim	Wheeler	Ozawa
Identify differences in contextual factors across clinics and healthcare systems in rural and nonrural areas that may influence the implementation and effectiveness of enhanced AAT interventions (Aim 1)	Support Dr. Ozawa	Primary responsibility
Develop a dynamic HPV transmission model to evaluate the population health impact, budget impact, and cost-effectiveness of HPV vaccine communication interventions (Aim 2)	Primary responsibility	Primary responsibility
Develop a web-based interactive decision support tool illustrating simulation model results to support stakeholder implementation planning (Aim 3)	Primary responsibility	Support Dr. Wheeler

Governance/Organizational Structure

Both Drs. Ozawa and Wheeler will provide oversight of the entire research project, including scientific direction, allocation of resources, implementation of the specific aims, development of publications, and reporting, while ensuring that systems are in place to guarantee institutional compliance with US laws and NIH policies, including protection of human subjects and management of data and facilities. Dr. Ozawa will serve as the contact Project Lead for Project 4 and will be responsible for communications with the funding agency and

for the overall administrative functions of the project. The proposed project's primary intellectual responsibilities will be shared as follows: Dr. Ozawa will lead the quantitative and qualitative work to identify differences in contextual factors across clinics and healthcare systems in rural and nonrural areas that may influence the implementation or effectiveness of HPV vaccine communication interventions **(Aim 1)**. Dr. Wheeler and Dr. Ozawa, along with the programmer and modeling consultants, will work closely together to develop, parameterize, and calibrate a microsimulation model to estimate the population health impact, budget impact, and cost-effectiveness of HPV vaccine communication interventions, including quality improvement visits from state health departments and enhanced AAT interventions from Projects 1-3 **(Aim 2).** Dr. Wheeler will lead the development and usability testing of the web-based interactive decision support tool illustrating simulation model results to support stakeholder implementation planning **(Aim 3)**.

Communication

Drs. Ozawa and Wheeler will maintain responsibility for overall administrative and fiscal management of the Program, including the central budget as well as preparation of progress reports, which will be prepared in collaboration. In general, consensus between Leads will be obtained prior to fiscal and administrative changes, NIH communication, and annual report submission.

Drs. Ozawa and Wheeler will meet at least biweekly with the study team, either in person or by phone, with more frequent meetings scheduled depending on project needs. These meetings will be used to develop study priorities, coordinate the study, review progress, discuss analyses and interpret results, and prepare manuscripts with input from all other co-investigators. Operational matters of grant progress as well as potential problems, anticipated upcoming issues, and general program oversight will also be discussed at these meetings. With input from co-investigators, the Project Co-Leads will make strategic decisions such as modifications of priorities, procedures, or timelines.

Publication and Dissemination Policies

Publication authorship will be based upon the relative scientific contributions of the Project Leads, key personnel and collaborators as outlined in NIH's Authorship Policy. Additionally, we plan to disseminate results to relevant stakeholders on our IMPACT Program website (hpviq.org) and through our existing and ongoing collaborative networks, such as the Cancer Prevention and Control Research Network (http://www.cpcrn.org/), our ongoing engagement as members of the American Society for Clinical Oncology and AcademyHealth, and through stakeholder webinars, onsite workshops, and learning institutes that unite science and practice.

Conflict Resolution

If any conflict arises as to scientific direction, the Project Co-Leads will meet to try and resolve the disagreement. If they fail to resolve the dispute, the disagreement shall be referred to an arbitration committee consisting of two impartial senior faculty members at the University of North Carolina, one from the Department of Health Policy and Management, and one from the School of Pharmacy. Neither members of the arbitration committee will be directly involved in the research grant or disagreement.

Change in Project Lead location

No relocation for either Project Lead is anticipated. If, however, in the highly unlikely event that a Project Lead moves to a different institution, attempts will be made to transfer the relevant portions of the grant to the new institution. In the event that transfer is not possible, an appropriate replacement Lead from UNC will be recruited as necessary.

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June 25, 2020

Noel T. Brewer, PhD
Department of Health Behavior
Gillings School of Global Public Health
University of North Carolina
325 Rosenau Hall CB7440
Chapel Hill, NC 27599

Dear Dr. Brewer:

I am writing to offer my enthusiastic support for your NCI P01 proposal "Improving Provider Announcement Communication Training (IMPACT) Program Project," PAR-20-077. As a part of your Project 4 Research Project titled "Budget impact, cost-effectiveness, and population outcomes of interventions to improve HPV vaccine communication and uptake in rural and nonrural communities" led by Drs. Stephanie Wheeler and Sachiko Ozawa, I will consult on the HPV cost-effectiveness modeling. As your team has demonstrated the ability to conduct meaningful HPV prevention research, including advanced modeling work, I am pleased to contribute to this effort.

