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

Notice of Award
FAIN# K22CA258675
Federal Award Date
08-02-2022

Recipient Information

1. Recipient Name
RUTGERS, THE STATE UNIVERSITY OF NEW JERSEY
65 BERGEN ST

NEWARK, 07107

2. Congressional District of Recipient
10

3. Payment System Identifier (ID)
1226001086A1

4. Employer Identification Number (EIN)
226001086

5. Data Universal Numbering System (DUNS)
090299830

6. Recipient's Unique Entity Identifier
YVVTQD8CJC79

7. Project Director or Principal Investigator
Racquel Elizabeth Kohler, PHD

kelly.kohler@rutgers.edu
732-258-6031

8. Authorized Official
Latona M Thompson

Federal Agency Information

9. Awarding Agency Contact Information
Nailah Agyemann
Grants Technical Assistant
NATIONAL CANCER INSTITUTE
agyemann@mail.nih.gov
(240) 276-6290

10. Program Official Contact Information
SONIA B JAKOWLEW
Program Director
NATIONAL CANCER INSTITUTE
jakowles@mail.nih.gov
240-276-5630

Federal Award Information

11. Award Number
1K22CA258675-01A1

12. Unique Federal Award Identification Number (FAIN)
K22CA258675

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
Addressing HPV vaccination disparities through tailored messaging for hesitant families

15. Assistance Listing Number
93.398

16. Assistance Listing Program Title
Cancer Research Manpower

17. Award Action Type
New Competing

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information

19. Budget Period Start Date 08-02-2022 **– End Date** 07-31-2023	
20. Total Amount of Federal Funds Obligated by this Action	$219,899
20 a. Direct Cost Amount	$203,610
20 b. Indirect Cost Amount	$16,289
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$219,899
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$219,899
26. Project Period Start Date 08-02-2022 **– End Date** 07-31-2025	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$219,899

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Carey Beckley

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.

ACADEMIC CAREER AWARD
Department of Health and Human Services
National Institutes of Health

NATIONAL CANCER INSTITUTE

SECTION I – AWARD DATA – 1K22CA258675-01A1

Principal Investigator(s):
Racquel Elizabeth Kohler, PHD

Award e-mailed to: rsp-rbhs@research.rutgers.edu

Dear Authorized Official:

The National Institutes of Health hereby awards a grant in the amount of $219,899 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to RUTGERS BIOMEDICAL AND HEALTH SCIENCES 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 K22CA258675. 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,

Carey Beckley
Grants Management Officer
NATIONAL CANCER INSTITUTE

Additional information follows

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

Salaries and Wages	$100,000
Fringe Benefits	$53,610
Personnel Costs (Subtotal)	$153,610
Other	$50,000
Federal Direct Costs	$203,610
Federal F&A Costs	$16,289
Approved Budget	$219,899
Total Amount of Federal Funds Authorized (Federal Share)	$219,899
TOTAL FEDERAL AWARD AMOUNT	$219,899
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$219,899

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
1	$219,899	$219,899
2	Future Costs, Recommended	
3		

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

Fiscal Information:

Payment System Identifier:	1226001086A1
Document Number:	KCA258675A
PMS Account Type:	P (Subaccount)
Fiscal Year:	2022

IC	CAN	2022	2023	2024
CA	8481719	$219,899	Future Costs, Recommended	

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

NIH Administrative Data:
PCC: 1STR / **OC**: 41033 / **Released**: Beckley, Carey 08-01-2022
Award Processed: 08/02/2022 12:04:51 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 1K22CA258675-01A1

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

SECTION III – STANDARD TERMS AND CONDITIONS – 1K22CA258675-01A1

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

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

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

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

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

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

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

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) K22CA258675. 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 – 1K22CA258675-01A1

Clinical Trial Indicator: Yes

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

REQUIREMENT: This award is subject to the conditions set forth in PAR 18-466, "The NCI Transition Career Development Award (K22 Independent Clinical Trial Required)," NIH Guide to Grants and Contracts, (12/06/2017), which are hereby incorporated by reference as special terms and conditions of this award.

Copies of this funding opportunity announcement may be accessed at: http://www.nih.gov/grants/guide/index.html

Copies may also be obtained from the Grants Management Contact indicated in the terms of award.

RESTRICTION: National Institutes of Health (NIH) research or training grant funds (both direct costs and associated facilities and administrative costs) released as a result of this Career Development Award may not be retained by the awardee institution without written prior approval of the NIH awarding unit.

REQUIREMENT: Recipients of a National Cancer Institute Transition Career Development Award (K22) must apply for National Institutes of Health or other independent research project grant support for peer review and funding consideration prior to the end of the second year of support.

REQUIREMENT: The clinical trial(s) supported by this award is subject to the plan dated 07/15/2022 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: 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 with 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.

INFORMATION: Although the budget period start date for this award is 08/02/2022, this award includes funds for twelve months of support. Future year budget periods will cycle on 08/01. Allowable pre-award costs may be charged to this award, in accordance with the conditions in the NIH Grants Policy Statement, and with institutional requirements for prior approval.

INFORMATION: This award, including the budget and the budget period, has been discussed between Nailah Agyemann of the National Cancer Institute and Latona Thompson on 08/01/2022.

SPREADSHEET SUMMARY
AWARD NUMBER: 1K22CA258675-01A1

INSTITUTION: RUTGERS BIOMEDICAL AND HEALTH SCIENCES

Budget	Year 1	Year 2	Year 3
Salaries and Wages	$100,000	Future Costs, Recommended	
Fringe Benefits	$53,610		
Personnel Costs (Subtotal)	$153,610		
Other	$50,000		
TOTAL FEDERAL DC	$203,610		
TOTAL FEDERAL F&A	$16,289		

TOTAL COST	$219,899

Future Costs, Recommended

Facilities and Administrative Costs	Year 1	Year 2	Year 3
F&A Cost Rate 1	8%		
F&A Cost Base 1	$203,610		
F&A Costs 1	$16,289		

Future Costs, Recommended

Form Approved Through 09/30/2024 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Application

Do not exceed character length restrictions indicated.

LEAVE BLANK—FOR PHS USE ONLY.

