Department of Health and Human Services
National Institutes of Health
NATIONAL CANCER INSTITUTE

Notice of Award
FAIN# P01CA250989
Federal Award Date
08-31-2022

Recipient Information

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

CHAPEL HILL, 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
D3LHU66KBLD5

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

8. Authorized Official
Jack Hartley
grants@unc.edu
919-962-3950

Federal Agency Information

9. Awarding Agency Contact Information
Long Nguyen
Grants Management Representative
NATIONAL CANCER INSTITUTE
nguyen1@mail.nih.gov
240-276-5360

10. Program Official Contact Information
Sarah Kobrin

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

Federal Award Information

11. Award Number
5P01CA250989-02

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
Non-Competing Continuation

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information

19. Budget Period Start Date 09-01-2022 **– End Date** 08-31-2023	
20. Total Amount of Federal Funds Obligated by this Action	$2,345,967
20 a. Direct Cost Amount	$1,619,846
20 b. Indirect Cost Amount	$726,121
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$2,345,967
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$2,345,967
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	$4,727,014

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Jason Gill

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 – 5P01CA250989-02

Principal Investigator(s):
Noel Todd Brewer, PHD

Award e-mailed to: SponsoredPrograms@unc.edu

Dear Authorized Official:

The National Institutes of Health hereby awards a grant in the amount of $2,345,967 (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,

Jason Gill
Grants Management Officer
NATIONAL CANCER INSTITUTE

Additional information follows

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

Salaries and Wages	$802,114
Fringe Benefits	$257,501
Personnel Costs (Subtotal)	$1,059,615
Consultant Services	$51,244
Materials & Supplies	$14,045
Travel	$33,187
Other	$140,533
Subawards/Consortium/Contractual Costs	$288,895
Publication Costs	$3,660
Tuition Remission	$28,667
Federal Direct Costs	$1,619,846
Federal F&A Costs	$726,121
Approved Budget	$2,345,967
Total Amount of Federal Funds Authorized (Federal Share)	$2,345,967
TOTAL FEDERAL AWARD AMOUNT	$2,345,967
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$2,345,967

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
2	$2,345,967	$2,345,967
3	FUTURE COSTS, RECOMMENDED COSTS	
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:	2022

IC	CAN	2022	2023	2024	2025
CA	8479565	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**: 41025 / **Released**: Gill, Jason 08-30-2022
Award Processed: 08/31/2022 12:22:34 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 5P01CA250989-02

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

SECTION III – STANDARD TERMS AND CONDITIONS – 5P01CA250989-02

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 obtain a unique entity identifier (UEI) and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a UEI 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 – 5P01CA250989-02

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: The clinical trial(s) supported by this award is subject to the plan dated 9/23/2020 submitted to NIH and the NIH policy on Dissemination of NIH-Funded Clinical Trial Information. The plan states that the clinical trial(s) funded by this award will be registered in ClinicalTrials.gov not later than 21 calendar days after enrollment of the first participant and primary summary results reported in ClinicalTrials.gov, not later than one year after the completion date. The reporting of summary results is required by this term of award even if the primary completion date occurs after the period of performance.

REQUIREMENT: This award is subject to additional certification requirements with each submission of the Annual, Interim, and Final Research Performance Progress Report (RPPR). The recipient must agree to the following annual certification when submitting each RPPR. By submitting the RPPR, the AOR signifies compliance, as follows:

In submitting this RPPR, the SO (or PD/PI with delegated authority), certifies to the best of his/her knowledge that, for all clinical trials funded under this NIH award, the recipient and all investigators conducting NIH-funded clinical trials are in compliance with the recipient's plan addressing compliance with the NIH Policy on Dissemination of NIH-Funded Clinical Trial Information. Any clinical trial funded in whole or in part under this award has been registered in ClinicalTrials.gov or will be registered not later than 21 calendar days after enrollment of the first participant. Summary results have been submitted to ClinicalTrials.gov or will be submitted not later than one year after the completion date, even if the completion date occurs after the period of performance.

REQUIREMENT: The awardee is required to follow the data and safety monitoring plan included in the application and may not implement any changes in the plan without the written prior approval of the National Cancer Institute.

INFORMATION: In accordance with the National Cancer Institute's (NCI's) Fiscal Year (FY) 2022 funding policies, this award has been issued at 98% of the level indicated for this budget period on the prior Notice of Grant Award.

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: 5P01CA250989-02

INSTITUTION: UNIV OF NORTH CAROLINA CHAPEL HILL

Budget	Year 2	Year 3	Year 4	Year 5
Salaries and Wages	$802,114	FUTURE COSTS		
Fringe Benefits	$257,501			
Personnel Costs (Subtotal)	$1,059,615			
Consultant Services	$51,244			
Materials & Supplies	$14,045			
Travel	$33,187			
Other	$140,533			
Subawards/Consortium/Contractual Costs	$288,895			
Publication Costs	$3,660			
Tuition Remission	$28,667			
TOTAL FEDERAL DC	$1,619,846			
TOTAL FEDERAL F&A	$726,121			
TOTAL COST	$2,345,967			

Facilities and Administrative Costs	Year 2	Year 3	Year 4	Year 5
F&A Cost Rate 1	55.5%	FUTURE COSTS		
F&A Cost Base 1	$1,308,326			
F&A Costs 1	$726,121			

A. OVERALL COVER PAGE

Project Title: Program Project – Improving Provider Announcement Communication Training (IMPACT)	
Grant Number: 5P01CA250989-02	**Project/Grant Period:** 09/23/2021 - 08/31/2026
Reporting Period: 09/23/2021 - 08/31/2022	**Requested Budget Period:** 09/01/2022 - 08/31/2023
Report Term Frequency: Annual	**Date Submitted:** 06/29/2022
Program Director/Principal Investigator Information: NOEL TODD BREWER , PHD **Phone Number:** 919-966-3282 **Email:** ntb@unc.edu	**Recipient Organization:** UNIV OF NORTH CAROLINA CHAPEL HILL UNIVERSITY OF NORTH CAROLINA CHAPEL HILL Office of Sponsored Research CHAPEL HILL, NC 275995023 **DUNS:** 608195277 **UEI:** D3LHU66KBLD5 **EIN:** 1566001393A1 **RECIPIENT ID:**
Change of Contact PD/PI: NA	
Administrative Official: R DAVID PAUL 104 Airport Dr. Suite 2200 Chapel Hill, NC 275991350 **Phone number:** 919-966-3411 **Email:** resadminosr@unc.edu	**Signing Official:** JACK HARTLEY G-136 Physician's Office Building Chapel Hill, NC 27599 **Phone number:** (919) 843-8858 **Email:** jack_hartley@med.unc.edu
Human Subjects: Yes **HS Exempt:** NA **Exemption Number:** **Phase III Clinical Trial:** NA	**Vertebrate Animals:** No
hESC: No	**Inventions/Patents:** No

B. OVERALL ACCOMPLISHMENTS

B.1 WHAT ARE THE MAJOR GOALS OF THE PROJECT?

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 designated an Evidence-based Cancer Control Program. 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 evidence-based program 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.
Aim 2. Evaluate the impact and cost of HPV vaccine communication interventions in cluster RCTs.
Aim 3. Support implementation of HPV vaccine communication interventions in healthcare systems.

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.

B.1.a Have the major goals changed since the initial competing award or previous report?

No

B.2 WHAT WAS ACCOMPLISHED UNDER THESE GOALS?

File Uploaded : Accomplishments_Overall.pdf

B.3 COMPETITIVE REVISIONS/ADMINISTRATIVE SUPPLEMENTS

For this reporting period, is there one or more Revision/Supplement associated with this award for which reporting is required?

No

B.4 WHAT OPPORTUNITIES FOR TRAINING AND PROFESSIONAL DEVELOPMENT HAS THE PROJECT PROVIDED?

NOTHING TO REPORT

B.5 HOW HAVE THE RESULTS BEEN DISSEMINATED TO COMMUNITIES OF INTEREST?

NOTHING TO REPORT

B.6 WHAT DO YOU PLAN TO DO DURING THE NEXT REPORTING PERIOD TO ACCOMPLISH THE GOALS?

The research projects and cores will continue to work together to enhance the impact of the Announcement Approach Training (AAT), an HPV vaccine communication training for primary care professionals. In Year 2, Projects 1-3 will finalize their trial power analyses, recruit healthcare systems and clinics with an eye toward rurality, and begin their trials. Project 4 will develop a simulation model to evaluate the budget impact, cost-effectiveness, and population outcomes of HPV vaccine communication. The Administrative Core will continue to support the research efforts of the Program Project; the Data Core will develop and implement systems to integrate vaccination data across the 3 trials; and the Intervention Core will finalize changes to the AAT, training of AAT facilitators; and support collection of implementation measures.

B.2 (Accomplishments_Overall.pdf)

ACCOMPLISHMENTS – Overall, Year 1

Below are the IMPACT Program's overall specific aims and updates on major activities, specific objectives, and significant results for September 2021 through June 2022.

Aim 1. Identify opportunities to improve providers' HPV vaccine communication.

National survey (Year 1)
The research projects have collaborated on the national primary care team survey. The research projects and Data Core developed survey items related to HPV vaccine communication, conducted 40 cognitive interviews with providers and other primary care team members, and finalized items into an integrated survey with consistent terminology, section transitions, and response scales. The Clinical Advisory Board (CAB) has been highly functional and provided feedback that has significantly improved the national survey. The Data Core is managing survey implementation in collaboration with WebMD who is fielding the survey. The survey has gathered data from a national sample of 2,478 primary care professionals with a role in providing HPV vaccine as of June 20, 2022, on track to meet the goal of 2,500 participants by the end of the month.

Intervention development (Years 1-2)
Research projects have designed interview guides for qualitative formative research to inform the planned interventions that projects will evaluate in randomized control trials (RCTs) in Aim 2. Research projects have already begun developing and refining the interventions for their trials. The CAB has again been invaluable in providing feedback and ensuring the relevance of the research to clinical practice. In addition, the External Advisory Board (EAB) has provided strategic insight on recruiting for the trials in Aim 2. The Intervention Core and Project 1 are coordinating efforts to make the AAT available in an asynchronous format, update the demonstration video, incorporate information about age 9 recommendations, and strengthen the train-the-trainer materials.

Aim 2. Evaluate the impact and cost of HPV vaccine communication interventions in healthcare systems.

Projects 1-3 have begun working with large healthcare systems to work through details of their partnerships for trial recruitment. The Data Core has begun harmonizing the definitions of vaccination outcomes for the RCTs. Issues that we are addressing include incorporating ages 9-10 in data collection, the use of the HEDIS measure, collection of patient level vs. clinic level data, and use of retrospective cohorts or serial cross-sectional samples. The Intervention Core and Project 4 have begun harmonizing the collection of cost data to meet the needs of the planned budget impact and cost-effectiveness analyses. Aim 2 activities will begin in Year 2 as the projects prepare to pilot their interventions and in Years 2-4 as they conduct the RCTs. Given the budget cuts that may necessitate reducing sample sizes, the Data Core is helping Projects 1-3 revisit their power analyses to ensure the trials will be adequately powered. The Year 1 Annual Scientific Retreat in August 2022 will focus on best practices for recruiting large healthcare systems into trials and include strategic feedback from our EAB.

Aim 3. Support implementation of HPV vaccine communication interventions in healthcare systems.

Research projects have been conducting formative and pilot work to strengthen later implementation efforts. Project 1 has begun the development of a standing orders implementation plan template. Project 2 has begun the development of a feedback report that participating clinics will get summarizing their progress on HPV vaccination. The Intervention Core is developing implementation outcome measures for shared- and project-specific efforts, while Project 4 is operationalizing the concept of clinic-level rurality to guide efforts to implement our interventions in these areas. Aim 3 activities will begin in Years 2-4 as projects move into RCT data analysis and writing up findings for publications. They will also refine their modules for the package of interventions for healthcare systems.

Other accomplishments
We have established a Diversity, Equity, and Inclusion (DEI) Working Group to prioritize these topics in our work. Activities so far include standardizing the measurement of race, ethnicity, and rurality across projects,

evaluating the racial and ethnic diversity of our program members, filling open positions with an eye toward equity, supporting racial equity and inclusion trainings for all study personnel, having presentations and team discussions about DEI frameworks for our research, and including survey measures focused on DEI topics such as communication with Hispanic families about HPV vaccination.

Significance

The IMPACT Program Project integrated studies will expand the field's understanding of how to greatly increase the impact of HPV vaccine communication by enhancing the Announcement Approach Training (AAT) and leveraging its impact by using the whole primary care team, incentives, and champions. Through formative work, RCTs, cost-effectiveness analysis, and population outcomes, we will generate new insights that can inform healthcare systems' work on improving HPV vaccination uptake. We will also help decision makers within and outside of healthcare systems prioritize these interventions and understand how best to meet the needs of rural clinics and providers. In Year 1, the national survey, the formative interviews, and feedback from the CAB are actively informing the planned trials and ensuring the interventions' suitability for clinical implementation in large healthcare systems.

C. OVERALL PRODUCTS

C.1 PUBLICATIONS

Are there publications or manuscripts accepted for publication in a journal or other publication (e.g., book, one-time publication, monograph) during the reporting period resulting directly from this award?

No

C.2 WEBSITE(S) OR OTHER INTERNET SITE(S)

NOTHING TO REPORT

C.3 TECHNOLOGIES OR TECHNIQUES

NOTHING TO REPORT

C.4 INVENTIONS, PATENT APPLICATIONS, AND/OR LICENSES

Have inventions, patent applications and/or licenses resulted from the award during the reporting period? No

If yes, has this information been previously provided to the PHS or to the official responsible for patent matters at the grantee organization? No

C.5 OTHER PRODUCTS AND RESOURCE SHARING

NOTHING TO REPORT

D. OVERALL PARTICIPANTS

D.1 WHAT INDIVIDUALS HAVE WORKED ON THE PROJECT?

Commons ID	S/K	Name	Degree(s)	Role	Cal	Aca	Sum	Foreign Org	Component(s)	Country	SS
eRA COMMONS USER NAME	Y	Brewer, Noel Todd	PHD	PD/PI	CAL. MONTHS				Admin-Core-001 (Administrative Core – Impr...ning (IMPACT)), Project-001 (IMPACT Project 1 – The imp...on and uptake)		NA
	Y	Spees, Lisa Patterson	BA,MA,MA,PHD	Co-Investigator					Project-004 (IMPACT Project 4 – Budget ...l communities)		NA
	Y	Wheeler, Stephanie Brooke	BA,BS,MPH,PHD	Co-Investigator					Admin-Core-001 (Administrative Core – Impr...ning (IMPACT)), Project-004 (IMPACT Project 4 – Budget ...l communities)		NA
	N	Queen, Tara L	PHD	Statistician					Core-002 (Data Core – Improving Prov...ning (IMPACT))		NA
	N	Biddell, Caitlin Bissette	BS,PHD	Graduate Student (research assistant)					Project-004 (IMPACT Project 4 – Budget ...l communities)		NA
	N	Karnik, Poojan	BA,MOTH	Graduate Student (research assistant)					Admin-Core-001 (Administrative Core – Impr...ning (IMPACT))		NA
	Y	Trogdon, Justin	PHD	Co-I Admin Core; Project Lead Projec 2; Co-I Data Core					Admin-Core-001 (Administrative Core – Impr...ning (IMPACT)), Core-002 (Data Core – Improving Prov...ning (IMPACT)), Project-002 (IMPACT Project 2 – The imp...on and uptake)		NA
	Y	Gilkey, Melissa B	PHD,MPH,AB	Co-I Admin; Lead Proj 3; Core Lead Intv. Core					Admin-Core-001 (Administrative Core – Impr...ning (IMPACT)), Core-001 (Intervention Core - Improv...ning (IMPACT)), Project-		NA

									003 (IMPACT Project 3 – Engagin…hcare systems)		
	N	Keller, Chelsea		Pennsylvania Project Manager	CAL. MONTHS				Core-001 (Intervention Core - Improv…ning (IMPACT))		NA
eRA COMMONS USER NAME	Y	Calo, William Alexis	BS,JD,MPH,PHD	Pennsylvania Sub PI					Core-001 (Intervention Core - Improv…ning (IMPACT))		NA
	Y	Ozawa, Sachiko	OTH,PHD	Project Lead Project 4; Co-I Admin Core					Admin-Core-001 (Administrative Core – Impr…ning (IMPACT)), Project-004 (IMPACT Project 4 – Budget …l communities)		NA
	N	Brignole, Kathryn		Project Manager					Core-002 (Data Core – Improving Prov…ning (IMPACT)), Project-002 (IMPACT Project 2 – The imp…on and uptake)		NA
	N	Kritikos, Katherine		Project Manager					Project-001 (IMPACT Project 1 – The imp…on and uptake)		NA
eRA COMMONS USER NAME	N	Mendel, Jennifer		Project Manager					Admin-Core-001 (Administrative Core – Impr…ning (IMPACT))		NA
	N	Ilyasova, Anna Andreevna		Research Assistant					Project-004 (IMPACT Project 4 – Budget …l communities)		NA
	N	Stalford, Samantha		Wisconsin Research Specialist					Project-003 (IMPACT Project 3 – Engagin…hcare systems)		NA
eRA COMMONS USER NAME	Y	COX, ELIZABETH D.	MD,PHD	Wisconsin Sub PI					Project-003 (IMPACT Project 3 – Engagin…hcare systems)		NA

Glossary of acronyms:
S/K - Senior/Key
Cal - Person Months (Calendar)
Aca - Person Months (Academic)
Sum - Person Months (Summer)

Foreign Org - Foreign Organization Affiliation
SS - Supplement Support
RS - Reentry Supplement
DS - Diversity Supplement
OT - Other
NA - Not Applicable

D.2 PERSONNEL UPDATES

D.2.a Level of Effort

Will there be, in the next budget period, either (1) a reduction of 25% or more in the level of effort from what was approved by the agency for the PD/PI(s) or other senior/key personnel designated in the Notice of Award, or (2) a reduction in the level of effort below the minimum amount of effort required by the Notice of Award?

No

D.2.b New Senior/Key Personnel

Are there, or will there be, new senior/key personnel?

Yes

File Uploaded: D.2.b. Overall.pdf

D.2.c Changes in Other Support

Has there been a change in the active other support of senior/key personnel since the last reporting period?

Yes

File Uploaded: Combined OS_Brewer P01 RPPR YR2.pdf

D.2.d New Other Significant Contributors

Are there, or will there be, new other significant contributors?

No

D.2.e Multi-PI (MPI) Leadership Plan

Will there be a change in the MPI Leadership Plan for the next budget period?

NA

D.2.b (D.2.b. Overall.pdf)

D.2.d New Senior/Key Personnel

To co-lead the Intervention Core, we recruited Dr. Calo who has worked previously with the team and has extensive experience in HPV vaccination quality improvement, implementation science, and health equity research. The previous Co-Lead, Dr. Birken, started a new faculty position outside of UNC and received a new grant, which left her with not enough time to serve in this role. To co-lead the Data Core, we recruited Dr. Queen who has a doctoral degree in quantitative psychology and extensive experience with RCT design and advanced statistical analyses and has worked closely with several members of the P01 team. The previous Col-Lead, Dr. Gottfredson, received a large grant as PI, which left her with not enough FTEs to serve in this role.

OMB No. 0925-0001 and 0925-0002 (Rev. 10/2021 Approved Through 09/30/2024)

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: Calo, William Alexis

eRA COMMONS USER NAME: eRA COMMONS USER NAME

POSITION TITLE: Assistant Professor of Public Health Sciences

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 Puerto Rico, Rio Piedras, PR	B.S.	06/2004	Biology
University of Puerto Rico Medical Sciences Campus, San Juan, PR	M.P.H	07/2005	Public Health (concentration in epidemiology)
University of Puerto Rico School of Law, Rio Piedras, PR	J.D.	08/2010	Law
The University of Texas School of Public Health, Houston, TX	Ph.D.	06/2014	Health Policy and Management (concentration in health disparities)
University of North Carolina Gillings School of Global Public Health, Chapel Hill, NC	Postdoc	06/2017	Cancer Care Quality

A. Personal Statement

As an implementation scientist focusing on HPV vaccine communication, I am delighted to work with Drs. Noel Brewer and Melissa Gilkey on a study that aligns with my research program goal to improve the delivery of evidence-based interventions, like the Announcement Approach Training (AAT), to primary care clinics. In the Program Project, I serve as Co-Lead for the Intervention Core (with Dr. Melissa Gilkey). As part of my role, I will: 1) coordinate the Clinical Advisory Board, 2) consult on harmonization of implementation measures across projects, and 3) support the refinement of the AAT and dissemination of the AAT toolkit. My qualifications for this role include 10 years of experience working with healthcare partners and community members to adapt, implement, and evaluate interventions for diverse settings and populations. Of note, I am the Principal Investigator of a NCI-funded (MERIT R37 award) RCT using a hybrid effectiveness-implementation design to increase HPV vaccination rates in 36 rural primary care clinics in Pennsylvania. I am also the Implementation Research Director for Penn State Project ECHO and the Director of the Implementation Science Collaborative (ISC) in the Department of Public Health Sciences, leading the implementation evaluation of several NIH and PCORI-funded studies. Important to this project, the ISC offers consultative services to investigators, like Drs. Brewer and Gilkey, in many aspects of implementation science, including framing implementation research questions; selecting theories, models or frameworks; identifying promising implementation strategies; and choosing appropriate study measurements. I am also trained by the highly-competitive NCI's Training Institute for Dissemination and Implementation Research in Cancer (TIDIRC). I am the co-leader for the Pennsylvania HPV Vaccination Workgroup, part of the Pennsylvania Cancer Control Program, and have presented on vaccine communication topics at multiple regional and national conferences, including the 2021 meeting of the National HPV Vaccination Roundtable. In terms of existing collaborations, Drs. Brewer and Gilkey and I have worked on several HPV vaccine communication studies for the past seven years, yielding 21 publications and multiple national conference presentations. I was a postdoctoral trainee under the mentorship of Dr. Brewer during 2014-2017. As an active member of the P01 team, I will also participate in regular meetings, manuscript writing, and dissemination of study findings in scientific and community events. In sum, all of this expertise, experiences, and collaborations will make the team and me especially well-prepared to conduct the research activities under the leadership of Dr. Brewer.

D.2.b (D.2.b. Overall.pdf)

Ongoing and recently completed projects that I would like to highlight include:

R37-CA253279	Calo (PI)	NCI	08/10/2020-04/30/2025

HPV ECHO: Increasing the adoption of evidence-based communication strategies for HPV vaccination in rural primary care practices

P01-CA250989-01A1	Brewer (PI)	NCI	09/23/2021-08/31/2026

Improving Provider Announcement Communication Training (IMPACT)
Role: Co-lead Intervention Core

R01-CA254659	Schmitz (PI)	NCI	06/24/2021-03/31/2026

Nurse AMIE: Addressing Metastatic Individuals Everyday in Rural PA and WV
Role: Co-Investigator

Citations:

1. **Calo WA**, Doerksen SE, Spanos K, Pergolotti M, Schmitz KH. Implementing Strength after Breast Cancer (SABC) in outpatient rehabilitation clinics: Mapping clinician survey data onto key implementation outcomes. *Implement Sci Commun*. 2020; 1:69. PMCID: PMC7427930.
2. **Calo WA**, Shah PD, Gilkey MB, Vanderpool R, Barden S, Doucette W, Brewer NT. Implementing pharmacy-located HPV vaccination: Findings from pilot projects in five states. Hum Vaccin Immunother. 2019; 15(7-8):1831-8. doi: 10.1080/21645515.2019.1602433.
3. Fernandez ME, Walker TJ, Weiner BJ, **Calo WA**, Liang S, Risendal B, Friedman DB, Tu SP, Williams RS, Jacobs S, Hermann AK, Kegler MC. Developing measures to assess constructs from the Inner Setting domain of the Consolidated Framework for Implementation Research. *Implement Sci.* 2018; 13:52. PMCID: PMC5870186
4. **Calo WA**, Gilkey MB, Leeman J, MacKinnon J, Averette C, Sanchez S, Kornides M, Brewer NT. Coaching primary care clinics for HPV vaccination quality improvement: Comparing in-person and webinar implementation. *Transl Behav Med*. 2019; 9(1)23-31. PMCID:PMC6305561

B. Positions, Scientific Appointments, and Honors

Positions and Scientific Appointments

2021-Present	Co-leader, Pennsylvania HPV Workgroup
2017-Present	Assistant Professor, Department of Public Health Sciences, Penn State College of Medicine, Hershey, PA
2016-Present	Member, Society of Behavioral Medicine
2014-2017	Postdoctoral Research Associate, Department of Health Policy and Management, University of North Carolina Gillings School of Global Public Health, Chapel Hill, NC
2012-2014	Policy Consultant (contractor), Cancer Control Program, University of Puerto Rico, San Juan, PR
2012-2012	Policy Consultant (contractor), Division of Tobacco Control and Oral Health, Department of Health of Puerto Rico, San Juan, PR
2010-2014	Pre-doctoral Fellow, Center for Health Promotion and Prevention Research, The University of Texas School of Public Health, Houston, TX
2008-2010	Project Manager, University of Puerto Rico School of Medicine, San Juan, PR
2005-2008	Research Assistant, University of Puerto Rico School of Medicine, San Juan, PR

Honors

2021	Top 10 Most Talked About Articles of 2020, CDC's Preventing Chronic Disease journal
2021	Samuel Hinkle Junior Faculty Research Award, Penn State College of Medicine, Office of the Vice Dean for Research and Graduate Studies
2021	Outstanding Collaborative Research Team, awarded for work in The ONE (Oncology, Nutrition and Exercise) Group, Penn State College of Medicine, Office of the Vice Dean for Research and Graduate Studies
2019	Competitively Selected Participant, Training Institute for Dissemination and Implementation Research in Cancer (TIDIRC), National Cancer Institute
2018	Outstanding Journal Reviewer, Preventive Medicine Reports

D.2.b (D.2.b. Overall.pdf)

2014-2016	NCI-sponsored Postdoctoral Fellowship Award (R25), University of North Carolina-Chapel Hill
2010-2014	NCI-sponsored Fellowship Award (R25), The University of Texas School of Public Health

C. Contributions to Science

My overall program of research examines how to better adapt, implement, and evaluate best-practice interventions to reduce health inequities in cancer outcomes, especially among Hispanics and rural populations.

1. Implementation of best-practice interventions. My main area of research examines how clinics and community organizations adopt, adapt, and implement best practices for improving vaccine uptake. One of my studies identified low levels of awareness and use of resources for implementing best practices among cancer control planners serving Hispanic communities. I also collaborated with the Cancer Prevention and Control Research Network (CPCRN) on the development and testing of measures of the inner setting domain of the Consolidated Framework for Implementation Research. Our study provided psychometric evidence in support of these measures. This research moved the field of implementation science forward by describing valid and reliable measures of inner contexts that may influence implementation of cancer prevention and control services in practices that reach diverse populations. More recently, I led a project that documented the challenges and opportunities of implementing pharmacy-located HPV vaccination services in five US states by mapping process evaluation results onto key implementation science constructs: service penetration, acceptability, appropriateness, feasibility, fidelity, adoption, and sustainability. This work has motivated many pharmacies across the US to start or expand their vaccination programs to offer HPV vaccination for adolescents.

a. **Calo WA**, Fernandez ME, Rivera M, Díaz EC, Correa-Fernández V, Pattatucci A, Wetter DW. Assessing awareness and use of evidence-based programs for cancer control in Puerto Rico. *J Cancer Educ*. 2012; 27(3):486-93. PMCID: PMC3422596. PMCID:PMC3422596
b. Fernandez ME, Walker TJ, Weiner BJ, **Calo WA**, Liang S, Risendal B, Friedman DB, Tu SP, Williams RS, Jacobs S, Hermann AK, Kegler MC. Developing measures to assess constructs from the Inner Setting domain of the Consolidated Framework for Implementation Research. *Implement Sci.* 2018; 13:52. PMCID: PMC5870186
c. **Calo WA**, Shah PD, Gilkey MB, Vanderpool R, Barden S, Doucette W, Brewer NT. Implementing pharmacy-located HPV vaccination: Findings from pilot projects in five states. *Hum Vaccin Immunother.* 2019; 15(7-8):1831-8. doi: 10.1080/21645515.2019.1602433. PMCID: PMC6746514
d. **Calo WA**, Gilkey MB, Leeman J, MacKinnon J, Averette C, Sanchez S, Kornides M, Brewer NT. Coaching primary care clinics for HPV vaccination quality improvement: Comparing in-person and webinar implementation. *Transl Behav Med*. 2019; 9(1)23-31. PMCID:PMC6305561

2. Addressing cancer health inequities. Understanding the causes of cancer health inequities and how best to develop and test interventions for reducing such inequities represents a major focus of my work. My early research examined trends in incidence and mortality rates from cancer among Hispanic groups and how these data compared to those of other racial/ethnic groups in the US. These publications, five in total, found a higher burden of cancer among Puerto Ricans, particularly for breast, colorectal, and HPV-related cancers. These data were used for prioritizing, selecting, and evaluating goals and objectives of the Puerto Rico Cancer Control Plan 2015-2020. These publications also provided the evidence for supporting passing Puerto Rico's Law No. 49-2011, which established the state's public policy for cancer prevention and control. During my doctoral work, I expanded my research on cancer health disparities to examine potential mechanisms through which area-level factors may influence cancer screening behaviors using data from a racially and ethnically diverse population in Texas. I found that individuals living in areas with high levels of socioeconomic disadvantage were less likely to adhere to current mammography and colorectal screening guidelines. These two publications were among the first studies to use Census tract-level foreclosure data to study the potential link between local economies and cancer screening.

a. Spencer J, **Calo WA**, Brewer NT. Racial disparities and reverse disparities in HPV vaccination: A systematic review and meta-analysis. *Prev Med.* 2019; 123:197-203. PMCID: PMC6724708. doi: 10.1016/j.ypmed.2019.03.037.

D.2.b (D.2.b. Overall.pdf)

b. **Calo WA**, Fernández ME, Fernández-Espada N, Colón-López V. Exploring the role of ethnic identity on the attitudes towards HPV vaccine advertising among Puerto Ricans: A qualitative analysis. J Immigr Minor Health. 2015; 17(1): 314-7. PMCID:PMC3961571
c. **Calo WA**, Vernon SW, Lairson D, Linder S., Linder, S.H. Area-level socioeconomic inequalities in the use of mammography screening: A multilevel analysis of the Health of Houston Survey. *Womens Health Issues.* 2016; 26(2):201-7. PMCID:PMC4761271
d. **Calo WA**, Vernon SW, Lairson D, Linder S. Associations between contextual factors and colorectal cancer screening in a racially and ethnically diverse population in Texas. *Cancer Epidemiol*. 2015; 39(6):798-804. PMCID:PMC4680846

3. Vaccine communication and misinformation. Another major component of my research program has sought to understand and intervene on the problem of low HPV vaccination rates in the US. My early work identified key psychosocial factors influencing HPV vaccination among parents of adolescent girls and boys, health care providers, and Hispanic populations. Acknowledging that a key predictor in HPV vaccination is receiving a strong recommendation from a health care provider, I have expanded my work to focus on improving provider communication about HPV vaccine with parents and families. Notably, I led the first content analysis of existing HPV vaccination messages that providers might use when recommending vaccination, answering common questions and concerns, and persuading vaccine hesitant parents. My work has informed the Announcement Approach, a communication strategy that has been endorsed by the National Cancer Institute as an evidence-base practice for increasing HPV vaccine uptake. More recently, I have been studying the impact of social media misinformation on HPV vaccine hesitancy and refusal. My research has highlighted that exposure to negative stories (i.e. misinformation) about HPV vaccination may be associated more strongly with vaccination behavior than positive stories.

a. **Calo WA**, Gilkey MB, Malo T, Robichaud M, Brewer NT. A content analysis of HPV vaccination messages available online. *Vaccine.* 2018;36(49):7525-9. doi: 10.1016/j.vaccine.2018.10.053. PMID:30366803
b. Shah PD, **Calo WA**, Gilkey MB, Boynton MH, Alton Daily S, Todd KG, Margolis MA, Brewer NT. Questions and concerns about HPV vaccine: A communication experiment. *Pediatrics*. 143(2): e20181872. PMCID: PMC6361359. doi: 10.1542/peds.2018-1872.
c. **Calo WA**, Fernández ME, Fernández-Espada N, Colón-López V. Exploring the role of ethnic identity on the attitudes towards HPV vaccine advertising among Puerto Ricans: A qualitative analysis. *J Immigr Minor Health*. 2015; 17(1): 314-7. PMCID:PMC3961571
d. Margolis MA, Brewer NT, Shah PD, **Calo WA**, Gilkey MB. Stories about HPV vaccine in social media, traditional media, and conversations. *Prev Med.* 2019; 118:251-6. doi: 10.1016/j.ypmed.2018.11.005. PMID:30414396

4. Systems and policy strategies to support vaccination programs. I also study health care systems and policy interventions to support HPV vaccination. At the systems level, I study approaches for raising HPV vaccination rates through quality improvement coaching to primary care clinics. As part of a multi-state RCT with 148 high-volume primary care clinics, I found that ECHO-like coaching is an efficient, acceptable, and economically feasible solution for delivering HPV vaccination best practices to clinics. At the policy level, I have initiated research to establish the feasibility of alternative vaccination settings, such as pharmacies. These studies helped inform the President's Cancer Panel's policy recommendation to use pharmacies as an additional strategy to increase HPV vaccine uptake in the US. In addition, I conducted the first national study assessing parents' support for HPV vaccine school-entry requirements, without and with opt-out provisions. This study has brought large media attention to my research program.

a. **Calo WA**, Gilkey MB, Leeman J, MacKinnon J, Averette C, Sanchez S, Kornides M, Brewer NT. Coaching primary care clinics for HPV vaccination quality improvement: Comparing in-person and webinar implementation. *Transl Behav Med*. 2019; 9(1)23-31. PMCID:PMC6305561
b. **Calo WA**, Gilkey MB, Shah P, Marciniak MW, Brewer NT. Parents' willingness to get HPV vaccination for their adolescent children at a pharmacy. *Prev Med*. 2017; 99:251-6. PMCID:PMC5545978
c. **Calo WA**, Shah PD, Gilkey MB, Vanderpool R, Barden S, Doucette W, Brewer NT. Implementing pharmacy-located HPV vaccination: Findings from pilot projects in five states. *Hum Vaccin Immunother*. 2019; 15(7-8):1831-8. PMCID: PMC6746514

D.2.b (D.2.b. Overall.pdf)

d. **Calo WA**, Gilkey MB, Shah PD, Moss JL, Brewer NT. Parents' support for school-entry requirements for HPV vaccination: A national study. *Cancer Epidemiol Biomarkers Prev*. 2016; 25(9):1317-25. PMCID:PMC5010506

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

OMB No. 0925-0001 and 0925-0002 (Rev. 10/2021 Approved Through 09/30/2024)

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: Queen, Tara L.