My research expertise is in economic evaluation and health care modeling. Since beginning work with Dr. Ozawa in 2018, we have worked together with other team members, DPharm, and MSPH students to build and run an agent-based model to assess the impact of substandard and falsified antimalarials (SAFARI model) in five different countries, with more underway. With an interest in programming, I began with Java to support building agent-based models in AnyLogic, then transitioned to Python and NetLogo. Working on the SAFARI model, I was able to streamline the existing code, creating my own Python program from scratch with innovative techniques for data manipulation, which I researched and developed on my own. In doing so, I cut the processing time of the model, reduced user error through automation, and created a program unlike other agent-based models used in health economics today. Having laid this basis, I am excited to develop the agent-based transmission model proposed in Aim 2 of this project.

In the event of funding, I will be happy to serve as a consultant on this project by working with the project team to develop a model to assess the cost-effectiveness of HPV provider communication intervention strategies. I will help conceptualize the structure of the model, write and audit code, perform sensitivity analyses, and interpret and present output data. Additionally, I will conduct searches and/or data analyses to gather relevant data inputs. My efforts are estimated at $ in year 1 and $ in years 2 through 5 of the project.

I am excited to work with you and your team as a consultant on this project, and I wish you the best of luck on your application.

Best,

Colleen R. Higgins, MSPH

July 12, 2020

Noel T. Brewer, PhD
Department of Health Behavior
Gillings School of Global Public Health
University of North Carolina
325 Rosenau Hall CB7440
Chapel Hill, NC 27599

Dear Dr. Brewer:

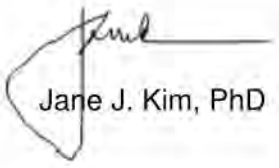
I am delighted to express my support for your NCI P01 proposal "Improving Provider Announcement Communication Training (IMPACT) Program Project," PAR-20-077. As a part of your Project 4 Research Project titled "Budget impact, cost-effectiveness, and population outcomes of interventions to improve HPV vaccine communication and uptake in rural and urban communities" led by Drs. Stephanie Wheeler and Sachiko Ozawa, I will consult on the HPV cost-effectiveness modeling. Given the demonstrated effectiveness of the Announcement Approach in increasing HPV vaccination uptake, research on the implementation and sustainability of provider communication strategies is critical to aid decision-making.

My research expertise focuses on the development and application of mathematical modeling methods to evaluate health policy issues related to women's health. In addition to extensively modeling and evaluating cervical cancer screening strategies, I have also worked closely over several years with the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention to inform guidelines on HPV catch-up vaccination, HPV vaccination of boys, and targeted HPV vaccination of men who have sex with men. Most recently this year, I led a group of modelers in the ACIP evaluation of mid-adult HPV vaccination up to age 45 years. I have also contributed to a systematic review and meta-analysis of existing HPV transmission dynamic models.

In the event of funding, my primary role as a consultant on this project will be to provide insight and expertise on the development of the agent-based HPV transmission model in Aim 2, specifically its development, parameterization, calibration and validation. I will also provide mentorship and oversee the work of Jennifer Spencer, another consultant on this project. I plan to provide oversight of model development via conference calls and email communication as needed. I expect to devote ☐ hours per year to this effort throughout years 2 through 5 of the project; for this work, I will be compensated [$] per year ([$] per hour).

I look forward to working with you and your team on this critical work aimed at reducing the burden of HPV and HPV-associated diseases in this country. I wish you the best on your grant application.

Sincerely,



Jane J. Kim, PhD

June 30, 2020

Noel T. Brewer, PhD
Department of Health Behavior
Gillings School of Global Public Health
University of North Carolina
325 Rosenau Hall CB7440
Chapel Hill, NC 27599

Dear Dr. Brewer:

I am writing to express my enthusiastic support for your NCI P01 proposal "Improving Provider Announcement Communication Training (IMPACT) Program Project," PAR-20-077. As a part of your Project 4 Research Project titled "Budget impact, cost-effectiveness, and population outcomes of interventions to improve HPV vaccine communication and uptake in rural and nonrural communities" led by Drs. Stephanie Wheeler and Sachiko Ozawa, I will consult on the HPV cost-effectiveness modeling. Widespread HPV vaccination is critical to reducing the burden of HPV and HPV-attributable cancers, and I believe that the research you and your team propose will significantly contribute to achieving this goal.