Type	Activity	Number
Review Group		Formerly
Council/Board (Month, Year)		Date Received

1. TITLE OF PROJECT *(Do not exceed 81 characters, including spaces and punctuation.)*
Addressing HPV vaccination disparities through tailored messaging for hesitant families

2. RESPONSE TO SPECIFIC REQUEST FOR APPLICATIONS OR PROGRAM ANNOUNCEMENT OR SOLICITATION ☐ NO ☐ YES
(If "Yes," state number and title)
Number: Title:

3. PROGRAM DIRECTOR/PRINCIPAL INVESTIGATOR

3a. NAME (Last, first, middle)
Kohler, Racquel Elizabeth

3b. DEGREE(S)

eRA Commons User Name

3c. POSITION TITLE
Instructor

3d. MAILING ADDRESS *(Street, city, state, zip code)*
195 Little Albany Street
New Brunswick NJ 08901

3e. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT

3f. MAJOR SUBDIVISION

3g. TELEPHONE AND FAX *(Area code, number and extension)*
TEL: 732-258-6031 FAX:

E-MAIL ADDRESS:

4. HUMAN SUBJECTS RESEARCH	4a. Research Exempt	If "Yes," Exemption No.
☐ No ■ Yes	☐ No ☐ Yes	

4b. Federal-Wide Assurance No.	4c. Clinical Trial	4d. NIH-defined Phase III Clinical Trial
00003913	☐ No ☐ Yes	☐ No ☐ Yes

5. VERTEBRATE ANIMALS ■ No ☐ Yes — 5a. Animal Welfare Assurance No. D16-00098

6. DATES OF PROPOSED PERIOD OF SUPPORT *(month, day, year—MM/DD/YY)*		7. COSTS REQUESTED FOR INITIAL BUDGET PERIOD		8. COSTS REQUESTED FOR PROPOSED PERIOD OF SUPPORT	
From	Through	7a. Direct Costs ($)	7b. Total Costs ($)	8a. Direct Costs ($)	8b. Total Costs ($)
12/01/2021	11/30/2024	203610	219899	610830	659697

9. APPLICANT ORGANIZATION
Name Rutgers Biomedical and Health Sciences
Address 65 Bergen Street, Suite 538
Newark, NJ 07107-3001

10. TYPE OF ORGANIZATION
Public: → ☐ Federal ■ State ☐ Local
Private: → ☐ Private Nonprofit
For-profit: → ☐ General ☐ Small Business
☐ Woman-owned ☐ Socially and Economically Disadvantaged

11. ENTITY IDENTIFICATION NUMBER
226001086
UEI. YVVTQD8CJC Cong. District NJ-010

12. ADMINISTRATIVE OFFICIAL TO BE NOTIFIED IF AWARD IS MADE
Name Latona Thompson
Title Grants Administrator
Address 33 Knightsbridge Road, 2nd Floor
Piscataway, NJ 08854-3925
Tel: 848-932-4054 FAX:
E-Mail: thompslm@research.rutgers.edu

13. OFFICIAL SIGNING FOR APPLICANT ORGANIZATION
Name Latona Thompson
Title Grants Administrator
Address 33 Knightsbridge Road, 2nd Floor
Piscataway, NJ 08854-3925
Tel: 848-932-4054 FAX:
E-Mail: thompslm@research.rutgers.edu

14. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware hat any false, ficti ious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

SIGNATURE OF OFFICIAL NAMED IN 13. *(In ink. "Per" signature not acceptable.)*
Latona Thompson

DATE 07/15/2022

PI: **Kohler, Racquel Elizabeth**	Title: Addressing HPV vaccination disparities through tailored messaging for hesitant families	
Received: 03/10/2021	FOA: PAR18-466	Council: 10/2021
Competition ID: FORMS-F	FOA Title: The NCI Transition Career Development Award (K22 Independent Clinical Trial Required)	
1 K22 CA258675-01A1	Dual:	Accession Number: 4559384
IPF: 10034168	Organization: RUTGERS BIOMEDICAL AND HEALTH SCIENCES	
Former Number: 1K22CA258675-01	Department: Cancer Health Equity	
IRG/SRG: ZCA1 RTRB-R (O2)	AIDS: N	Expedited: N
Subtotal Direct Costs (excludes consortium F&A) Year 1: 203,610 [redacted]	Animals: N Humans: Y Clinical Trial: Y Current HS Code: 30 HESC: N HFT: N	New Investigator: Early Stage Investigator:
Senior/Key Personnel:	*Organization:*	*Role Category:*
Racquel Kohler	Rutgers, The State University of New Jersey, RBHS-CINJ	PD/PI
Manuel Jimenez	Rutgers Robert Wood Johnson Medical School	Other (Specify)-Other Significant Contributor
Kathryn Greene	Rutgers University-Communication and Information	Other (Specify)-Other Significant Contributor
Rula Btoush	Rutgers University-School of Nursing	Other (Specify)-Other Significant Contributor

Reference Letters

Kasisomayajula Viswanath	Harvard/Dana-Farber	05/19/2021
Leslie Kantor	Rutgers University School of Public Health	05/19/2021
Jane Kim	Harvard T.H. Chan School of Public Health	05/19/2021
Anita Kinney	Rutgers School of Public Health, Rutgers Cancer Institute of New Jersey	05/19/2021

OMB Number: 4040-0010
Expiration Date: 12/31/2022

APPLICATION FOR FEDERAL ASSISTANCE
SF 424 (R&R)

3. DATE RECEIVED BY STATE	State Application Identifier

1. TYPE OF SUBMISSION*

❍ Pre-application ● Application ❍ Changed/Corrected Application

4.a. Federal Identifier
CA258675-01

b. Agency Routing Number

2. DATE SUBMITTED

Application Identifier
FP00019997_Res1

c. Previous Grants.gov Tracking Number

5. APPLICANT INFORMATION **Organizational DUNS*:** 078728091

Legal Name*: Rutgers, The State University of New Jersey, RBHS-CINJ
Department: ORSP, New Brunswick
Division:
Street1*: 33 Knightsbridge Road
Street2: 2nd Floor, East Wing
City*: Piscataway
County:
State*: NJ: New Jersey
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: 088543925

Person to be contacted on matters involving this application
Prefix: First Name*: Latona Middle Name: M Last Name*: Thompson Suffix:
Position/Title: Program Administrator
Street1*: 33 Knightsbridge Road
Street2: 2nd Floor, East Wing
City*: Piscataway
County: New Jersey
State*: NJ: New Jersey
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: 089010000
Phone Number*: 848-932-4054 Fax Number: Email: thompslm@ored.rutgers.edu

6. EMPLOYER IDENTIFICATION NUMBER *(EIN) or (TIN)** 1462354111A1

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

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

8. TYPE OF APPLICATION*

❍ New ● Resubmission
❍ Renewal ❍ Continuation ❍ Revision

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

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

9. NAME OF FEDERAL AGENCY*
National Institutes of Health

10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER
TITLE:

11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT*
Addressing HPV vaccination disparities through tailored messaging for hesitant families