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

POSITION TITLE: Statistician

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
Meredith College, Raleigh, NC	BS	05/2006	Psychology
North Carolina State University, Raleigh, NC	MA	12/2008	Developmental Psychology
North Carolina State University, Raleigh, NC	PhD	08/2011	Developmental Psychology
University of Michigan, Ann Arbor, MI	Postdoctoral	09/2013	Gerontology, Survey Methodology
University of Utah, Salt Lake City, UT	Postdoctoral	07/2014	Health Psychology, Methodology

A. Personal Statement

I am a social science researcher who specializes in quantitative methods to understand issues related to public health. My graduate training was in developmental psychology where I gained expertise in experimental methods. My postdoctoral training focused on survey methodology and secondary data analysis, with an emphasis on longitudinal designs. My research employs a variety of methodological and statistical techniques to investigate questions relevant to public health issues such as tobacco regulation, vaccine communication, chronic disease management, and healthy aging. As co-lead of the Data Core, I advise research teams on methodology and study designs and lead survey development, data preparation and management, and statistical analyses for multiple projects focused on HPV vaccine communication.

B. Positions, Scientific Appointments, and Honors

Positions & Appointments

2011-2013 Postdoctoral Research Fellow, Survey Research Center, Institute for Social Research, University of Michigan
2013-2014 Postdoctoral Researcher, Department of Psychology, University of Utah
2014-2016 Assistant Research Professor, Department of Psychology, University of Utah
2016-2019 Research Associate, Lineberger Comprehensive Cancer Center, University of North Carolina, Chapel-Hill
2021-Present Statistician, Gillings School of Global Public Health & Lineberger Comprehensive Cancer Center, University of North Carolina at Chapel Hill

Honors

2006 Outstanding Student in Psychology Award, Meredith College
2007 APA Division 20 Award for Proposed Master's Research
2009 Invited participant, APA Science Leadership Conference: Enhancing the Nation's Health through Psychological Science
2012 Travel sponsorship from the Michigan Center on the Demography of Aging (MiCDA) to RAND Summer Institute
2012 A. Regula Herzog Young Investigators Award, Institute for Social Research -Survey Research Center

D.2.b (D.2.b. Overall.pdf)

2014 Trainee Poster Award, Center on Aging Annual Research Retreat, University of Utah

C. Contributions to Science

1. My graduate research utilized **experimental methods** to investigate topics related to social cognition (e.g., decision making, motivation) in older adulthood. Much of this research explored how older adults approach complex decision making and focused on the roles of cognitive ability and knowledge.

a. Queen, T.L., Hess, T.M., Ennis, G.E., Dowd, K., & Grühn, D. (2013). Information search and decision making: Effects of age and complexity on strategy use. *Psychology and Aging*, 27, 817-824.
b. Hess, T.M., Queen, T.L., & Ennis, G. (2013). Age and self-relevance effects on information search during decision-making. *The Journals of Gerontology, Series B: Psychological Sciences and Social Sciences*, 68, 703-711.
c. Hess, T.M., Queen, T.L., & Patterson, T.R. (2012). To deliberate or not to deliberate: Interactions between age, task characteristics, and cognitive activity on decision making. *Journal of Behavioral Decision Making*, 25, 29-40.
d. Queen, T.L. & Hess, T.M. (2010). Age differences in the effects of conscious and unconscious thought on decision making. *Psychology and Aging,* 25, 251-261.

2. In my postdoctoral research, I further developed my quantitative abilities by gaining experience in **longitudinal modeling and complex survey designs.** Much of this work utilized data collected from the Health and Retirement Study, a longitudinal population survey of aging in the US.

a. Queen, T.L., Butner, J., Berg, C.A., & Smith, J. (2017). Activity engagement among older adult spousal caregivers. *Journals of Gerontology: Social Sciences*.
b. Queen, T.L. & Hess, T.M. (2018). Linkages between resources, motivation, and engagement in everyday activities. *Motivation Science*, 4, 26-38.
c. Giasson, H.L., Queen, T.L., Larkina, M., & Smith, J. (2017). Age group differences in perceived age discrimination: associations with self-perceptions of aging. *The Gerontologist*, 57, S160
d. Queen, T.L., Stawski, R.S., Ryan, L.H., & Smith, J. (2014). Loneliness in a day: Activity engagement, time alone, and experienced emotions. *Psychology and Aging*, 29, 297-305.

3. My postdoctoral training at the University of Utah extended my background in developmental psychology to include work on **adolescence and young adults coping with chronic illness.** This research utilized longitudinal survey data collected on parents and their child with a type 1 diabetes and examined how parents and children interact in managing complex health problems.

a. Queen, T.L., Baucom, K.J.W, Baker, A.C., Mello, D., Berg, C.A., & Wiebe, D.J. (2017). Neighborhood disorder and glycemic control in late adolescents with Type 1 diabetes. *Social Science and Medicine.*
b. Berg, C.A., Queen, T.L., Turner, S.A.,….Wiebe, D.J. (2017). Adolescent disclosure to parents and daily management of type 1 diabetes. *Journal of Pediatric Psychology*, 42, 75-84.
c. Queen, T.L., Butner, J., & Berg, C.A. (2016). A micro-developmental view of parental well-being in families coping with chronic illness. *Journal of Family Psychology*, 30, 843-853.
d. Baucom, K.J.W., Queen, T.L., Wiebe, D.J., Turner, S.L., Wolfe, K.L., Godbey, E.I. & Fortenberry, K.T. (*2015*). Depressive symptoms, daily stress, and adherence in late adolescents with type 1 diabetes. *Health Psychology,* 34, 522-530.

4. In my most recent work, I have continued to develop my quantitative skillsets within public health research. My role includes serving as a **statistical consultant for public health researchers studying tobacco use and prevention and vaccine support**. In this position, I have provided quantitative support on large national surveys, multiple randomized clinical trials, and a longitudinal national data collection on cigarette retailers.

a. Goldstein, A. O., Jarman, K. L., Kowitt, S. D., Queen, T. L., Kim, K. S., Shook-Sa, B. E., ... & Ranney, L. M. (2021). Effect of Cigarette Constituent Messages With Engagement Text on Intention to Quit Smoking Among Adults Who Smoke Cigarettes: A Randomized Clinical Trial. JAMA network open, 4(2), e210045-e210045.
b. Kowitt, S. D., Lazard, A. J., Queen, T. L., Noar, S. M., & Goldstein, A. O. (2018). Adolescents' Aided Recall of Targeted and Non-Targeted Tobacco Communication Campaigns in the United States. International journal of environmental research and public health, 15(11), 2363.

D.2.b (D.2.b. Overall.pdf)

c. Kong, A. Y., Queen, T. L., Golden, S. D., & Ribisl, K. M. (2020). Neighborhood disparities in the availability, advertising, promotion, and youth appeal of little cigars and cigarillos, United States, 2015. Nicotine and Tobacco Research, 22(12), 2170-2177.
d. Ranney, L. M., Kowitt, S. D., Queen, T. L., Jarman, K. L., & Goldstein, A. O. (2019). An Eye Tracking Study of Anti-Smoking Messages on Toxic Chemicals in Cigarettes. International Journal of Environmental Research and Public Health, 16(22), 4435.

OMB No. 0925-0001 and 0925-0002 (Rev. 12/2020 Approved Through 02/28/2023)

Name of Individual: Noel Brewer
Commons ID: eRA COMMONS USER NAME

Other Support – Project/Proposal

ACTIVE

*Title: Impact of AFIX and Physician-to-Physician Engagement on HPV Vaccination in Primary Care: An RCT

Major Goals: This grant funds a trial to examine how and for whom quality improvement visits (AFIX) and physician to physician engagement are effective in increasing HPV vaccine uptake.

*Status of Support: Active

Project Number: U01-IP001073

Name of PD/PI: Noel Brewer

*Source of Support: DHHS Centers for Disease Control and Prevention

*Primary Place of Performance: The University of North Carolina at Chapel Hill

Project/Proposal Start and End Date: (MM/YYYY) (if available): 08/01/2017 – 07/31/2022

* Total Award Amount (including Indirect Costs): $1,499,698

* Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
2021-2022	CAL. MONTHS

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

Major Goals: This grant funds development of a perceived message effectiveness measures for youth tobacco use prevention campaigns.

*Status of Support: Active

Project Number: R01-CA246600

Name of PD/PI: Seth Noar

*Source of Support: NIH National Cancer Institute

*Primary Place of Performance: The University of North Carolina at Chapel Hill

Project/Proposal Start and End Date: (MM/YYYY): 09/17/2019 – 08/31/2022

* Total Award Amount (including Indirect Costs): $1,364,699

* Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
2021-2022	CAL. MONTHS

*Title: Informing ENDS policies: Studying the impact of e-cigarette warnings on behavior

Major Goals: This grant funds several studies to develop and evaluate warnings for e-cigarettes, including a field RCT.

OMB No. 0925-0001 and 0925-0002 (Rev. 12/2020 Approved Through 02/28/2023)

Name of Individual: Noel Brewer
Commons ID: eRA COMMONS USER NAME

*Status of Support: Active

Project Number: R01-DA048390

Name of PD/PI: Noel Brewer

*Source of Support: National Institutes of Health (NIH)

*Primary Place of Performance: The University of North Carolina at Chapel Hill

Project/Proposal Start and End Date: (MM/YYYY): 04/01/2020 – 03/31/2025

* Total Award Amount (including Indirect Costs): $3,073,665

* Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
2021-2022	CAL. MONTHS
2022-2023	
2023-2024	
2024-2025	

*Title: Understanding uncontrolled vaping among vulnerable populations

Major Goals: This grant funds development of the first set of measures of vaping restraint and controlled vaping.

*Status of Support: Active

Project Number: R01-CA246606

Name of PD/PI: Noel Brewer

*Source of Support: NIH National Cancer Institute

*Primary Place of Performance: The University of North Carolina at Chapel Hill

Project/Proposal Start and End Date: (MM/YYYY): 09/10/2020 – 08/31/2023

* Total Award Amount (including Indirect Costs): $1,377,835

* Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
2021-2023	CAL. MONTHS
2022-2023	

*Title: Program Project – Improving Provider Announcement Communication Training (IMPACT) – Project 1 and Program Core

Major Goals: This grant funds a program Project on ways to improve provider communication about HPV vaccination and increase uptake among adolescents.

*Status of Support: Active

Project Number: P01-CA250989

Name of PD/PI: Noel Brewer

OMB No. 0925-0001 and 0925-0002 (Rev. 12/2020 Approved Through 02/28/2023)

Name of Individual: Noel Brewer
Commons ID: eRA COMMONS USER NAME

*Source of Support: NIH National Cancer Institute

*Primary Place of Performance: The University of North Carolina at Chapel Hill

Project/Proposal Start and End Date: (MM/YYYY): 09/23/2021 – 08/31/2026

* Total Award Amount (including Indirect Costs): $11,755,859

* Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months – Proj 1	Person Months - Program Core
2021-2022	CAL. MONTHS	
2022-2023		
2023-2024		
2024-2025		
2025-2026		

PENDING

PENDING SUPPORT

PENDING SUPPORT

***Overlap** (summarized for each individual):

No Overlap to report.

I, PD/PI or other senior/key personnel, 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: Noel Brewer Digitally signed by Noel Brewer
Date: Date: 2022.05.17 10:10:52 -04'00'

OMB No. 0925-0001 and 0925-0002 (Rev. 12/2020 Approved Through 02/28/2023)

OTHER SUPPORT

*Name of Individual: Wheeler, Stephanie
Commons ID: eRA COMMONS USER NAME

Other Support – Project/Proposal

ACTIVE

*Title: Cancer Center Support Grant

Major Goals: The CCSG budget supports technological and operational expansion of cores and faculty recruitment in the basic, translational, clinical, and population sciences.

*Status of Support: Active

Project Number: 2-P30-CA016086-45

Name of PD/PI: Earp

*Source of Support: NIH/National Cancer Institute

*Primary Place of Performance: The University of North Carolina at Chapel Hill

Project/Proposal Start and End Date: (MM/YYYY) (if available): 06/01/1997-11/30/2025

* Total Award Amount (including Indirect Costs): $4,715,160

* Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##) (Admin Core, COE AD)	Person Months (##.##) Component: Community Outreach and Engagement
2021-2022	CAL. MONTHS	
2022-2023		
2023-2024		
2024-2025		

*Title: Cancer Care Quality Research Training Program

Major Goals: This program trains a cadre of clinician and non-clinician junior scientists to work collaboratively in multidisciplinary teams to improve the quality of cancer care delivered across the cancer care continuum.

*Status of Support: Active

Project Number: T-32-CA116339-13

Name of PD/PI: Basch, Wheeler

*Source of Support: NIH/National Cancer Institute

*Primary Place of Performance: The University of North Carolina at Chapel Hill

Project/Proposal Start and End Date: (MM/YYYY) (if available): 07/01/2005-7/31/2023

* Total Award Amount (including Indirect Costs): $4,837,486

* Person Months (Calendar/Academic/Summer) per budget period.

OMB No. 0925-0001 and 0925-0002 (Rev. 12/2020 Approved Through 02/28/2023)

Name of Individual: Wheeler, Stephanie
Commons ID: eRA COMMONS USER NAME

Year (YYYY)	Person Months (##.##)
2021-2022	CAL. MONTHS
2022-2023	

*Title: Racial Disparities Hot-spotting to Improve Breast Cancer Outcomes in North Carolina

Major Goals: Our long-term goal is to develop a scalable, reproducible statewide program to localize racial gaps in cancer care quality across tumor types using administrative data and to engage community stakeholders in a bi-directional learning system developing and testing targeted interventions to close quality gaps.

*Status of Support: Active

Project Number: WITHHELD

Name of PD/PI: Reeder-Hayes

PRIVATE SUPPORT

*Primary Place of Performance: The University of North Carolina at Chapel Hill

Project/Proposal Start and End Date: (MM/YYYY) (if available): 01/01/2021-12/31/2022

* Total Award Amount (including Indirect Costs): $398,888

* Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
2022	CAL. MONTHS

*Title: Scaling Colorectal Cancer Screening Through Outreach, Referral, and Engagement (SCORE): A State-Level Program to Reduce Colorectal Cancer Burden in Vulnerable Populations

Major Goals: The long-term goal of this proposal is to reduce CRC disease burden and disparities in our region and nationally.

*Status of Support: Active

Project Number: 5-UH3-CA233251-03

Name of PD/PI: Reuland

*Source of Support: NIH/ National Cancer Institute

*Primary Place of Performance: The University of North Carolina at Chapel Hill

Project/Proposal Start and End Date: (MM/YYYY) (if available): 09/30/2018-08/31/2023

* Total Award Amount (including Indirect Costs): $3,031,921

* Person Months (Calendar/Academic/Summer) per budget period.

OMB No. 0925-0001 and 0925-0002 (Rev. 12/2020 Approved Through 02/28/2023)

Name of Individual: Wheeler, Stephanie
Commons ID: eRA COMMONS USER NAME

Year (YYYY)	Person Months (##.##)
2021-2022	CAL. MONTHS
2022-2023	

*Title: Optimizing Endocrine Therapy Adherence Through Motivational Interviewing and Text Interventions

Major Goals: The long-term goal of this research is to improve survival and reduce disparities in HR+ breast cancer by optimizing the delivery of widely available, highly effective and cost-effective ET through interventions to support ET adherence.

*Status of Support: Active

Project Number: 5-R01-CA237357-02

Name of PD/PI: Wheeler, Reeder-Hayes

*Source of Support: NIH/National Cancer Institute

*Primary Place of Performance: The University of North Carolina at Chapel Hill

Project/Proposal Start and End Date: (MM/YYYY) (if available): 09/01/2019-8/31/2024

* Total Award Amount (including Indirect Costs): $2,978,759

* Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
2021-2022	CAL. MONTHS
2022-2023	
2023-2024	

*Title: Addressing Cancer-Related Financial Toxicity in Rural Oncology Care Settings

Major Goals: Our long-term goal is to improve cancer care delivery, reduce FT, and improve outcomes in underserved, rural populations through sustainable, scalable interventions

*Status of Support: Active

Project Number: 5R01CA240092-03

Name of PD/PI: Wheeler, Rosenstein

*Source of Support: NIH, National Cancer Institute

*Primary Place of Performance: The University of North Carolina at Chapel Hill

Project/Proposal Start and End Date: (MM/YYYY) (if available): 08/15/2019-07/31/2023

* Total Award Amount (including Indirect Costs): $2,260,617

* Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
2021-2022	CAL. MONTHS

OMB No. 0925-0001 and 0925-0002 (Rev. 12/2020 Approved Through 02/28/2023)

Name of Individual: Wheeler, Stephanie
Commons ID: eRA COMMONS USER NAME

Year (YYYY)	Person Months (##.##)
2022-2023	CAL. MONTHS

*Title: Disparities in the Use of Oral Anticancer Agents in Kidney Cancer

Major Goals: The proposed study addresses this critical gap in our knowledge by using three complementary data sources to capture both nationally representative, yet diverse populations to include patients of all ages, insurance, geography, and race to study modifiable barriers to optimal OAA utilization and adherence at the level of patients, providers, facilities, and region.

*Status of Support: Active

Project Number: CON-80002965 (GR112429)

Name of PD/PI: Dinan

*Source of Support: NIH, Yale University

*Primary Place of Performance: The University of North Carolina at Chapel Hill

Project/Proposal Start and End Date: (MM/YYYY) (if available): 01/01/2021-12/31/2023

* Total Award Amount (including Indirect Costs): $212,368

* Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
2022	CAL. MONTHS
2023	

*Title: Cancer Prevention & Control Research Network Coordinating Center (SIP 19-004 CPCRN)

Major Goals: CPCRN centers undertake site-based and cross-site projects to accelerate the adoption and implementation of evidence-based cancer prevention and control programs.

*Status of Support: Active

Project Number: 5-U48-DP006400-01-02

Name of PD/PI: Ammerman

*Source of Support: CDC, Health Promotion and Disease Prevention Research Centers: 2019 Special Interest Project Competitive Supplements (SIPS)

*Primary Place of Performance: The University of North Carolina at Chapel Hill

Project/Proposal Start and End Date: (MM/YYYY) (if available): 09/30/2019-09/29/2024

* Total Award Amount (including Indirect Costs): $1,424,999

* Person Months (Calendar/Academic/Summer) per budget period.

OMB No. 0925-0001 and 0925-0002 (Rev. 12/2020 Approved Through 02/28/2023)

Name of Individual: Wheeler, Stephanie
Commons ID: eRA COMMONS USER NAME

Year (YYYY)	Person Months (##.##) (CPCRN)
2021-2022	CAL. MONTHS
2022-2023	
2023-2024	

*Title: Program Project-Improving Provider Announcement Communication Training (IMPACT)

Major Goals: The goal of IMPACT is to improve HPV vaccine communication and uptake among adolescents

*Status of Support: Active

Project Number: 1P01CA250989-01A1

Name of PD/PI: Brewer

*Source of Support: NIH/National Cancer Institute

*Primary Place of Performance: The University of North Carolina at Chapel Hill

Project/Proposal Start and End Date: (MM/YYYY) (if available): 09/23/2021-08/31/2026

* Total Award Amount (including Indirect Costs): $11,755,859

* Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##) (Project 4)	Person Months (##.##) (Admin Core)
2021-2022	CAL. MONTHS	
2022-2023		
2023-2024		
2024-2025		
2025-2026		

*Title: Understanding Cancer Health Disparities Among American Indians in North Carolina

*Major Goals: We seek to advance and expand the Southeastern American Indian cancer health equity partnership (SAICEP) by comprehensively describing cancer burden, assessing cancer-related needs and mapping community strengths in NC AI communities.

*Status of Support: Active

Project Number: WITHHELD

Name of PD/PI: Wheeler

*Source of Support: PRIVATE SUPPORT

*Primary Place of Performance: The University of North Carolina at Chapel Hill

Project/Proposal Start and End Date: (MM/YYYY) (if available): 05/01/2022 – 04/30/2023

* Total Award Amount (including Indirect Costs): $225,000

OMB No. 0925-0001 and 0925-0002 (Rev. 12/2020 Approved Through 02/28/2023)

Name of Individual: Wheeler, Stephanie
Commons ID: eRA COMMONS USER NAME

* Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
2022-2023	CAL. MONTHS

*Title: Development of Cancer Survivorship Risk Models to Inform Pathways of Care

Major Goals: Specifically, the proposed research will help develop a claims-based oncologic risk algorithm to predict recurrence & cancer-specific mortality.

*Status of Support: Active

Project Number: WITHHELD

Name of PD/PI: Dinan

*Source of Support: PRIVATE SUPPORT

*Primary Place of Performance: The University of North Carolina at Chapel Hill

Project/Proposal Start and End Date: (MM/YYYY) (if available): 07/01/2021-06/30/2026

* Total Award Amount (including Indirect Costs): $126,833

* Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
2021-2022	CAL. MONTHS
2022-2023	
2023-2024	
2024-2025	
2025-2026	

PENDING

PENDING SUPPORT

OMB No. 0925-0001 and 0925-0002 (Rev. 12/2020 Approved Through 02/28/2023)

PENDING SUPPORT

IN-KIND

None.

OMB No. 0925-0001 and 0925-0002 (Rev. 12/2020 Approved Through 02/28/2023)

PENDING SUPPORT

I, PD/PI or other senior/key personnel, 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: Stephanie Wheeler Digitally signed by Stephanie Wheeler Date: 2022.06.13 14:50:14 -04'00'

Date: 6/13/2022

OMB No. 0925-0001 and 0925-0002 (Rev. 12/2020 Approved Through 02/28/2023)

OTHER SUPPORT

*Name of Individual: Trogdon Justin
Commons ID: eRA COMMONS USER NAME

Other Support – Project/Proposal

ACTIVE

*Title: Center for Health Promotion and Disease Prevention

Major Goals: The Comprehensive Cancer Control Collaborative of North Carolina (4CNC), a Collaborating Center of the CPCRN, promotes the use of evidence-based interventions (EBIs) to prevent cancer, detect cancer at earlier stages, and improve treatment outcomes in communities across NC. We provide training, technical assistance, and tools to support the adoption and implementation of proven cancer prevention and control interventions and conduct research to understand factors that contribute to the effective implementation of evidence-based cancer prevention and control strategies. The 4CNC vision includes health care providers, community members, and researchers working together to reduce the burden of cancer, especially among those who are disproportionately affected.

*Status of Support: Pending

Project Number: U48-DP006400

Name of PD/PI: Ammerman, Alice

*Source of Support: DHHS, Centers for Disease Control (CDC)

*Primary Place of Performance: The University of North Carolina at Chapel Hill

Project/Proposal Start and End Date: (MM/YYYY) (if available): 09/30/2019 – 09/29/2024

* Total Award Amount (including Indirect Costs): $1,424,999

* Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
2021-2022	CAL. MONTHS
2022-2023	
2023-2024	

*Title: Medicaid Waiver Implementation

Major Goals: The Cecil G. Sheps Center for Health Services Research at UNC-Chapel Hill in partnership with NC DHHS will serve as Evaluators on the 1115 NC Medicaid Waiver Evaluation. We will continue to work closely with DHHS implement and refine the evaluation design to examine the effect of the 1115 Medicaid waiver on a variety of outcomes. We will provide rapid cycle reporting through data visualization, dashboard metrics, and interim reports.

*Status of Support: Active

Project Number: WITHHELD

Name of PD/PI: Holmes, George M.

*Source of Support: PRIVATE SUPPORT

OMB No. 0925-0001 and 0925-0002 (Rev. 12/2020 Approved Through 02/28/2023)

Name of Individual: Trogdon, Justin
Commons ID: eRA COMMONS USER NAME

*Primary Place of Performance: The University of North Carolina at Chapel Hill

Project/Proposal Start and End Date: (MM/YYYY) (if available): 07/01/2021 – 12/31/2026

* Total Award Amount (including Indirect Costs): $10,813,317

* Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
2022-2023	CAL. MONTHS
2023-2024	
2024-2025	
2025-2026	

*Title: Program Project – Improving Provider Announcement Communication Training (IMPACT) - DATA CORE; ADMINISTRATIVE CORE; and Project 2 The impact of clinic-level financial incentives on HPV vaccine communication and uptake

Major Goals: This grant funds a program Project on ways to improve provider communication about HPV vaccination and increase uptake among adolescents.

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.

Project 2: The impact of clinic-level financial incentives on HPV vaccine communication and uptake: 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.

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)."

*Status of Support: Active

Project Number: P01-CA250989

Name of PD/PI: Noel Brewer

*Source of Support: NIH National Cancer Institute

*Primary Place of Performance: The University of North Carolina at Chapel Hill Project/Proposal

Start and End Date: (MM/YYYY): 09/23/2021 – 08/31/2026

* Total Award Amount (including Indirect Costs): $11,755,859

* Person Months (Calendar/Academic/Summer) per budget period.

OMB No. 0925-0001 and 0925-0002 (Rev. 12/2020 Approved Through 02/28/2023)

Name of Individual: Trogdon, Justin
Commons ID: eRA COMMONS USER NAME

Year (YYYY)	Person Months – DATA CORE	Person Months - ADMINISTRATIVE CORE	Person Months - PROJECT 2 IMPACT OF FI
2021-2022	CAL. MONTHS		
2022-2023			
2023-2024			
2024-2025			
2025-2026			

*Title: Affordability and Efficiency for COMprehensive Post-Acute Stroke Services (COMPASS)

Major Goals: The overall goal of this study is to analyze the business case for both payers and hospital systems for the post-acute services for stroke included in COMPASS. The results will inform the design of an alternative payment models for post-acute stroke services that achieve lower cost without sacrificing quality of care.

*Status of Support: Active

Project Number: R01-HS025723

Name of PD/PI: Trogdon, Justin

*Source of Support: DHHS, Agency for Healthcare Research and Quality

*Primary Place of Performance: The University of North Carolina at Chapel Hill

Project/Proposal Start and End Date: (MM/YYYY) (if available): 08/01/2018-05/31/2023 (NCE)

* Total Award Amount (including Indirect Costs): $1,592,551

* Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
2022-2023	CAL. MONTHS

*Title: A Hybrid Effectiveness-Implementation Trial of Go NAPSACC: A Childcare-Based Obesity Prevention Program

Major Goals: This study will evaluate the effectiveness of the Go NAPSACC online program on the childcare centers' practices and compare Enhanced vs Basic implementation strategies impact on attempt to change the completeness of their efforts, continued use of the change process and effectiveness.

*Status of Support: Active

Project Number: R01-HL137929

Name of PD/PI: Ward, Dianne

*Source of Support: NIH, National Heart, Lung, and Blood Institute

*Primary Place of Performance: The University of North Carolina at Chapel Hill

Project/Proposal Start and End Date: (MM/YYYY) (if available): 08/15/2018-07/31/2023 (NCE)

OMB No. 0925-0001 and 0925-0002 (Rev. 12/2020 Approved Through 02/28/2023)

Name of Individual: Trogdon, Justin
Commons ID: eRA COMMONS USER NAME

* Total Award Amount (including Indirect Costs): $2,988,647

* Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
2021-2022	CAL. MONTHS
2022-2023	

PENDING

PENDING SUPPORT

OMB No. 0925-0001 and 0925-0002 (Rev. 12/2020 Approved Through 02/28/2023)

Name of Individual: Trogdon, Justin
Commons ID: eRA COMMONS USER NAME

I, PD/PI or other senior/key personnel, 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: Justin Trogdon Digitally signed by Justin Trogdon DN: cn=Justin Trogdon, o=University of North Carolina at Chapel Hill, ou=Health Policy and Management, email=trogdonj@email.unc.edu, c=US Date: 2022.06.22 08:24:29 -04'00'

Date: _____

OMB No. 0925-0001 and 0925-0002 (Rev. 12/2020 Approved Through 02/28/2023)

OTHER SUPPORT

*Name of Individual: Lisa Spees
Commons ID: eRA COMMONS USER NAME

Other Support – Project/Proposal

ACTIVE

*Title: Disparities in the Use of Oral Anticancer Agents in Kidney Cancer

Major Goals: In this study, we propose to use three complementary data sets to explore real world adoption, disparities, outcomes, and costs in AIM 1) using the SEER-Medicare linked claims data of nationally representative patients over the age of 65, AIM 2) The North Carolina State Cancer Registry and linked claims data base (CIPHR) data to examine patients of all ages in a demographically diverse setting, and AIM 3) examine future and evolving nationwide use of these technologies in the Medicare 20% data.

*Status of Support: Active

Project Number: CON-800002965 (GR112429) (Yale University); R01CA226842 (NIH)

Name of PD/PI: Wheeler, Shephanie

*Source of Support: NIH/Yale University

*Primary Place of Performance: The University of North Carolina at Chapel Hill

Project/Proposal Start and End Date: (MM/YYYY) (if available): 01/01/2021-12/31/2023

* Total Award Amount (including Indirect Costs): $212,368

* Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
2021-2022	CAL. MONTHS
2022-2023	

*Title: North Carolina Clinical Genomic Evaluation by Nest-gen Exome Sequencing 2

Major Goals: Genomic sequencing has the potential to allow patients with heterogeneous genetic disorders to receive a prompt and specific molecular diagnosis, allowing physicians, patients, and families to benefit from early management, treatment, and prevention. In this proposal we will generate the evidence necessary for a variety of stakeholders (patients, physicians, and payers) to determine when the use of this technology will result in an overall benefit.

*Status of Support: Active

Project Number: U01-HG006487

Name of PD/PI: Berg, Jonathan

*Source of Support: NIH, National Human Genome Research Institute

*Primary Place of Performance: The University of North Carolina at Chapel Hill

Project/Proposal Start and End Date: (MM/YYYY) (if available): 12/05/2011-05/31/2022

OMB No. 0925-0001 and 0925-0002 (Rev. 12/2020 Approved Through 02/28/2023)

Name of Individual: Lisa Spees
Commons ID: eRA COMMONS USER NAME

* Total Award Amount (including Indirect Costs): $22,717,612

* Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
2020-2021	CAL. MONTHS
2021-2022	

*Title: Program Project-Improving Provider Announcement Communication Training (IMPACT)

Major Goals: The goal of IMPACT is to improve HPV vaccine communication and uptake among adolescents

*Status of Support: Active

Project Number: P01-CA250989

Name of PD/PI: Brewer, Noel

*Source of Support: NIH, National Cancer Institute

*Primary Place of Performance: The University of North Carolina at Chapel Hill

Project/Proposal Start and End Date: (MM/YYYY) (if available): 09/23/2021 – 08/31/2026

* Total Award Amount (including Indirect Costs): $11,755,859

* Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
2021-2022	CAL. MONTHS
2022-2023	
2023-2024	
2024-2025	
2025-2026	

*Title: Understanding Cancer Health Disparities Among American Indians in North Carolina

Major Goals: North Carolina (NC) has the largest American Indian (AI) population east of the Mississippi River with 8 state and federally recognized tribes and 4 urban AI organizations; however, research on cancer in the AI population in NC is very limited, and this population is often misclassified in data reporting. This research will lay the groundwork for future efforts that target modifiable determinants of cancer health disparities and seek to strengthen and grow AI community-based resources that can improve cancer care delivery and outcomes in native populations.

*Status of Support: Active

Project Number: WITHHELD

Name of PD/PI: Wheeler, Stephanie

*Source of Support: PRIVATE SUPPORT

*Primary Place of Performance: The University of North Carolina at Chapel Hill

OMB No. 0925-0001 and 0925-0002 (Rev. 12/2020 Approved Through 02/28/2023)

Name of Individual: Lisa Spees
Commons ID: eRA COMMONS USER NAME

Project/Proposal Start and End Date: (MM/YYYY) (if available): 05/01/2022 – 05/01/2023

* Total Award Amount (including Indirect Costs): $225,000

* Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
2022-2023	CAL. MONTHS

*Title: Population-level Incidence, Treatment, and Outcomes of Patients with HER2 Indeterminate Breast Cancer

Major Goals: To characterize the prevalence of the HER2 low population in a NC breast cancer cohort; To characterize current HER2-based treatment and resource utilization in HER2 positive, negative, and low patients; To characterize outcomes of breast-cancer specific and overall survival (BCS & OS) in HER2 positive, negative, and low patients.

*Status of Support: Active

Project Number: Not assigned

Name of PD/PI: Wheeler, Stephanie

*Source of Support: PRIVATE SUPPORT

*Primary Place of Performance: The University of North Carolina at Chapel Hill

Project/Proposal Start and End Date: (MM/YYYY) (if available): 06/03/2021 – 06/03/2023

* Total Award Amount (including Indirect Costs): $138,132

* Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
2020-2021	CAL. MONTHS
2021-2022	

*Title: Rethink the Strip: De-adoption of Glucose Monitoring in Non-Insulin Treated Type 2 Diabetes in Primary Care

Major Goals: We propose estimating costs of de-adoption strategies in Rethink the Strip from the healthcare system perspective with the goal of informing their decision making related to adoption and implementation of Rethink the Strip strategies. Estimating the cost of strategies used to de-adopt low value practices is a novel contribution to our work and the D&I literature.

*Status of Support: Active

Project Number: WITHHELD

Name of PD/PI: Donahue, Katrina

*Source of Support: PRIVATE SUPPORT

*Primary Place of Performance: The University of North Carolina at Chapel Hill

Project/Proposal Start and End Date: (MM/YYYY) (if available): 02/01/2019 – 08/31/2022

* Total Award Amount (including Indirect Costs): $1,926,748

OMB No. 0925-0001 and 0925-0002 (Rev. 12/2020 Approved Through 02/28/2023)

Name of Individual: Lisa Spees
Commons ID: eRA COMMONS USER NAME

* Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
2021-2022	CAL. MONTHS

PENDING

PENDING SUPPORT

OMB No. 0925-0001 and 0925-0002 (Rev. 12/2020 Approved Through 02/28/2023)

PENDING SUPPORT

OMB No. 0925-0001 and 0925-0002 (Rev. 12/2020 Approved Through 02/28/2023)

Name of Individual: Lisa Spees
Commons ID: eRA COMMONS USER NAME

I, PD/PI or other senior/key personnel, 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: Lisa Spees Digitally signed by Lisa Spees Date: 2022.06.02 16:33:21 -04'00'

Date: 6/2/2022

OMB No. 0925-0001 and 0925-0002 (Rev. 10/2021 Approved Through 09/30/2024)

*Name of Individual: Ozawa, Sachiko
Commons ID: eRA COMMONS USER NAME

Other Support

Title: ***Assessing the Economic Burden of Covid-19 Vaccine Hesitancy in the US and Globally***

Major Goals: This grant funds research to evaluate the immediate impact of the Covid-19 outbreak and response measures on people's confidence in Covid-19 vaccines, by forecasting the expected demand and examining the economic burden of Covid-19 vaccine hesitancy.