My qualifications for serving as a consultant on this project include my demonstrated expertise in the application of quantitative methods, especially mathematical modeling and decision analysis, to problems in women's health. As a Professor of Obstetrics and Gynecology in the Duke University School of Medicine and a trained Ob/Gyn clinician, I bring a clinical perspective to this modeling work. I also have experience with guidelines development, clinical decision support, and working with multiple stakeholders.

In the event of funding, my primary role as a consultant on this project will be to provide oversight and expertise on the development of the agent-based HPV transmission model in Aim 2, specifically its development, parameterization, and testing. I will also provide a clinical perspective to inform model development. I plan to share this expertise with the research team via conference calls and email communication as needed. I expect to devote [ ] hours per year to this effort throughout years 2 through 5 of the project; for this work, I will be compensated [$] per year ([$] per hour).

I look forward to future collaborations and am excited about the potential impact of this work on HPV vaccination rates and HPV-attributable disease burden.

Sincerely,

Evan R. Myers, MD, MPH

June 25, 2020

Noel T. Brewer, PhD
Department of Health Behavior
Gillings School of Global Public Health
University of North Carolina
325 Rosenau Hall CB7440
Chapel Hill, NC 27599

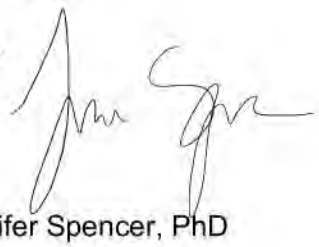
Dear Dr. Brewer:

I am pleased to provide a strong letter of support for your NCI P01 proposal "Improving Provider Announcement Communication Training (IMPACT) Program Project," PAR-20-077. As a part of your Project 4 Research Project titled "Budget impact, cost-effectiveness, and population outcomes of interventions to improve HPV vaccine communication and uptake in rural and urban communities" led by Drs. Stephanie Wheeler and Sachiko Ozawa, I look forward to supporting the work of your research team, which has proven track record of publishing impactful cancer prevention and disparities studies.

My qualifications for this role include developing a dynamic model of HPV transmission and vaccination to model current and future HPV cancer disparities between low-poverty and high-poverty US counties as a part of my dissertation, of which Dr. Wheeler was the committee chair. Through this model I evaluated the potential effect of current vaccination rates, the cost-effectiveness of vaccination both low- and high-poverty settings, and identified cost-effective strategies for increasing HPV vaccine uptake. I am now working as a post-doctoral fellow in the Training in Oncology Population Sciences (TOPS) program at Dana Farber/Harvard Cancer Center under the mentorship of Dr. Jane Kim. In this position I have continued in training related to model development as well as conducting projects creating and adapting models of HPV vaccination with a focus on modeling interventions to reduce HPV cancer disparities. As an HPV modeling expert with a focus on health equity, I am looking forward to the opportunity for collaboration on this project.

In the event of funding, I would be interested in consulting with the study team as an HPV transmission modeling expert. In this role, my primary responsibility will be to provide modeling expertise on the development, testing, and visualization of the dynamic HPV model in Aim 2. I expect to devote approximately ☐ hours per year to this work in years 2 through 5 of the project and will collaborate with the team via conference calls and email. I will be compensated $ ($ per hour) for this effort. I would be pleased to contribute my modeling expertise to this study and firmly believe that expanding vaccine uptake is a crucial step toward achieving population-level protection against HPV. I look forward to collaborating with your research team in the future.

Best,



Jennifer Spencer, PhD

THE UNIVERSITY of NORTH CAROLINA at CHAPEL HILL

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June 30, 2020

Noel T. Brewer, PhD
Department of Health Behavior
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325 Rosenau Hall CB7440
Chapel Hill, NC 27599

Dear Dr. Brewer,

The Communication for Health Applications and Interventions (CHAI) Core is pleased to offer our enthusiastic support for your NCI P01 proposal "Improving Provider Announcement Communication Training (IMPACT) Program Project," PAR- 20-077. As a part of your Project 4 Research Project titled "Budget impact, cost-effectiveness, and population outcomes of interventions to improve HPV vaccine communication and uptake in rural and nonrural communities" led by Drs. Stephanie Wheeler and Sachiko Ozawa, we will work with you to provide qualitative research, graphic design, website development, and intervention consultation services.