12. PROPOSED PROJECT
Start Date* Ending Date*
12/01/2021 11/30/2024

13. CONGRESSIONAL DISTRICTS OF APPLICANT
NJ-006

SF 424 (R&R) APPLICATION FOR FEDERAL ASSISTANCE

14. PROJECT DIRECTOR/PRINCIPAL INVESTIGATOR CONTACT INFORMATION

Prefix: First Name*: Racquel Middle Name: Last Name*: Kohler Suffix:
Position/Title: Instructor of Social and Behavioral Sciences
Organization Name*: Rutgers, The State University of New Jersey, RBHS-CINJ
Department: Cancer Health Equity
Division: Public Health/Health Behavior
Street1*: 195 Little Albany Street
Street2:
City*: New Brunswick
County:
State*: NJ: New Jersey
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: 089011914
Phone Number*: 732-258-6031 Fax Number: Email*: kelly.kohler@rutgers.edu

15. ESTIMATED PROJECT FUNDING

a. Total Federal Funds Requested*	$0.00
b. Total Non-Federal Funds*	$659,697.00
c. Total Federal & Non-Federal Funds*	$0.00
d. Estimated Program Income*	$659,697.00

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

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

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

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

● I agree*

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

18. SFLLL or OTHER EXPLANATORY DOCUMENTATION File Name:

19. AUTHORIZED REPRESENTATIVE

Prefix: First Name*: Latona Middle Name: M Last Name*: Thompson Suffix:
Position/Title*: Program Administrator
Organization Name*: Rutgers, The State University of New Jersey
Department:
Division:
Street1*: 33 Knightsbridge Road
Street2: 2nd Floor, East Wing
City*: Piscataway
County:
State*: NJ: New Jersey
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: 088543925
Phone Number*: 848-932-4054 Fax Number: (732)-932-0162 Email*: thompslm@ored.rutgers.edu

Signature of Authorized Representative*
Latona.Thompson

Date Signed*
03/10/2021

20. PRE-APPLICATION File Name:

21. COVER LETTER ATTACHMENT File Name:Kohler_K22_Cover_Letter_08March.pdf

424 R&R and PHS-398 Specific
Table Of Contents

OMB Number: 4040-0010
Expiration Date: 12/31/2022

Project/Performance Site Location(s)

Project/Performance Site Primary Location

❍ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name:	Rutgers, The State University of New Jersey, RBHS-CINJ
Duns Number:	078728091
Street1*:	195 Little Albany Street
Street2:	
City*:	New Brunswick
County:	
State*:	NJ: New Jersey
Province:	
Country*:	USA: UNITED STATES
Zip / Postal Code*:	089011914
Project/Performance Site Congressional District*:	NJ-006

Additional Location(s) File Name:

Funding Opportunity Number: PAR-18-466. Received Date: 2021-03-10T15:05:11.000-05:00

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED Other Project Information

1. Are Human Subjects Involved?* ● **Yes** ○ **No**

1.a. If YES to Human Subjects

Is the Project Exempt from Federal regulations? ○ Yes ● No

If YES, check appropriate exemption number: _ 1 _ 2 _ 3 _ 4 _ 5 _ 6 _ 7 _ 8

If NO, is the IRB review Pending? ○ **Yes** ● **No**

IRB Approval Date: 09-28-2020

Human Subject Assurance Number 00003913

2. Are Vertebrate Animals Used?* ○ **Yes** ● **No**

2.a. If YES to Vertebrate Animals

Is the IACUC review Pending? ○ Yes ○ No

IACUC Approval Date:

Animal Welfare Assurance Number

3. Is proprietary/privileged information included in the application?* ○ **Yes** ● **No**

4.a. Does this project have an actual or potential impact - positive or negative - on the environment?* ○ **Yes** ● **No**

4.b. If yes, please explain:

4.c. If this project has an actual or potential impact on the environment, has an exemption been authorized or an environmental assessment (EA) or environmental impact statement (EIS) been performed? ○ Yes ○ No

4.d. If yes, please explain:

5. Is the research performance site designated, or eligible to be designated, as a historic place?* ○ **Yes** ● **No**

5.a. If yes, please explain:

6. Does this project involve activities outside the United States or partnership with international collaborators?* ○ **Yes** ● **No**

6.a. If yes, identify countries:

6.b. Optional Explanation:

	Filename
7. Project Summary/Abstract*	K22_Abstract_10March.pdf
8. Project Narrative*	K22_Narrative_05March.pdf
9. Bibliography & References Cited	References_10March.pdf
10.Facilities & Other Resources	Facilities_and_Other_Resources.pdf
11.Equipment	Equipment.pdf

Funding Opportunity Number: PAR-18-466. Received Date: 2021-03-10T15:05:11.000-05:00

PROJECT SUMMARY

Human papillomavirus (HPV) causes over 34,800 cancers in the United States each year that disproportionately affect Black women. The HPV vaccine is highly effective, but less than half of adolescents aged 13-15 years have received recommended doses, with Blacks having the greatest disparity in completion. HPV vaccine hesitancy is associated with under-vaccination and refusal. An estimated 23% of parents with adolescents are hesitant about the HPV vaccine, but parents' concerns vary due to a myriad of individual, interpersonal, and sociocultural factors. Effective strategies to overcome parents' concerns are needed, especially among Black families, who have higher prevalence of general vaccine hesitancy and medical mistrust due to racial inequities. The purpose of this NCI Transition Career Development Award (K22) is to support me through specific training and research experiences as I become an independent investigator specializing in multilevel cancer prevention interventions to reduce cervical cancer disparities. Building on my strong health services research and behavioral science background in HPV screening, I will develop expertise in HPV vaccination communication, community-engaged intervention planning, and intervention trials. The objectives of this rigorous mixed methods proposal are to: (1) use a stakeholder-engaged approach to develop and refine an interactive, tailored text messaging intervention to address Black parents' HPV vaccine hesitancy determinants and vaccination barriers; and (2) conduct a two-arm pilot RCT to determine feasibility, acceptability, appropriateness, and preliminary efficacy of the tailored messages compared to untailored messages. Following a provider's initial recommendation, the intervention will allow parents of young adolescents to process HPV vaccination information on their preferred timeline, answer lingering questions and concerns, provide links to additional information from trusted sources, and support connections to local resources to help overcome barriers. By accomplishing these aims, I will address current gaps in strategies to increase vaccine confidence and motivation among high-risk Black families. Rutgers Cancer Institute with its well-funded behavioral research program, robust research infrastructure, and deep community connections is an exceptional environment to conduct high-impact, community-engaged cancer disparities research. As a logical next step in my career development, this K22 will give me the skills required to design, implement, and evaluate multilevel interventions to achieve HPV health equity. Findings and preliminary efficacy estimates will inform an R01 application of a multi-site trial to test a multiple component intervention addressing the complex, context-specific determinants of HPV vaccine hesitancy to motivate vaccination and change behaviors. Ultimately, this K22 proposal will facilitate my long-term goal to build an independent research program investigating community-driven solutions to reduce HPV disparities and advance the elimination of cervical cancer.