Status of Support: Active

Project Number: No number Name of PD/PI: Ozawa

Source of Support: PRIVATE SUPPORT

Primary Place of Performance: University of North Carolina at Chapel Hill

Project/Proposal Start and End Date: (MM/YYYY) (if available): 04/19/2021 – 04/18/2023

Total Award Amount (including Indirect Costs): $399,890

Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
1. [2023]	CAL. MONTHS

Title: ***UNC-AESARA Market Access and Health Informatics Fellowship***

Major Goals: This grant funds research in market access, informatics and communication of evidence through a fellowship program between UNC and AESARA.

Status of Support: Active

Project Number: None Name of PD/PI: Ozawa, Sachiko/Seyerle, Amanda

Source of Support: PRIVATE SUPPORT

Primary Place of Performance: University of North Carolina at Chapel Hill

Project/Proposal Start and End Date: (MM/YYYY) (if available): 07/01/2021 – 06/30/2022

Total Award Amount (including Indirect Costs): $218,472

Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
1. [2022]	CAL. MONTHS

Title: ***Assessing the Burden of Misinformation on COVID-19 Vaccine Hesitancy in Canada***

OMB No. 0925-0001 and 0925-0002 (Rev. 10/2021 Approved Through 09/30/2024)

Name of Individual: Ozawa, Sachiko
Commons ID: eRA COMMONS USER NAME

Major Goals: This contract aims will use a quantitative model to estimate the economic costs of the contribution of misinformation to vaccine hesitancy in Canada.

Status of Support: Active

Project Number: None Name of PD/PI: Ozawa

Source of Support: PRIVATE SUPPORT

Primary Place of Performance: University of North Carolina at Chapel Hill

Project/Proposal Start and End Date: (MM/YYYY) (if available): 11/1/2021 – 08/31/2022

Total Award Amount (including Indirect Costs): $32,000

Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
1. [2022]	CAL. MONTHS

Title: ***Uterotonic Medication Quality: Contributions toward Universal Health Coverage***

Major Goals: This grant funds research to evaluate the immediate impact of the Covid-19 outbreak and response measures on people's confidence in Covid-19 vaccines, by forecasting the expected demand and examining the economic burden of Covid-19 vaccine hesitancy.

Status of Support: Active

Project Number: None

Name of PD/PI: Ozawa

Source of Support: PRIVATE SUPPORT

Primary Place of Performance: University of North Carolina at Chapel Hill

Project/Proposal Start and End Date: (MM/YYYY) (if available): 04/19/2021 – 04/18/2023

Total Award Amount (including Indirect Costs): $300,000

Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
1. [2023]	CAL. MONTHS

Title: ***Data 4 Impact (D4I): Costs of vertical versus horizontal programs in Nigeria***

Major Goals: This grant funds research to estimate the differences in costs between vertical verses horizontal health programs supported by USAID in Nigeria.

Status of Support: Active

Project Number: 7200AA18LA00008

Name of PD/PI: Jessica Fehringer

Source of Support: U.S. Agency for International Development

OMB No. 0925-0001 and 0925-0002 (Rev. 10/2021 Approved Through 09/30/2024)

Name of Individual: Ozawa, Sachiko
Commons ID: eRA COMMONS USER NAME

Primary Place of Performance: University of North Carolina at Chapel Hill

Project/Proposal Start and End Date: (MM/YYYY) (if available): 07/01/2020 – 09/30/2022

Total Award Amount (including Indirect Costs): $257,959

Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
1. [2022]	CAL. MONTHS

Title: ***Program Project – Improving Provider Announcement Communication Training (IMPACT)***

Major Goals: This grant will fund a Program Project on ways to improve provider communication about HPV vaccination and increase uptake among adolescents.

Status of Support: Active

Project Number: P01CA250989

Name of PD/PI: Brewer, Noel

Source of Support: National Institutes of Health

Primary Place of Performance: University of North Carolina at Chapel Hill

Project/Proposal Start and End Date: (MM/YYYY) (if available): 09/23/2021 – 08/31/2026

Total Award Amount (including Indirect Costs): $2,381,047

Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
1. [2022]	CAL. MONTHS
2. [2023]	
3. [2024]	
4. [2025]	
5. [2026]	

Title: ***The Broader Impact of Maternal Immunization in Sub-Saharan Africa and Asia: a multisite study in randomized clinical controlled trials***

Major Goals: 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.

Status of Support: Active

Project Number: WITHHELD

Name of PD/PI: Omer

Source of Support: PRIVATE SUPPORT

Primary Place of Performance: University of North Carolina at Chapel Hill

OMB No. 0925-0001 and 0925-0002 (Rev. 10/2021 Approved Through 09/30/2024)

Name of Individual: Ozawa, Sachiko
Commons ID: eRA COMMONS USER NAME

Project/Proposal Start and End Date: (MM/YYYY) (if available): 7/1/2019 – 12/31/2022

Total Award Amount (including Indirect Costs): $41,908

Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
1. [2022]	CAL. MONTHS

Title: ***Year 2: Estimating Health and Economic Costs of Substandard and Falsified Medicines, PQM+ Project***

Major Goals: This grant funds research to support the development of a model to estimate the costs of substandard and falsified medicines by reviewing existing models and data sources.

Status of Support: Active

Project Number: None

Name of PD/PI: Ozawa

Source of Support: PRIVATE SUPPORT

Primary Place of Performance: University of North Carolina at Chapel Hill

Project/Proposal Start and End Date: (MM/YYYY) (if available): 01/1/2022 – 09/30/2022

Total Award Amount (including Indirect Costs): $10,000

Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
1. [2022]	CAL. MONTHS

PENDING SUPPORT

OMB No. 0925-0001 and 0925-0002 (Rev. 10/2021 Approved Through 09/30/2024)

Name of Individual: Ozawa, Sachiko
Commons ID: eRA COMMONS USER NAME

PENDING SUPPORT

IN-KIND

*Summary of In-Kind Contribution: Collaboration with World Health Organization and Tanzania Medicines and Medical Devices Regulatory Authority

*Status of Support: Active

*Primary Place of Performance: University of North Carolina at Chapel Hill

Project/Proposal Start and End Date (MM/YYYY) (if available): ongoing

*Person Months (Calendar/Academic/Summer) per budget period

Year (YYYY)	Person Months (##.##)
1. [2022]	CAL. MONTHS

*Estimated Dollar Value of In-Kind Information:

OMB No. 0925-0001 and 0925-0002 (Rev. 10/2021 Approved Through 09/30/2024)

Name of Individual: Ozawa, Sachiko
Commons ID: eRA COMMONS USER NAME

***Overlap**:
There is no budgetary, scientific or commitment overlap. Potential future overlap will be resolved by working with funding agencies and project collaborators to adjust budget, level of effort and effective dates accordingly.

I, PD/PI or other senior/key personnel, 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: Sachiko Ozawa Digitally signed by Sachiko Ozawa Date: 2022.06.27 20:00:23 -10'00'

Date: June 27, 2022

OMB No. 0925-0001 and 0925-0002 (Rev. 10/2021 Approved Through 09/30/2024)

*Name of Individual: Tara L. Queen
Commons ID: eRA COMMONS USER NAME

Other Support – Project/Proposal

ACTIVE

*Title: Improving Provider Announcement Communication Training (IMPACT)

*Major Goals: This grant will fund a Program Project on ways to improve provider communication about HPV vaccination and increase uptake among adolescents.

*Status of Support: Active

Project Number: P01-CA250989

Name of PD/PI: Noel Brewer

*Source of Support: NCI

*Primary Place of Performance: The University of North Carolina at Chapel Hill

Project/Proposal Start and End Date: (MM/YYYY): 09/23/2021-08/31/2026

* Total Award Amount (including Indirect Costs): $11,755,859

* Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY-YYYY)	Person Months (##.##)
1. 2021-2022	CAL. MONTHS
2. 2022-2023	
3. 2023-2024	
4. 2024-2025	
5. 2025-2026	

*Title: Little Cigar and Cigarillo Warnings to Reduce Tobacco-Related Cancers and Disease

*Major Goals: The goal of the study to fill the existing gaps by understanding which LCC warning characteristics (i.e., content, format, size) are most influential in reducing LCC use, and how an additional LCC policy, the removal of flavor descriptors on packaging, influences the impact of LCC warnings.

*Status of Support: Active

Project Number: 5-R01-CA240732-02

Name of PD/PI: Adam Goldstein

*Source of Support: NCI

*Primary Place of Performance: The University of North Carolina at Chapel Hill

Project/Proposal Start and End Date: (MM/YYYY): 9/2/2019 – 8/31/2024

* Total Award Amount (including Indirect Costs): $1,205,358

* Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY-YYYY)	Person Months (##.##)
3. 2021-2022	CAL. MONTHS
4. 2022-2023	

OMB No. 0925-0001 and 0925-0002 (Rev. 10/2021 Approved Through 09/30/2024)

Name of Individual: Tara L. Queen
Commons ID: eRA COMMONS USER NAME

Year (YYYY-YYYY)	Person Months (##.##)
5. 2023-2024	CAL. MONTHS

*Title: Measuring the impact of structural racism and discrimination during adolescence on substance use, psychological distress, and criminal justice outcomes in adulthood

*Major Goals: The goal of this proposed study is to study the unique and interactive effects of adolescent experiences with structural racism and discrimination (SRD) on interactions with the criminal legal system, mental health substance use, and treatment-seeking in adulthood.

*Status of Support: Active

Project Number: 1-R01-DA056264-01

Name of PD/PI: Nisha C. Gottfredson, Tamara Taggart

*Source of Support: NIDA

*Primary Place of Performance: The University of North Carolina at Chapel Hill

Project/Proposal Start and End Date: (MM/YYYY): 05/15/2022 - 02/28/2026

* Total Award Amount (including Indirect Costs): $2,196,471.00

* Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY-YYYY)	Person Months (##.##)
1. 2022-2023	CAL. MONTHS
2. 2023-2024	
3. 2024-2025	
4. 2025-2026	

*Title: Designing and evaluating high-impact pictorial health warnings for food products

*Major Goals: The goal of this career development award is to design and evaluate pictorial health warnings for ultra-processed food using innovative methods including eye tracking and virtual store environments.

*Status of Support: Active

Project Number: 5-K01-HL147713-03

Name of PD/PI: Marissa Hall

*Source of Support: NHLBI

*Primary Place of Performance: The University of North Carolina at Chapel Hill

Project/Proposal Start and End Date: 07/15/2019 – 06/30/2024

* Total Award Amount (including Indirect Costs): $738,012.00

* Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
4. 2022-2023	CAL. MONTHS
5. 2023-2024	

OMB No. 0925-0001 and 0925-0002 (Rev. 10/2021 Approved Through 09/30/2024)

Name of Individual: Tara L. Queen
Commons ID: eRA COMMONS USER NAME

PENDING

PENDING SUPPORT

OMB No. 0925-0001 and 0925-0002 (Rev. 10/2021 Approved Through 09/30/2024)

PENDING SUPPORT

I, PD/PI or other senior/key personnel, 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: Tara L. Queen Digitally signed by Tara L. Queen Date: 2022.06.22 09:28:44 -04'00'

OMB No. 0925-0001 and 0925-0002 (Rev. 10/2021 Approved Through 09/30/2024)

Joseph G. Ibrahim
Commons ID: eRA COMMONS USER NAME

OTHER SUPPORT

ACTIVE

Supported Research Agreement

Major Goals: The Sponsor and the University agree to undertake a joint project in statistical research and training in statistical practice.

Status of Support: Active

Project Number: N/A

Name of PD/PI: Ibrahim

Source of Support: PRIVATE SUPPORT

Primary Place of Performance: UNC Chapel Hill

Project/Proposal Start and End Date: 07/2008 – 12/2022

Total Award Amount (including Indirect Costs): 2,926,314

Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
14. 2022	CAL. MONTHS

Methods for Interim Analysis with Incomplete Adjudication of Events

Major Goals: We propose to develop methods for analyzing outcome events assuming a Poisson process for the underlying event occurrence.

Status of Support: Active

Project Number: N/A

Name of PD/PI: Ibrahim

Source of Support: PRIVATE SUPPORT

Primary Place of Performance: UNC Chapel Hill

Project/Proposal Start and End Date: 07/2009 – 12/2022

Total Award Amount (including Indirect Costs): 2,327,430

Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
13. 2022	CAL. MONTHS

SPORE in Breast Cancer - Core B: Biostatistics & Bioinformatics

Major Goals: 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.

OMB No. 0925-0001 and 0925-0002 (Rev. 10/2021 Approved Through 09/30/2024)

Joseph G. Ibrahim
Commons ID: eRA COMMONS USER NAME

Status of Support: Active

Project Number: P50 CA058223

Name of PD/PI: Perou

Source of Support: National Cancer Institute

Primary Place of Performance: UNC Chapel Hill

Project/Proposal Start and End Date: 09/2018 - 08/2023

Total Award Amount (including Indirect Costs): 1,294,390

Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
4. 2022	CAL. MONTHS
5. 2023	

UNITS: The UNC / UT National Clinical Trials Network Group Integrated Translational Science Production and Consultation Center

Major Goals: 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.

Status of Support: Active

Project Number: UG1 CA233333

Name of PD/PI: Perou

Source of Support: National Cancer Institute

Primary Place of Performance: UNC Chapel Hill

Project/Proposal Start and End Date: 03/2019 – 02/2025

Total Award Amount (including Indirect Costs): 61,979,698

Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
4. 2023	CAL. MONTHS
5. 2024	
6. 2025	

Applying Novel Statistical Approaches to Develop a Decision Framework for Hybrid Randomized Controlled Trial Designs which Combine Internal Control Arms with Patients' Data from Real-world Data Source

Major Goals: The University of North Carolina (UNC) shall conduct research collaborations with Genentech on the use of the hybrid clinical trial designs that incorporate data from external controls focusing on trials with time-to-event and other endpoints.

OMB No. 0925-0001 and 0925-0002 (Rev. 10/2021 Approved Through 09/30/2024)

Joseph G. Ibrahim
Commons ID: eRA COMMONS USER NAME

Status of Support: Active

Project Number: Not Assigned

Name of PD/PI: Lieberman

Source of Support: PRIVATE SUPPORT

Primary Place of Performance: UNC Chapel Hill

Project/Proposal Start and End Date: 10/2020 – 08/2023

Total Award Amount (including Indirect Costs): 482,389

Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
2. 2022	CAL. MONTHS
3. 2023	

Cancer Center Support Grant: Biostatistics Core

Major Goals: The Lineberger Comprehensive Cancer Center (LCCC) forms the nexus for researchers focused on understanding and identifying the mechanisms leading to, the prevention of, and treatments for cancer. The Biostatistics Shared Resource (BIOS) provides access for LCCC faculty across the basic, clinical, translational and population science spectrum to an experienced staff and recognized national leaders in statistical modeling and analysis. The Center's breadth of science requires a broad range of expertise available in BIOS and includes for example: population sciences, psychometric analysis, clinical trial design and analysis, basic experimental science as well as "big data" –omics.

Status of Support: Active

Project Number: P30 CA016086

Name of PD/PI: Earp, III

Source of Support: National Cancer Institute

Primary Place of Performance: UNC Chapel Hill

Project/Proposal Start and End Date: 12/2020 – 11/2025

Total Award Amount (including Indirect Costs): 1,861,135

Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
2. 2022	CAL. MONTHS
3. 2023	
4. 2024	
5. 2025	

Program Project - Improving Provider Announcement Communication Training (IMPACT): Data Core

Major Goals: The goal of IMPACT is to improve HPV vaccine communication and uptake among adolescents. The projects will work together to enhance the impact of the Announcement Approach Training (AAT), a provider HPV vaccination communication training that received

designation as a Research-Tested Intervention Program (RTIP) from the National Cancer Institute. 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.

Status of Support: Active

Project Number: P01 CA250989

Name of PD/PI: Brewer

Source of Support: National Cancer Institute

Primary Place of Performance: UNC Chapel Hill

Project/Proposal Start and End Date: 09/2021 – 08/2026

Total Award Amount (including Indirect Costs): 1,898,975

Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
1. 2022	CAL. MONTHS
2. 2023	
3. 2024	
4. 2025	
5. 2026	

Complex Innovative Design Project for Genentech

Major Goals: The University of North Carolina will develop complex innovative designs for Genentech.

Status of Support: Active

Project Number: Not Assigned

Name of PD/PI: Ibrahim

Source of Support: PRIVATE SUPPORT

Primary Place of Performance: UNC Chapel Hill

Project/Proposal Start and End Date: 09/2019 – 10/2023

Total Award Amount (including Indirect Costs): 228,959

Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
3. 2022	CAL. MONTHS
4. 2023	

<u>PENDING</u>

None.

OMB No. 0925-0001 and 0925-0002 (Rev. 10/2021 Approved Through 09/30/2024)

Joseph G. Ibrahim
Commons ID: eRA COMMONS USER NAME

IN-KIND

Summary of In-Kind Contribution: Active Domestic Collaborations that have, and will continue to, support my research: PRIVATE SUPPORT: I Direct the Biostatistics Core which is an available resource to over 40 departments from across the University of North Carolina at Chapel Hill. Full details can be provided upon request.

Status of Support: Active

Primary Place of Performance: UNC Chapel Hill

Project/Proposal Start and End Date: N/A

Person Months per budget period:) Calendar

Estimated Dollar Value of In-Kind Information: N/A

Summary of In-Kind Contribution: PRIVATE SUPPORT Students supported by other funding: Approximately 10 graduate students and 2 undergraduate students work with me either on collaborative projects or in development of statistical methodologies. Some of these students are funded wholly or in part by sources other than my own grants; these other sources of funding are primarily from NIH.

Status of Support: Active

Primary Place of Performance: UNC Chapel Hill

Project/Proposal Start and End Date: N/A

Person Months per budget period: Calendar

Estimated Dollar Value of In-Kind Information: N/A

Summary of In-Kind Contribution: Active Foreign Collaboration that has, and will continue to, result in co-authored publications: Di Xiong, Visiting student from PRIVATE SUPPORT: I have several ongoing method papers with her group

Status of Support: Active

Primary Place of Performance: UNC Chapel Hill

Project/Proposal Start and End Date: N/A

Person Months per budget period: Calendar

Estimated Dollar Value of In-Kind Information: N/A

Overlap: None.

There is no scientific or fiscal overlap of Dr. Ibrahim's current commitments, and current efforts will be decreased as needed prior to any award such that commitment will not exceed 12 Calendar Months.

OMB No. 0925-0001 and 0925-0002 (Rev. 10/2021 Approved Through 09/30/2024)

Joseph G. Ibrahim
Commons ID: eRA COMMONS USER NAME

I, PD/PI or other senior/key personnel, 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 & Date: Joseph G. Ibrahim Digitally signed by Joseph G. Ibrahim Date: 2022.06.13 15:22:37 -04'00'

OMB No. 0925-0001 and 0925-0002 (Rev. 10/2021 Approved Through 09/30/2024)

*Name of Individual: Hernandez, Michelle L.
Commons ID: eRA COMMONS USER NAME

Other Support – Project/Proposal

*Title: IL-1 receptor Blockade as a Novel Treatment for Exacerbation of Allergic Airway Responses in Humans

*Major Goals: The goal of the studies is to test and demonstrate the feasibility of using anakinra as an effective adjunctive therapy to treat asthma exacerbations

*Status of Support: Active

Project Number: 5-R01HL135235-05

Name of PD/PI: Hernandez, Michelle

*Source of Support: NHLBI

*Primary Place of Performance: University of NC at Chapel Hill

Project/Proposal Start and End Date: (MM/YYYY) (if available): 08/2017-06/30/2022

* Total Award Amount (including Indirect Costs): $2,715,534

* Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
5. 2021-2022	CAL. MONTHS

*Title: Environment, Epigenetics, Neurodevelopment & Health of Extremely Preterm Children

*Major Goals: 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

*Status of Support: Active

Project Number: 5-UH3-OD023348-06

Name of PD/PI: O'Shea, M.

*Source of Support: NIH

*Primary Place of Performance: University of NC at Chapel Hill

Project/Proposal Start and End Date: (MM/YYYY) (if available): 09/2016-08/2023

* Total Award Amount (including Indirect Costs): $22,103,458

* Person Months (Calendar/Academic/Summer) per budget period.

OMB No. 0925-0001 and 0925-0002 (Rev. 10/2021 Approved Through 09/30/2024)

Name of Individual: Hernandez, Michelle L.
Commons ID: eRA COMMONS USER NAME

Year (YYYY)	Person Months (##.##)
6. 2021-2022	CAL. MONTHS
7. 2022-2023	

*Title: North Carolina Translational & Clinical Science Institute (NC TraCS)

*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.

*Status of Support: Active

Project Number: 5-UL1TR002489-05

Name of PD/PI: Buse, John

*Source of Support: NIH/NCATS

*Primary Place of Performance: University of NC at Chapel Hill

Project/Proposal Start and End Date: (MM/YYYY) (if available): 03/2018-02/2023

* Total Award Amount (including Indirect Costs): $47,058,714

* Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
4. 2021-2022	CAL. MONTHS
5. 2022-2023	

*Title: SCH: INT: Collaborative Research: A Data-Driven Approach for Enhancing Wearable Device Performance - A Study on Early Detection of Asthma Exacerbation

*Major Goals: In this proposal, we aim to provide an innovative framework for characterizing performance of wearable devices in the real-world based on contextual information of their usage, and demonstrate its value by focusing on its impact to early asthma exacerbation detection
*Status of Support: Active

Project Number: IIS1915169

OMB No. 0925-0001 and 0925-0002 (Rev. 10/2021 Approved Through 09/30/2024)

Name of Individual: Hernandez, Michelle L.
Commons ID: eRA COMMONS USER NAME

Name of PD/PI: Hernandez, Michelle L.-UNC, Lobaton, E.-NCSU

*Source of Support: NCSU/NSF

*Primary Place of Performance: University of NC at Chapel Hill

Project/Proposal Start and End Date: (MM/YYYY) (if available): 09/2019-08/2023

* Total Award Amount (including Indirect Costs): $333,000

* Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
3. 2021-2022	CAL. MONTHS
4. 2022-2023	

*Title: North Carolina Translational and Clinical Science Institute (NC TraCS) KL2

*Major Goals: Train KL2 Scholars to apply their disciplinary expertise to translational science and equip them with the strategic thinking and management skills needed to create and sustain transformative interdisciplinary research programs in a rapidly changing environment.

*Status of Support: Active

Project Number: 5-KL2-TR002490-05

Name of PD/PI: Weinberger, Morris

*Source of Support: NIH/NCATS

*Primary Place of Performance: University of NC at Chapel Hill

Project/Proposal Start and End Date: (MM/YYYY) (if available): 03/2018-02/2023

* Total Award Amount (including Indirect Costs): $10,834,596

* Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
4. 2021-2022	CAL. MONTHS
5. 2022-2023	

*Title: Developing a Brief Intervention for Parental Alcohol Socialization to be Delivered by Pediatric Providers: A Feasibility Study

*Major Goals: The long-term objective of this R34 Planning Grant is to develop and assess feasibility of an initial version of the Brief Intervention to Prevent Alcohol Socialization (BI-PAS),

OMB No. 0925-0001 and 0925-0002 (Rev. 10/2021 Approved Through 09/30/2024)

Name of Individual: Hernandez, Michelle L.
Commons ID: eRA COMMONS USER NAME

which will be delivered to parents of rising 6th graders by pediatric healthcare practitioners during the annual well-child visit. Messages contained within the brief encounter with providers will be bolstered by weekly text messages that contain tailored intervention content based on parents' self-reported attitudes about adolescent alcohol use

*Status of Support: Active

Project Number: 5 R34AA028856-01A1

Name of PD/PI: Gottfredson, Nisha

*Source of Support: NIH/NIAAA

*Primary Place of Performance: University of NC at Chapel Hill

Project/Proposal Start and End Date: (MM/YYYY) (if available): 09/2021-08/2024

* Total Award Amount (including Indirect Costs): $670,593

* Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
1. 2021-2022	CAL. MONTHS
2. 2022-2023	
3. 2023-2024	

*Title: Program Project – Improving Provider Announcement Communication Training (IMPACT)

*Major Goals: The goal of IMPACT is to improve HPV vaccine communication and coverage 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 large healthcare systems; and 3) Support implementation of interventions to improve HPV vaccine uptake in large healthcare systems.

*Status of Support: Active

Project Number: 1-P01CA250989-01A1

Name of PD/PI: Brewer, Noel

*Source of Support: NIH/NCI

*Primary Place of Performance: University of NC at Chapel Hill

Project/Proposal Start and End Date: (MM/YYYY) (if available): 09/2021-08/2026

* Total Award Amount (including Indirect Costs): $11,755,859

* Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
1. 2021-2022	CAL. MONTHS

OMB No. 0925-0001 and 0925-0002 (Rev. 10/2021 Approved Through 09/30/2024)

Name of Individual: Hernandez, Michelle L.
Commons ID: eRA COMMONS USER NAME

Year (YYYY)	Person Months (##.##)
2. 2022-2023	CAL. MONTHS
3. 2023-2024	
4. 2024-2025	
5. 2025-2026	

*Title: PANDEMIC RESPONSE REPOSITORY - MICROBIAL AND IMMUNE SURVEILLANCE AND EPIDEMIOLOGY (PREMISE): ENTEROVIRUS D68 (EV-D68) PILOT STUDY

*Major Goals: Our study will focus on the pathogen enterovirus-D68. We will be collecting pediatric blood specimens from neonatal to 10 years of age with repeat samples over a 2-year period. Those specimens will be processed and stored in a biorepository at UNC, then periodically shipped to the NIH/NIAID Vaccine Research Center for use in biomedical research focused on the above deliverables.

*Status of Support: Active

Project Number: 1001629480 FY22.1135-UNC; UC Denver HHSN261201500003

Name of PD/PI: Vogt, Matthew UNC-CH; Messacar, Kevin UC Denver

*Source of Support: UC Denver/Leidos Biomed Res, Inc. (DHHS/NIH/NCI)

*Primary Place of Performance: University of NC at Chapel Hill

Project/Proposal Start and End Date: (MM/YYYY) (if available): 07/2021-06/2023

* Total Award Amount (including Indirect Costs): $426,641

* Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
1. 2021-2022	CAL. MONTHS
2. 2022-2023	

*Title: 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) Primary Prevention of Asthma and Wheezing in Children-CCC Lead Application (CORE)

*Major Goals: To test the hypothesis that Bronchovaxom, given to 6-18 month old children at high risk for asthma, can prevent the development of persistent wheezing by age 3.5-4.5 years

*Status of Support: Active

Project Number: UNC #463942; U. Ariz. 5-U01HL130045-05

Name of PD/PI: Davis, Stephanie-UNC; Martinez, Fernando-U. Ariz

OMB No. 0925-0001 and 0925-0002 (Rev. 10/2021 Approved Through 09/30/2024)

Name of Individual: Hernandez, Michelle L.
Commons ID: eRA COMMONS USER NAME

*Source of Support: U. Arizona/NHLBI

*Primary Place of Performance: University of NC at Chapel Hill

Project/Proposal Start and End Date: (MM/YYYY) (if available): 07/2018-04/2023

* Total Award Amount (including Indirect Costs): $439,587

* Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
5. 2021-2022	CAL. MONTHS
6. 2022-2023	

*Title: Mapping the Pediatric Inhalation Interface: Nose, Mouth, and Airways

*Major Goals: To engage diverse communities and create an open-access single-cell/spatial multi-omic atlas of the oral, nasal and pulmonary interface in infancy, childhood and adolescence

*Status of Support: Active

Project Number: WITHHELD

Name of PD/PI: Hagood, Jim

*Source of Support: PRIVATE SUPPORT

*Primary Place of Performance: University of NC at Chapel Hill

Project/Proposal Start and End Date: (MM/YYYY) (if available): 10/2021-09/2024

* Total Award Amount (including Indirect Costs): $3,499,788

* Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
1. 2021-2022	CAL. MONTHS
2. 2022-2023	
3. 2023-2024	

*Title: REGISTRY OF ASTHMA PATIENTS INITIATING DUPIXENT® (RAPID) R668-AS-1885

*Major Goals: Clinical Trial- The primary objective of the study is to characterize the patients who initiate treatment for asthma with DUPIXENT in a real-world setting

OMB No. 0925-0001 and 0925-0002 (Rev. 10/2021 Approved Through 09/30/2024)

Name of Individual: Hernandez, Michelle L.
Commons ID: eRA COMMONS USER NAME

*Status of Support: Active

Project Number: WITHHELD

Name of PD/PI: Hernandez, Michelle

*Source of Support: PRIVATE SUPPORT

*Primary Place of Performance: University of NC at Chapel Hill

Project/Proposal Start and End Date: (MM/YYYY) (if available): 10/2021-10/2024

* Total Award Amount (including Indirect Costs): $86,093 milestone based

* Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
1. 2021-2022	CAL. MONTHS
2. 2022-2023	
3. 2023-2024	

*Title: Rural Health Carolina Link

*Major Goals: Children's Outreach

*Status of Support: Active

Project Number: CHMED

Name of PD/PI: Steiner, Mike

*Source of Support: PRIVATE SUPPORT

*Primary Place of Performance: University of NC at Chapel Hill

Project/Proposal Start and End Date: (MM/YYYY) (if available): 2021-2023

* Total Award Amount (including Indirect Costs): $20,000

* Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
1. 2021-2022	CAL. MONTHS
2. 2022-2023	

*Title: Per- and polyfluoroalkyl substances in children and impaired antibody response to COVID-19 vaccination-Pilot Award-CEHS

OMB No. 0925-0001 and 0925-0002 (Rev. 10/2021 Approved Through 09/30/2024)

Name of Individual: Hernandez, Michelle L.
Commons ID: eRA COMMONS USER NAME

*Major Goals: This is a pilot and feasibility study to collect preliminary data on the association between blood levels of per- and polyfluoroalkyl substances in children and antibody response to vaccination against SARS-CoV-2

*Status of Support: Active

Project Number: 5-P30ES010126-21

Name of PD/PI: Troester, Melissa Overall PI; Pilot Award PI: Starling, Anne

*Source of Support: NIH/NIEHS

*Primary Place of Performance: University of NC at Chapel Hill

Project/Proposal Start and End Date: (MM/YYYY) (if available): 03/2022-02/2023

* Total Award Amount (including Indirect Costs): $49,329

* Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
1. 2022-2023	CAL. MONTHS

OMB No. 0925-0001 and 0925-0002 (Rev. 10/2021 Approved Through 09/30/2024)

Name of Individual: Hernandez, Michelle L.
Commons ID: eRA COMMONS USER NAME

PENDING

PENDING SUPPORT

OMB No. 0925-0001 and 0925-0002 (Rev. 10/2021 Approved Through 09/30/2024)

PENDING SUPPORT

OMB No. 0925-0001 and 0925-0002 (Rev. 10/2021 Approved Through 09/30/2024)

PENDING SUPPORT

OMB No. 0925-0001 and 0925-0002 (Rev. 10/2021 Approved Through 09/30/2024)

PENDING SUPPORT

OMB No. 0925-0001 and 0925-0002 (Rev. 10/2021 Approved Through 09/30/2024)

Name of Individual: Hernandez, Michelle L.
Commons ID: eRA COMMONS USER NAME

IN-KIND

*NONE

***Overlap** (summarized for each individual):

There is no scientific or budgetary overlap.

I, PD/PI or other senior/key personnel, 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: Michelle Hernandez Digitally signed by Michelle Hernandez Date: 2022.04.26 20:50:40 -04'00'

Date: April 26, 2022

OMB No. 0925-0001 and 0925-0002 (Rev. 10/2021 Approved Through 09/30/2024)

PHS OTHER SUPPORT
For All Application Types – DO NOT SUBMIT UNLESS REQUESTED

There is no "form page" for reporting Other Support. Information on Other Support should be provided in the format shown below.

*Name of Individual: **Melissa Gilkey**
Commons ID: eRA COMMONS USER NAME

Other Support – Project/Proposal

*Title: **Impact of AFIX and Physician-to-Physician Engagement on HPV Vaccination in Primary Care: An RCT**

*Major Goals: This randomized clinical trial will compare two strategies for improving HPV vaccination in primary care: AFIX (or Assessment Feedback Incentives and eXchange) and P2P (or physician-to-physician engagement). Working with health departments in three states, 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.

*Status of Support: ACTIVE

Project Number: **U01 IP001073**

Name of PD/PI: MPIs Brewer/Gilkey

*Source of Support: CDC

*Primary Place of Performance: The University of North Carolina at Chapel Hill

Project/Proposal Start and End Date: 08/01/2017 – 07/31/2022

* Total Award Amount (including Indirect Costs): $1,499,255

* Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
08/01/21 – 07/31/22 (NCE)	CAL. MONTHS

*Title: **Evaluating the Feasibility of a Mobile Coaching Intervention to Improve HPV Vaccine Delivery**

*Major Goals: This study will test the feasibility of a mobile coaching intervention to improve healthcare providers' communication about HPV vaccination. The intervention consists of a brief in-clinic training for healthcare teams, followed by 12 weeks of individualized coaching for providers via a mobile application.

*Status of Support: ACTIVE

Project Number: **R21CA241518**

Name of PD/PI: Gilkey

*Source of Support: NIH

*Primary Place of Performance: The University of North Carolina at Chapel Hill

OMB No. 0925-0001 and 0925-0002 (Rev. 10/2021 Approved Through 09/30/2024)

Name of Individual: Melissa Gilkey
Commons ID: eRA COMMONS USER NAME

Project/Proposal Start and End Date: 09/20/2019 – 07/31/2022

* Total Award Amount (including Indirect Costs): $399,363

* Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
08/01/21 – 07/31/22	CAL. MONTHS

*Title: **Provider-Focused Multi-Component Intervention for Maximizing HPV Vaccine Uptake in Young Cancer Survivors receiving Follow-Up Care in Pediatric Oncology Practices**

*Major Goals: This study will be providing implementation science expertise, specifically regarding i) testing and implementing provider-focused interventions to increase HPV vaccine uptake (how these interventions have been carried out successfully in the general population and how those might be adapted in pediatric oncology); and ii) use of state vaccine registry data for measuring baseline and post-intervention vaccine rates.

*Status of Support: ACTIVE

Project Number: **000526841-SC002**

Name of PD/PI: Landier/Gilkey

*Source of Support: NIH/NCI/UAB

*Primary Place of Performance: The University of North Carolina at Chapel Hill

Project/Proposal Start and End Date: 09/18/2020 – 08/31/2022

* Total Award Amount (including Indirect Costs): $51,064

* Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
09/01/21 – 08/31/22	CAL. MONTHS

*Title: **Engaging Specialty Care Teams to Help Families Discuss and Manage the Cost of Asthma Care**

*Major Goals: 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.