For the proposed project, CHAI Core will be responsible for a) conducting one-time in-depth telephone interviews with rural and nonrural primary care team members (in Aim 1), and b) creating a web-based decision support tool, including user testing during the development of the tool, logo and color palette creation, and assistance in simulated experimental evaluation of the tool (in Aim 3). We will also provide ongoing maintenance of the decision support tool through the life of the project and needed technical support to the research team. We are excited about your work and are well positioned to fully assist your research team with this project.

CHAI Core (www.chaicore.com), a NIH-funded core facility, has been collaborating with researchers since 2000 to develop and conduct behavioral intervention research, qualitative research and e-health and m-health intervention development. The mission of CHAI Core is to apply state-of-the-art resources and techniques to the development of high quality and rigorously evaluated behavioral science interventions aimed at promoting health and preventing disease in populations at risk. The Core fills a critical gap in existing resources for researchers by facilitating access to and translation of science-based research relevant to communication, health behavior theory, intervention design, and evaluation into strategies and tools that can produce more effective interventions.

Funding provided by the Gillings School of Global Public Health Nutrition Obesity Research Center (NIDDK: P30 DK56350) and the Lineberger Comprehensive Cancer Center (NCI: P30 CA16086)

CHAI Core has developed a highly collaborative team who are available to provide consultation and assistance with grant submissions, methodology, and intervention development. Specifically, CHAI Core offers consulting and services in behavior change intervention and decision-aid websites and applications; logos and brochures, recruitment and presentation materials; user research, such as usability testing, qualitative interviews and focus groups; tailored messaging and feedback; and responsive design for mobile technology. CHAI Core also has the ability to test the usability of developed interventions against the FDA specified human factors standards for medical devices. Our infrastructure and personnel are funded through the Gillings School of Global Public Health Nutrition Obesity Research Center (NIDDK funded; P30 DK56350) and the Lineberger Comprehensive Cancer Center (NCI funded; P30-CA16086).

Dr. Deborah Tate is the faculty director of CHAI Core and brings substantial expertise in qualitative and technology-based interventions. Dr. Tate has been continuously funded by the NIH either as PI or Co-I on behavioral intervention work involving web and/or mobile technology since 2001 and has published some of the earliest RCTs using the web to deliver behavior therapy in top tiered journals such as JAMA and NEJM.

We look forward to working with you on this important and interesting research study.

Sincerely,

Jennifer Wills Gallagher

Jennifer Wills Gallagher, MPPA, RD
Administrative Director
Connected Health Applications & Interventions (CHAI) Core
Lineberger Comprehensive Cancer Center
Nutrition Obesity Research Center
UNC | Chapel Hill

RESOURCE SHARING PLAN – Project 4

We agree with the NIH principle that data sharing is essential for expedited translation of research results into knowledge, products, and procedures to improve human health. All projects and cores will follow the same procedures. We will make data collection instruments available online for public use after data collection and analyses are complete. Leads of the research projects and the Data Core will oversee sharing of de-identified data produced by the Program Project. Dr. Brewer will oversee this process.

One of the key products of the planned research is a shared national primary care team survey conducted with the Data Core who will be the primary contact for requests. The Data Core will contact the Project Co-Leads for approval to share the de-identified dataset with external requestors. For the budget impact, cost-effectiveness and population outcome analyses, model inputs and outputs will be shared following the Program's Overall Resource Sharing Plan. Most data to be used in Project 4's modeling work will come from publicly available, high quality secondary data sources (e.g., CDC Wonder Database and National Immunization Survey-Teen) or will be drawn from existing HPV modeling literature. Other data to inform model building will come from high- quality data sources that can be made available to the public with a signed Data Use Agreement (e.g., Surveillance, Epidemiology, and End Results Program). All of these data will be appropriately described and cited, along with details of any manipulation performed on raw data, in publications, and other products from the research. The remainder of the data used in the modeling study will be generated or modified by IMPACT Projects 1-3, and protocols set by those components will be followed for sharing those data. See the Resource Sharing Plans for the individual projects. For the decision support tool usability testing survey, we will follow the Program's standard procedure for sharing the de-identified dataset with external requestors. Per the Program's Overall Resource Sharing Plan, interview data will not be shared because it would be difficult to protect participants' identities even if we were to remove all identifiers.