PROJECT NARRATIVE

HPV vaccination among adolescents is suboptimal, and parental delays and refusals are common. Addressing the unique vaccine hesitancy concerns and information needs of underserved families is critical to increase vaccination. This study will engage multiple stakeholders to develop and pilot a tailored intervention to address HPV vaccine hesitancy among Black families to increase vaccine confidence, vaccination, and ultimately help reduce HPV-related cancer disparities.

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FACILITIES & OTHER RESOURCES

Institutional Environment:

This project is being submitted through Rutgers Cancer Institute of New Jersey (Rutgers Cancer Institute), Center for Cancer Health Equity in the Division of Population Sciences and Community Outreach, in close collaboration with the Rutgers University School of Public Health. Racquel Kelly Kohler, PhD, the PI, is a Resident Member of Rutgers Cancer Institute and an Instructor of Social and Behavioral Sciences in the Department of Health Behavior, Society, and Policy at the School of Public Health. As identified below, this study will benefit from the rich scientific and facility resources available through Rutgers Biomedical and Health Sciences and Rutgers, The State University of New Jersey.

Rutgers Cancer Institute arranges a Works-In-Progress seminar that meets monthly to review grant proposals and to provide insights from multidisciplinary investigators. Rutgers Cancer Institute also provides an array of educational and training opportunities that can benefit junior investigators, including a Distinguished Lecture Series, which invites prominent scientists from around the country to visit and meet with faculty and Cancer Center Grand Rounds, a weekly series that invites clinical/translational investigators from affiliated institutions and national speakers to present their work with the goal of enhancing collaborations. Each program (e.g., Cancer Prevention and Control) and center (e.g., Cancer Health Equity) also offers training activities in seminars, works-in-progress, and meetings. The Cancer Prevention and Control program hosts a Dissemination and Implementation working group meeting monthly connecting investigators from across Rutgers Biomedical and Health Sciences to discuss papers, grants, works-in-progress, and to host guest speakers on selected topics. Other educational activities include an Annual Retreat on Cancer Research, which is jointly sponsored by Rutgers Cancer Institute of New Jersey and the New Jersey Commission on Cancer Research to enhance collaborations among cancer researchers statewide; and a Governor's Conference on Effective Partnering in Cancer Research, which brings together experts from academia, clinics, industry, and state government to discuss emerging issues in cancer research.

RUTGERS, THE STATE UNIVERSITY OF NEW JERSEY

Rutgers, The State University of New Jersey (RU) is a statewide, multi-institutional, multi-campus scholarly community dedicated to improving the health of diverse populations in New Jersey and elsewhere through collaborative research, teaching, and service. The University consists of three campuses in Camden, New Brunswick, and Newark. Rutgers Biomedical and Health Sciences spans the three geographically bound campuses.

RUTGERS BIOMEDICAL AND HEALTH SCIENCES

The New Jersey Medical and Health Sciences Education Restructuring Act, signed into law on August 22, 2012, and effective July 1, 2013, transferred most schools of the University of Medicine and Dentistry of New Jersey (UMDNJ) to RU, to form Rutgers Biomedical and Health Sciences (RBHS). The resulting integration builds on the rich histories, talent, and expertise of both institutions. As New Jersey's academic health center, RBHS takes an integrated approach to educating students, providing clinical care, and conducting research, all with the goal of improving human health. RBHS includes eight schools, a behavioral health network, and five centers and institutes that focus on cancer treatment and research, neuroscience, advanced biotechnology and medicine, environmental and occupational health, and health care policy and aging research. The eight schools are the Ernest Mario School of Pharmacy, New Jersey Medical School, Robert Wood Johnson Medical School (RWJMS), Rutgers School of Dental Medicine, School of Graduate Studies, School of Health Professions, School of Nursing, and School of Public Health. The six centers and institutes are the Brain Health Institute; Center for Advanced Biotechnology and Medicine; Environmental and Occupational Health Sciences Institute; Institute for Health, Health Care Policy and Aging Research; Rutgers Cancer Institute of New Jersey; and Rutgers Institute for Translational Medicine and Science. RBHS is now New Jersey's largest and most influential constellation of academic institutions devoted to education and research across the full spectrum of health professions. All RBHS units have access to the abundant resources of the broader Rutgers University, to promote innovative research, education, and service. Along with Rutgers Camden, New Brunswick and Newark, RBHS is led by one of the four university chancellors.

RUTGERS CANCER INSTITUTE OF NEW JERSEY

Rutgers Cancer Institute of New Jersey (Rutgers Cancer Institute) is designated by the National Cancer Institute (NCI) as a Comprehensive Cancer Center (one of only 51 centers) and is a recipient of a NCI Cancer Center Support Grant (CCSG) (P30 CA072720). Rutgers Cancer Institute is an interdisciplinary institute comprised of more than 300 faculty members from RU, RWJMS, Princeton University, and the Institute for Advanced Study in Princeton, NJ. Rutgers Cancer Institute members have expertise in basic, clinical, and population sciences and with a concerted focus on basic and clinical research and training, as well as the development and application of methods for the diagnosis, treatment and prevention of cancer. Faculty research laboratories and offices are centrally located in the Rutgers Cancer Institute building, which consists of approximately 225,000 ft^2 of research and clinical space in New Brunswick, NJ located immediately adjacent to the Robert Wood Johnson University Hospital (RWJUH), the Bristol-Myers-Squibb Children's Hospital, and the Cancer Hospital of New Jersey. The first two floors house clinical services and related facilities. The third and fourth floors provide laboratory space and shared resources. The fifth floor is devoted to Behavioral Science and Community Outreach, which is Dr. Kohler's home department. The Office of Human Research Services is also located on the fifth floor. The building's design encourages transdisciplinary collaborations, allowing the physical proximity of basic, clinical, and population science researchers. The Rutgers Cancer Institute building houses a collaborative and collegial network of investigators that are committed to providing a highly interactive atmosphere in which trainees and faculty can flourish. Each member of Rutgers Cancer Institute embraces the belief that the success of individual members of the Institute is enhanced through day-to-day interactions with other investigators. As such, many groups hold joint lab meetings and the Institute hosts weekly research seminars and symposia fostering interactions between basic, clinical, and population science investigators.

Rutgers Cancer Institute Research Facilities: The Rutgers Cancer Institute building is a state-of-the-art biomedical research facility. Rutgers Cancer Institute has outstanding shared resources (see below) supported through the NCI Cancer Center grant and/or institutional funds to provide essential technical support for the operation and maintenance of specialized equipment, more affordable means to access technology and services that cannot be supported by individual faculty. The physical resources necessary for the successful completion of the proposed research are within close proximity of Dr. Kohler's office and will be easily accessible.