*Status of Support: ACTIVE

Project Number: WITHHELD

Name of PD/PI: Gilkey

*Source of Support: PRIVATE SUPPORT

*Primary Place of Performance: The University of North Carolina at Chapel Hill

Project/Proposal Start and End Date: 03/01/2020 – 09/30/2022

* Total Award Amount (including Indirect Costs): $400,000

OMB No. 0925-0001 and 0925-0002 (Rev. 10/2021 Approved Through 09/30/2024)

Name of Individual: Melissa Gilkey
Commons ID: eRA COMMONS USER NAME

* Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
03/01/22 – 09/30/22 (NCE)	CAL. MONTHS

*Title: **Connecting Behavioral Science to Covid-19 Vaccine Demand (CBS-CVD) Network**

*Major Goals: This supplement to UNC's Prevention Research Center award will fund projects to support Covid-19 vaccine confidence, uptake, and equity in North Carolina primary care clinics.

*Status of Support: ACTIVE

Project Number: **U48DP006400-02-01**

Name of PD/PI: Ammerman

*Source of Support: CDC

*Primary Place of Performance: The University of North Carolina at Chapel Hill

Project/Proposal Start and End Date: 05/11/2021 – 09/10/2022

* Total Award Amount (including Indirect Costs): $500,000

* Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
05/11/21 – 09/10/22	CAL. MONTHS

*Title: **Effectiveness and mechanisms of multilevel implementation strategies to improve provider recommendation and advance HPV vaccination: a cluster randomized trial**

*Major Goals: This randomized clinical trial will assess the effectiveness of a multi-level intervention to improve HPV vaccination coverage among adolescents in a large integrated delivery system.

*Status of Support: ACTIVE

Project Number: **R01CA255872**

Name of PD/PI: Chao/Gilkey

*Source of Support: NCI/Kaiser Foundation Research Institute

*Primary Place of Performance: The University of North Carolina at Chapel Hill

Project/Proposal Start and End Date: 07/15/2021 – 06/30/2026

* Total Award Amount (including Indirect Costs): $10,843

* Person Months (Calendar/Academic/Summer) per budget period.

OMB No. 0925-0001 and 0925-0002 (Rev. 10/2021 Approved Through 09/30/2024)

Name of Individual: Melissa Gilkey
Commons ID: eRA COMMONS USER NAME

Year	Person Months
07/15/21 – 06/30/22	CAL. MONTHS
07/01/22 – 06/30/23	
07/01/23 – 06/30/24	
07/01/24 – 06/30/25	
07/01/25 – 06/30/26	

*Title: **Developing a Brief Intervention for Parental Alcohol Socialization to be Delivered by Pediatric Providers: A Feasibility Study**

*Major Goals: The long-term objective of this R34 Planning Grant is to develop and assess feasibility of an initial version of the Brief Intervention to Prevent Alcohol Socialization (BI-PAS), which will be delivered to parents of rising 6th graders by pediatric healthcare practitioners (PHP; e.g., physicians, nurses) during the annual well-child visit.

*Status of Support: ACTIVE

Project Number: **R34AA028856**

Name of PD/PI: Gottfredson

*Source of Support: NIH/NIAAA

*Primary Place of Performance: The University of North Carolina at Chapel Hill

Project/Proposal Start and End Date: 09/25/2021 – 08/31/2024

* Total Award Amount (including Indirect Costs): $223,531

* Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
09/25/21 – 08/31/22	CAL. MONTHS
09/01/22 – 08/31/23	
09/01/23 – 08/31/24	

*Title: **Program Project – Improving Provider Announcement Communication Training (IMPACT)**

*Major Goals: This grant will fund a Program Project on ways to improve provider communication about HPV vaccination and increase uptake among adolescents.

*Status of Support: ACTIVE

Project Number: **P01CA250989**

Name of PD/PI: Brewer

*Source of Support: NIH

*Primary Place of Performance: The University of North Carolina at Chapel Hill

Project/Proposal Start and End Date: 09/23/2021 – 08/31/2026

* Total Award Amount (including Indirect Costs): $13,999,475

OMB No. 0925-0001 and 0925-0002 (Rev. 10/2021 Approved Through 09/30/2024)

Name of Individual: Melissa Gilkey
Commons ID: eRA COMMONS USER NAME

* Person Months (Calendar/Academic/Summer) per budget period.

Year	Person Months
09/23/21 – 08/31/22	CAL. MONTHS
09/01/22 – 08/31/23	
09/01/23 – 08/31/24	
09/01/24 – 08/31/25	
09/01/25 – 08/31/26	

IN-KIND

***Summary of In-Kind Contribution**: Dr. Gilkey serves as a mentor to Brigid Grabert, a PostDoc who is supported by T32-CA057726, which supports five pre- and three postdoctoral fellows yearly and train them for careers in cancer prevention and control that emphasize multidisciplinary and collaborative research. Salary is supported by UNC-Chapel Hill.

*Status of Support: ACTIVE

Project Number: **5-T32-CA057726-28**

Name of PD/PI: Kurt Ribisl

*Primary Place of Performance: The University of North Carolina at Chapel Hill

Project/Proposal Start and End Date 07/01/2019 - 06/30/2022

*Person Months (Calendar/Academic/Summer) per budget period: 0 calendar

*Estimated Dollar Value of In-Kind Information: $0

***Overlap** (summarized for each individual):

NONE

I, PD/PI or other senior/key personnel, 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: Melissa Gilkey Digitally signed by Melissa Gilkey Date: 2022.04.25 15:31:22 -04'00'

Date: April 25, 2022

OMB No. 0925-0001 and 0925-0002 (Rev. 12/2020 Approved Through 02/28/2023)

Name of Individual: Cox, Elizabeth
Commons ID: eRA COMMONS USER NAME

OTHER SUPPORT

ACTIVE

Title: ICTR CAP Program of Research on Outcomes for Kids
Major Goals: The goal of this project is to design and deliver resources that will equip researchers with specific skills to improve health and healthcare for children.
Status of Support: Active, in NCE
Project Number: UL1 TR002373
Name of PD/PI: Brasier
Source of Support: National Institutes of Health (NIH) & University of Wisconsin Institute for Clinical and Translational Research (UW ICTR)
Primary Place of Performance: University of Wisconsin-Madison
Project/Proposal Start and End Date: 04/2019-08/2022
Total Award Amount (including Indirect Costs): $199,860
Person Months per budget period:

Year (YYYY)	Person Months
3. 2022	CAL. MONTHS

Title: Building a Translational Research Pipeline to Personalize Diabetes Prevention and Treatment
Major Goals: To facilitate multi-disciplinary translational diabetes research and to demonstrate the efficacy of this resource in the development of personalized medicine for diabetes (both type 1 and type 2).
Status of Support: Active, in NCE
Project Number: WITHHELD
Name of PD/PI: Cox
Source of Support: PRIVATE SUPPORT
Primary Place of Performance: University of Wisconsin-Madison
Project/Proposal Start and End Date: 07/2018-04/2023. *Effective 07/01/20, project entered a no-cost extension period.*
Total Award Amount (including Indirect Costs): $511,656
Person Months per budget period:

Year (YYYY)	Person Months
4. 2022	CAL. MONTHS
5. 2023	

Title: Engaging Families as Care Partners in Community Nursing Homes
Major Goals: This project's goal is to collaborate with stakeholders from community nursing homes in Wisconsin (e.g., leadership, staff, residents, and families) to form a sustainable nursing home network to identify, synthesize, share, and implement effective strategies to engage families in the care of nursing home residents.
Status of Support: Active, in NCE
Project Number: WITHHELD
Name of PD/PI: Cox & Roberts
Source of Support: PRIVATE SUPPORT
Primary Place of Performance: University of Wisconsin-Madison
Project/Proposal Start and End Date: 07/2018-12/2022. *Effective 07/01/20, project entered a no-cost extension period.*
Total Award Amount (including Indirect Costs): $120,000
Person Months per budget period:

Year (YYYY)	Person Months
4. 2022	CAL. MONTHS

OMB No. 0925-0001 and 0925-0002 (Rev. 12/2020 Approved Through 02/28/2023)

Name of Individual: Cox, Elizabeth
Commons ID: eRA COMMONS USER NAME

Title: On-Time HPV Vaccination for Rural Wisconsin Youth
Major Goals: 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.*
Status of Support: Active
Project Number: WITHHELD
Name of PD/PI: Cox
Source of Support: PRIVATE SUPPORT
Primary Place of Performance: University of Wisconsin-Madison
Project/Proposal Start and End Date: 05/2020-10/2022. *Effective 05/01/21, project entered a no-cost extension period.*
Total Award Amount (including Indirect Costs): $75,000
Person Months per budget period:

Year (YYYY)	Person Months
2. 2022	CAL. MONTHS

Title: Expanding the evidence-base for prevention strategies to improve the health of women, infants, and families
Major Goals: 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.
Status of Support: Active
Project Number: U48DP006383
Name of PD/PI: Cox
Source of Support: Centers for Disease Control (CDC)
Primary Place of Performance: University of Wisconsin-Madison
Project/Proposal Start and End Date: 09/2019-09/2024
Total Award Amount (including Indirect Costs): $3,749,827
Person Months per budget period:

Year (YYYY)	Person Months
3. 2022	CAL. MONTHS
4. 2023	
5. 2024	

Title: Connecting Behavioral Science to COVID-19 Vaccine Demand (COVID Supplement)
Major Goals: Working in close collaboration with our community partners, this project will: (1) use existing and newly collected mixed methods data to determine attitudes, barriers, and facilitators to vaccine uptake among rural providers and families with children; (2) co-design interventions components with key stakeholders; and 3) evaluate their impact.
Status of Support: Active, in NCE
Project Number: U48DP006383; (UW: AAJ2529)
Name of PD/PI: Cox
Source of Support: Centers for Disease Control (CDC)
Primary Place of Performance: University of Wisconsin-Madison
Project/Proposal Start and End Date: 05/2021-09/2022
Total Award Amount (including Indirect Costs): $499,999
Person Months per budget period:

Year (YYYY)	Person Months
1. 2022	CAL. MONTHS

OMB No. 0925-0001 and 0925-0002 (Rev. 12/2020 Approved Through 02/28/2023)

Name of Individual: Cox, Elizabeth
Commons ID: eRA COMMONS USER NAME

Title: Primary Care Research Fellowship
Major Goals: The main objective of the fellowship is to train primary care physicians and PhD scientists to become independent investigators in the areas of organization, delivery, or effectiveness of primary health care and preventive medicine
Status of Support: Active
Project Number: T32HP10010
Name of PD/PI: Barrett
Source of Support: Health Resources & Services (HRSA)
Primary Place of Performance: University of Wisconsin-Madison
Project/Proposal Start and End Date: 07/2021-06/2026
Total Award Amount (including Indirect Costs): $2,524,669
Person Months per budget period:

Year (YYYY)	Person Months
1. 2022	CAL. MONTHS
2. 2023	
3. 2024	
4. 2025	
5. 2026	

Title: Clinic Catchment Areas To Address Cervical Cancer Prevention in Wisconsin
Major Goals: This study will use geospatial techniques to link catchment areas for Wisconsin primary care clinics with publicly available demographic and health data. Results will identify clinics that serve high risk populations and also populations without a source of cervical cancer prevention services.
Status of Support: Active
Project Number: WITHHELD
Name of PD/PI: Cox
Source of Support: PRIVATE SUPPORT (OVCRGE)
Primary Place of Performance: University of Wisconsin-Madison
Project/Proposal Start and End Date: 07/2021-06/2022
Total Award Amount (including Indirect Costs): $55,526
Person Months per budget period:

Year (YYYY)	Person Months
1. 2022	CAL. MONTHS

Title: Optimizing Secondary Acceptance of Human Papillomavirus Vaccine
Major Goals: This project examines the effectiveness of care processes in response to families initially decline the HPV vaccination.
Status of Support: Active
Project Number: WITHHELD
Name of PD/PI: Cox
Source of Support: PRIVATE SUPPORT
Primary Place of Performance: University of Wisconsin-Madison
Project/Proposal Start and End Date: 11/2021-10/2023
Total Award Amount (including Indirect Costs): $50,000
Person Months per budget period:

OMB No. 0925-0001 and 0925-0002 (Rev. 12/2020 Approved Through 02/28/2023)

Name of Individual: Cox, Elizabeth
Commons ID: eRA COMMONS USER NAME

Year (YYYY)	Person Months
1. 2022	CAL. MONTHS
2. 2023	

Title: Improving Provider Announcement Communication Training (IMPACT) Program Project
Major Goals: This study will implement and evaluate the Announcement Approach to HPV vaccination across at least 10 Wisconsin primary care clinics to bring this evidence-based practice into real world clinical settings.
Status of Support: Active
Project Number: P01 CA250989
Name of PD/PI: Gilkey
Source of Support: National Institutes of Health/National Cancer Institute (NIH/NCI) & University of North Carolina
Primary Place of Performance: University of North Carolina
Project/Proposal Start and End Date: 09/2021-08/2026
Total Award Amount (including Indirect Costs): $769,810, total UW site project costs

Person Months per budget period:

Year (YYYY)	Person Months
1. 2022	CAL. MONTHS
2. 2023	
3. 2024	
4. 2025	
5. 2026	

PENDING

PENDING SUPPORT

OMB No. 0925-0001 and 0925-0002 (Rev. 12/2020 Approved Through 02/28/2023)

PENDING SUPPORT

OMB No. 0925-0001 and 0925-0002 (Rev. 12/2020 Approved Through 02/28/2023)

PENDING SUPPORT

ATTESTATION

I, PD/PI or other senior/key personnel, 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: DocuSigned by: Elizabeth D. Cox B8B34DD7B45B46C...

Date: 6/13/2022

OMB No. 0925-0001 and 0925-0002 (Rev. 10/2021 Approved Through 09/30/2024)

For New and Renewal Applications – DO NOT SUBMIT UNLESS REQUESTED
PHS 398 OTHER SUPPORT

*Name of Individual: **Calo, William Alexis**
Commons ID: eRA COMMONS USER NAME

Other Support – Project/Proposal

ACTIVE

*Title: **COVID-19 Project ECHO for Nursing Homes: A Patient-centered, Randomized-controlled Trial to Implement Infection Control and Quality of Life Best Practices**

Major Goals: The goal of this project is to compare the effectiveness of COVID-19 Project ECHO intervention with usual care in reducing nursing home resident with COVID-19 infections.

*Status of Support: Active

Project Number: WITHHELD

Name of PD/PI: Kraschnewski

*Source of Support: PRIVATE SUPPORT

*Primary Place of Performance: The Pennsylvania State University, Hershey, PA

Project/Proposal Start and End Date: (MM/YYYY) (if available): 09/2020 – 12/2023

* Total Award Amount (including Indirect Costs): $2,542,028 TA

* Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
2. 2022	CAL. MONTHS
3. 2023	

*Title: **HPV ECHO: Increasing the adoption of evidence-based communication strategies for HPV vaccination in rural primary care practices**

Major Goals: The goal of this project is to demonstrate the effectiveness of a highly efficient and scalable implementation strategy, ECHO, to support HPV vaccination in rural clinics.

*Status of Support: Active

Project Number: R37 CA253279

Name of PD/PI: Calo

*Source of Support: NIH

*Primary Place of Performance: The Pennsylvania State University, Hershey, PA

Project/Proposal Start and End Date: (MM/YYYY) (if available): 08/2020 – 04/2025

* Total Award Amount (including Indirect Costs): $1,864,061

* Person Months (Calendar/Academic/Summer) per budget period.

OMB No. 0925-0001 and 0925-0002 (Rev. 12/2020 Approved Through 02/28/2023)

Name of Individual: **Calo, William Alexis**
Commons ID: eRA COMMONS USER NAME

Year (YYYY)	Person Months (##.##)
2. 2022	CAL. MONTHS
3. 2023	
4. 2024	
5. 2025	

*Title: **Nurse AMIE: Addressing Metastatic Individuals Every day in Rural PA and WV**

Major Goals: To determine whether a distance based supportive care intervention (Nurse AMIE) will have significant effects on rural patients overall survival (primary outcome), cancer treatment-related symptoms, function, and health related quality of life.

*Status of Support: Active

Project Number: R01CA254659

Name of PD/PI: Schmitz, Kathryn

*Source of Support: NIH/NCI

*Primary Place of Performance: The Pennsylvania State University, Hershey, PA

Project/Proposal Start and End Date: (MM/YYYY) (if available): 06/2021 – 04/2026

* Total Award Amount (including Indirect Costs): $3,221,457

* Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
2. 2022	CAL. MONTHS
3. 2023	
4. 2024	
5. 2025	

*Title: **Better Together: Enhancing Hispanic Health in Rural Pennsylvania through Healthy Lifestyle Strategies**

Major Goals: The major goals of this project are to evaluate multi-level locally tailored practice- and evidence-based strategies related to nutrition, physical activity, and community-clinical linkages in Latino communities across central Pennsylvania.

*Status of Support: Active

Project Number: 5 NU 58DP006587-03-00

Name of PD/PI: Kraschnewski

*Source of Support: CDC

*Primary Place of Performance: The Pennsylvania State University, Hershey, PA

Project/Proposal Start and End Date: (MM/YYYY) (if available): 09/2018 – 09/2023

* Total Award Amount (including Indirect Costs): $2,376,979

OMB No. 0925-0001 and 0925-0002 (Rev. 12/2020 Approved Through 02/28/2023)

Name of Individual: **Calo, William Alexis**
Commons ID: eRA COMMONS USER NAME

* Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
2. 2022	CAL. MONTHS
3. 2023	

*Title: **Glucose Management Clinical Decision Support to Improve Outcomes in Academic and Community Hospitals**

Major Goals: To study the impact of our CDS tool on clinical, economic and providers' performance outcomes among non-intensive care patients both in an academic and a community hospital.

*Status of Support: Active

Project Number: R01DK130992

Name of PD/PI: Pichardo-Lowden

*Source of Support: NIH

*Primary Place of Performance: The Pennsylvania State University, Hershey, PA

Project/Proposal Start and End Date: (MM/YYYY) (if available): 12/2021 – 11/2026

* Total Award Amount (including Indirect Costs): $3,241,037

* Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
1. 2022	CAL. MONTHS
2. 2023	
3. 2024	
4. 2025	
5. 2026	

*Title: **Increasing Physical Activity in Rural Pennsylvanians: The PA Moves Trial**

Major Goals: This multi-level intervention will address physical inactivity at the level of organizations (health care systems), communities (with assessment and promotion of community resources), and individuals (counseling from a physician and from a community source), with the ultimate goal of reducing cancer risks.

*Status of Support: Active

Project Number: R01CA268017

Name of PD/PI: Schmitz / Ruffin

*Source of Support: NIH/NCI

*Primary Place of Performance: The Pennsylvania State University, Hershey, PA

Project/Proposal Start and End Date: (MM/YYYY) (if available): 03/2022 – 02/2027

OMB No. 0925-0001 and 0925-0002 (Rev. 12/2020 Approved Through 02/28/2023)

Name of Individual: **Calo, William Alexis**
Commons ID: eRA COMMONS USER NAME

* Total Award Amount (including Indirect Costs): $4,808,045 TA

* Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
1. 2022	CAL. MONTHS
2. 2023	
3. 2024	
4. 2025	
5. 2026	

*Title: **Program Project – Improving Provider Announcement Communication Training (IMPACT)**

Major Goals: The project will examine the budget impact, cost-effectiveness, and population health impact of HPV vaccine interventions in rural and non-rural communities and aid decision makers with a decision support tool to facilitate the adoption of promising interventions.

*Status of Support: active

Project Number: P01CA250989

Name of PD/PI: Brewer, Noel Todd

*Source of Support: UNC Chapel Hill / NIH

*Primary Place of Performance: UNC Chapel Hill, NC

Project/Proposal Start and End Date: (MM/YYYY) (if available): 09/2021 – 08/2026

* Total Award Amount (including Indirect Costs): $346,605

* Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
2. 2022	CAL. MONTHS
3. 2023	
4. 2024	
5. 2025	

*Title: **Advancing Health Literacy with Community Health Workers**

Major Goals: In order to ensure that the citizens of the City of Reading have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions The Penn State College of Medicine plans to work alongside The City of Reading, Reading Area Community College and Latino Connection to complete Health Literate Organizational Assessments of six health organizations located in the City of Reading. Penn State College of Medicine will provide a general oversite to the project, create and provide trainings as well as a toolkit for the proposed project, and assist in project evaluation.

OMB No. 0925-0001 and 0925-0002 (Rev. 12/2020 Approved Through 02/28/2023)

Name of Individual: **Calo, William Alexis**
Commons ID: eRA COMMONS USER NAME

*Status of Support: Active

Project Number: 6 CPIMP211290-01-01

Name of PD/PI: Kraschnewski, Jennifer

*Source of Support: City of Reading (DHHS)

*Primary Place of Performance: The Pennsylvania State University, Hershey, PA

Project/Proposal Start and End Date: (MM/YYYY) (if available): 07/2021 – 06/2022

* Total Award Amount (including Indirect Costs): $346,605

* Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
1. 2022	CAL. MONTHS

PENDING

PENDING SUPPORT

OMB No. 0925-0001 and 0925-0002 (Rev. 12/2020 Approved Through 02/28/2023)

PENDING SUPPORT

OMB No. 0925-0001 and 0925-0002 (Rev. 12/2020 Approved Through 02/28/2023)

PENDING SUPPORT

OMB No. 0925-0001 and 0925-0002 (Rev. 12/2020 Approved Through 02/28/2023)

PENDING SUPPORT

I, PD/PI or other senior/key personnel, 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: William A. Calo Digitally signed by William A. Calo Date: 2022.06.14 15:26:50 -04'00'

OMB No. 0925-0001 and 0925-0002 (Rev. 10/2021 Approved Through 09/30/2024)

*Name of Individual: Elizabeth L. Ciemins
Commons ID: eRA COMMONS USER NAME

Other Support – Project/Proposal

ACTIVE

*Title: *Understanding Chronic Pain Management including Opioid Prescribing in the Context of Clinical Practice Guidelines and Policies*

*Major Goals: In response to external mandates as well as internal priorities, many U.S. health care systems have pursued initiatives to address the opioid epidemic. Given the multitude of policies and guidelines affecting practice, it is critical to understand the effect of these various changes on the care of patients with chronic pain and on clinicians' beliefs, attitudes and behaviors, including the benefits and unintended consequences, for both patients and clinicians.

*Status of Support: ACTIVE

Project Number: 2002015M53890/75D30119F06485

Name of PD/PI: Abt. Associates

*Source of Support: CDC

*Primary Place of Performance: Abt. Associates

Project/Proposal Start and End Date: (MM/YYYY): 09/2019 – 03/2024

* Total Award Amount (including Indirect Costs): $463,590.22

* Person Months (Calendar/Academic/Summer) per budget period.

Year (2022-2024)	Person Months (##.##)
1. Jan – June 2022	CAL. MONTHS
2. July – Dec 2022	
3. 2023	
4. Jan-March 2024	
5.	

*Title: *NIA AD/ADRD Health Care Systems Research Collaboratory*

*Major Goals: A one-year pilot study, Implementation of MIND at Home in Primary Care for Patients Living with Dementia, seeks to implement an evidence-based, non-pharmacologic dementia care coordination model into primary care practices at two health systems.

*Status of Support: ACTIVE

Project Number: 5U54AG063546-03

Name of PD/PI: V. Mor

*Source of Support: NIA

*Primary Place of Performance: Brown University

Project/Proposal Start and End Date: (MM/YYYY): 09/2021 – 08/2022

OMB No. 0925-0001 and 0925-0002 (Rev. 10/2021 Approved Through 09/30/2024)

Name of Individual:
Commons ID:

* Total Award Amount (including Indirect Costs): $237,750.84

* Person Months (Calendar/Academic/Summer) per budget period.

Year (2021-2022)	Person Months (##.##)
1. 2021 – 2022	CAL. MONTHS

PENDING SUPPORT

OMB No. 0925-0001 and 0925-0002 (Rev. 10/2021 Approved Through 09/30/2024)

Name of Individual:
Commons ID:

IN-KIND

No In-Kind Support

***Overlap** (summarized for each individual):

No Overlap to report

I, PD/PI or other senior/key personnel, 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: Elizabeth Ciemins Digitally signed by Elizabeth Ciemins Date: 2022.06.29 09:40:08 -06'00'

E. OVERALL IMPACT

E.1 WHAT IS THE IMPACT ON THE DEVELOPMENT OF HUMAN RESOURCES?
Not Applicable
E.2 WHAT IS THE IMPACT ON PHYSICAL, INSTITUTIONAL, OR INFORMATION RESOURCES THAT FORM INFRASTRUCTURE?
NOTHING TO REPORT
E.3 WHAT IS THE IMPACT ON TECHNOLOGY TRANSFER?
Not Applicable
E.4 WHAT DOLLAR AMOUNT OF THE AWARD'S BUDGET IS BEING SPENT IN FOREIGN COUNTRY(IES)?
NOTHING TO REPORT

F. OVERALL CHANGES

F.1 CHANGES IN APPROACH AND REASONS FOR CHANGE

Not Applicable

F.2 ACTUAL OR ANTICIPATED CHALLENGES OR DELAYS AND ACTIONS OR PLANS TO RESOLVE THEM

Administrative Core Aim 3. Administer the Rapid Response Pilot Grant Program:
A review of Year 1 priorities, including preparation for the 3 planned trials, indicated that the projects did not have capacity to take on additional research as part of the pilot grants in Year 1. For this reason, we moved the pilot grant program start date to Year 2.

F.3 SIGNIFICANT CHANGES TO HUMAN SUBJECTS, VERTEBRATE ANIMALS, BIOHAZARDS, AND/OR SELECT AGENTS

F.3.a Human Subject

No Change

F.3.b Vertebrate Animals

No Change

F.3.c Biohazards

No Change

F.3.d Select Agents

No Change

G. OVERALL SPECIAL REPORTING REQUIREMENTS SPECIAL REPORTING REQUIREMENTS

G.1 SPECIAL NOTICE OF AWARD TERMS AND FUNDING OPPORTUNITIES ANNOUNCEMENT REPORTING REQUIREMENTS

NOTHING TO REPORT

G.2 RESPONSIBLE CONDUCT OF RESEARCH

Not Applicable

G.3 MENTOR'S REPORT OR SPONSOR COMMENTS

Not Applicable

G.4 HUMAN SUBJECTS

Sub-Project ID	Study ID	Study Title	Delayed Onset	Clinical Trial	NCT	NIH-Defined Phase 3	ACT
Project-003	347965	Engaging Clinical Champions to Improve HPV Vaccine Communication and Uptake in Healthcare Systems	NO	YES		NO	NO
Project-004	347966	Budget impact, cost-effectiveness, and population outcomes of interventions to improve HPV vaccine communication and uptake in rural and nonrural communities	NO	NO			
Project-001	347963	The impact of standing orders support on HPV vaccine communication and uptake	NO	YES		NO	NO
Project-002	347964	The impact of clinic-level financial incentives on HPV vaccine communication and uptake	NO	YES		NO	NO

Core-002	347967	Data Core: Improving Provider Announcement Communication Training (IMPACT)	NO	NO			

G.5 HUMAN SUBJECTS EDUCATION REQUIREMENT

Are there personnel on this project who are newly involved in the design or conduct of human subjects research?

No

G.6 HUMAN EMBRYONIC STEM CELLS (HESCS)

Does this project involve human embryonic stem cells (only hESC lines listed as approved in the NIH Registry may be used in NIH funded research)?

No

G.7 VERTEBRATE ANIMALS

Does this project involve vertebrate animals?

No

G.8 PROJECT/PERFORMANCE SITES

Organization Name	UEI	Congressional District	Address
Primary: The University of North Carolina at Chapel Hill	D3LHU66KBLD5	NC-004	104 Airport Drive, Suite 2200 Campus Box 1350 Chapel Hill, NC 275991350
The University of North Carolina at Chapel Hill	D3LHU66KBLD5	NC-004	104 Airport Drive, Suite 2200 Campus Box 1350 Chapel Hill, NC 275991350

G.9 FOREIGN COMPONENT

No foreign component

G.10 ESTIMATED UNOBLIGATED BALANCE

G.10.a Is it anticipated that an estimated unobligated balance (including prior year carryover) will be greater than 25% of the current year's total approved budget?

Yes

Estimated unobligated balance: $733,233

G.10.b Provide an explanation for unobligated balance:
Due to the shorter grant year, routine timeline for onboarding new staff, and unexpected staffing shortages and work delays in UNC's Office of Sponsored Research and Lineberger's post-award finance team due to the COVID-19 pandemic, projects and cores had delays in expending personnel budgets. After a review of Year 1 priorities, we also decided to move the start date of the Rapid Response Pilot Grant Program to Year 2. Additionally, some funds remain due to small changes in FTEs for study personnel and unused travel and supplies due to the pandemic. For example, the first meeting of the Clinical Advisory Board was virtual and not in-person in Chapel Hill, NC.

G.10.c If authorized to carryover the balance, provide a general description of how it is anticipated that the funds will be spent
The carryover funds will be fully expended in Year 2, primarily on the three randomized clinical trials. Carryover funds are necessary, in addition to the Year 2 budget, to ensure the trials are adequately powered given the P01's reduced funding. Specifically, Project 1 carryover will support AMGA's recruitment of healthcare systems and personnel for conducting its trial. Project 2 carryover will cover a substantial increased cost for the UNC Sheps Center producing an EHR data capture tool for its trial. Project 3 carryover funds will cover trial participant incentives and personnel. Project 4 carryover will support participant incentives and personnel for building the simulation models that will integrate trial findings. Administrative Core carryover will be reallocated to support the three trials and an expanded Rapid Response Pilot Grant Program. Data Core carryover will address a shortfall in funding for a programmer to manage the various data streams from the three trials and statistician support on data analyses. Intervention Core carryover will be expended on restructuring and professionalizing the Announcement Approach Training materials for the trials and personnel. We do not expect any carryover from Years 2 to 3.

G.11 PROGRAM INCOME

Is program income anticipated during the next budget period? No

G.12 F&A COSTS

Not Applicable

Section 1 - Basic Information (Study 347965)

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 347965)

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 medicine

Aim 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 patients

Aim 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 patients

Aim 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 workshop

Aim 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 participant

Aim 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 Virginia

Aim 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	Recruiting
2.7. Study Timeline	TimelineP3r1045594852.pdf
2.8. Enrollment of First Participant (SEE SECTION 6.3)	

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)

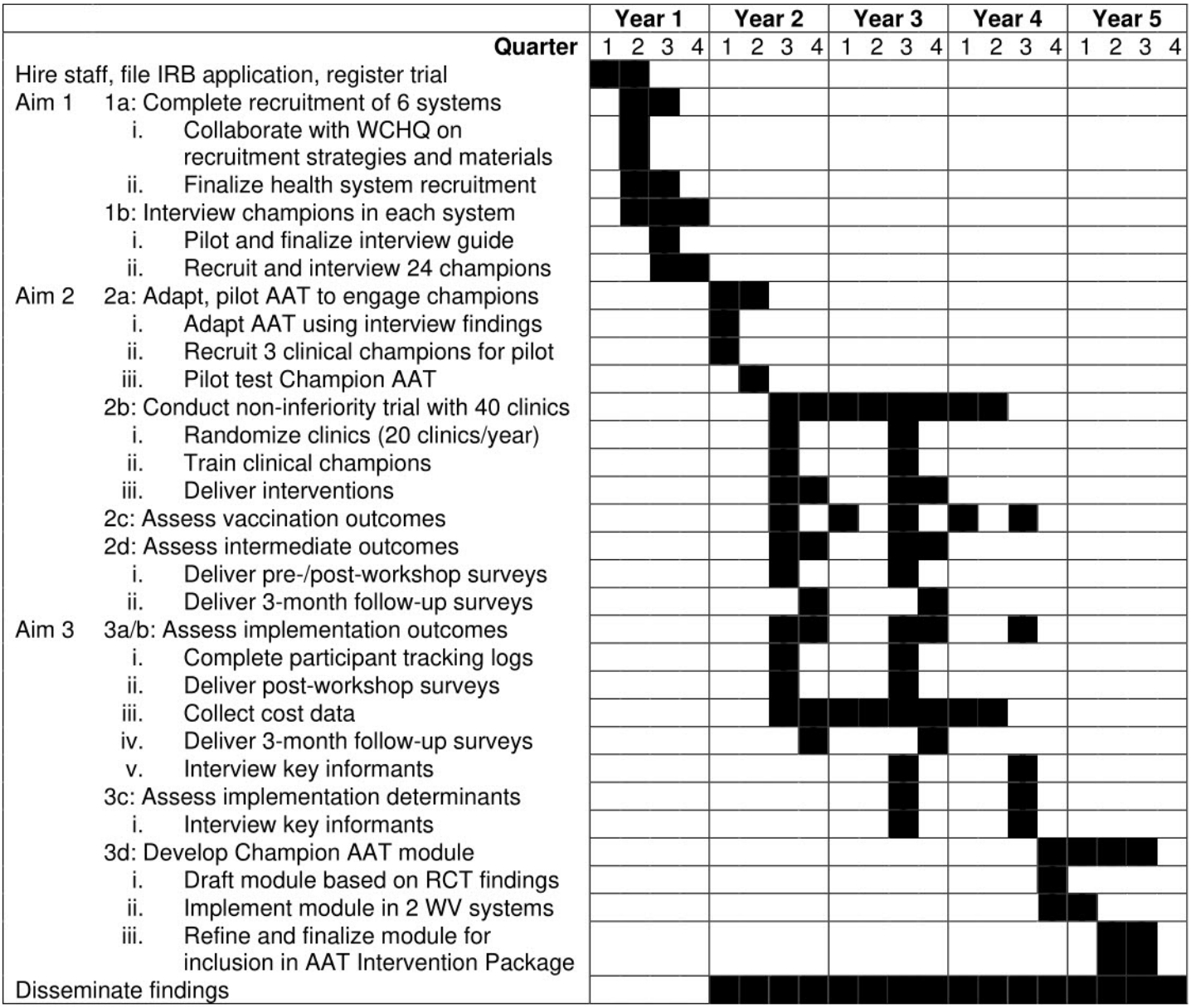
Using the methods described in Aim 1 (in-depth interviews), we will recruit two clinical champions in each of the participating healthcare systems in West Virginia (or 4 total) to pilot test the Champion ATT intervention module. Eligibility criteria are as described in Aim 1.

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
IER 348998	Domestic	Wisconsin
IER 348999	Domestic	Wisconsin
IER 349000	Domestic	Wisconsin
IER 349001	Domestic	Wisconsin
IER 349002	Domestic	West Virginia
IER 349003	Domestic	West Virginia

Inclusion Enrollment Report 348998

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	1	0	0	0	0	0	0	0	0	1
Native Hawaiian or Other Pacific Islander	0	0	0	0	0	0	0	0	0	0
Black or African American	1	0	0	0	0	0	0	0	0	1
White	7	0	0	0	0	0	0	0	0	7
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	9	0	0	0	0	0	0	0	0	9

Inclusion Enrollment Report 348999

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 349000

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 349001

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 349002

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 349003

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. Enrollment of 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 347965)

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
Single IRB plan attachment	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	P3_StudyTeam.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.
- *William Calo, 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 347965)

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 1
Activities 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 2
Activity 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 3
Activity 3a
1. 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-c
1. 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 3d
1. 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? (SEE SECTION 6.6)

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**).

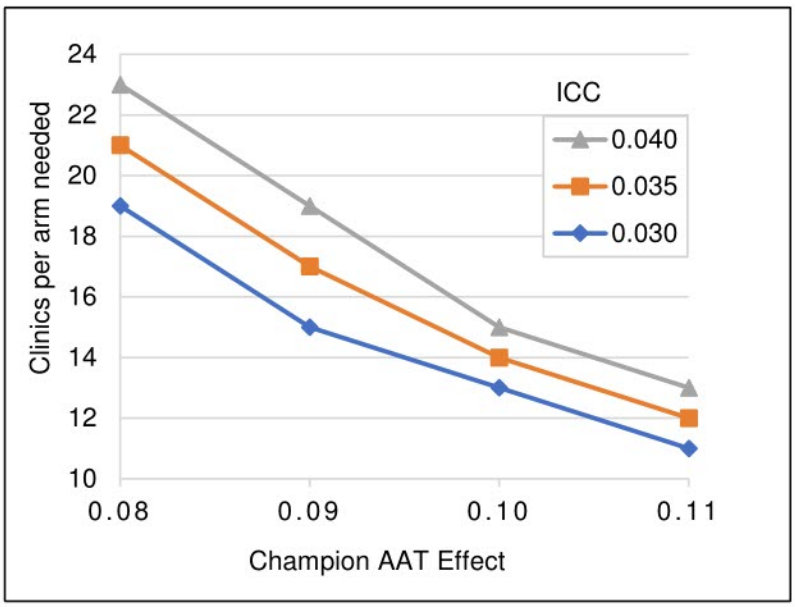


Figure. Sensitivity analyses for ≥80% power

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.

Section 6 - Clinical Trial Milestone Plan (Study 347965)

6.1. Study Primary Completion Date	05/31/2025	Anticipated
6.2. Study Final Completion Date	05/31/2026	Anticipated
6.3. Enrollment and randomization		
Enrollment of the First Participant (Study Start Date)	12/01/2022	Anticipated
25% of planned enrollment recruited by	12/31/2022	Anticipated
50% of planned enrollment recruited by	03/01/2023	Anticipated
75% of planned enrollment recruited by	12/31/2023	Anticipated
100% of planned enrollment recruited by	10/31/2025	Anticipated
6.4. Completion of primary endpoint data analyses	03/01/2026	Anticipated
6.5. Reporting of results in ClinicalTrials.gov	05/31/2026	Anticipated
6.6. Is this an applicable clinical trial under FDAAA?	○ Yes ● No	

Section 1 - Basic Information (Study 347966)

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 347966)

2.1. Conditions or Focus of Study

- This study is focused on provider communication about HPV vaccine.

2.2. Eligibility Criteria

Aim 1a
1) 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 1b
1) Ages 18+
2) Primary care team members (MDs, PAs, NPs, RNs, MAs)

Aim 3b
1) 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	Recruiting
2.7. Study Timeline	TimelineP4r1045594896.pdf
2.8. Enrollment of First Participant (SEE SECTION 6.3)	

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

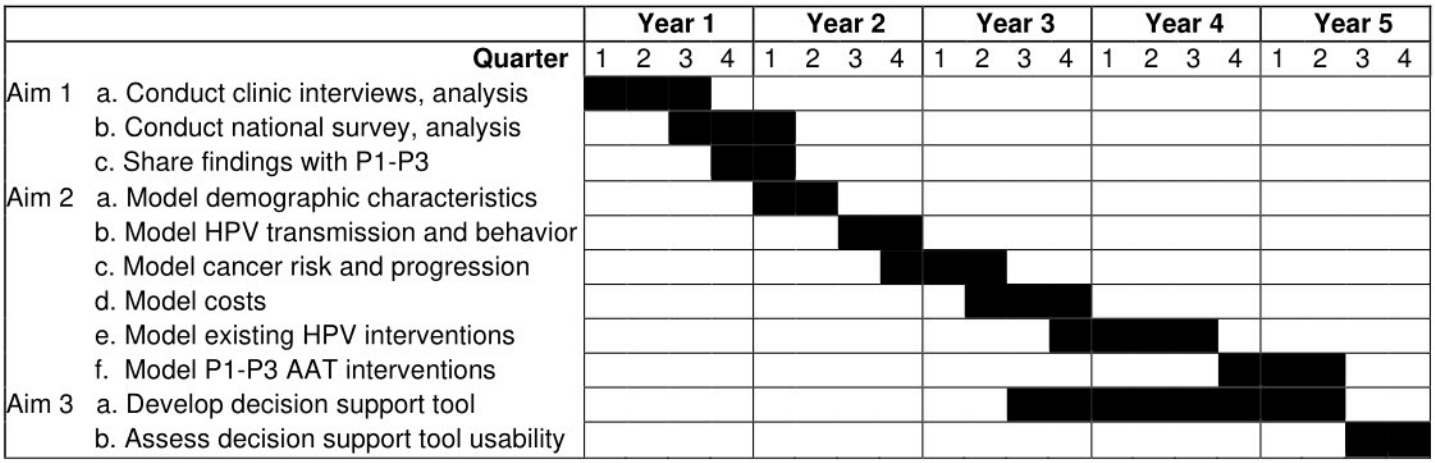
Project 4 will work with the Data Core and Projects 1 and 2 to conduct a national online survey of primary care professionals. Project 4 will add questions to assess contextual differences in rural and nonrural clinical settings that may influence the implementation and effectiveness of HPV vaccine communication 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



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
IER 349004	Domestic	

Inclusion Enrollment Report 349004

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	4	0	0	0	0	0	0	0	0	4
Native Hawaiian or Other Pacific Islander	0	0	0	0	0	0	0	0	0	0
Black or African American	5	0	0	0	0	0	0	0	0	5
White	8	2	0	1	0	0	0	0	0	11
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	17	2	0	1	0	0	0	0	0	20

Section 3 - Protection and Monitoring Plans (Study 347966)

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
Single IRB plan attachment	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	P4_StudyTeam.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, *William A. Calo, 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. Calo 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 (Aim 2)

- *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 347966)

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? (SEE SECTION 6.6)

4.7. Dissemination Plan

Section 6 - Clinical Trial Milestone Plan (Study 347966)

6.1. Study Primary Completion Date		
6.2. Study Final Completion Date		
6.3. Enrollment and randomization		
Enrollment of the First Participant (Study Start Date)	02/21/2022	Actual
25% of planned enrollment recruited by		
50% of planned enrollment recruited by		
75% of planned enrollment recruited by		
100% of planned enrollment recruited by		
6.4. Completion of primary endpoint data analyses		
6.5. Reporting of results in ClinicalTrials.gov		

6.6. Is this an applicable clinical trial under FDAAA? ❍ Yes ❍ No

Section 1 - Basic Information (Study 347963)

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 347963)

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 1a
1) Ages 18+
2) Physicians and other primary care team members, including nurse practitioners (NPs), physician assistants (PAs), registered nurses(RNs), medical assistants (MAs).

Activity 1b
1) 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	Recruiting	
2.7. Study Timeline	TimelineP1r1045594805.pdf	
2.8. Enrollment of First Participant (SEE SECTION 6.3)		

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).

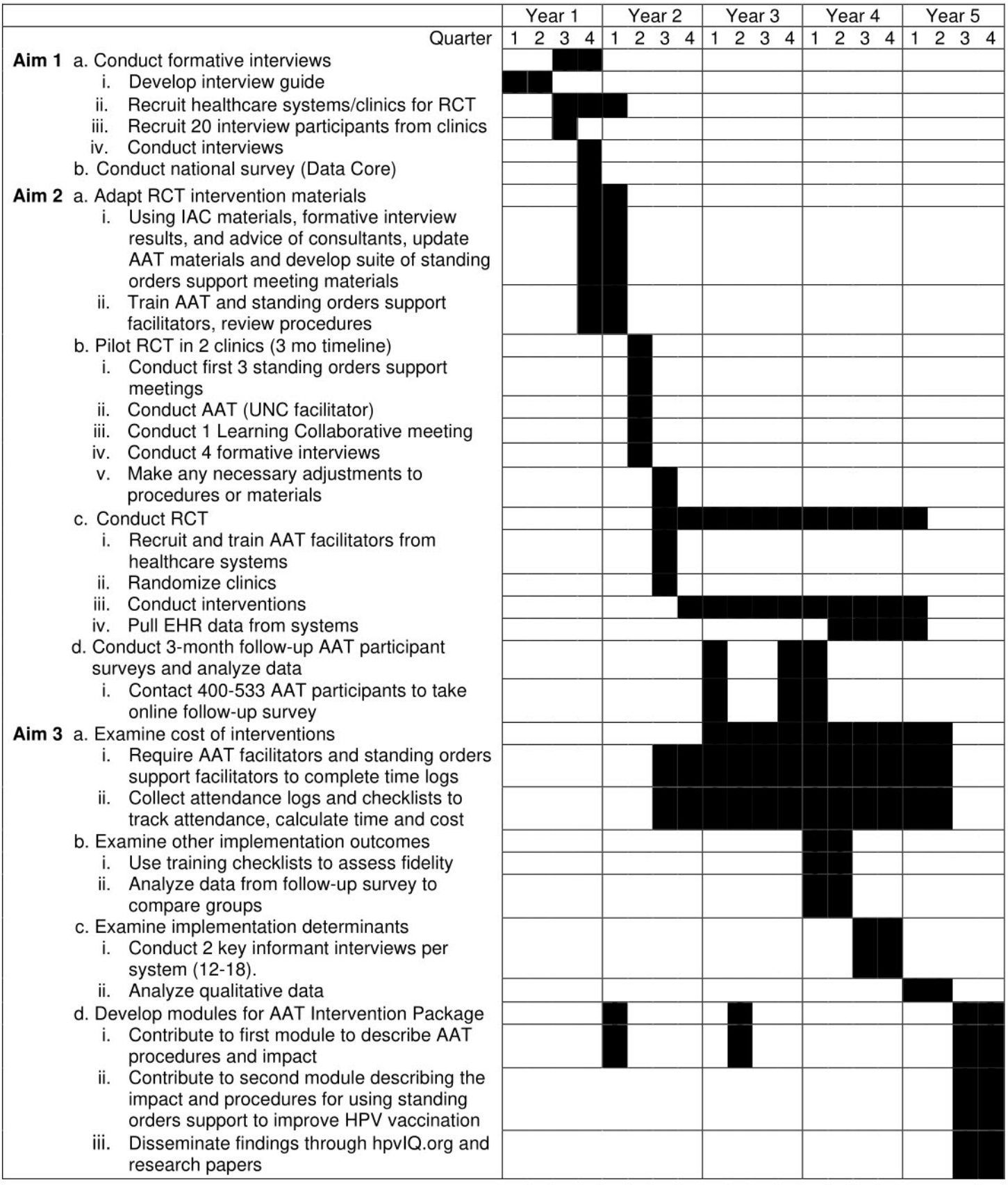
Key informant interviews

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
IER 348993	Domestic	Mississippi, Missouri, Texas
IER 348994	Domestic	Mississippi, Missouri, Texas
IER 348995	Domestic	Mississippi, Missouri, Texas
IER 348996	Domestic	Mississippi, Missouri, Texas

Inclusion Enrollment Report 348993

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	1	0	0	0	0	0	0	0	0	1
Native Hawaiian or Other Pacific Islander	0	0	0	0	0	0	0	0	0	0
Black or African American	4	0	0	0	0	0	0	0	0	4
White	8	0	0	0	0	0	0	0	0	8
More than One Race	2	0	0	1	0	0	0	0	0	3
Unknown or Not Reported	0	0	0	0	0	0	0	0	0	0
Total	15	0	0	1	0	0	0	0	0	16

Inclusion Enrollment Report 348994

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 348995

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 348996

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 347963)

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
Single IRB plan attachment	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

Section 4 - Protocol Synopsis (Study 347963)

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? (SEE SECTION 6.6)	
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

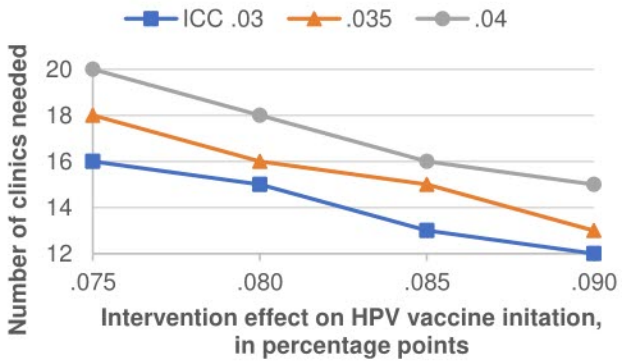
Trial vaccination outcomes

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,

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.

Section 6 - Clinical Trial Milestone Plan (Study 347963)

6.1. Study Primary Completion Date	04/01/2025	Anticipated
6.2. Study Final Completion Date	04/01/2026	Anticipated
6.3. Enrollment and randomization		
Enrollment of the First Participant (Study Start Date)	12/01/2022	Anticipated
25% of planned enrollment recruited by	03/01/2023	Anticipated
50% of planned enrollment recruited by	06/01/2023	Anticipated
75% of planned enrollment recruited by	10/01/2023	Anticipated
100% of planned enrollment recruited by	02/01/2024	Anticipated
6.4. Completion of primary endpoint data analyses	03/01/2026	Anticipated
6.5. Reporting of results in ClinicalTrials.gov	04/01/2026	Anticipated
6.6. Is this an applicable clinical trial under FDAAA?	○ Yes ● No	

Section 1 - Basic Information (Study 347964)

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 347964)

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 1
Activity 1b
• Electronic health record (EHR) data will be queried for patients meeting the following criteria:
1) Aged 9 to 17
2) 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 years

Aim 2

Activity 2a
Clinics will be recruited into the trial that meet the following criteria:
1) Specialize in pediatric or family medicine
2) Have at least 50 or more patients aged 11 to 12 in the prior two years
3) Have at least two HPV vaccine provider who provided HPV vaccine in the prior two years
4) No Announcement Approach Training (AAT) in last 6 months or coming 6 months
5) No existing financial incentives tied specifically to HPV vaccination
6) HEDIS HPV up-to-date measure < 80%.

Activity 2b
Vaccine coverage at the clinic level will be evaluated using EHR data for patients who meet the following criteria:
1) Aged 11-12 or 13-17
2) Had at least one visit with a clinic that was recruited into the trial in Activity 2a during the study

Activity 2c
Change 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 2a

Aim 3
Activities 3b and 3c
1) 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	Recruiting
2.7. Study Timeline	TimelineP2r1045595417.pdf
2.8. Enrollment of First Participant (SEE SECTION 6.3)	

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

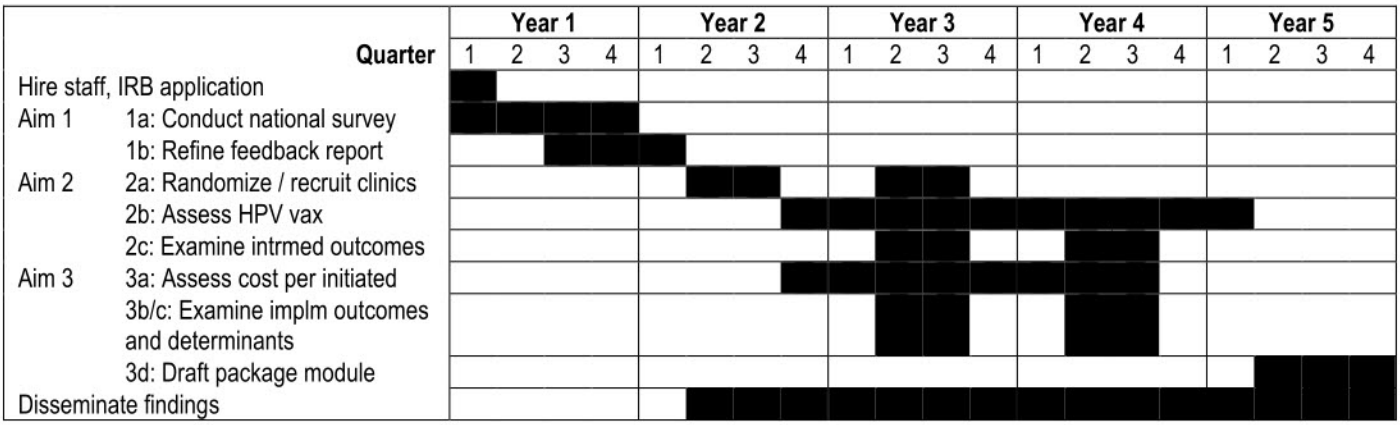
Twelve months after the AAT workshops take place in the clinics, trial participants from each clinic will complete an online follow-up survey (T2). Those who complete the follow-up online surveys will be paid $100. We will use web-based RedCap surveys for T2; to improve response rates, participants will 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
IER 348997	Domestic	Family medicine and pediatric clinics

Inclusion Enrollment Report 348997

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	2	1	0	0	0	0	3	0	0	6
More than One Race	0	0	0	0	1	0	0	0	0	1
Unknown or Not Reported	0	0	0	0	0	0	0	0	0	0
Total	2	1	0	0	1	0	3	0	0	7

Section 3 - Protection and Monitoring Plans (Study 347964)

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
Single IRB plan attachment	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	P2_StudyTeam.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.
- *William Calo*, 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 347964)

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? (SEE SECTION 6.6)

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.

Section 6 - Clinical Trial Milestone Plan (Study 347964)

6.1. Study Primary Completion Date	05/31/2025	Anticipated
6.2. Study Final Completion Date	05/31/2026	Anticipated
6.3. Enrollment and randomization		
Enrollment of the First Participant (Study Start Date)	02/01/2023	Anticipated
25% of planned enrollment recruited by	03/01/2023	Anticipated
50% of planned enrollment recruited by	05/31/2023	Anticipated
75% of planned enrollment recruited by	03/01/2024	Anticipated
100% of planned enrollment recruited by	05/31/2024	Anticipated
6.4. Completion of primary endpoint data analyses	08/31/2025	Anticipated
6.5. Reporting of results in ClinicalTrials.gov	05/31/2026	Anticipated
6.6. Is this an applicable clinical trial under FDAAA?	○ Yes ● No	

Section 1 - Basic Information (Study 347967)

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 347967)

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 assistants
2) Provided HPV vaccine to adolescent patients aged 9-17 in the prior two years
3) 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	Recruiting
2.7. Study Timeline	TimelineDCr1045595177.pdf
2.8. Enrollment of First Participant (SEE SECTION 6.3)	

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.

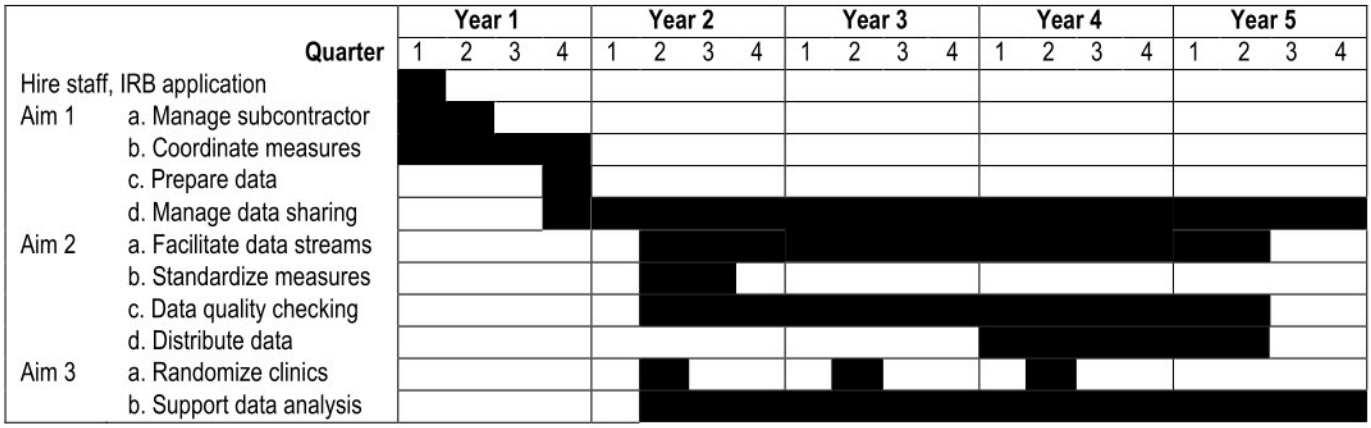
RECRUITMENT AND RETENTION PLAN – Data Core

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
IER 349005	Domestic	Web-based survey

Inclusion Enrollment Report 349005

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	7	2	1	1	0	0	0	0	0	11
Asian	230	114	1	2	0	1	0	0	0	348
Native Hawaiian or Other Pacific Islander	2	1	1	0	0	0	0	0	0	4
Black or African American	110	9	0	1	0	0	0	0	0	120
White	1219	411	6	30	10	1	0	0	0	1677
More than One Race	28	11	0	5	1	0	0	0	0	45
Unknown or Not Reported	74	36	65	70	25	3	0	0	0	273
Total	1670	584	74	109	36	5	0	0	0	2478

Section 3 - Protection and Monitoring Plans (Study 347967)

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
Single IRB plan attachment	DC_MultisiteStudy.pdf
3.3. Data and Safety Monitoring Plan	DC_Dsmp.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	DC_StudyTeam.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 Queen, 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 Tara Queen, 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 Tara Queen. 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

- *Tara Queen*, PhD, will serve as the contact lead, responsible for the Data Core's administration and interface with IMPACT research projects and cores. Dr. Queen, a quantitative psychologist, is Assistant Professor of Health Behavior at UNC. Trained in the L.L. Thurstone Psychometric Lab at UNC, Dr. Queen will apply her expertise in psychometrics to support the questionnaire design, psychometric modeling, and data integration across projects and data sources. Dr. Queen 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 a 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. Queen 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 347967)

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? (SEE SECTION 6.6)

4.7. Dissemination Plan

Section 6 - Clinical Trial Milestone Plan (Study 347967)

6.1. Study Primary Completion Date		
6.2. Study Final Completion Date		
6.3. Enrollment and randomization		
Enrollment of the First Participant (Study Start Date)	05/26/2022	Actual
25% of planned enrollment recruited by		
50% of planned enrollment recruited by		
75% of planned enrollment recruited by		
100% of planned enrollment recruited by		
6.4. Completion of primary endpoint data analyses		
6.5. Reporting of results in ClinicalTrials.gov		

6.6. Is this an applicable clinical trial under FDAAA? ❍ Yes ❍ No

Composite Application Budget Summary

Categories	Budget Period
Salary, Wages and Fringe Benefits	1,076,043
Equipment	0
Travel	24,000
Participant/Trainee Support Costs	0
Human Fetal Tissue Costs*	
Other Direct Costs (excluding Consortium)	214,229
Consortium Costs	356,709
Direct Costs	1,670,981
Indirect Costs	722,864
Total Direct and Indirect Costs	2,393,845

*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)"

Component Budget Summary

Components	Categories	Budget Period
001-001 (Admin Core)	Salary, Wages and Fringe Benefits	151,050
	Equipment	0
	Travel	6,000
	Participant/Trainee Support Costs	0
	Human Fetal Tissue Costs	
	Other Direct Costs (excluding Consortium)	45,000
	Consortium Costs	0
	Direct Costs	202,050
	Indirect Costs	112,138
TOTALS	Total Direct and Indirect Costs	314,188
001-001 (Core)	Salary, Wages and Fringe Benefits	93,199
	Equipment	0
	Travel	0
	Participant/Trainee Support Costs	0
	Human Fetal Tissue Costs	
	Other Direct Costs (excluding Consortium)	12,988
	Consortium Costs	63,257
	Direct Costs	169,444
	Indirect Costs	58,934
TOTALS	Total Direct and Indirect Costs	228,378

002-002 (Core)	Salary, Wages and Fringe Benefits	143,071
	Equipment	0
	Travel	0
	Participant/Trainee Support Costs	0
	Human Fetal Tissue Costs	
	Other Direct Costs (excluding Consortium)	4,417
	Consortium Costs	0
	Direct Costs	147,488
	Indirect Costs	81,856
TOTALS	Total Direct and Indirect Costs	229,344
004-001 (Project)	Salary, Wages and Fringe Benefits	163,571
	Equipment	0
	Travel	0
	Participant/Trainee Support Costs	0
	Human Fetal Tissue Costs	
	Other Direct Costs (excluding Consortium)	44,000
	Consortium Costs	0
	Direct Costs	207,571
	Indirect Costs	115,202
TOTALS	Total Direct and Indirect Costs	322,773
001-002 (Project)	Salary, Wages and Fringe Benefits	223,042
	Equipment	0
	Travel	3,000

	Participant/Trainee Support Costs	0
	Human Fetal Tissue Costs	
	Other Direct Costs (excluding Consortium)	38,585
	Consortium Costs	70,981
	Direct Costs	335,608
	Indirect Costs	140,310
TOTALS	Total Direct and Indirect Costs	475,918
002-003 (Project)	Salary, Wages and Fringe Benefits	164,791
	Equipment	0
	Travel	6,000
	Participant/Trainee Support Costs	0
	Human Fetal Tissue Costs	
	Other Direct Costs (excluding Consortium)	62,200
	Consortium Costs	0
	Direct Costs	232,991
	Indirect Costs	129,310
TOTALS	Total Direct and Indirect Costs	362,301
003-004 (Project)	Salary, Wages and Fringe Benefits	137,319
	Equipment	0
	Travel	9,000
	Participant/Trainee Support Costs	0
	Human Fetal Tissue Costs	
	Other Direct Costs (excluding Consortium)	7,039

	Consortium Costs	222,471
	Direct Costs	375,829
	Indirect Costs	85,114
TOTALS	Total Direct and Indirect Costs	460,943
TOTALS		**2,393,845**

Categories Budget Summary

Categories	Components	Budget Period
R&R Budget - Senior/Key Person Funds Requested	001-001 (Admin Core)	90,329
	001-001 (Core)	15,349
	002-002 (Core)	62,940
	004-001 (Project)	96,107
	001-002 (Project)	26,404
	002-003 (Project)	77,627
	003-004 (Project)	67,154
TOTALS		**435,910**
R&R Budget - Other Personnel Funds Requested	001-001 (Admin Core)	60,721
	001-001 (Core)	77,850
	002-002 (Core)	80,131
	004-001 (Project)	67,464
	001-002 (Project)	196,638
	002-003 (Project)	87,164
	003-004 (Project)	70,165
TOTALS		**640,133**
R&R Budget - Section A & B. Total Salary, Wages and Fringe Benefits (A+B)	001-001 (Admin Core)	151,050
	001-001 (Core)	93,199
	002-002 (Core)	143,071
	004-001 (Project)	163,571

	001-002 (Project)	223,042
	002-003 (Project)	164,791
	003-004 (Project)	137,319
TOTALS		**1,076,043**
R&R Budget - Section C. Total Equipment	001-001 (Admin Core)	0
	001-001 (Core)	0
	002-002 (Core)	0
	004-001 (Project)	0
	001-002 (Project)	0
	002-003 (Project)	0
	003-004 (Project)	0
TOTALS		**0**
R&R Budget - Domestic Travel	001-001 (Admin Core)	6,000
	001-001 (Core)	0
	002-002 (Core)	0
	004-001 (Project)	0
	001-002 (Project)	3,000
	002-003 (Project)	6,000
	003-004 (Project)	9,000
TOTALS		**24,000**
R&R Budget - Foreign Travel	001-001 (Admin Core)	0
	001-001 (Core)	0
	002-002 (Core)	0

	004-001 (Project)	0
	001-002 (Project)	0
	002-003 (Project)	0
	003-004 (Project)	0
TOTALS		**0**
R&R Budget - Section D. Total Travel	001-001 (Admin Core)	6,000
	001-001 (Core)	0
	002-002 (Core)	0
	004-001 (Project)	0
	001-002 (Project)	3,000
	002-003 (Project)	6,000
	003-004 (Project)	9,000
TOTALS		**24,000**
R&R Budget - Tuition/Fees/Health Insurance	001-001 (Admin Core)	0
	001-001 (Core)	0
	002-002 (Core)	0
	004-001 (Project)	0
	001-002 (Project)	0
	002-003 (Project)	0
	003-004 (Project)	0
TOTALS		**0**
R&R Budget - Stipends	001-001 (Admin Core)	0
	001-001 (Core)	0

	002-002 (Core)	0
	004-001 (Project)	0
	001-002 (Project)	0
	002-003 (Project)	0
	003-004 (Project)	0
TOTALS		**0**
R&R Budget - Trainee Travel	001-001 (Admin Core)	0
	001-001 (Core)	0
	002-002 (Core)	0
	004-001 (Project)	0
	001-002 (Project)	0
	002-003 (Project)	0
	003-004 (Project)	0
TOTALS		**0**
R&R Budget - Subsistence	001-001 (Admin Core)	0
	001-001 (Core)	0
	002-002 (Core)	0
	004-001 (Project)	0
	001-002 (Project)	0
	002-003 (Project)	0
	003-004 (Project)	0
TOTALS		**0**
R&R Budget - Other Participants/Trainee Support Costs	001-001 (Admin Core)	0

	001-001 (Core)	0
	002-002 (Core)	0
	004-001 (Project)	0
	001-002 (Project)	0
	002-003 (Project)	0
	003-004 (Project)	0
TOTALS		**0**
R&R Budget - Section E. Total Participants/Trainee Support Costs	001-001 (Admin Core)	0
	001-001 (Core)	0
	002-002 (Core)	0
	004-001 (Project)	0
	001-002 (Project)	0
	002-003 (Project)	0
	003-004 (Project)	0
TOTALS		**0**
R&R Budget - Materials and Supplies	001-001 (Admin Core)	1,000
	001-001 (Core)	0
	002-002 (Core)	2,800
	004-001 (Project)	0
	001-002 (Project)	4,869
	002-003 (Project)	2,500
	003-004 (Project)	89
TOTALS		**11,258**

R&R Budget - Publication Costs	001-001 (Admin Core)	0
	001-001 (Core)	0
	002-002 (Core)	0
	004-001 (Project)	0
	001-002 (Project)	1,500
	002-003 (Project)	1,500
	003-004 (Project)	0
TOTALS		**3,000**
R&R Budget - Consultant Services	001-001 (Admin Core)	0
	001-001 (Core)	0
	002-002 (Core)	0
	004-001 (Project)	44,000
	001-002 (Project)	2,000
	002-003 (Project)	0
	003-004 (Project)	0
TOTALS		**46,000**
R&R Budget - ADP/Computer Services	001-001 (Admin Core)	0
	001-001 (Core)	0
	002-002 (Core)	617
	004-001 (Project)	0
	001-002 (Project)	0
	002-003 (Project)	0
	003-004 (Project)	0

TOTALS		**617**
R&R Budget - Subawards/Consortium/Contractual Costs	001-001 (Admin Core)	0
	001-001 (Core)	63,257
	002-002 (Core)	0
	004-001 (Project)	0
	001-002 (Project)	70,981
	002-003 (Project)	0
	003-004 (Project)	222,471
TOTALS		**356,709**
R&R Budget - Equipment or Facility Rental User Fees	001-001 (Admin Core)	0
	001-001 (Core)	0
	002-002 (Core)	0
	004-001 (Project)	0
	001-002 (Project)	0
	002-003 (Project)	0
	003-004 (Project)	0
TOTALS		**0**
R&R Budget - Alterations and Renovations	001-001 (Admin Core)	0
	001-001 (Core)	0
	002-002 (Core)	0
	004-001 (Project)	0
	001-002 (Project)	0
	002-003 (Project)	0

	003-004 (Project)	0
TOTALS		**0**
R&R Budget - Other Direct Cost 1	001-001 (Admin Core)	44,000
	001-001 (Core)	12,988
	002-002 (Core)	1,000
	004-001 (Project)	0
	001-002 (Project)	11,816
	002-003 (Project)	58,200
	003-004 (Project)	6,950
TOTALS		**134,954**
R&R Budget - Other Direct Cost 2	001-001 (Admin Core)	0
	001-001 (Core)	0
	002-002 (Core)	0
	004-001 (Project)	0
	001-002 (Project)	18,400
	002-003 (Project)	0
	003-004 (Project)	0
TOTALS		**18,400**
R&R Budget - Other Direct Cost 3	001-001 (Admin Core)	0
	001-001 (Core)	0
	002-002 (Core)	0
	004-001 (Project)	0
	001-002 (Project)	0

	002-003 (Project)	0
	003-004 (Project)	0
TOTALS		**0**
R&R Budget - Other Direct Cost 4	001-001 (Admin Core)	0
	001-001 (Core)	0
	002-002 (Core)	0
	004-001 (Project)	0
	001-002 (Project)	0
	002-003 (Project)	0
	003-004 (Project)	0
TOTALS		**0**
R&R Budget - Other Direct Cost 5	001-001 (Admin Core)	0
	001-001 (Core)	0
	002-002 (Core)	0
	004-001 (Project)	0
	001-002 (Project)	0
	002-003 (Project)	0
	003-004 (Project)	0
TOTALS		**0**
R&R Budget - Other Direct Cost 6	001-001 (Admin Core)	0
	001-001 (Core)	0
	002-002 (Core)	0
	004-001 (Project)	0

	001-002 (Project)	0
	002-003 (Project)	0
	003-004 (Project)	0
TOTALS		**0**
R&R Budget - Other Direct Cost 7	001-001 (Admin Core)	0
	001-001 (Core)	0
	002-002 (Core)	0
	004-001 (Project)	0
	001-002 (Project)	0
	002-003 (Project)	0
	003-004 (Project)	0
TOTALS		**0**
R&R Budget - Other Direct Cost 8	001-001 (Admin Core)	0
	001-001 (Core)	0
	002-002 (Core)	0
	004-001 (Project)	0
	001-002 (Project)	0
	002-003 (Project)	0
	003-004 (Project)	0
TOTALS		**0**
R&R Budget - Other Direct Cost 9	001-001 (Admin Core)	0
	001-001 (Core)	0
	002-002 (Core)	0

	004-001 (Project)	0
	001-002 (Project)	0
	002-003 (Project)	0
	003-004 (Project)	0
TOTALS		**0**
R&R Budget - Other Direct Cost 10	001-001 (Admin Core)	0
	001-001 (Core)	0
	002-002 (Core)	0
	004-001 (Project)	0
	001-002 (Project)	0
	002-003 (Project)	0
	003-004 (Project)	0
TOTALS		**0**
R&R Budget - Section F. Total Other Direct Cost	001-001 (Admin Core)	45,000
	001-001 (Core)	76,245
	002-002 (Core)	4,417
	004-001 (Project)	44,000
	001-002 (Project)	109,566
	002-003 (Project)	62,200
	003-004 (Project)	229,510
TOTALS		**570,938**
R&R Budget - Section G. Total Direct Cost (A thru F)	001-001 (Admin Core)	202,050
	001-001 (Core)	169,444

	002-002 (Core)	147,488
	004-001 (Project)	207,571
	001-002 (Project)	335,608
	002-003 (Project)	232,991
	003-004 (Project)	375,829
TOTALS		**1,670,981**
R&R Budget - Section H. Indirect Costs	001-001 (Admin Core)	112,138
	001-001 (Core)	58,934
	002-002 (Core)	81,856
	004-001 (Project)	115,202
	001-002 (Project)	140,310
	002-003 (Project)	129,310
	003-004 (Project)	85,114
TOTALS		**722,864**
R&R Budget - Section I. Total Direct and Indirect Costs (G +H)	001-001 (Admin Core)	314,188
	001-001 (Core)	228,378
	002-002 (Core)	229,344
	004-001 (Project)	322,773
	001-002 (Project)	475,918
	002-003 (Project)	362,301
	003-004 (Project)	460,943
TOTALS		**2,393,845**

A. COMPONENT COVER PAGE

Project Title: IMPACT Project 1 – The impact of standing orders support on HPV vaccine communication and uptake
Component Project Lead Information: Brewer, Noel Todd

B. COMPONENT ACCOMPLISHMENTS

B.1 WHAT ARE THE MAJOR GOALS OF THE PROJECT?