Office and Computer: Dr. Kohler has her own office at Rutgers Cancer Institute, New Brunswick, with a computer, desk, phone, and file storage space. This space includes adjoining administrative and research staff space with a fax machine, copier and scanner equipment, audio-taping and transcription equipment, telephone equipment with voice mail, and conference call capabilities. Dr. Kohler's computer is equipped with appropriate software (e.g., Microsoft Office, Stata, Atlas.ti, EndNote) and is connected to the Internet and larger computing and network systems at RU. The computer network at RU complies with HIPAA and other regulations and is extremely proactive about the network and system security.

Biometrics: The Biometrics shared resource provides statistical support for Rutgers Cancer Institute members in the areas of basic, clinical, and population research. Most members require biostatistical expertise beyond that acquired within their field of scientific training. Biometrics ensures that the scientific rigor of cancer center studies is supported by outstanding, centralized and cost-effective biostatistical support. The specific objectives of the Biometrics shared resource are to: (1) collaborate with investigators on grant proposals and the design and development of cancer studies to ensure statistical and methodological integrity; (2) develop new, cancer-specific statistical methodologies, when necessary, to support the research needs of Rutgers Cancer Institute investigators; (3) provide statistical review and consultation regarding grant writing for basic-, clinical-, and population-based studies; (4) support statistical monitoring and interim analysis of ongoing clinical trials; (5) provide computational and statistical analyses of data; (6) collaborate in the publication and/or presentation of research results; and (7) provide education, consultation and training activities in statistics for research staff.

Population Science Research Support: The Population Science Research Support shared resource provides technical support in the areas of development and implementation of data collection protocols from study participants, quality control of data collection processes, and data management. The Shared Resource has successfully supported diverse research projects, including those using cross-sectional, prospective cohort, and randomized controlled trial designs. For the proposed project, the Shared Resource will utilize DatStat Discovery, a cloud-based study management and implementation software tool. It provides advanced participant recruitment and management tools, longitudinal workflow automation, and electronic and online data collection.

The software will facilitate the following project activities: participant recruitment and tracking database (includes eligibility determination); participant online surveys; eligibility and consent surveys for research staff; automated participant communications; data management; and creation of automated reports to monitor participant recruitment, completion of study activities, and dropouts. The secure online portal allows for real-time reporting and data downloads. Research study personnel can be assigned data access and privileges specific to their role on the study (e.g., principal investigator, project coordinator, data manager, biostatistician).

DatStat Illume is commonly used in combination with DatStat Discovery to provide advanced web-based and mobile-responsive surveys (e.g., including scheduling of multiple surveys over time, use of automated email reminders, etc.). The study workflow is fully automated to allow tracking of eligibility, consenting, baseline survey completion, disbursement of incentives, randomization, and completion of subsequent surveys (with automated emails to study participants; the system can also handle automated text messaging if needed) and study activities. This workflow automation streamlines data capture and improves staff efficiency by automating survey and communication tasks and task tracking, thereby improving overall quality through standardization. The system facilitates tracking of individual research participants, as well as the creation of summary reports of overall study progress (e.g., recruitment, completion of study activities, and dropouts). Project staff can access the cloud-based platform across the multiple study sites. The workflow automation targets four key parameters: (1) Tasks – what needs to be done? e.g., participant surveys, research staff forms, phone calls, emails, appointments; (2) Timing – when should it be done? e.g., automated reminder email five days and two days before a scheduled clinic visit; (3) Rules – what determines what needs to be done? e.g., if preferred survey mode is “web”, then send email, if “phone”, schedule call; and (4) Status – what happened? e.g., email was sent, phone call was completed.

The DatStat software is HIPAA-compliant, and approval for use of this software in research studies has been provided by the Rutgers Biomedical and Health Sciences Institutional Review Board (IRB). DatStat secure servers are registered with site certificates provided by AddTrust that provide for advanced encryption over the wire. As each user moves through a survey form, his/her responses are encrypted while in-transit between the browser and DatStat's server using SSL (Secure Sockets Layer) and 40, 56, or 128-bit Public Key Encryption. All servers used for data collection are highly fault-tolerant and equipped with redundant, hot-pluggable power supplies, redundant network interfaces, and RAID 5 hot-swappable disk storage. All primary servers are plugged into a monitored, uninterruptible power supply (UPS). DatStat servers are stored in a locked server cabinet/rack, which are housed in a state-of-the-art, well-ventilated data center. Physical access to servers and data backup is restricted to a minimal number of information technology professionals. The servers are secured with physical and firewall security.

Office of Human Research Services: The Office of Human Research Services (OHRS) is Rutgers Cancer Institute's resource for the conduct of clinical trials. OHRS is a full-service clinical research enterprise that provides a range of management and quality control functions, including trial activation and monitoring, a centralized protocol repository, a centralized database of protocol-specific data, lists of currently active trials, protocol status reports, and assistance with complex regulatory issues. OHRS is comprised of four service areas and other support personnel who assist investigators in protocol management, study conduct and data and safety monitoring. Some of the responsibilities of OHRS are: (1) pre-study start-up training services, including activation meetings prior to activation of each Rutgers Cancer Institute and Oncology Group protocol; (2) centralized patient enrollment and verification of eligibility; (3) monitoring of protocol evaluations and treatment by research nurses at Rutgers Cancer Institute; (4) centralized reporting of serious adverse events to the IRB, the sponsoring organization, the National Cancer Institute, and the Food and Drug Administration and/or NIH Office of Biotechnology Activities when indicated; (5) centralized collection of clinical trial data from source documentation; (6) ensuring compliance with Good Clinical Practice guidelines and the regulations of applicable regulatory bodies; (7) monitoring of Rutgers Cancer Institute's multi-center trials and auditing of all clinical trials in accordance with OHRS Standard Operating Procedures.

Computer Facilities and Data Integrity: Rutgers Cancer Institute provides staff access to a secure Windows network, and Internet and email capability with antivirus protection. The network includes word processing, literature searching, an online library, research resources (e.g., statistical and reference information, abstracts), administrative databases, including an IRB protocols database, database management systems, and institute-

wide printing. Computers are supported and maintained by dedicated onsite computer services staff. All investigators and project staff have access to Academic Systems and Technology (AST), a division of the department of Information Services and Technology (IST), which provides quality information technology resources in support of the academic units. Resources include large-scale campus hosts and public computer laboratories, university-wide networking facilities and a professional staff with skills spanning academic computing disciplines and information services delivery. RU is committed to excellence in academic and research computing and has an outstanding research computing infrastructure. RU is equipped with a SunFire 6900 scientific multiple CPU server with 24 dual-core, 1.2 GHz ultrasparc IV cpus dedicated to clinical and basic science research applications. To address storage needs, a Sun Storage Area Network (SAN) with 8 Terabytes of available data storage space is available to all researchers. RBHS employs Virtual Local Area Networks (VLAN) and Virtual Private Networks (VPN), in conjunction with Intrusion Detection Systems (IDS), encryption techniques and virus protection. Access to the server is only allowed for authorized users with a password.