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.
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.
Aim 3. Generate guidance for healthcare systems to implement standing orders support.

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.

B.1.a Have the major goals changed since the initial competing award or previous report?

No

B.2 WHAT WAS ACCOMPLISHED UNDER THESE GOALS?

File Uploaded : Accomplishments_P1.pdf

B.3 COMPETITIVE REVISIONS/ADMINISTRATIVE SUPPLEMENTS

Not Applicable

B.4 WHAT OPPORTUNITIES FOR TRAINING AND PROFESSIONAL DEVELOPMENT HAS THE PROJECT PROVIDED?

NOTHING TO REPORT

B.5 HOW HAVE THE RESULTS BEEN DISSEMINATED TO COMMUNITIES OF INTEREST?

NOTHING TO REPORT

B.6 WHAT DO YOU PLAN TO DO DURING THE NEXT REPORTING PERIOD TO ACCOMPLISH THE GOALS?

We will write up the findings from our formative interviews and the national survey for publication (Activity 1a and 1b). Our work over Year 2 will inform intervention development (Activity 2a). Based on formative interview feedback and data from the national survey, we will develop enhanced intervention materials that meet the needs of RNs and MAs. Findings will suggest opportunities to successfully leverage the whole primary care team in HPV vaccine communication and implementing standing orders; they will also inform Aim 2, which encompasses our main trial.

Recruitment for the trial pilot will begin in July 2022 (Activity 2b). The trial pilot itself will begin in October 2022. Two clinics from one small healthcare system will participate, and we anticipate pilot testing to last for five months, include one learning collaborative meeting, and end in February 2023. Recruitment for the first cohort of health care systems for the main trial will begin in September 2022 (Activity 2c). Enrollment will occur on a rolling basis and conclude in April 2023. We will recruit 3-4 healthcare systems and recruit and enroll 17 clinics throughout Year 2; this represents 50% of our total recruitment target (n=34 clinics). As part of the trial, we will survey primary care team members (Activity 2d).

B.2 (Accomplishments_P1.pdf)

ACCOMPLISHMENTS – Project 1, Year 1

Below are Project 1 specific aims and updates on major activities, specific objectives, and significant results for September 2021 through June 2022.

Aim 1. Characterize the role of primary care team members and standing orders in human papillomavirus (HPV) vaccination.

In the first two months, we focused on hiring staff and establishing the administrative infrastructure for the planned research. A strategic review across the P01 identified that preparation for the national survey in Activity 1b would need to happen in the fall and winter of 2021 to be ready to field the survey in May 2022. This led us to reorder Year 1 efforts to focus first on Activity 1b, followed by Activity 1a.

Activity 1a. Conduct formative interviews to better understand RNs' and MAs' roles in HPV vaccination
Project 1 developed a formative interview guide to address: 1) HPV vaccine standing orders, 2) communication by nursing staff and MAs, and 3) equity for Black and Latinx families. We vetted the guide with our Clinical Advisory Board (CAB) in February 2022; finalized it in March 2022; began staff training for qualitative analyses in April of 2022; and started recruitment of providers, nurses, and MAs in May 2022. We have refocused recruitment for the formative interviews to clinics outside the healthcare systems where the Aim 2 interventions will happen. The reason is that the formative interview findings will inform intervention development, and we wanted to ensure that the interventions could begin immediately once each system signs on. We intend to enroll upwards of 20 participants, with pairs of providers and nurses or MAs representing ~10 clinics overall. Formative interviews and analyses will occur through the end of Year 1.

Activity 1b. Conduct a national primary care team survey
Working alongside the Data Core and Projects 2-4, our team developed 15 survey questions on HPV vaccine communication roles across the primary care team, content of standing orders for adolescent vaccination, use of age 9 recommendations, and opportunities for improving communication with Latinx families. We elicited feedback on these draft items from the Data Core, Projects 2, 3, and 4, and the CAB. We conducted cognitive interviews with 16 participants from February-March 2022 and refined our final items for the national primary care team survey in April 2022. In collaboration with the Data Core, we launched the national primary care team survey in May 2022, and data collection is currently ongoing with 2,478 participants as of June 20, 2022. See the Data Core component for more details.

Aim 2. Evaluate the impact of standing orders support for the whole primary care team on HPV vaccine communication and uptake in a cluster randomized controlled trial.

Activity 2a. Develop enhanced AAT and standing orders support materials
Since our standing orders support materials are new, we focused our efforts on developing them first. We drafted: 1) a slide deck for the first two working meetings, which details learning objectives, 2) an implementation plan, which facilitates the use of standing orders, and 3) an agenda for the all-hands clinic meeting, which promotes kickoff. We presented our slide deck to the CAB in April 2022 and have elicited feedback from our standing orders content expert, Paul Darden, MD and the Intervention Core. We are also working with UNC's Office of Digital and Lifelong Learning which specializes in pedagogy and will help us refine our materials.

Project 1 also partnered with the Intervention Core to enhance the existing AAT materials. We updated HPV data, included age 9 in HPV vaccine recommendations, and made edits to both the slide set and script. Changes to the AAT were vetted with the CAB in June 2022. See the Intervention Core component for more details. Our work on these intervention components will continue through the end of Year 1 and will be finalized in Year 2, ahead of our trial's pilot.

Activity 2b. Pilot test the procedures for the AAT and standing orders support
We have started meeting with AMGA to plan recruitment of healthcare systems. AMGA has already begun discussions with several large healthcare systems about the trial. We anticipate recruiting clinics for pilot testing at the end of Year 1. All other Aim 2 activities, noted below, will begin in Year 2.

B.2 (Accomplishments_P1.pdf)

2c. Conduct cluster RCT
We worked with the Data Core to revise our power analysis and ensure that our trial will still be adequately powered given the budget cuts that necessitated reducing the number of systems and clinics. Our updated recruitment target is 6-8 healthcare systems and 34 of their clinics. We have confirmed with AMGA that this remains a feasible recruitment goal. We have also expanded our primary trial outcome to include children ages 9 to 10, addressing the national move to begin HPV vaccination at age 9, which yields more patients per clinic. To ensure 80% power, we assumed 400 patients per clinic, ICC values from 0.03 to 0.04, and secular trend values from 0.075 to 0.12 (0.075, 0.1, 0.12). Low-end values (secular trend = 0.075, ICC = 0.03, and treatment effect = 0.06) yielded an estimate of 15 clinics in each trial arm, while high-end values (secular trend = 0.12, ICC = 0.04, and treatment effect = 0.075) yielded an estimate of 17 clinics in each trial arm. The rest of Activity 2c will begin in Year 2.

2d. Survey AAT workshop participants
Activity 2d will begin in Year 2.

Aim 3. Generate guidance for healthcare systems to implement standing orders support.

As noted above, we have begun the development of the standing orders implementation plan template. Other Aim 3 activities will begin in Year 2.

Significance
In Year 1, the national primary care team survey and formative interviews (Aim 1) are offering a better understanding of RNs' and MAs' role in HPV vaccine communication and how to use existing standing orders to expand their role. These findings are informing the development of the intervention and trial (Aim 2).

C. COMPONENT PRODUCTS

C.1 PUBLICATIONS
Not Applicable
C.2 WEBSITE(S) OR OTHER INTERNET SITE(S)
Not Applicable
C.3 TECHNOLOGIES OR TECHNIQUES
NOTHING TO REPORT
C.4 INVENTIONS, PATENT APPLICATIONS, AND/OR LICENSES
Not Applicable
C.5 OTHER PRODUCTS AND RESOURCE SHARING
NOTHING TO REPORT

D. COMPONENT PARTICIPANTS

Not applicable

E. COMPONENT IMPACT

E.1 WHAT IS THE IMPACT ON THE DEVELOPMENT OF HUMAN RESOURCES? Not Applicable
E.2 WHAT IS THE IMPACT ON PHYSICAL, INSTITUTIONAL, OR INFORMATION RESOURCES THAT FORM INFRASTRUCTURE? Not Applicable
E.3 WHAT IS THE IMPACT ON TECHNOLOGY TRANSFER? NOTHING TO REPORT
E.4 WHAT DOLLAR AMOUNT OF THE AWARD'S BUDGET IS BEING SPENT IN FOREIGN COUNTRY(IES)? Not Applicable

F. COMPONENT CHANGES

F.1 CHANGES IN APPROACH AND REASONS FOR CHANGE

Not Applicable

F.2 ACTUAL OR ANTICIPATED CHALLENGES OR DELAYS AND ACTIONS OR PLANS TO RESOLVE THEM

NOTHING TO REPORT

F.3 SIGNIFICANT CHANGES TO HUMAN SUBJECTS, VERTEBRATE ANIMALS, BIOHAZARDS, AND/OR SELECT AGENTS

F.3.a Human Subject

No Change

F.3.b Vertebrate Animals

No Change

F.3.c Biohazards

No Change

F.3.d Select Agents

No Change

G. COMPONENT SPECIAL REPORTING REQUIREMENTS SPECIAL REPORTING REQUIREMENTS

G.1 SPECIAL NOTICE OF AWARD TERMS AND FUNDING OPPORTUNITIES ANNOUNCEMENT REPORTING REQUIREMENTS

Not Applicable

G.2 RESPONSIBLE CONDUCT OF RESEARCH

Not Applicable

G.3 MENTOR'S REPORT OR SPONSOR COMMENTS

Not Applicable

G.4 HUMAN SUBJECTS

Not Applicable

G.5 HUMAN SUBJECTS EDUCATION REQUIREMENT

NOT APPLICABLE

G.6 HUMAN EMBRYONIC STEM CELLS (HESCS)

Does this project involve human embryonic stem cells (only hESC lines listed as approved in the NIH Registry may be used in NIH funded research)?

No

G.7 VERTEBRATE ANIMALS

Not Applicable

G.8 PROJECT/PERFORMANCE SITES

Not Applicable

G.9 FOREIGN COMPONENT

Not Applicable

G.10 ESTIMATED UNOBLIGATED BALANCE

Not Applicable

G.11 PROGRAM INCOME

Not Applicable

G.12 F&A COSTS

Not Applicable

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 1

FINAL

UEI*: D3LHU66KBLD5

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: UNIV OF NORTH CAROLINA CHAPEL HILL

Start Date*: 09-01-2022 **End Date*:** 08-31-2023 **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		Brewer		Project Lead	CAL. MONTHS, INST. BASE SALARY				20,370.00	6,034.00	26,404.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **26,404.00**

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	12.0	0.0	0.0	25,500.00	4,692.00	30,192.00
	Undergraduate Students						
	Secretarial/Clerical						
3	Other Personnel	23.16	0.0	0.0	121,181.00	45,265.00	166,446.00
4	**Total Number Other Personnel**					**Total Other Personnel**	**196,638.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**223,042.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 1

UEI*: D3LHU66KBLD5

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: UNIV OF NORTH CAROLINA CHAPEL HILL

Start Date*: 09-01-2022 **End Date*:** 08-31-2023 **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	**0.00**

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	0.00
Total Travel Cost	**3,000.00**

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:		
0 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

UEI*: D3LHU66KBLD5

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: UNIV OF NORTH CAROLINA CHAPEL HILL

Start Date*: 09-01-2022 **End Date*:** 08-31-2023 **Budget Period: 1**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	4,869.00
2. Publication Costs	1,500.00
3. Consultant Services	2,000.00
4. ADP/Computer Services	0.00
5. Subawards/Consortium/Contractual Costs	70,981.00
6. Equipment or Facility Rental/User Fees	0.00
7. Alterations and Renovations	0.00
8. Tuition	11,816.00
9. Other Costs	18,400.00
10.	0.00
11.	0.00
12.	0.00
13.	0.00
14.	0.00
15.	0.00
16.	0.00
17.	0.00
Total Other Direct Costs	**109,566.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**335,608.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. MTDC	55.5	252,810.00	140,310.00
		Total Indirect Costs	**140,310.00**

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)	**475,918.00**

J. Fee	Funds Requested ($)*
	0.00

K. Total Costs and Fee	Funds Requested ($)*
	475,918.00

L. Budget Justification* File Name: Budget Justification P1.pdf

RESEARCH & RELATED Budget {F-K} (Funds Requested)

BUDGET JUSTIFICATION – Project 1, Year 2

KEY PERSONNEL

Noel T. Brewer, PhD, Project Lead (CM)
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.

OTHER PERSONNEL

Katherine Kritikos, Project Manager (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 (9.72 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, Standing Orders Support Facilitator (1.44 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.

TBN, Graduate Research Assistant (12.00 CM)
We will employ a Graduate Research Assistant to help the study team with research activities that pertain to the RCT to help with dissemination and publication of findings. The GRA will also support data analysis of the provider surveys and the change in vaccine uptake.

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 the following fringe benefit rates to the personnel on this proposal: Basic permanent employee benefits are 26.174% of annual salary plus $7,019.00/FTE/YR for fixed health insurance. Graduate Student employee benefits are 9.49% of annual salary plus $4,223.04/FTE/YR for fixed health insurance.

TRAVEL
$3,000

Travel for Conferences (1 Trip for 2 People; $1,500/person)
A member of the project team will attend 2 national conferences to disseminate findings. 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.

TUITION
$11,816

We will provide the annual in-state tuition at the UNC Gillings School of Global Public Health to the Graduate Research Assistant as compensation for work 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.

MATERIALS & SUPPLIES
$4,869

Computer Data Storage ($1,500)
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). The Standing Orders Support Facilitator laptop computer will not be in use once the warranty expires and thus will not need to be replaced.

Project Supplies ($1,569)
Funds 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.

Software ($1,800)
Statistical and reference management software will be purchased for up to 3 computers as necessary. 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).

PUBLICATION COSTS
$1,500

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).

CONSULTANTS
$

Paul Darden, MD ($)
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 ($)
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.

OTHER COSTS
$18,400

Interview Incentives ($400)
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).

Training Participant Follow-up Survey Incentives ($18,000)
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 18 clinics. (18 X 10 X $100 =$18,000).

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 09/16/2021), 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
$70,981

Ohio State University – Paul Reiter, PhD
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 (AMGA) – Elizabeth Ciemens, PhD
As AMGA is currently being registered with eRA Commons, the American Medical Group Foundation is currently serving as a placeholder in the budget section of the RPPR in eRA Commons.
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.

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 1

FINAL

UEI*: NFK8M2SM78S7

Budget Type*: ❍ Project ● Subaward/Consortium

Enter name of Organization: AMERICAN MEDICAL GROUP FOUNDATION

Start Date*: 09-01-2022 **End Date*:** 08-31-2023 **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		Ciemins		AMGA Subcontract PI	CAL. MONTHS, INST. BASE SALARY				13,936.00	2,741.00	16,677.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **16,677.00**

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	Res. Coordinator	2.1	0.0	0.0	15,902.48	3,200.52	19,103.00
1	**Total Number Other Personnel**					**Total Other Personnel**	**19,103.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**35,780.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 1

UEI*: NFK8M2SM78S7

Budget Type*: ❍ Project ● Subaward/Consortium

Enter name of Organization: AMERICAN MEDICAL GROUP FOUNDATION

Start Date*: 09-01-2022 **End Date*:** 08-31-2023 **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	**0.00**

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:		
0 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

UEI*: NFK8M2SM78S7

Budget Type*: ❍ Project ● Subaward/Consortium

Enter name of Organization: AMERICAN MEDICAL GROUP FOUNDATION

Start Date*: 09-01-2022 **End Date*:** 08-31-2023 **Budget Period: 1**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	0.00
2. Publication Costs	0.00
3. Consultant Services	0.00
4. ADP/Computer Services	0.00
5. Subawards/Consortium/Contractual Costs	0.00
6. Equipment or Facility Rental/User Fees	0.00
7. Alterations and Renovations	0.00
8. Honoraria	18,000.00
9.	0.00
10.	0.00
11.	0.00
12.	0.00
13.	0.00
14.	0.00
15.	0.00
16.	0.00
17.	0.00
Total Other Direct Costs	**18,000.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**53,780.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. Salary & Wages	15.0	35,780.00	5,367.00
		Total Indirect Costs	**5,367.00**

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)	**59,147.00**

J. Fee	Funds Requested ($)*
	0.00

K. Total Costs and Fee	Funds Requested ($)*
	59,147.00

L. Budget Justification* File Name: AMGA budget justificaion v2.pdf

RESEARCH & RELATED Budget {F-K} (Funds Requested)

BUDGET JUSTIFICATION – American Medical Group Association, Inc., Year 2

KEY PERSONNEL

Elizabeth Ciemins, Research Director (CM)

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.

OTHER PERSONNEL

Monette McKinnon, Research Coordinator (CM)

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.

Fringe Benefits

Fringe benefits are included for all personnel.

Other Direct Costs

Honoraria payments: $18,000

Healthcare System Honoraria

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

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.

Indirect Costs

Indirect Costs are at the 15% rate per the American Medical Group Association, Inc. policy

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 1

FINAL

UEI*: DLWBSLWAJWR1

Budget Type*: ❍ Project ● Subaward/Consortium

Enter name of Organization: OHIO STATE UNIVERSITY

Start Date*: 09-01-2022 **End Date*:** 08-31-2023 **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		Ohio State Subcontract PI	CAL. MONTHS, INST. BASE SALARY				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 ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
0	**Total Number Other Personnel**					**Total Other Personnel**	**0.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**7,586.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 1

UEI*: DLWBSLWAJWR1

Budget Type*: ❍ Project ● Subaward/Consortium

Enter name of Organization: OHIO STATE UNIVERSITY

Start Date*: 09-01-2022 **End Date*:** 08-31-2023 **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	**0.00**

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:		
0 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

UEI*: DLWBSLWAJWR1

Budget Type*: ❍ Project ● Subaward/Consortium

Enter name of Organization: OHIO STATE UNIVERSITY

Start Date*: 09-01-2022 **End Date*:** 08-31-2023 **Budget Period: 1**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	0.00
2. Publication Costs	0.00
3. Consultant Services	0.00
4. ADP/Computer Services	0.00
5. Subawards/Consortium/Contractual Costs	0.00
6. Equipment or Facility Rental/User Fees	0.00
7. Alterations and Renovations	0.00
8.	0.00
9.	0.00
10.	0.00
11.	0.00
12.	0.00
13.	0.00
14.	0.00
15.	0.00
16.	0.00
17.	0.00
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	56.0	7,586.00	4,248.00
		Total Indirect Costs	**4,248.00**

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)	**11,834.00**

J. Fee	Funds Requested ($)*
	0.00

K. Total Costs and Fee	Funds Requested ($)*
	11,834.00

L. Budget Justification*	File Name: Ohio State Univ_Budget Justification YR 2 v2.pdf

RESEARCH & RELATED Budget {F-K} (Funds Requested)

BUDGET JUSTIFICATION – Ohio State University, Year 2

KEY PERSONNEL

Paul Reiter, PhD, Co-Investigator (☐ AM, ☐ SM)

Dr. Reiter is a 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.

Fringe Benefits

Fringe Benefits are budgeted per our approved F&A rate agreement at 23.4% for faculty academic, 13.9% for faculty summer.

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%.

A. COMPONENT COVER PAGE

Project Title: IMPACT Project 2 – The impact of clinic-level financial incentives on HPV vaccine communication and uptake
Component Project Lead Information: Trogdon, Justin

B. COMPONENT ACCOMPLISHMENTS

B.1 WHAT ARE THE MAJOR GOALS OF THE PROJECT?

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.

The overall goal of Project 2's 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 will 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.
Aim 2. Demonstrate the impact of clinic-level financial incentives on HPV vaccine communication and uptake in healthcare systems.
Aim 3. Generate guidance for systems to compare and implement AAT and financial incentives.

The proposed research addresses the IMPACT Program Project theme of amplifying the impact of an Evidence-based Cancer Control 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.

B.1.a Have the major goals changed since the initial competing award or previous report?

No

B.2 WHAT WAS ACCOMPLISHED UNDER THESE GOALS?

File Uploaded : Accomplishments_P2.pdf

B.3 COMPETITIVE REVISIONS/ADMINISTRATIVE SUPPLEMENTS

Not Applicable

B.4 WHAT OPPORTUNITIES FOR TRAINING AND PROFESSIONAL DEVELOPMENT HAS THE PROJECT PROVIDED?

NOTHING TO REPORT

B.5 HOW HAVE THE RESULTS BEEN DISSEMINATED TO COMMUNITIES OF INTEREST?

NOTHING TO REPORT

B.6 WHAT DO YOU PLAN TO DO DURING THE NEXT REPORTING PERIOD TO ACCOMPLISH THE GOALS?

We will write up the findings from our formative interviews and the national survey for publication (Activity 1a and 1b). Our work over Year 2 will continue to inform intervention development (Activity 1b). Based on formative interview feedback and data from the national survey, we will develop intervention materials to maximize salience of and engagement with the incentive intervention. Findings will inform our Aim 2 trial.

We will work with the Data Core to finalize our power analysis for the Aim 2 trial. In September through November 2022, we will use existing EHR data to identify eligible clinics, guide planning for clinic recruitment in North Carolina, and refine tools for EHR data collection for clinical trial outcomes monitoring and populating the feedback reports to be disseminated monthly to participating clinics (Activity 1b). In December 2022, we will begin reaching out to identified systems and clinics for recruitment to the clinical trial with help from Dr. Michelle Hernandez and North Carolina Network Consortium (Activity 2a). We will have our first clinic recruited for participation in February 2023 and all 17 clinics to participate in the first wave of the Project 2 clinical trial will be recruited and randomized by May 2023 (Activity 2a). By June 2023, we will be collecting EHR data monthly to monitor outcomes (Activity 2b).

B.2 (Accomplishments_P2.pdf)

ACCOMPLISHMENTS – Project 2, Year 1

Below are Project 2 specific aims and updates on major activities, specific objectives, and significant results for September 2021 through June 2022.

Aim 1. Characterize perceptions of financial incentives with behavioral nudges tied to HPV vaccination.

In the first two months, we focused on hiring staff and establishing the administrative infrastructure for the planned work. A strategic review across the P01 identified that preparation for the national survey in Activity 1a would need to happen in the fall of 2021 and winter of 2022 to field the survey in May and June 2022.

Activity 1a. Conduct national primary care team survey
The Project 2 team developed 15 survey questions on performance feedback and financial incentives. We elicited feedback on these draft items from the Data Core, Projects 1, 3, and 4, and the Clinical Advisory Board. We conducted 8 cognitive interviews to evaluate survey item comprehensibility and refined the survey items. In collaboration with the Data Core, we launched the national primary care team survey in May 2022, and data collection is currently ongoing with 2,478 participants as of June 20, 2022. See the Data Core component for more details.

Activity 1b. Refine feedback report using EHR data to calculate HPV vaccination rates
In February 2022, the Project 2 team developed a draft EHR data shell of variables to collect at the clinic and patient level during Aim 2 efforts in Year 2 using aggregate, deidentified data from Carolina Data Warehouse for Health. These variables will enable us to both measure outcomes of Aim 2 efforts in Year 2 and provide provider level feedback on their HPV vaccination performance in a Feedback Report. Currently, UNC's Sheps Center is establishing and testing linkages to EHR data. CHAI Core is collaborating with us to define a simple interface for feedback report using EHR data to calculate HPV vaccination rates. With the CHAI Core, we are currently conducting usability tests of the feedback report with 6-8 providers.

Aim 2. Demonstrate the impact of clinic-level financial incentives on HPV vaccine communication and uptake in healthcare systems.

We currently plan to recruit 34 clinics, as described in the grant proposal. If the budget cuts necessitate a small reduction in sample size, we will work with the Data Core to revisit our power analysis to ensure that our trial remains adequately powered. We have begun meeting with NCnet to discuss recruitment of clinics for the trial. Our analysis of the Carolina Data Warehouse for Health in the first quarter of Year 2 will provide an initial set of qualifying clinics from withing the UNC system; our target is 17 clinics in each wave of the trial. Other Aim 2 activities will begin in Year 2.

Aim 3. Generate guidance for systems to compare and implement AAT and financial incentives.

As noted above, we have begun the development of a feedback report that participating clinics will get summarizing their progress on HPV vaccination. Other Aim 3 activities will begin in Year 2.

Significance
In Year 1, the national primary care team survey (Aim 1) is generating new national findings on opportunities for expanding financial incentives with behavioral nudges for HPV vaccination, which will inform the intervention and trial of a tool to monitor HPV vaccination rates at the provider and clinic levels (Aim 2).

C. COMPONENT PRODUCTS

C.1 PUBLICATIONS
Not Applicable
C.2 WEBSITE(S) OR OTHER INTERNET SITE(S)
Not Applicable
C.3 TECHNOLOGIES OR TECHNIQUES
NOTHING TO REPORT
C.4 INVENTIONS, PATENT APPLICATIONS, AND/OR LICENSES
Not Applicable
C.5 OTHER PRODUCTS AND RESOURCE SHARING
NOTHING TO REPORT

D. COMPONENT PARTICIPANTS

Not applicable

E. COMPONENT IMPACT

E.1 WHAT IS THE IMPACT ON THE DEVELOPMENT OF HUMAN RESOURCES? Not Applicable
E.2 WHAT IS THE IMPACT ON PHYSICAL, INSTITUTIONAL, OR INFORMATION RESOURCES THAT FORM INFRASTRUCTURE? Not Applicable
E.3 WHAT IS THE IMPACT ON TECHNOLOGY TRANSFER? NOTHING TO REPORT
E.4 WHAT DOLLAR AMOUNT OF THE AWARD'S BUDGET IS BEING SPENT IN FOREIGN COUNTRY(IES)? Not Applicable

F. COMPONENT CHANGES

F.1 CHANGES IN APPROACH AND REASONS FOR CHANGE

Not Applicable

F.2 ACTUAL OR ANTICIPATED CHALLENGES OR DELAYS AND ACTIONS OR PLANS TO RESOLVE THEM

NOTHING TO REPORT

F.3 SIGNIFICANT CHANGES TO HUMAN SUBJECTS, VERTEBRATE ANIMALS, BIOHAZARDS, AND/OR SELECT AGENTS

F.3.a Human Subject

No Change

F.3.b Vertebrate Animals

No Change

F.3.c Biohazards

No Change

F.3.d Select Agents

No Change

G. COMPONENT SPECIAL REPORTING REQUIREMENTS SPECIAL REPORTING REQUIREMENTS

G.1 SPECIAL NOTICE OF AWARD TERMS AND FUNDING OPPORTUNITIES ANNOUNCEMENT REPORTING REQUIREMENTS

Not Applicable

G.2 RESPONSIBLE CONDUCT OF RESEARCH

Not Applicable

G.3 MENTOR'S REPORT OR SPONSOR COMMENTS

Not Applicable

G.4 HUMAN SUBJECTS

Not Applicable

G.5 HUMAN SUBJECTS EDUCATION REQUIREMENT

NOT APPLICABLE

G.6 HUMAN EMBRYONIC STEM CELLS (HESCS)

Does this project involve human embryonic stem cells (only hESC lines listed as approved in the NIH Registry may be used in NIH funded research)?

No

G.7 VERTEBRATE ANIMALS

Not Applicable

G.8 PROJECT/PERFORMANCE SITES

Not Applicable

G.9 FOREIGN COMPONENT

Not Applicable

G.10 ESTIMATED UNOBLIGATED BALANCE

Not Applicable

G.11 PROGRAM INCOME

Not Applicable

G.12 F&A COSTS

Not Applicable

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 1

FINAL

UEI*: D3LHU66KBLD5

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: UNIV OF NORTH CAROLINA CHAPEL HILL

Start Date*: 09-01-2022 **End Date*:** 08-31-2023 **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		Trogdon		Project Lead	CAL. MONTHS, INST. BASE SALARY				38,539.00	11,491.00	50,030.00
2.	Michelle		Hernandez		Co-Investigator					20,370.00	7,227.00	27,597.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **77,627.00**

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						
3	Other Personnel	10.4	0.0	0.0	63,738.00	23,426.00	87,164.00
3	**Total Number Other Personnel**					**Total Other Personnel**	**87,164.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**164,791.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 1

UEI*: D3LHU66KBLD5

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: UNIV OF NORTH CAROLINA CHAPEL HILL

Start Date*: 09-01-2022 **End Date*:** 08-31-2023 **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	**0.00**

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	0.00
Total Travel Cost	**6,000.00**

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:		
0 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

UEI*: D3LHU66KBLD5

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: UNIV OF NORTH CAROLINA CHAPEL HILL

Start Date*: 09-01-2022 **End Date*:** 08-31-2023 **Budget Period: 1**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	2,500.00
2. Publication Costs	1,500.00
3. Consultant Services	0.00
4. ADP/Computer Services	0.00
5. Subawards/Consortium/Contractual Costs	0.00
6. Equipment or Facility Rental/User Fees	0.00
7. Alterations and Renovations	0.00
8. Other Costs	58,200.00
9.	0.00
10.	0.00
11.	0.00
12.	0.00
13.	0.00
14.	0.00
15.	0.00
16.	0.00
17.	0.00
Total Other Direct Costs	**62,200.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**232,991.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. MTDC	55.5	232,991.00	129,310.00
		Total Indirect Costs	**129,310.00**

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)	**362,301.00**

J. Fee	Funds Requested ($)*
	0.00

K. Total Costs and Fee	Funds Requested ($)*
	362,301.00

L. Budget Justification* File Name: Budget Justification P2.pdf

RESEARCH & RELATED Budget {F-K} (Funds Requested)

BUDGET JUSTIFICATION – Project 2, Year 2

KEY PERSONNEL

Justin Trogdon, PhD, Project Lead (CM)
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 (CM)
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.

OTHER PERSONNEL

Kathleen Mottus, NCnet Project Manager (CM)
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 (0.84 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.

Kathryn Brignole, Project Manager (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.

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 the following fringe benefit rates to the personnel on this proposal: Basic permanent employee benefits are 26.174% of annual salary plus $7,019.00/FTE/YR for fixed health insurance. Graduate Student employee benefits are 9.49% of annual salary plus $4,223.04/FTE/YR for fixed health insurance. P&A Practice Plan member benefits calculate at 31.081% of annual salary plus $8,962.76/FTE/YR for fixed health insurance.

TRAVEL
$6,000

Travel for Domestic Conferences ($1,500)
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 Announcement Approach Training ($4,500)
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.

MATERIALS & SUPPLIES
$2,500

Data Storage ($1,500)
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 ($1,000)
We have budgeted $1,000 per year, totaling $5,000, for printing project materials, including surveys, training materials, consent forms, and letters.

PUBLICATION COSTS
$1,500

It is increasingly common for top journals to charge publication fees. Thus, we have budgeted for 1 article in Years 2-5.

OTHER COSTS
$58,200

Participation Incentives ($17,000)
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.

Sheps Center ($41,200)
The Sheps Center will support the design, development, and testing of the electronic health records data (EHR) capture tools for intervention outcome monitoring in the Aim 2 trial. They also will produce, populate, and send the monthly feedback reports on HPV vaccination rates to clinics participating in the incentive arm as a behavioral nudge.

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 09/16/2021), 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.

A. COMPONENT COVER PAGE

Project Title: IMPACT Project 3 – Engaging clinical champions to improve HPV vaccine communication and uptake in healthcare systems
Component Project Lead Information: Gilkey, Melissa B

B. COMPONENT ACCOMPLISHMENTS

B.1 WHAT ARE THE MAJOR GOALS OF THE PROJECT?

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.

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.
Aim 2. Compare the impact of Champion AAT to Traditional AAT on HPV vaccine uptake and communication in healthcare systems.
Aim 3. Generate guidance to help healthcare systems compare and implement Champion AAT and 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. With Project 4, we will model our intervention's cost-effectiveness and disseminate research findings and intervention packages to US healthcare systems.

B.1.a Have the major goals changed since the initial competing award or previous report?

No

B.2 WHAT WAS ACCOMPLISHED UNDER THESE GOALS?

File Uploaded : Accomplishments_P3.pdf

B.3 COMPETITIVE REVISIONS/ADMINISTRATIVE SUPPLEMENTS

Not Applicable

B.4 WHAT OPPORTUNITIES FOR TRAINING AND PROFESSIONAL DEVELOPMENT HAS THE PROJECT PROVIDED?

NOTHING TO REPORT

B.5 HOW HAVE THE RESULTS BEEN DISSEMINATED TO COMMUNITIES OF INTEREST?

NOTHING TO REPORT

B.6 WHAT DO YOU PLAN TO DO DURING THE NEXT REPORTING PERIOD TO ACCOMPLISH THE GOALS?

We will write up the findings from our formative interviews and the national survey for publication (Activity 1b). We are currently recruiting healthcare systems in coordination with our subcontract partners at the University of Wisconsin and WCHQ. In Year 2, we will synthesize the data that we collect from champion interviews with primary care professionals from the recruited healthcare systems and the national primary care team survey to refine and adapt our intervention materials.