Center for Cancer Health Equity: The Center for Cancer Health Equity (CCHE), a partnership between Rutgers School of Public Health and Rutgers Cancer Institute, is located within Rutgers Cancer Institute. This central NJ office location, a block away from rail transit and within a few miles of a highway hub of all major NJ highways, provides multiple routes to and from New Brunswick, resulting in easy bidirectional flow of community and government partners, academic colleagues and students from around the state. This strategic location facilitates the work and goal achievement for the CCHE. The Community Outreach and Engagement (COE) team consists of the Director, Assistant Director, eight Community Cancer Control Specialists (CCCS), and a Program Manager; and a Program Assistant for our important ScreenNJ program. In addition, COE has a vibrant Community Cancer Action Board (CCAB) whose purpose is to build and foster partnerships between cancer researchers and community outreach staff and NJ communities. The CCAB provides input from over 30 community thought leaders and patient advocates to ensure community outreach and engagement, and research activities are informed, promote health equity and strengthen local capacity, and are responsive to community needs. The reciprocal flow of information between researchers and outreach staff and the community build trust and mutual understanding between communities and researchers, and help ensure that values, and cultural differences among persons and communities are respected. There is also an administrative core with CCHE dedicated staff serving the center with clerical, logistical and data management and reporting support. Community Cancer Control Specialists support planning, implementation, and follow-up of community engagement and outreach activities with community partners and Rutgers Cancer Institute faculty. The close collaboration with ScreenNJ extends the reach of COE via bidirectional engagement with the over 100 ScreenNJ partners, including healthcare systems, Federally Qualified Health Centers, Community-Based Organizations and Regional Chronic Disease Consortia, throughout the state. Through relationships with CCAB and ScreenNJ, Community Cancer Control Specialists amplify cancer prevention and screening guideline education to community health workers and health care providers in our partner organizations throughout all counties in New Jersey, which will facilitate Dr. Kohler's partnerships and data collection in primary care practices. Together with ScreenNJ partners, the COE participates in community events and engages in cancer prevention and screening activities utilizing standard techniques, as well as innovative interactive educational techniques, such as a large inflatable interactive colon, a table top inflatable lung display and youth and adult educational games.

RUTGERS SCHOOL OF PUBLIC HEALTH

Rutgers School of Public Health (SPH) seeks to improve health and prevent disease in diverse populations in New Jersey and around the world by educating students to become well-qualified and productive public health leaders, researchers and practitioners; conducting research to advance public health science and policies; and providing service programs that promote population and individual health. SPH is a statewide, multi-institutional, multi-campus scholarly community with over 51,000 square feet of research, training, administrative and academic space, across two campuses: New Brunswick and Newark. SPH is accredited to December 31, 2022 by the Council on Education for Public Health (CEPH), an independent agency recognized by the U.S. Department of Education to accredit schools of public health. Dr. Kohler is in the Department of Health Behavior, Society and Policy. SPH organizes a monthly orientation meeting for the new faculty cohort to connect junior faculty with various school and campus resources and support their transition to SPH. Dr. Kohler's department hosts a monthly Ten Talk during departmental meetings and Half-Baked seminar where faculty present manuscript, grant, and teaching ideas in preparation. Faculty research is facilitated through a range of school, RBHS, and RU support services, including state-of-the-art computer and library resources and access to Rutgers Office of Research and Sponsored Programs, Office of Grant and Contract Accounting, and IRB.

Library: RU, a member of the Association of American Universities, is a major research institution, and has a premier research library composed of 30 libraries and centers to serve the educational and research needs of more than 50,000 students, faculty, and staff on three campuses. RU offers access to comprehensive health, medical and social science collections, including online access to hundreds of journals and other publications. The Rutgers University libraries allow for access to major bibliographic databases, such as OVID, MEDLINE, PsychINFO, PubMed, Web of Science, as well as many other searchable databases. The library also provides training and support to RU affiliated students, faculty, and staff on use of the citation management tool EndNote X8 – which permits research teams of up to 100 members to share a project-based or topical library of citations; and associated full-text articles' faculty, students, and staff also have access to a specialized collection in the Robert Wood Johnson Library of the Health Sciences with 15,600 clinical and social science monographs and bound journals and 600 journal subscriptions.

RUTGERS ROBERT WOOD JOHNSON MEDICAL SCHOOL

The Rutgers Robert Wood Johnson Medical School (RWJMS) Founded in 1962, RWJMS has over 2,500 faculty members on three campuses in Piscataway, New Brunswick, and Camden. RWJMS encompasses 20 basic science and clinical departments, and hosts centers and institutes including The Cardiovascular Institute, the Child Health Institute of New Jersey, the Center for Advanced Biotechnology and Medicine, the Environmental and Occupational Health Sciences Institute, and the Stem Cell Institute of New Jersey. Ranked among the top fifty primary care medical schools in the United States and rated second for community health, the school has four missions dedicated to the pursuit of excellence in: (1) the undergraduate, postgraduate and continuing education of health professionals and scientists; (2) the conduct of basic biomedical, psychosocial, clinical, and public health research; (3) health promotion, disease prevention and the delivery of health care; and (4) service to our communities and the entire state. The medical school maintains educational programs at the undergraduate, graduate, and postgraduate levels for more than 1,500 students on its campuses. RWJMS offers postgraduate medical specialty training in 12 major clinical areas and their relevant subspecialties.

Research Division, Department of Family Medicine and Community Health, Rutgers RWJMS

The mission and vision of the Rutgers RWJMS Family Medicine Research Division is to develop and sustain a nurturing and productive research environment that fosters collaborative trans-disciplinary approaches to promote the health of individuals, families, and communities by improving quality of care, and eliminating health-related disparities. The core faculty members in the Research Division have well-developed primary care research portfolios focused on organizational capacity and patient centered care. In 2017, the Department of Family Medicine and Community Health's Research Division was ranked #21 among Family Medicine Departments in the country in NIH funding by the Blue Ridge Institute for Medical Research. Division research efforts have received major funding through federal and foundation sources, including the National Cancer Institute (NCI), National Institute on Drug Abuse (NIDA), National Heart, Lung & Blood Institute (NHLBI), the National Institute for Diabetes and Digestive and Kidney Diseases (NIDDK), the Centers for Disease Control (CDC), the Robert Wood Johnson Foundation (RWJF), the Centers for Medicare and Medicaid Services (CMS), and the Agency for Health Care Research and Quality (AHRQ). This funding provides support for a well-established, ongoing line of implementation science research that uses mixed methods to examine strategies to enhance quality of care in primary care practices. In addition to our faculty, the Research Division also employees 6 core staff members with expertise in quantitative data collection/management (e.g., medical record abstraction, automated survey data collection using DatStat, SNAP and Teleform) and analysis, qualitative data collection (e.g., depth interviews, field observations, participant observation, focus groups) and analysis using ATLAS.ti software, and practice facilitation. The Research Division has expertise in the development of multilevel health care interventions focused on enhancing care for vulnerable populations, particularly underserved groups including racial/ethnic minorities.

New Jersey Primary Care Research Network

The New Jersey Primary Care Research Network (NJPCRN) is an Agency for Healthcare Research and Quality (AHRQ)-recognized Practice-Based Research Network (PBRN) founded in 2001 by the Department of Family Medicine and Community Health at Robert Wood Johnson Medical School. The NJPCRN is one of the largest and most successful PBRNs in the US including over 300 primary care physicians caring for more than 750,000 patients across approximately 114 primary care practices. The NJPCRN participating practices are located throughout New Jersey, serving its diverse minority patient populations, including Hispanic, African American

and Asian American communities. The Advisory Board, consisting of ten community primary care physicians, provides important feedback on practice-based research from both the "community" physicians' perspective. The Network has developed transparent systems for tracking utilization of its services by investigators and for accurately tracking costs and expenses. NJPCRN may also provide access to patients and providers within their network for recruitment and participant enrollment.

RWJBARNABAS HEALTH SYSTEM

The partnership of the Rutgers Cancer Institute and the RWJBarnabas Health System not only created New Jersey's largest academic health care system, it advances our mission of eliminating cancer by enabling collaborations with hospitals and physicians across the system through one integrated cancer service line and clinical research office, to improve the quality of care throughout the State and beyond. The strategic partnership includes a substantial investment in clinical research and medical student internships. Through the two medical schools, RWJBarnabas Health collaborates to train and educate medical residents and interns throughout the hospitals each year.

RWJBarnabas Health is the largest, most comprehensive academic health care system in New Jersey, with a service area covering nine counties across the state. RWJBarnabas partners with Rutgers Cancer Institute to provide a single integrated oncology service line across its 14 acute cancer hospitals – Rutgers Cancer Institute in New Brunswick, Rutgers Cancer Institute at Robert Wood Johnson University Hospital (RWJUH) in Newark, RWJUH in New Brunswick, RWJUH in Hamilton, RWJUH Rahway, RWJUH Somerset, Saint Barnabas Medical Center in Livingston, Clara Mass Medical Center in Belleville, Community Medical Center in Toms River, Jersey City Medical Center in Jersey City, Monmouth Medical Center in Long Branch, Monmouth Medical Center Southern Campus in Lakewood, Newark Beth Israel Medical Center in Newark, and Trinitas Regional Medical Center in Elizabeth, four acute care children's hospitals and a leading pediatric rehabilitation hospital with a network of 14 pediatric care centers (Children's Specialized Hospital), 33 outpatient care centers, a freestanding 100-bed behavioral health center, two trauma centers, a satellite emergency department, ambulatory care centers, geriatric centers, and the state's largest behavioral health network. The system also provides comprehensive home care and hospice programs, fitness and wellness centers, retail pharmacy services, a medical group, multi-site imaging centers and two accountable care organizations.

Patients Treated Per Year:

- Patients Treated: Over 3 million
- Outpatient Visits: 2 million
- Inpatients and Same Day Surgery Patients: 283,000
- Emergency Department Patients: 700,000
- Pediatric Patients: 200,000
- Births: 23,000

Staff:

- Employees: 32,000
- Physicians: 9,000
- Residents and Interns: 1,000

Specialties and Centers:

- New Jersey's only certified burn treatment facility
- World-class cardiac surgery services for adults
- New Jersey's oldest, most experienced heart transplant program, top 10 in the nation by volume
- New Jersey's only lung transplant program
- Six nationally certified chest pain centers
- Accredited, certified comprehensive and primary stroke centers
- Two kidney transplant centers (both top 10 in the nation)
- Renowned neurology and neurosurgery program
- Comprehensive cancer services for adults and children
- Nationally recognized geriatric services
- Renowned women's and children services

OTHER RESOURCES

CTSA: Coordinated by RBHS, the New Jersey Alliance for Clinical and Translational Science (NJ ACTS) comprises a consortium with Rutgers and Princeton Universities, NJ Institute for Technology, medical, nursing, dental and public health schools, hospitals, community health centers, outpatient practices, industry, policymakers and health information exchanges. NJ ACTS has access to a large health system with significant member diversity; a rich legacy of community engagement and community-based research platforms; and proven approaches to enhance workforce development in clinical research. To build our capacity for participant and clinical interactions as a CTSA Hub, the newly established Trial Accelerator and Recruitment Office coordinates feasibility assessment, implementation, recruitment, and evaluation of clinical studies. Additionally, our organization of five clinical research units into a cohesive network provides extraordinary expertise in strategic locations to enhance participant recruitment from diverse communities with a particular focus on: children; the elderly; those with serious mental illness or substance abuse issues; low-income individuals served by Medicaid; those with HIV/AIDS; and people of all ages who are minorities, underserved, and victims of health and environmental disparities. With a history of collaboration, partners and affiliates share unique expertise, training and mentoring capabilities, including a grant-writing course for postdoctoral fellows and junior faculty and R-level grant writing course for early stage investigators.

RU – Institutional Review Board
The RU IRB offers training to supplement research compliance and human research protection requirements. Open consultation hours are also offered by IRB staff. Investigators may meet with RU IRB professionals to discuss regulatory, policy, and procedural questions. Mandatory, web-based training on good clinical practices, human subjects' protection, HIPAA policies, and research with minors and animals (if applicable) is required for any individual involved with research at RU.

Overview of Relevance to K22 Application
In summary, the facilities and resources available at RBHS are outstanding. Dr. Kohler has full access to the rich resources and expertise available. She has the support of Rutgers Cancer Institute and Center for Cancer Health Equity leadership as she develops into an independent investigator through this award. The resources available at Rutgers Cancer Institute will provide Dr. Kohler with an environment that is unique, collaborative, and community-focused, which will enhance Dr. Kohler's trajectory towards an independent career focused on eliminating HPV-related cancer disparities through multilevel intervention trials.

EQUIPMENT

All major equipment as described in the Facilities and Other Resources (e.g., computers, printers, network security, etc.) is located in Rutgers Cancer Institute of New Jersey and located at 195 Little Albany Street, New Brunswick, NJ.