We will work with the Data Core to finalize our power analysis for the Aim 2 trial. Our pilot work in the beginning of Year 2 will additionally inform intervention and material development (Activity 2a). We anticipate having recruited 3 health care systems by the Fall 2022. These healthcare systems will participate in our pilot work and in the first wave of our intervention in Year 2. We anticipate recruiting and enrolling 20 clinics from the 3 recruited healthcare systems to participate in our intervention by March 2023. We anticipate recruiting and enrolling 20 more clinics from 3 additional healthcare systems to participate in the second wave of our intervention by the start of Year 3. In the upcoming years, we will conduct our non-inferiority trial and compare interventions on vaccination, intermediate, and implementation outcomes (Activities 2b-3b).

B.2 (Accomplishments_P3.pdf)

ACCOMPLISHMENTS – Project 3, Year 1

Below are Project 3 specific aims and updates on major activities, specific objectives, and significant results for September 2021 through June 2022.

Aim 1. Identify opportunities to engage clinical champions in delivering AAT within their own healthcare systems.

In September and October 2021 our team hired staff and established administrative infrastructure for the planned work. In addition to beginning Aim 1 activities, we worked with the projects and cores in the Program Project on the national primary care team survey. We developed ~15 survey questions exploring how to characterize vaccination champions, including the prevalence, professional roles, and activities of vaccination champions in healthcare systems. We elicited feedback on these draft items from the Data Core, Projects 1, 2, and 4, and the Clinical Advisory Board and conducted 9 cognitive interviews in February-March 2022. We then refined survey items and contributed them to the national survey. In collaboration with the Data Core, we launched the national primary care team survey in May 2022, and data collection is currently ongoing with 2,478 participants as of June 20, 2022. See the Data Core component for more details.

Activity 1a. Partner with healthcare systems in Wisconsin
In October 2021, our team began meeting bi-weekly with our partners at the University of Wisconsin to begin the planned work. In February 2022 we finalized our recruitment strategy and materials for partnering with healthcare systems. We also met with leaders at the Wisconsin Collaborative for Healthcare Quality (WCHQ) to begin recruiting healthcare systems. We engaged WCHQ leadership to strategize the best approach for getting buy-in from healthcare systems and which systems to target for recruitment. In March 2022, WCHQ leaders contacted the three healthcare systems that previously expressed interest to reconfirm their engagement in the project. WCHQ also began outreach to their other members to recruit additional healthcare systems.

Activity 1b. Interview vaccine champions
Our team developed recruitment and interview protocols in January 2022. We drafted our champion interview guide and trained interviewers in February-May 2022. We are recruiting for and conducting interviews in May-August 2022. We will analyze interview data in July-September 2022. Interview findings will inform the development of intervention materials for use in pilot testing in Fall of 2022 and the planned RCT in Spring of 2023.

Aim 2. Compare the impact of Champion AAT to Traditional AAT on HPV vaccine uptake and communication in healthcare systems.

Activity 2a. Use Aim 1 findings to adapt and pilot Champion AAT in partnering healthcare systems
Development of the adapted materials is ongoing. We will pilot test at the end of Year 1, finalizing materials in Year 2.

Activity 2b. Conduct a non-inferiority trial to compare Champion AAT to Traditional AAT
We currently plan to recruit 40 clinics across six healthcare systems, as described in the grant proposal. If the budget cuts necessitate a small reduction in sample size, we will work with the Data Core to revisit our power analysis to ensure that our trial remains adequately powered. Other Aim 2 activities will begin in Year 2.

Aim 3. Generate guidance for healthcare systems compare and implement Champion AAT and Traditional AAT.

Aim 3 activities will begin in Year 2.

Significance
In Year 1, the formative work is yielding a better understanding of the role of vaccine champions in healthcare systems and how their work can be leveraged to enhance the impact of HPV vaccine communication training (Aim 1). These findings are informing the development of the intervention and trial (Aim 2).

C. COMPONENT PRODUCTS

C.1 PUBLICATIONS Not Applicable
C.2 WEBSITE(S) OR OTHER INTERNET SITE(S) Not Applicable
C.3 TECHNOLOGIES OR TECHNIQUES NOTHING TO REPORT
C.4 INVENTIONS, PATENT APPLICATIONS, AND/OR LICENSES Not Applicable
C.5 OTHER PRODUCTS AND RESOURCE SHARING NOTHING TO REPORT

D. COMPONENT PARTICIPANTS

Not applicable

E. COMPONENT IMPACT

E.1 WHAT IS THE IMPACT ON THE DEVELOPMENT OF HUMAN RESOURCES?

Not Applicable

E.2 WHAT IS THE IMPACT ON PHYSICAL, INSTITUTIONAL, OR INFORMATION RESOURCES THAT FORM INFRASTRUCTURE?

Not Applicable

E.3 WHAT IS THE IMPACT ON TECHNOLOGY TRANSFER?

NOTHING TO REPORT

E.4 WHAT DOLLAR AMOUNT OF THE AWARD'S BUDGET IS BEING SPENT IN FOREIGN COUNTRY(IES)?

Not Applicable

F. COMPONENT CHANGES

F.1 CHANGES IN APPROACH AND REASONS FOR CHANGE

Not Applicable

F.2 ACTUAL OR ANTICIPATED CHALLENGES OR DELAYS AND ACTIONS OR PLANS TO RESOLVE THEM

NOTHING TO REPORT

F.3 SIGNIFICANT CHANGES TO HUMAN SUBJECTS, VERTEBRATE ANIMALS, BIOHAZARDS, AND/OR SELECT AGENTS

F.3.a Human Subject

No Change

F.3.b Vertebrate Animals

No Change

F.3.c Biohazards

No Change

F.3.d Select Agents

No Change

G. COMPONENT SPECIAL REPORTING REQUIREMENTS SPECIAL REPORTING REQUIREMENTS

G.1 SPECIAL NOTICE OF AWARD TERMS AND FUNDING OPPORTUNITIES ANNOUNCEMENT REPORTING REQUIREMENTS

Not Applicable

G.2 RESPONSIBLE CONDUCT OF RESEARCH

Not Applicable

G.3 MENTOR'S REPORT OR SPONSOR COMMENTS

Not Applicable

G.4 HUMAN SUBJECTS

Not Applicable

G.5 HUMAN SUBJECTS EDUCATION REQUIREMENT

NOT APPLICABLE

G.6 HUMAN EMBRYONIC STEM CELLS (HESCS)

Does this project involve human embryonic stem cells (only hESC lines listed as approved in the NIH Registry may be used in NIH funded research)?

No

G.7 VERTEBRATE ANIMALS

Not Applicable

G.8 PROJECT/PERFORMANCE SITES

Not Applicable

G.9 FOREIGN COMPONENT

Not Applicable

G.10 ESTIMATED UNOBLIGATED BALANCE

Not Applicable

G.11 PROGRAM INCOME

Not Applicable

G.12 F&A COSTS

Not Applicable

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 1

FINAL

UEI*: D3LHU66KBLD5

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: UNIV OF NORTH CAROLINA CHAPEL HILL

Start Date*: 09-01-2022 **End Date*:** 08-31-2023 **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				51,276.00	15,878.00	67,154.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **67,154.00**

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						
3	Other Personnel	6.7	0.0	0.0	51,386.00	18,779.00	70,165.00
3	**Total Number Other Personnel**					**Total Other Personnel**	**70,165.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**137,319.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 1

UEI*: D3LHU66KBLD5

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: UNIV OF NORTH CAROLINA CHAPEL HILL

Start Date*: 09-01-2022 **End Date*:** 08-31-2023 **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	**0.00**

Additional Equipment: File Name:

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	9,000.00
2. Foreign Travel Costs	0.00
Total Travel Cost	**9,000.00**

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:		
0 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

UEI*: D3LHU66KBLD5

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: UNIV OF NORTH CAROLINA CHAPEL HILL

Start Date*: 09-01-2022 **End Date*:** 08-31-2023 **Budget Period: 1**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	89.00
2. Publication Costs	0.00
3. Consultant Services	0.00
4. ADP/Computer Services	0.00
5. Subawards/Consortium/Contractual Costs	222,471.00
6. Equipment or Facility Rental/User Fees	0.00
7. Alterations and Renovations	0.00
8. Other Costs	6,950.00
9.	0.00
10.	0.00
11.	0.00
12.	0.00
13.	0.00
14.	0.00
15.	0.00
16.	0.00
17.	0.00
Total Other Direct Costs	**229,510.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**375,829.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. MTDC	55.5	375,829.00	85,114.00
		Total Indirect Costs	**85,114.00**

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number)	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.

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**460,943.00**

J. Fee	Funds Requested ($)*
	0.00

K. Total Costs and Fee	Funds Requested ($)*
	460,943.00

L. Budget Justification*	File Name: Budget Justification Project 3.pdf

RESEARCH & RELATED Budget {F-K} (Funds Requested)

BUDGET JUSTIFICATION – Project 3, Year 2

KEY PERSONNEL

Melissa Gilkey, PhD, Project Lead (CM)

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.

OTHER PERSONNEL

Jennifer Heisler-MacKinnon, MPH, Project Manager (CM)

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 #1, Announcement Approach Training (AAT) Facilitator, MD (0.96 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 #2, Announcement Approach Training (AAT) Facilitator, MD (0.96 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.

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 the following fringe benefit rates to the personnel on this proposal: Basic permanent employee benefits are 26.174% of annual salary plus $7,019.00/FTE/YR for fixed health insurance. P&A Practice Plan member benefits calculate at 31.081% of annual salary plus $8,962.76/FTE/YR for fixed health insurance.

TRAVEL
$9,000

AAT Facilitator Travel ($9,000)
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). Each trip is budgeted at $1,500.

Champion Travel ($1,000)
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).

MATERIALS & SUPPLIES
$89

Project Supplies ($89)
Each year, funds 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.

OTHER COSTS
$6,950

Participant Incentives ($6,950)
Incentives are budgeted at $2,700 in Year 1, $6,950 in Year 2, $6,950 in Year 3, 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), $25 gift card incentives for 150 AAT workshop participants for completing surveys (150 X $25 = $3,750) (we anticipate a 75% response rate for completing all three surveys), and $100 incentives for in-depth interviews at six-month follow-up with 6 clinical champions who participated in the intervention (6 X $100 = $1,200) ($2,000 + $3,750 + $1,200 = $6,950 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), $25 incentives for 150 AAT workshop participants for completing surveys (150 X $25 = $3,750) and $100 incentives for in-depth interviews at six-month follow-up with 6 clinical champions who participated in the intervention (6 X $100 = $1,200) ($2,000 + $3,750 + $1,200 = $6,950 in Y3). 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).

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

09/16/2021), 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
$222,471

The University of Wisconsin

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.

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 1

FINAL

UEI*: LCLSJAGTNZQ7

Budget Type*: ❍ Project ● Subaward/Consortium

Enter name of Organization: UNIVERSITY OF WISCONSIN-MADISON

Start Date*: 09-01-2022 **End Date*:** 08-31-2023 **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		Co-Investigator	CAL. MONTHS, INST. BASE SALARY				27,705.00	9,891.00	37,596.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name: **Total Senior/Key Person** **37,596.00**

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						
4	Other Personnel	9.1	0.0	0.0	54,143.00	19,329.00	73,472.00
4	**Total Number Other Personnel**					**Total Other Personnel**	**73,472.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**111,068.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 1

UEI*: LCLSJAGTNZQ7

Budget Type*: ❍ Project ● Subaward/Consortium

Enter name of Organization: UNIVERSITY OF WISCONSIN-MADISON

Start Date*: 09-01-2022 **End Date*:** 08-31-2023 **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	**0.00**

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	0.00
Total Travel Cost	**2,000.00**

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:		
0 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

UEI*: LCLSJAGTNZQ7

Budget Type*: ❍ Project ● Subaward/Consortium

Enter name of Organization: UNIVERSITY OF WISCONSIN-MADISON

Start Date*: 09-01-2022 **End Date*:** 08-31-2023 **Budget Period: 1**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	0.00
2. Publication Costs	0.00
3. Consultant Services	0.00
4. ADP/Computer Services	0.00
5. Subawards/Consortium/Contractual Costs	0.00
6. Equipment or Facility Rental/User Fees	0.00
7. Alterations and Renovations	0.00
8. WCHQ Data Fee	25,000.00
9. HIP Data Service Fee	5,000.00
10.	0.00
11.	0.00
12.	0.00
13.	0.00
14.	0.00
15.	0.00
16.	0.00
17.	0.00
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)

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**222,471.00**

J. Fee	Funds Requested ($)*
	0.00

K. Total Costs and Fee	Funds Requested ($)*
	222,471.00

L. Budget Justification*	File Name: Wisconsin_Budget Justification v2.pdf

RESEARCH & RELATED Budget {F-K} (Funds Requested)

BUDGET JUSTIFICATION – University of Wisconsin-Madison, Year 2

KEY PERSONNEL

Elizabeth Cox, MD, PhD, Co-Investigator, 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, will dedicate [%] FTE ([ ] cal months) in Year 2 of the project. 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 and 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 collaborate with Dr. Gilkey 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, Associate Researcher in the Department of Pediatrics at the University of Wisconsin School of Medicine and Public Health, will dedicate [%] FTE ([ ] cal months) in Year 2 of the project. Under the guidance of Dr. Cox, Mr. Kliems will be responsible for all aspects of IRB processes including securing and maintaining all human subject certifications at the University of Wisconsin-Madison, ensuring protocol adherence by study team members and partners, and reporting any changes to the University of North Carolina-Chapel Hill IRB. He will also oversee Ms. Stalford's efforts in all aspects of health system recruitment, intervention delivery, and data collection/management. Mr. Kliems has previously performed similar duties successfully as a member of Dr. Cox's research team.

Allie DeLonay, MS, Programmer in the Health Innovation Program at the University of Wisconsin School of Medicine and Public Health, will dedicate [%] FTE ([ ] cal months) in Year 2 of the project. 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 in the Health Innovation Program at the University of Wisconsin School of Medicine and Public Health, will dedicate [%] FTE ([ ] cal months) in Year 2 of the project. Ms. Bednarz leads community partnership efforts at the 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.

Samantha Stalford, MPH, Research Specialist in the Department of Pediatrics at University of Wisconsin School of Medicine and Public Health will dedicate [%] FTE ([ ] cal months) in Year 2 of the project. Under the guidance of Dr. Cox and Mr. Kliems, Ms. Stalford will recruit health systems, coordinate workshop trainings and intervention implementation at clinics, and also collect/manage data from clinics and providers. Ms. Stalford will also provide project management. She will perform administrative duties related to this project including organizing meetings, developing meeting agendas and task lists, and assisting with drafting and revising documents. Ms. Stalford has successfully performed these duties previously as a member of Dr. Cox's research team.

TRAVEL

Travel for data collection: $2,000 in Year 2 – Travel in Year 2 to the clinic sites for data collection will be $2,000.

OTHER EXPENSES

Wisconsin Collaborative for Healthcare Quality: $25,000 in Year 2 – 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.

Health Innovative Program Data Services: $5,000 in Year 2 – 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.

F&A

UW-Madison's negotiated F&A rate agreement is 55.5% of Modified Total Direct Costs.

A. COMPONENT COVER PAGE

Project Title: IMPACT Project 4 – Budget impact, cost-effectiveness, and population outcomes of interventions to improve HPV vaccine communication and uptake in rural and nonrural communities
Component Project Lead Information: Ozawa, Sachiko

B. COMPONENT ACCOMPLISHMENTS

B.1 WHAT ARE THE MAJOR GOALS OF THE PROJECT?

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.
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.
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.

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.

B.1.a Have the major goals changed since the initial competing award or previous report?

No

B.2 WHAT WAS ACCOMPLISHED UNDER THESE GOALS?

File Uploaded : Accomplishments_P4.pdf

B.3 COMPETITIVE REVISIONS/ADMINISTRATIVE SUPPLEMENTS

Not Applicable

B.4 WHAT OPPORTUNITIES FOR TRAINING AND PROFESSIONAL DEVELOPMENT HAS THE PROJECT PROVIDED?

NOTHING TO REPORT

B.5 HOW HAVE THE RESULTS BEEN DISSEMINATED TO COMMUNITIES OF INTEREST?

NOTHING TO REPORT

B.6 WHAT DO YOU PLAN TO DO DURING THE NEXT REPORTING PERIOD TO ACCOMPLISH THE GOALS?

Our work over Year 2 will consist of synthesizing and publishing findings from our Year 1 Activity 1a and Activity 1b, which will also inform intervention implementation in Projects 1-3. We also plan to submit our systematic review (Activity 2a) for publication during Year 2. Finally, we will begin developing a national county-specific HPV microsimulation model reflecting patterns of HPV vaccination, transmission, and progression to HPV cancers (Activity 2a) using published data on HPV transmission and HPV-related cancer incidence. Modeling steps to be conducted in Year 2 include simulating population demographic characteristics, HPV transmission and behavior, and HPV cancer risk and progression. We also plan to meet with our Modeler's Advisory Board to seek feedback on the structure, inputs, and assumptions of the microsimulation model.

B.2 (Accomplishments_P4.pdf)

ACCOMPLISHMENTS – Project 4, Year 1

Below are Project 4 specific aims and updates on major activities, specific objectives, and significant results for September 2021 through June 2022.

Aim 1. Identify differences in contextual factors in rural and nonrural clinical settings that may influence the implementation and effectiveness of enhanced AAT interventions.

In the first two months, we hired staff including a project manager and research assistants and established the administrative infrastructure for the planned work. Across the Data Core and Projects 1-4, a strategic review identified that preparation for the national survey in Activity 1b would need to happen in the fall and winter of 2021 to be ready to field the survey in April and May 2022. This led us to reorder Year 1 efforts to focus first on Activity 1b, followed by Activity 1a.

Activity 1a. Conduct interviews to understand contextual differences across rural and nonrural clinical settings
We completed the interview guide, incorporating feedback from members of Projects 1-3 and the Clinical Advisory Board (CAB), and finalized our recruitment strategy. The interviews focus on the provider role and previous HPV communication training, implementation of the Announcement Approach, and strategies to enhance the Announcement Approach in the context of rural and nonrural clinical settings. In May 2022, we commenced conducting interviews with primary care team members in North Carolina and have completed 15 interviews (4 rural, 11 nonrural) thus far. We plan to conduct a total of 40 interviews (20 rural, 20 nonrural) by end of August 2022. We have also drafted an initial codebook with codes based on Consolidated Framework for Intervention Research (CFIR) constructs and plan to add additional, relevant codes that emerge from the interview data during analysis.

Activity 1b. Conduct national primary care team survey
Working alongside the Data Core and Projects 1-3, our team developed 15 survey questions to assess the differences in HPV vaccine communication challenges based on clinic and patient characteristics, the impact of Covid-19 on HPV vaccine communication, and the training needs of different practice contexts. We elicited feedback from members of Projects 1-3, the Project 4 Modelers Advisory Board, and the CAB; conducted cognitive interviews with 7 participants in February and March 2022; and refined our final survey items for the national primary care team survey in March 2022. In collaboration with the Data Core, we launched the national primary care team survey in May 2022, and data collection is currently ongoing with 2,478 participants as of June 20, 2022. See the Data Core component for more details.

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.

Activity 2a. Develop a national county-specific HPV microsimulation model using secondary data
We convened a Modeler's Advisory Board in January 2022 to receive expert input, which will inform future Aim 2 efforts beginning in Year 2. We are also conducting a systematic review to summarize and compare methodological decisions among simulations models developed to provide estimates of HPV vaccination coverage in systematically marginalized populations. After registering the review in PROSPERO, we searched PubMed, Scopus, Embase, and CINAHL and identified 3,686 unique titles/abstracts for screening. Title/abstract screening is now almost complete, and we are planning to have the complete manuscript drafted by the end of Year 1. Review findings will inform methodological decisions in Aim 2 model development. Lastly, along with the Intervention Core, we have begun harmonizing the collection of cost data across the planned randomized controlled trials in Projects 1-3 for our planned cost-effectiveness analyses.

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.

Aim 3 activities will begin in Year 3. Findings from Activity 1a interviews will inform the development of the Activity 3a decision support tool.

B.2 (Accomplishments_P4.pdf)

Significance
In Year 1, the national primary care team survey and formative interviews are yielding a deeper understanding of how rural/nonrural differences in contextual, clinic and patient differences and Covid-19 impacts may influence the implementation of enhanced AAT interventions in clinics and healthcare systems (Aim 1). These findings are informing the development of the simulation model (Aim 2).

C. COMPONENT PRODUCTS

C.1 PUBLICATIONS
Not Applicable
C.2 WEBSITE(S) OR OTHER INTERNET SITE(S)
Not Applicable
C.3 TECHNOLOGIES OR TECHNIQUES
NOTHING TO REPORT
C.4 INVENTIONS, PATENT APPLICATIONS, AND/OR LICENSES
Not Applicable
C.5 OTHER PRODUCTS AND RESOURCE SHARING
NOTHING TO REPORT

D. COMPONENT PARTICIPANTS

Not applicable

E. COMPONENT IMPACT

E.1 WHAT IS THE IMPACT ON THE DEVELOPMENT OF HUMAN RESOURCES? Not Applicable
E.2 WHAT IS THE IMPACT ON PHYSICAL, INSTITUTIONAL, OR INFORMATION RESOURCES THAT FORM INFRASTRUCTURE? Not Applicable
E.3 WHAT IS THE IMPACT ON TECHNOLOGY TRANSFER? NOTHING TO REPORT
E.4 WHAT DOLLAR AMOUNT OF THE AWARD'S BUDGET IS BEING SPENT IN FOREIGN COUNTRY(IES)? Not Applicable

F. COMPONENT CHANGES

F.1 CHANGES IN APPROACH AND REASONS FOR CHANGE

Not Applicable

F.2 ACTUAL OR ANTICIPATED CHALLENGES OR DELAYS AND ACTIONS OR PLANS TO RESOLVE THEM

NOTHING TO REPORT

F.3 SIGNIFICANT CHANGES TO HUMAN SUBJECTS, VERTEBRATE ANIMALS, BIOHAZARDS, AND/OR SELECT AGENTS

F.3.a Human Subject

No Change

F.3.b Vertebrate Animals

No Change

F.3.c Biohazards

No Change

F.3.d Select Agents

No Change

G. COMPONENT SPECIAL REPORTING REQUIREMENTS SPECIAL REPORTING REQUIREMENTS

G.1 SPECIAL NOTICE OF AWARD TERMS AND FUNDING OPPORTUNITIES ANNOUNCEMENT REPORTING REQUIREMENTS

Not Applicable

G.2 RESPONSIBLE CONDUCT OF RESEARCH

Not Applicable

G.3 MENTOR'S REPORT OR SPONSOR COMMENTS

Not Applicable

G.4 HUMAN SUBJECTS

Not Applicable

G.5 HUMAN SUBJECTS EDUCATION REQUIREMENT

NOT APPLICABLE

G.6 HUMAN EMBRYONIC STEM CELLS (HESCS)

Does this project involve human embryonic stem cells (only hESC lines listed as approved in the NIH Registry may be used in NIH funded research)?

No

G.7 VERTEBRATE ANIMALS

Not Applicable

G.8 PROJECT/PERFORMANCE SITES

Not Applicable

G.9 FOREIGN COMPONENT

Not Applicable

G.10 ESTIMATED UNOBLIGATED BALANCE

Not Applicable

G.11 PROGRAM INCOME

Not Applicable

G.12 F&A COSTS

Not Applicable

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 1

FINAL

UEI*: D3LHU66KBLD5

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: UNIV OF NORTH CAROLINA CHAPEL HILL

Start Date*: 09-01-2022 **End Date*:** 08-31-2023 **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.		Kristen		Hassmiller-Lich		Co-Investigator	CAL. MONTHS, INST. BASE SALARY				3,542.00	1,085.00	4,627.00
2.		Lisa		Spees		Program Director					12,095.00	3,868.00	15,963.00
3.		Sachiko		Ozawa		Project Lead					23,689.00	7,306.00	30,995.00
4.		Sarah		Mills		Co-Investigator					2,216.00	720.00	2,936.00
5.		Stephanie		Wheeler		Co-Investigator					32,083.00	9,503.00	41,586.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **96,107.00**

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						
3	Other Personnel	10.2	0.0	0.0	48,706.00	18,758.00	67,464.00
3	**Total Number Other Personnel**					**Total Other Personnel**	**67,464.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**163,571.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 1

UEI*: D3LHU66KBLD5

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: UNIV OF NORTH CAROLINA CHAPEL HILL

Start Date*: 09-01-2022 **End Date*:** 08-31-2023 **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	**0.00**

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:		
0 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

UEI*: D3LHU66KBLD5

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: UNIV OF NORTH CAROLINA CHAPEL HILL

Start Date*: 09-01-2022 **End Date*:** 08-31-2023 **Budget Period: 1**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	0.00
2. Publication Costs	0.00
3. Consultant Services	44,000.00
4. ADP/Computer Services	0.00
5. Subawards/Consortium/Contractual Costs	0.00
6. Equipment or Facility Rental/User Fees	0.00
7. Alterations and Renovations	0.00
8.	0.00
9.	0.00
10.	0.00
11.	0.00
12.	0.00
13.	0.00
14.	0.00
15.	0.00
16.	0.00
17.	0.00
Total Other Direct Costs	**44,000.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**207,571.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. MTDC	55.5	207,571.00	115,202.00
		Total Indirect Costs	**115,202.00**

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)	**322,773.00**

J. Fee	Funds Requested ($)*
	0.00

K. Total Costs and Fee	Funds Requested ($)*
	322,773.00

L. Budget Justification* File Name: Budget Justification P4.pdf

RESEARCH & RELATED Budget {F-K} (Funds Requested)

BUDGET JUSTIFICATION – Project 4, Year 2

KEY PERSONNEL

Sachiko Ozawa, PhD, Project Co-Lead (CM)
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 (CM)
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 (CM)
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.

Lisa Spees, PhD, Program Director (CM)
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 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 (CM)
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

Tatenda Yemeke, Project Manager (CM)
Tatenda Yemeke will serve as the project manager for Project 4. He will serve as a liaison between Project 4 and the rest of the PO1, attending PO1 integration meetings, budget meetings, and project management meetings. He will manage the project budget activities, oversee study IRB protocol submissions, and lead recruitment of study participants for Aim 1 interviews. He will also conduct qualitative interviews of participants under Aim 1 activities and contribute to analysis of the qualitative data.

TBD, Research Assistant (2.23 CM)
The 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 Research Assistant will transition to full-time work to support the writing of manuscripts, conference presentations, and progress reports to disseminate project findings.

TBN, Programmer (2.04 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.

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 the following fringe benefit rates to the personnel on this proposal: Basic permanent employee benefits are 26.174% of annual

salary plus $7,019.00/FTE/YR for fixed health insurance.

CONSULTANTS / EXPERT MODELING ADVISORY COMMITTEE
$44,000

Jennifer Spencer, PhD ($)
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.

Colleen Higgins, MSPH ($)
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).

Jane Kim, PhD ($)
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 ($)
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).

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 09/16/2021), 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.

A. COMPONENT COVER PAGE

Project Title: Administrative Core – Improving Provider Announcement Communication Training (IMPACT)
Component Project Lead Information: Brewer, Noel Todd

B. COMPONENT ACCOMPLISHMENTS

B.1 WHAT ARE THE MAJOR GOALS OF THE PROJECT?

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 an Evidence-based Cancer Control 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 Project'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.

Aim 1. Foster effective collaboration across IMPACT's research projects and cores to achieve integration of their research activities and products.
Aim 2. Manage IMPACT's operations and progress toward milestones.
Aim 3. Administer the Rapid Response Pilot Grant Program.

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.

B.1.a Have the major goals changed since the initial competing award or previous report?

No

B.2 WHAT WAS ACCOMPLISHED UNDER THESE GOALS?

File Uploaded : Accomplishments_AC.pdf

B.3 COMPETITIVE REVISIONS/ADMINISTRATIVE SUPPLEMENTS

Not Applicable

B.4 WHAT OPPORTUNITIES FOR TRAINING AND PROFESSIONAL DEVELOPMENT HAS THE PROJECT PROVIDED?

NOTHING TO REPORT

B.5 HOW HAVE THE RESULTS BEEN DISSEMINATED TO COMMUNITIES OF INTEREST?

NOTHING TO REPORT

B.6 WHAT DO YOU PLAN TO DO DURING THE NEXT REPORTING PERIOD TO ACCOMPLISH THE GOALS?

In Year 2, we will continue to facilitate communication and coordination, monitor progress toward milestones, oversee fiscal

management and regulatory compliance, and support dissemination of IMPACT findings. A focus of Year 2 is to ensure adequate financial and logistical support for the three planned RCTs, timely registration of the trials, and timely launch including recruitment of systems and clinics. Our work over Year 2 will also include coordinating the Program Project's Annual Scientific Retreat, which includes a closed session for strategic input from our External Advisory Board. At the Annual Scientific Retreat, we will review accomplishments in diversity, equity, and inclusion, and identify plans for the coming year.

B.2 (Accomplishments_AC.pdf)

ACCOMPLISHMENTS – Administrative Core, Year 1

Below are Administrative Core specific aims and updates on major activities, specific objectives, and significant results for September 2021 through June 2022.

Aim 1. Foster effective collaboration across IMPACT's research projects and cores to achieve integration of their activities and research products.

Activity 1a. Facilitate communication and coordination across research projects and cores
We established our biweekly Integration Meetings, attended by Leads of the four research projects, the Data Core, and the Intervention Core and key staff and trainees. The Integration Meeting facilitates communication and coordination across the IMPACT Program Project. Meeting topics have included cross-cutting logistics and financial management, the national primary care team survey, planning for recruiting cognitive and qualitative interview participants, planning the projects' trial design, vaccination outcomes, and implementation science outcomes, and other progress updates. Our Program Project is committed to better promoting diversity, equity, and inclusion (DEI) in our work. To ensure that we address these issues, the Administrative Core established a DEI working group that is responsible for maintaining the visibility of these issues in our work. The DEI working group facilitated trainings, facilitated discussions, and tracked data related to DEI.

Activity 1b. Convene the External Advisory Board
We established our External Advisory Board (EAB) that includes a distinguished group of 7 HPV vaccine stakeholders: Dr. Lynne Fiscus (UNC), Dr. Kristin Oliver (AAP), Dr. Margot Savoy (AAFP), Dr. Shannon Stokley (CDC), Dr. Peter Szilagyi (UCLA), Dr. Tami Thomas (FIU), and Dr. Wendell Yarbrough (UNC). We recently recruited Dr. Savoy to increase the representation of people of color and family physicians in our Program Project. We also confirmed our CDC representative to the EAB, Dr. Stokley. We hosted an EAB Kick-off meeting in February 2022 to give an overview of the IMPACT Program, discuss the role of the board, prepare members to attend our Annual Scientific Retreat, and elicit discussion on key topics relevant to our projects.

Activity 1c. Coordinate the Program's Annual Scientific Retreat
We have scheduled our Annual Scientific Retreat for August 26, 2022. The Retreat theme is "Innovations in partnering with clinics in healthcare systems," with keynote presentations by Dr. Alex Fiks (UPenn) and Dr. Heather Brandt (St. Jude). The objectives of the meeting will be to enhance integration of IMPACT activities, present findings from Year 1 to the EAB and IMPACT collaborators, and receive input on Year 2 plans for our research projects and cores to garner new insights.

Aim 2. Manage IMPACT's operations and monitor progress toward milestones.

Activity 2a. Oversee fiscal management and monitor projects' and cores' progress toward milestone
The Administrative Core meets weekly to develop agendas and materials for the Integration Meetings, plan other work of the Core, and monitor progress toward milestones. The Core works closely with the UNC business offices to manage all fiscal aspects of the grant, including subcontracts, budget changes, and day-to-day operations. We manage the budget cuts across projects and cores, have supported projects and cores as they prepared Year 2 budgets, and planned for Years 3-5 budgets. We established a weekly research staff meeting for project and core managers to communicate about fiscal management processes, budgets, integration efforts, and progress toward milestones.

Activity 2b. Oversee regulatory compliance of project and cores
The four research projects and Data Core currently have IRB approvals for the ongoing research activities including conducting qualitative interviews and the national primary care team survey. We have regular discussions about clinical trials registration, Data Safety Monitoring Plans, appropriate data storage, data sharing as described in our Resource Sharing Plan, and sharing conflict of interest information.

Activity 2c. Support efforts to disseminate Program findings
We have planned the first Annual Scientific Retreat to support the dissemination of findings across research projects and cores and to invited key stakeholders. We have already secured space in a special issue on age 9

vaccination for two papers from our national survey. We have also developed a website for IMPACT that we expect to launch at the Annual Retreat. The website will also be used to disseminate findings and news for the Program Project.

Aim 3. Administer the Rapid Response Pilot Grant Program.

Due to the shorter Year 1 period, delays in hiring study personnel, and the pandemic, the pilot grant program will start in Year 2.

Significance
The Administrative Core has a central function in establishing linkages and integration between all program elements, ensuring regular communication both within the Program Project and with external organizations, and overseeing the Program Project as a whole and the pilot grant program. 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.

C. COMPONENT PRODUCTS

C.1 PUBLICATIONS
Not Applicable
C.2 WEBSITE(S) OR OTHER INTERNET SITE(S)
Not Applicable
C.3 TECHNOLOGIES OR TECHNIQUES
NOTHING TO REPORT
C.4 INVENTIONS, PATENT APPLICATIONS, AND/OR LICENSES
Not Applicable
C.5 OTHER PRODUCTS AND RESOURCE SHARING
NOTHING TO REPORT

D. COMPONENT PARTICIPANTS

Not applicable

E. COMPONENT IMPACT

E.1 WHAT IS THE IMPACT ON THE DEVELOPMENT OF HUMAN RESOURCES? Not Applicable
E.2 WHAT IS THE IMPACT ON PHYSICAL, INSTITUTIONAL, OR INFORMATION RESOURCES THAT FORM INFRASTRUCTURE? Not Applicable
E.3 WHAT IS THE IMPACT ON TECHNOLOGY TRANSFER? NOTHING TO REPORT
E.4 WHAT DOLLAR AMOUNT OF THE AWARD'S BUDGET IS BEING SPENT IN FOREIGN COUNTRY(IES)? Not Applicable

F. COMPONENT CHANGES

F.1 CHANGES IN APPROACH AND REASONS FOR CHANGE

Not Applicable

F.2 ACTUAL OR ANTICIPATED CHALLENGES OR DELAYS AND ACTIONS OR PLANS TO RESOLVE THEM

Aim 3. Administer the Rapid Response Pilot Grant Program: A review of Year 1 priorities, including preparation for the 3 planned trials indicated that the projects did not have capacity to take on additional research as part of the pilot grants in Year 1. For this reason, we moved the start date to Year 2.

F.3 SIGNIFICANT CHANGES TO HUMAN SUBJECTS, VERTEBRATE ANIMALS, BIOHAZARDS, AND/OR SELECT AGENTS

F.3.a Human Subject

No Change

F.3.b Vertebrate Animals

No Change

F.3.c Biohazards

No Change

F.3.d Select Agents

No Change

G. COMPONENT SPECIAL REPORTING REQUIREMENTS SPECIAL REPORTING REQUIREMENTS

G.1 SPECIAL NOTICE OF AWARD TERMS AND FUNDING OPPORTUNITIES ANNOUNCEMENT REPORTING REQUIREMENTS

Not Applicable

G.2 RESPONSIBLE CONDUCT OF RESEARCH

Not Applicable

G.3 MENTOR'S REPORT OR SPONSOR COMMENTS

Not Applicable

G.4 HUMAN SUBJECTS

Not Applicable

G.5 HUMAN SUBJECTS EDUCATION REQUIREMENT

NOT APPLICABLE

G.6 HUMAN EMBRYONIC STEM CELLS (HESCS)

Does this project involve human embryonic stem cells (only hESC lines listed as approved in the NIH Registry may be used in NIH funded research)?

No

G.7 VERTEBRATE ANIMALS

Not Applicable

G.8 PROJECT/PERFORMANCE SITES

Not Applicable

G.9 FOREIGN COMPONENT

Not Applicable

G.10 ESTIMATED UNOBLIGATED BALANCE

Not Applicable

G.11 PROGRAM INCOME

Not Applicable

G.12 F&A COSTS

Not Applicable

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 1

FINAL

UEI*: D3LHU66KBLD5

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: UNIV OF NORTH CAROLINA CHAPEL HILL

Start Date*: 09-01-2022 **End Date*:** 08-31-2023 **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		Trogdon		Co-Investigator	CAL. MONTHS, INST. BASE SALARY				3,854.00	1,149.00	5,003.00
2.	Melissa		Gilkey		Co-Investigator					2,930.00	907.00	3,837.00
3.	Noel		Brewer		Core Lead					50,925.00	15,084.00	66,009.00
4.	Sachiko		Ozawa		Co-Investigator					7,520.00	2,319.00	9,839.00
5.	Stephanie		Wheeler		Co-Investigator					4,074.00	1,207.00	5,281.00
6.	Tara		Queen		Co-Investigator					230.00	130.00	360.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **90,329.00**

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						
2	Other Personnel	7.3	0.0	0.0	44,712.00	16,009.00	60,721.00
2	**Total Number Other Personnel**					**Total Other Personnel**	**60,721.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**151,050.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 1

UEI*: D3LHU66KBLD5

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: UNIV OF NORTH CAROLINA CHAPEL HILL

Start Date*: 09-01-2022 **End Date*:** 08-31-2023 **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	**0.00**

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	0.00
Total Travel Cost	**6,000.00**

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:		
0 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

UEI*: D3LHU66KBLD5

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: UNIV OF NORTH CAROLINA CHAPEL HILL

Start Date*: 09-01-2022 **End Date*:** 08-31-2023 **Budget Period: 1**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	1,000.00
2. Publication Costs	0.00
3. Consultant Services	0.00
4. ADP/Computer Services	0.00
5. Subawards/Consortium/Contractual Costs	0.00
6. Equipment or Facility Rental/User Fees	0.00
7. Alterations and Renovations	0.00
8. Other Costs	44,000.00
9.	0.00
10.	0.00
11.	0.00
12.	0.00
13.	0.00
14.	0.00
15.	0.00
16.	0.00
17.	0.00
Total Other Direct Costs	**45,000.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**202,050.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. MTDC	55.5	202,050.00	112,138.00
		Total Indirect Costs	**112,138.00**

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)	**314,188.00**

J. Fee	Funds Requested ($)*
	0.00

K. Total Costs and Fee	Funds Requested ($)*
	314,188.00

L. Budget Justification*	File Name: Budget Justification Admin Core.pdf

RESEARCH & RELATED Budget {F-K} (Funds Requested)

BUDGET JUSTIFICATION – Administrative Core, Year 2

KEY PERSONNEL

Noel T. Brewer, PhD, Core Lead (CM)
Dr. Brewer is Distinguished 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 (CM)
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.

Justin G. Trogdon, PhD, Co-Investigator (CM)
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 (CM)
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.

Tara Queen, PhD, Co-Investigator (CM)
Dr. Queen is a Statistician 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. Queen 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 (CM)
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 and lead efforts of our Diversity, Equity, and Inclusion (DEI) Working Group.

William A. Calo, PhD, Co-Investigator (CM, charged to Intervention Core)
Dr. Calo is Assistant Professor in the Department of Public Health Sciences at the Penn State College of Medicine and will Co-Lead the Intervention 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. Calo 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. The cost for his effort is kept administratively in the Intervention Core to simplify subcontracts to his 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.

OTHER PERSONNEL

Jennifer Mendel Sheldon, Program Manager (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 (1.96 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.

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 the following fringe benefit rates to the personnel on this proposal: Basic permanent employee benefits are 26.174% of annual salary plus $7,019.00/FTE/YR for fixed health insurance.

TRAVEL
$6,000

Travel for Annual Conferences ($1,500)
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 ($4,500)
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.

MATERIALIS & SUPPLIES
$1,000

Project Supplies ($1,000)
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.

OTHER COSTS
$44,000

Rapid Response Pilot Grant Program ($40,000)
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.

External Advisory Board (EAB) ($4,000)
We established 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 consists 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 have also confirmed our CDC representative to the EAB, Dr. Shannon Stokley (DrPH, CDC), who is an HPV vaccine expert to join the advisors. 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. 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.

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 09/16/2021), 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.

A. COMPONENT COVER PAGE

Project Title: Intervention Core - Improving Provider Announcement Communication Training (IMPACT)
Component Project Lead Information: Gilkey, Melissa B

B. COMPONENT ACCOMPLISHMENTS

B.1 WHAT ARE THE MAJOR GOALS OF THE PROJECT?

The Intervention Core is a service core created to provide coordination and standardization of intervention and implementation data collection materials for the Program Project, 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.
Aim 2. Prepare AAT facilitators and training materials for intervention delivery. Projects 1-3.
Aim 3. Harmonize assessment of key implementation measures, including cost. Projects 1-4.
Aim 4. Facilitate national dissemination of study findings and intervention materials. Projects 1-4.

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.

B.1.a Have the major goals changed since the initial competing award or previous report?

No

B.2 WHAT WAS ACCOMPLISHED UNDER THESE GOALS?

File Uploaded : Accomplishments_IC.pdf

B.3 COMPETITIVE REVISIONS/ADMINISTRATIVE SUPPLEMENTS

Not Applicable

B.4 WHAT OPPORTUNITIES FOR TRAINING AND PROFESSIONAL DEVELOPMENT HAS THE PROJECT PROVIDED?

NOTHING TO REPORT

B.5 HOW HAVE THE RESULTS BEEN DISSEMINATED TO COMMUNITIES OF INTEREST?

NOTHING TO REPORT

B.6 WHAT DO YOU PLAN TO DO DURING THE NEXT REPORTING PERIOD TO ACCOMPLISH THE GOALS?

Our work over Year 2 will include continuing to hold CAB meetings and refining AAT intervention and data collection materials. In Years 2-3, we will train AAT facilitators to prepare them for intervention work in the trials. In Years 2-3 we will also facilitate the collection of implementation outcomes data across the trials. We will continue to work with Project 4 to ensure the usability of trial implementation data for cost-effectiveness analyses.

B.2 (Accomplishments_IC.pdf)

ACCOMPLISHMENTS – Intervention Core, Year 1

Below are Intervention Core specific aims and updates on major activities, specific objectives, and significant results for September 2021 through June 2022.

Aim 1. Convene a Clinical Advisory Board for multi-disciplinary implementation support.

Activity 1a. Recruit a Clinical Advisory Board
We successfully recruited 7 members to our Clinical Advisory Board (CAB). These members include a physician assistant, parent vaccine advocate, 2 physicians, 2 nurses, and a certified medical assistant, all of whom practice in diverse geographic locations across the US. CAB members include four women and one person of color.

Activity 1b. Hold meetings of the Clinical Advisory Board
We have already convened the planned 4 CAB meetings between December 2021 and April 2022. The CAB meetings have allowed research projects to get detailed feedback on survey questions for the national primary care team survey and for upcoming formative interviews. Attendance at CAB meetings has been excellent, with all 7 CAB members attending the first two meetings, and 6 members attending the third and fourth meetings. Because of the success of these meetings and the value they are bringing, we have planned 2 more CAB meetings in Year 1 that will focus on eliciting feedback on intervention materials, including updates to the AAT.

Aim 2. Prepare AAT facilitators and training materials for intervention delivery.

Activity 2a. Coordinate updates to intervention materials
In collaboration with Project 1, our team has reviewed and begun updating the traditional AAT materials, including making the AAT adaptable to an asynchronous format, updating demonstration videos, incorporating information about age 9 recommendations, and strengthening the train-the-trainer materials. In February 2022, our team selected a digital learning consultant to help adapt materials. Work to update materials began in March 2022, including the development of a detailed timeline and work plan. Updates will continue throughout Year 1. In Year 2, we will make additional updates to materials based on findings from pilot work in the research projects. Updates will be completed in time for Projects' 1-3 intervention work in Year 2.

Activity 2b. Coordinate across Projects 1-3 to prepare the AAT facilitators
In February 2022, our team began the search for an Orientation Leader to train AAT facilitators and have identified a promising candidate for this position. This candidate is a pediatrician and has also trained in preventive medicine. The candidate has a particular interest in adolescent health and has conducted quality improvement projects in HPV vaccination. Once the Orientation Leader is hired, they will advise and assist with updates to the AAT materials as part of Activity 2a.

Aim 3. Harmonize assessment of key implementation measures, including cost.

Activity 3a. Establish shared tools and procedures to assess implementation measures in Projects 1-3
In October through December 2021, our team met with Projects 1-4 to assess plans for data collection during the RCTs. We met with our implementation science consultant, Dr. Bryan Weiner, in early March 2022, and are currently drafting tools and procedures that each research project will use. The development of these shared tools to assess implementation outcomes will continue throughout Year 1. In the early months of Year 2, we will make final updates to these implementation evaluation materials based on feedback and usability testing from pilot work in the research projects. Revised tools and procedures will be completed in time for Projects' 1-3 intervention work later in Year 2.

Aim 4. Facilitate national dissemination of study findings and intervention materials.

Work on Aim 4 activities will occur in future years of the Program Project.

B.2 (Accomplishments_IC.pdf)

Significance
In Year 1, the Intervention Core maximized the potential impact of trials and interventions through advice from the CAB, optimization of the AAT materials and curriculum, and harmonization of implementation measures.

C. COMPONENT PRODUCTS

C.1 PUBLICATIONS
Not Applicable
C.2 WEBSITE(S) OR OTHER INTERNET SITE(S)
Not Applicable
C.3 TECHNOLOGIES OR TECHNIQUES
NOTHING TO REPORT
C.4 INVENTIONS, PATENT APPLICATIONS, AND/OR LICENSES
Not Applicable
C.5 OTHER PRODUCTS AND RESOURCE SHARING
NOTHING TO REPORT

D. COMPONENT PARTICIPANTS

Not applicable

E. COMPONENT IMPACT

E.1 WHAT IS THE IMPACT ON THE DEVELOPMENT OF HUMAN RESOURCES?
Not Applicable
E.2 WHAT IS THE IMPACT ON PHYSICAL, INSTITUTIONAL, OR INFORMATION RESOURCES THAT FORM INFRASTRUCTURE?
Not Applicable
E.3 WHAT IS THE IMPACT ON TECHNOLOGY TRANSFER?
NOTHING TO REPORT
E.4 WHAT DOLLAR AMOUNT OF THE AWARD'S BUDGET IS BEING SPENT IN FOREIGN COUNTRY(IES)?
Not Applicable

F. COMPONENT CHANGES

F.1 CHANGES IN APPROACH AND REASONS FOR CHANGE

Not Applicable

F.2 ACTUAL OR ANTICIPATED CHALLENGES OR DELAYS AND ACTIONS OR PLANS TO RESOLVE THEM

NOTHING TO REPORT

F.3 SIGNIFICANT CHANGES TO HUMAN SUBJECTS, VERTEBRATE ANIMALS, BIOHAZARDS, AND/OR SELECT AGENTS

F.3.a Human Subject

No Change

F.3.b Vertebrate Animals

No Change

F.3.c Biohazards

No Change

F.3.d Select Agents

No Change

G. COMPONENT SPECIAL REPORTING REQUIREMENTS SPECIAL REPORTING REQUIREMENTS

G.1 SPECIAL NOTICE OF AWARD TERMS AND FUNDING OPPORTUNITIES ANNOUNCEMENT REPORTING REQUIREMENTS

Not Applicable

G.2 RESPONSIBLE CONDUCT OF RESEARCH

Not Applicable

G.3 MENTOR'S REPORT OR SPONSOR COMMENTS

Not Applicable

G.4 HUMAN SUBJECTS

Not Applicable

G.5 HUMAN SUBJECTS EDUCATION REQUIREMENT

NOT APPLICABLE

G.6 HUMAN EMBRYONIC STEM CELLS (HESCS)

Does this project involve human embryonic stem cells (only hESC lines listed as approved in the NIH Registry may be used in NIH funded research)?

No

G.7 VERTEBRATE ANIMALS

Not Applicable

G.8 PROJECT/PERFORMANCE SITES

Not Applicable

G.9 FOREIGN COMPONENT

Not Applicable

G.10 ESTIMATED UNOBLIGATED BALANCE

Not Applicable

G.11 PROGRAM INCOME

Not Applicable

G.12 F&A COSTS

Not Applicable

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 1

FINAL

UEI*: D3LHU66KBLD5

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: UNIV OF NORTH CAROLINA CHAPEL HILL

Start Date*: 09-01-2022 **End Date*:** 08-31-2023 **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				11,720.00	3,629.00	15,349.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **15,349.00**

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						
2	Other Personnel	8.2	0.0	0.0	57,205.00	20,645.00	77,850.00
2	**Total Number Other Personnel**					**Total Other Personnel**	**77,850.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**93,199.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 1

UEI*: D3LHU66KBLD5

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: UNIV OF NORTH CAROLINA CHAPEL HILL

Start Date*: 09-01-2022 **End Date*:** 08-31-2023 **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	**0.00**

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:		
0 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

UEI*: D3LHU66KBLD5

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: UNIV OF NORTH CAROLINA CHAPEL HILL

Start Date*: 09-01-2022 **End Date*:** 08-31-2023 **Budget Period: 1**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	0.00
2. Publication Costs	0.00
3. Consultant Services	0.00
4. ADP/Computer Services	0.00
5. Subawards/Consortium/Contractual Costs	63,257.00
6. Equipment or Facility Rental/User Fees	0.00
7. Alterations and Renovations	0.00
8. Other Costs	12,988.00
9.	0.00
10.	0.00
11.	0.00
12.	0.00
13.	0.00
14.	0.00
15.	0.00
16.	0.00
17.	0.00
Total Other Direct Costs	**76,245.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**169,444.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. MTDC	55.5	169,444.00	58,934.00
		Total Indirect Costs	**58,934.00**

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number)	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.

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**228,378.00**

J. Fee	Funds Requested ($)*
	0.00

K. Total Costs and Fee	Funds Requested ($)*
	228,378.00

L. Budget Justification*	File Name: Budget Justification Intervention Core.pdf

RESEARCH & RELATED Budget {F-K} (Funds Requested)

BUDGET JUSTIFICATION – Intervention Core, Year 2

KEY PERSONNEL

Melissa Gilkey, PhD, Core Co-Lead (☐ CM)
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. William Calo), 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. Calo 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.

William A. Calo, PhD, Core Co-Lead
See Pennsylvania State University Consortium/Contractual Costs.

OTHER PERSONNEL

Jennifer Heisler-MacKinnon, Project Manager (☐ CM)
The 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. She 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. She will coordinate preparation of progress reports and will manage the Intervention Core budget.

TBN, Announcement Approach Training (AAT) Orientation Leader, MD (1.08 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.

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 the following fringe benefit rates to the personnel on this proposal: Basic permanent employee benefits are 26.174% of annual salary plus $7,019.00/FTE/YR for fixed health insurance. P&A Practice Plan member benefits calculate at 31.081% of annual salary plus $8,962.76/FTE/YR for fixed health insurance.

OTHER COSTS
$12,988

Continuing Medical Education (CME) costs ($600)
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).

Clinical Advisory Board (CAB) ($8,000)
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).

Honorarium, Bryan Weiner, PhD ($)
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.

Continuing Education (CE) costs ($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).

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 09/16/2021), 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
$

Pennsylvania State University, William Calo
The budget includes one domestic subcontract with Pennsylvania State University. A detailed budget and a justification for the proposed subcontract is included in this application. Under this subcontract, Dr. William Calo, PhD (Co-Investigator) will collaborate closely with the IMPACT Principal Investigator, Dr. 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 Program project. In all years, Dr. Calo will serve as Co-Lead of the Intervention Core (in partnership with Dr. Melissa Gilkey). Additionally, in all five years of the Program Project, Dr. Calo 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, he will advise the team on how to meaningfully translate evidence from the research projects into tools that can be disseminated in a variety of settings. He will also contribute to manuscript preparation.

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 1

FINAL

UEI*: TNKGNDAWB445

Budget Type*: ❍ Project ● Subaward/Consortium

Enter name of Organization: PENNSYLVANIA STATE UNIV HERSHEY MED CTR

Start Date*: 09-01-2022 **End Date*:** 08-31-2023 **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.		William		Calo		Core Lead	CAL. MONTHS, INST. BASE SALARY				12,041.00	4,250.00	16,291.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name: **Total Senior/Key Person** **16,291.00**

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	3.4	0.0	0.0	14,586.00	5,151.00	19,737.00
1	**Total Number Other Personnel**					**Total Other Personnel**	**19,737.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**36,028.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 1

UEI*: TNKGNDAWB445

Budget Type*: ❍ Project ● Subaward/Consortium

Enter name of Organization: PENNSYLVANIA STATE UNIV HERSHEY MED CTR

Start Date*: 09-01-2022 **End Date*:** 08-31-2023 **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	**0.00**

Additional Equipment: File Name:

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	2,933.00
2. Foreign Travel Costs	0.00
Total Travel Cost	**2,933.00**

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:		
0 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

UEI*: TNKGNDAWB445

Budget Type*: ❍ Project ● Subaward/Consortium

Enter name of Organization: PENNSYLVANIA STATE UNIV HERSHEY MED CTR

Start Date*: 09-01-2022 **End Date*:** 08-31-2023 **Budget Period: 1**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	0.00
2. Publication Costs	0.00
3. Consultant Services	0.00
4. ADP/Computer Services	0.00
5. Subawards/Consortium/Contractual Costs	0.00
6. Equipment or Facility Rental/User Fees	0.00
7. Alterations and Renovations	0.00
8.	0.00
9.	0.00
10.	0.00
11.	0.00
12.	0.00
13.	0.00
14.	0.00
15.	0.00
16.	0.00
17.	0.00
Total Other Direct Costs	**0.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**38,961.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. MTDC	62.36	38,961.00	24,296.00
		Total Indirect Costs	**24,296.00**

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)	**63,257.00**

J. Fee	Funds Requested ($)*
	0.00

K. Total Costs and Fee	Funds Requested ($)*
	63,257.00

L. Budget Justification*	File Name: Penn State_Budget Justification v2.pdf

RESEARCH & RELATED Budget {F-K} (Funds Requested)

BUDGET JUSTIFICATION – Pennsylvania State University, Year 2

KEY PERSONNEL

William A. Calo, PhD, Core Co-Lead (CM)

Dr. Calo is an Assistant Professor in the Department of Public Health Sciences in the Penn State College of Medicine. He is the PI of a NCI-funded (MERIT R37 award) RCT using a hybrid effectiveness- implementation design to increase HPV vaccination rates in 36 rural primary care clinics in Pennsylvania. Dr. Calo is also the Implementation Research Director for Penn State Project ECHO and the Director of the Implementation Science Collaborative (ISC) in the Department of Public Health Sciences, leading the implementation evaluation of several NIH and PCORI-funded studies. He also joined the highly-competitive NCI's Training Institute for Dissemination and Implementation Research in Cancer (TIDIRC). Dr. Calo has conducted multiple studies on HPV vaccination including experimental and observational research evaluating parental vaccine hesitancy, immunization quality improvement in primary care clinics, and alternative settings for expanding adolescent vaccine services. Dr. Calo will collaborate closely with the IMPACT Principal Investigator, Dr. 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 Program project. In all years, Dr. Calo will serve as Co-Lead of the Intervention Core (in partnership with Dr. Melissa Gilkey). In Year 1 of the Program Project, Dr. Calo will consult on developing the provider survey. Additionally, in all five years of the Program Project, Dr. Calo 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, he will advise the team on how to meaningfully translate evidence from the research projects into tools that can be disseminated in a variety of settings. Dr. Calo will also contribute to manuscript preparation.

OTHER PERSONNEL

Chelsea Keller, MPH, Project Manager (CM)

Ms. Keller is currently the Research Project Manager of the Implementation Science Collaborative under the supervision of Dr. Calo. She will support Dr. Calo and the Intervention Core team by assisting with the development and harmonization of implementation outcome measures for use across projects. Ms. Keller will also assist the Intervention Core with coordination of Clinical Advisory Board meeting logistics. She will work with the Project Manager at the University of North Carolina-Chapel Hill in the preparation of progress reports and the organization of team meetings and communications. Ms. Keller will manage the budget of the subaward to Dr. Calo.

Fringe Benefits

Fringe benefits are computed using the fixed rates of 35.31% applicable to Category I Salaries, 11.26% applicable to Category II Graduate Assistants, 7.98% applicable to Category III Salaries and Wages, 0.35% applicable to Category IV Student Wages, and 24.78% for Category V, Postdoctoral Scholars and Fellows, for fiscal year 2022 (July 1, 2021, through June 30, 2022). If this proposal is funded, the rates quoted above shall, at the time of funding, be subject to adjustment for any period subsequent to June 30, 2022, if superseding Government approved rates have been established. Fringe benefit rates are negotiated and approved by the Office of Naval Research, Penn State's cognizant federal agency.

TRAVEL

Programmatic Travel

$2,933 has been budgeted for Dr. Calo and/or Keller to travel to UNC-Chapel Hill for the P01 retreat that is planned to be held annually.

Facilities & Administration (F&A) Fee

F&A rates are negotiated and approved by the Office of Naval Research, Penn State's cognizant federal agency. Penn State Hershey's current fixed on-campus rate for research is 62.36% of MTDC of MTDC from July 1, 2021, through June 30, 2022. New awards and new competitive segments with an effective date of July 1, 2022, or later shall be subject to adjustment when superseding Government approved rates are established. Per 2 CFR 200 (Appendix III, Section C.7), the actual F&A rates used will be fixed at the time of the initial award for the duration of the competitive segment.

A. COMPONENT COVER PAGE

Project Title: Data Core – Improving Provider Announcement Communication Training (IMPACT)
Component Project Lead Information: Brewer, Noel Todd

B. COMPONENT ACCOMPLISHMENTS

B.1 WHAT ARE THE MAJOR GOALS OF THE PROJECT?

The Data Core is a service core created to support the 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. This Core will support integration and create efficiencies and cost-savings across research projects by centralizing data-related services. They will achieve this by providing services that include acquisition and harmonization of large datasets of vaccination outcomes, data analysis, and consulting to support its goal of improving HPV vaccine communication quality and uptake.

Aim 1. Manage the national primary care team survey.
Aim 2. Facilitate access to, and standardize structure of, large vaccination datasets generated by research project randomized clinical trials.
Aim 3. Provide statistical and methodological support to research projects.

The Data Core implemented Aim 1 in Year 1. The centralized administration of the national primary care team survey by the Data Core gave IMPACT research projects access to a large and diverse group of primary care professionals and formative research that will inform Year 2 Project trials. To further support the planned project trials and subsequent budget impact and cost-effectiveness analysis, the Data Core will implement Aims 2 and 3 throughout the IMPACT Program (Years 1-5). The Data Core will increase the collective scientific contribution of IMPACT and contribute to the IMPACT Program Project theme of amplifying the impact of an Evidence-based Cancer Control 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.

B.1.a Have the major goals changed since the initial competing award or previous report?

No

B.2 WHAT WAS ACCOMPLISHED UNDER THESE GOALS?

File Uploaded : Accomplishments_DC.pdf

B.3 COMPETITIVE REVISIONS/ADMINISTRATIVE SUPPLEMENTS

Not Applicable

B.4 WHAT OPPORTUNITIES FOR TRAINING AND PROFESSIONAL DEVELOPMENT HAS THE PROJECT PROVIDED?

NOTHING TO REPORT

B.5 HOW HAVE THE RESULTS BEEN DISSEMINATED TO COMMUNITIES OF INTEREST?

NOTHING TO REPORT

B.6 WHAT DO YOU PLAN TO DO DURING THE NEXT REPORTING PERIOD TO ACCOMPLISH THE GOALS?

Regarding the national survey, the Data Core will consult quarterly with projects on data analysis planning and offer support

to provide high level consultation to help projects finalize and coordinate their analytic plans. In the first quarter of Year 2, the Data Core will provide high level support to Projects 1-4 in their analysis of their data from the national survey and ensure appropriate analyses of survey data (e.g., statistical models appropriate for the response scales, appropriate use of control variables).

Regarding the RCTs, the Data Core will standardize vaccination outcomes measures across projects in preparation to manage multiple data streams of EHR data from Project 1-3 randomized control trials. 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. Data Core will also provide statistical and methodological support to research projects to randomize clinics for trials in Projects 1-3.

B.2 (Accomplishments_DC.pdf)

ACCOMPLISHMENTS – Data Core, Year 1

Below are Data Core specific aims and updates on major activities, specific objectives, and significant results for September 2021 through June 2022.

Aim 1. Manage the national primary care team survey.

In the first two months, we focused on hiring staff and establishing the administrative infrastructure for the planned work. A strategic review across the P01 identified that preparation for the national survey in Activity 1a would need to begin in the fall of 2021 through winter of 2022 to be ready to field the survey in May and June 2022.

Activity 1a. Collaborate with WebMD Market Research to conduct national survey
In collaboration with Projects 1-4, and with input from the Clinical Advisory Board, the Data Core developed a series of screener, demographic, and background survey items for the IMPACT national primary care team survey. We conducted cognitive interviews on the screener and demographic items with 8 primary care professionals in February and early March 2022. The interviews were done in collaboration with Project 2 and thus are included in their enrollment report. The other research projects also conducted cognitive interviews; see more details in each project's component.

Activity 1b. Coordinate and integrate the research projects' survey measures and core demographic measures
Following Data Core and Project 1-4 revisions of survey questions based on cognitive interviews, the Data Core integrated the projects' ~75 survey items and developed consensus on appropriate order and structure for the full survey, including standardizing language and response scales. We fielded the survey in May 2022. As of June 20, 2022, we have collected data from 2,478 primary care professionals with a role in providing HPV vaccine (69% of those invited to participate in the survey). We expect to complete the survey by the end of June 2022. This was a large effort given the many scientists involved, quick deadlines, and novelty of research topics.

Activity 1c and 1d. Prepare survey data for use by the research projects and manage survey data sharing
The Data Core has received and reviewed preliminary survey datasets throughout the live survey period. By late June, the Data Core will have the final survey dataset from WebMD and will review and clean the dataset, draft a data dictionary, create composite variables, and ensure a de-identified final dataset ready for analyses by all projects. The Data Core will provide Projects 1-4 with a final dataset, stored on a password protected server accessible only to key research staff from password protected computers before July. The Data Core will also draft a data sharing plan for researchers within and outside the IMPACT Program Project. National survey results will also be shared with key stakeholders during the Annual Scientific Retreat to be held in August 2022.

Aim 2. Facilitate access to, and standardize structure of, large vaccination datasets generated by research project randomized clinical trials.

The Data Core has begun harmonizing the definitions of vaccination outcomes for the RCTs. Issues that we are addressing include incorporating ages 9-10 in data collection, the use of the HEDIS measure, collection of patient level vs. clinic level data, and use of retrospective cohorts or cross-sectional samples. Other Aim 2 activities will begin in Year 2.

Aim 3. Provide statistical and methodological support to research projects.

The Data Core is helping Projects 1-3 review their power analyses to ensure the trials remain adequately powered given the budget cuts that may necessitate reducing sample sizes. Other Aim 3 activities will begin in Year 2.

B.2 (Accomplishments_DC.pdf)

Significance
In Year 1, the main product was the Aim 1 national survey of primary care professionals. The survey findings will support the formative work of IMPACT research projects and implementation of the interventions being evaluated in trials.

C. COMPONENT PRODUCTS

C.1 PUBLICATIONS
Not Applicable
C.2 WEBSITE(S) OR OTHER INTERNET SITE(S)
Not Applicable
C.3 TECHNOLOGIES OR TECHNIQUES
NOTHING TO REPORT
C.4 INVENTIONS, PATENT APPLICATIONS, AND/OR LICENSES
Not Applicable
C.5 OTHER PRODUCTS AND RESOURCE SHARING
NOTHING TO REPORT

D. COMPONENT PARTICIPANTS

Not applicable

E. COMPONENT IMPACT

E.1 WHAT IS THE IMPACT ON THE DEVELOPMENT OF HUMAN RESOURCES? Not Applicable
E.2 WHAT IS THE IMPACT ON PHYSICAL, INSTITUTIONAL, OR INFORMATION RESOURCES THAT FORM INFRASTRUCTURE? Not Applicable
E.3 WHAT IS THE IMPACT ON TECHNOLOGY TRANSFER? NOTHING TO REPORT
E.4 WHAT DOLLAR AMOUNT OF THE AWARD'S BUDGET IS BEING SPENT IN FOREIGN COUNTRY(IES)? Not Applicable

F. COMPONENT CHANGES

F.1 CHANGES IN APPROACH AND REASONS FOR CHANGE

Not Applicable

F.2 ACTUAL OR ANTICIPATED CHALLENGES OR DELAYS AND ACTIONS OR PLANS TO RESOLVE THEM

NOTHING TO REPORT

F.3 SIGNIFICANT CHANGES TO HUMAN SUBJECTS, VERTEBRATE ANIMALS, BIOHAZARDS, AND/OR SELECT AGENTS

F.3.a Human Subject

No Change

F.3.b Vertebrate Animals

No Change

F.3.c Biohazards

No Change

F.3.d Select Agents

No Change

G. COMPONENT SPECIAL REPORTING REQUIREMENTS SPECIAL REPORTING REQUIREMENTS

G.1 SPECIAL NOTICE OF AWARD TERMS AND FUNDING OPPORTUNITIES ANNOUNCEMENT REPORTING REQUIREMENTS

Not Applicable

G.2 RESPONSIBLE CONDUCT OF RESEARCH

Not Applicable

G.3 MENTOR'S REPORT OR SPONSOR COMMENTS

Not Applicable

G.4 HUMAN SUBJECTS

Not Applicable

G.5 HUMAN SUBJECTS EDUCATION REQUIREMENT

NOT APPLICABLE

G.6 HUMAN EMBRYONIC STEM CELLS (HESCS)

Does this project involve human embryonic stem cells (only hESC lines listed as approved in the NIH Registry may be used in NIH funded research)?

No

G.7 VERTEBRATE ANIMALS

Not Applicable

G.8 PROJECT/PERFORMANCE SITES

Not Applicable

G.9 FOREIGN COMPONENT

Not Applicable

G.10 ESTIMATED UNOBLIGATED BALANCE

Not Applicable

G.11 PROGRAM INCOME

Not Applicable

G.12 F&A COSTS

Not Applicable

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 1

FINAL

UEI*: D3LHU66KBLD5

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: UNIV OF NORTH CAROLINA CHAPEL HILL

Start Date*: 09-01-2022 **End Date*:** 08-31-2023 **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.	Joseph		Ibrahim		Co-Investigator	CAL. MONTHS, INST. BASE SALARY				20,370.00	6,034.00	26,404.00
2.	Justin		Trogdon		Co-Investigator					19,270.00	5,746.00	25,016.00
3.	Tara		Queen		Core Lead					7,350.00	4,170.00	11,520.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **62,940.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
2	Other Personnel	9.1	0.0	0.0	59,274.00	20,857.00	80,131.00
2	**Total Number Other Personnel**					**Total Other Personnel**	**80,131.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**143,071.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 1

UEI*: D3LHU66KBLD5

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: UNIV OF NORTH CAROLINA CHAPEL HILL

Start Date*: 09-01-2022 **End Date*:** 08-31-2023 **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	**0.00**

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:		
0 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

UEI*: D3LHU66KBLD5

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: UNIV OF NORTH CAROLINA CHAPEL HILL

Start Date*: 09-01-2022 **End Date*:** 08-31-2023 **Budget Period: 1**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	2,800.00
2. Publication Costs	0.00
3. Consultant Services	0.00
4. ADP/Computer Services	617.00
5. Subawards/Consortium/Contractual Costs	0.00
6. Equipment or Facility Rental/User Fees	0.00
7. Alterations and Renovations	0.00
8. Other Costs	1,000.00
9.	0.00
10.	0.00
11.	0.00
12.	0.00
13.	0.00
14.	0.00
15.	0.00
16.	0.00
17.	0.00
Total Other Direct Costs	**4,417.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**147,488.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. MTDC	55.5	147,488.00	81,856.00
		Total Indirect Costs	**81,856.00**

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)	**229,344.00**

J. Fee	Funds Requested ($)*
	0.00

K. Total Costs and Fee	Funds Requested ($)*
	229,344.00

L. Budget Justification*	File Name: Budget Justification Data Core v2.pdf

RESEARCH & RELATED Budget {F-K} (Funds Requested)

BUDGET JUSTIFICATION – Data Core, Year 2

KEY PERSONNEL

Tara Queen, PhD, Core Co-Lead (CM)
Dr. Queen will serve as Core Co-Lead for the Data Core. Dr. Queen is a Statistician in the UNC Gillings School of Global Public Health. As Co-Lead, Dr. Queen 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. Queen 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 (CM)
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.

Joseph Ibrahim, PhD, Co-Investigator (CM)
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).

OTHER PERSONNEL

Kathryn Brignole, Project Manager (CM)
The Project Manager will assist Drs. Queen 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, Statistician (Programmer) (5.53 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.

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 the following fringe benefit rates to the personnel on this proposal: Basic permanent employee benefits are 26.174% of annual salary plus $7,019.00/FTE/YR for fixed health insurance.

MATERIALS & SUPPLIES
$2,800

Data Storage ($1,000)
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 ($1,800)
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
$617

We have budgeted funds for computer service fees. 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.

OTHER COSTS
$1,000

Data Use Agreements ($1,000)
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.

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 09/16/2021), 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.