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED Senior/Key Person Profile (Expanded)

PROFILE - Project Director/Principal Investigator

Prefix: First Name*: Racquel Middle Name Last Name*: Kohler Suffix:

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Organization Name*: Rutgers, The State University of New Jersey, RBHS-CINJ
Department: Cancer Health Equity
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Zip / Postal Code*: 089011914

Phone Number*: 732-258-6031 Fax Number:

E-Mail*: kelly.kohler@rutgers.edu

Credential, e.g., agency login: [redacted] eRA Commons User Name

Project Role*: PD/PI Other Project Role Category:

Degree Type: PhD Degree Year: 2015

Attach Biographical Sketch*: File Name: Kohler_biosketch_10Mar.pdf

Attach Current & Pending Support: File Name:

Tracking Number: GRANT13318726

Funding Opportunity Number: PAR-18-466 . Received Date: 2021-03-10T15:05:11.000-05:00

PROFILE - Senior/Key Person

Prefix: First Name*: Manuel Middle Name Last Name*: Jimenez Suffix:

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County:
State*: NJ: New Jersey
Province:
Country*: USA: UNITED STATES
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Project Role*: Other (Specify) Other Project Role Category: Other Significant Contributor

Degree Type: MD Degree Year: 2006

Attach Biographical Sketch*: File Name: Jimenez_biosketch.pdf

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

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Division:
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Province:
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Project Role*: Other (Specify) Other Project Role Category: Other Significant Contributor

Degree Type: PhD Degree Year: 1992

Attach Biographical Sketch*: File Name: Greene_Biosketch.pdf

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Rula Middle Name Last Name*: Btoush Suffix:

Position/Title*: Associate Professor
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State*: NJ: New Jersey
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Project Role*: Other (Specify) Other Project Role Category: Other Significant Contributor

Degree Type: PhD Degree Year: 2004

Attach Biographical Sketch*: File Name: Btoush_biosketch.pdf

Attach Current & Pending Support: File Name:

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

BIOGRAPHICAL SKETCH

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

NAME: Kohler, Racquel Elizabeth "Kelly"

eRA ACOMMONS USER NAME (credential, e.g., agency login): [redacted] eRA Commons User Name

POSITION TITLE: Instructor

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

INSTITUTION AND LOCATION	DEGREE	Completion Date MM/YYYY	FIELD OF STUDY
University of Central Florida, FL	BS	05/2007	Molecular Biology & Microbiology
University of North Carolina at Chapel Hill, NC	MSPH	05/2011	Public Health
University of North Carolina at Chapel Hill, NC	PhD	05/2015	Health Policy & Management
Harvard TH Chan School of Public Health, MA	Postdoc	08/2018	Cancer Prevention

A. Personal Statement

I am a cancer disparities researcher committed to improving prevention and control behaviors for vulnerable populations. For 10 years my work has focused on identifying and addressing behavioral, social, and structural factors that influence access to and use of cancer services in low-resource settings and low-income populations. Through my master's and doctoral training, I gained skills in health services research methods, including decision science modeling and discrete choice experiments. As a Fogarty Global Health fellow, I moved to Malawi for 1.5 years where I developed and conducted a mixed methods study on factors affecting breast cancer diagnosis and screening preferences. My research shifted to HPV and cervical cancer prevention during my postdoctoral fellowship where I trained in behavioral and implementation sciences. Much of my postdoctoral work evaluated patient and provider perspectives on novel HPV screening interventions among marginalized women in Southern Africa, South America, and the United States. In addition to the publications listed below, I have manuscripts under review at *Journal of Cancer Education* and *BMC Public Health* explaining the unique barriers to cervical cancer screening homeless women face and the feasibility of HPV self-sampling, especially as it relates to street medicine. As I continue my work in Botswana, one manuscript [redacted] Unpublished Material [redacted] Unpublished Material

Upon joining Rutgers Cancer Institute of New Jersey, I quickly established HPV prevention collaborations with other faculty and public health practitioners. I am MPI on a Rutgers Cancer Institute Pilot Award where we are adapting and testing a tailored text message intervention to improve adherence to colposcopy among women with abnormal screening results, which largely involves Black and Hispanic women. A co-authored publication on usability testing is in preparation. My work with Drs. Rula Btoush and Kathryn Greene on a mixed methods investigation of social determinants of vaccine hesitancy (P30CA072720-21S2) is directly related to the proposed K22. I have co-authored papers with Dr. Btoush and under review [redacted] Unpublished Material [redacted] Unpublished Material [redacted] Unpublished Material Another co-authored paper with Rutgers colleagues on [redacted] Unpublished Material [redacted] Unpublished Material Dr. Jimenez and I are members of the Rutgers Dissemination and Implementation Working Group and have begun to collaborate given shared interests in behavior change text interventions, which will also facilitate execution of this study. I have a demonstrated record of high-quality research on multilevel determinants of delayed cancer prevention behaviors, service use, and treatment outcomes. This K22 will allow me to develop expertise in HPV vaccination communication, intervention mapping with stakeholders, and conducting intervention trials as I progress towards my goal of being an independent cancer disparities investigator.

B. Positions and Honors

Positions and Employment

2007-2009 Educational Leadership Consultant, Kappa Kappa Gamma Fraternity, Columbus, OH
2010 Research Assistant, Lineberger Comprehensive Cancer Center, UNC-CH
2011 Teaching Assistant, Program Evaluation, Health Policy and Management, UNC-CH
2011-2013 Research Assistant, Health Policy and Management, UNC-CH
2013-2014 Fogarty R25 Pre-doctoral scholar, UJMT Fogarty Global Health Fellows Program, Malawi
2013-2015 NCI R25 Pre-doctoral Fellow, Cancer Care Quality Training Program, UNC-CH
2015-2018 NCI R25 Postdoctoral Fellow, Cancer Prevention Fellowship, Harvard TH Chan School
2018-2019 Research Associate, Harvard TH Chan School of Public Health, Dana-Farber Cancer Institute
2019- Instructor, Rutgers Cancer Institute of New Jersey and School of Public Health

Other Experience and Professional Memberships

2009- Member, Academy Health
2009- Member, Global Health Council
2015- Member, American Association for Cancer Research (AACR)
2015- Member, International Papillomavirus Society (IPVS)
2017- Member, International AIDS Society (IAS)
2019- Member, American Public Health Association (APHA)
2020- Member, American Society of Preventive Oncology (ASPO)

Honors

2003-2007 Florida Bright Futures Scholarship
2003-2007 Florida High Academic Achievement Scholarship
2008-2010 Graduate Student Leadership Scholarship, Kappa Kappa Gamma Foundation
2009-2011 Graduate Academic Merit Scholar, Health Policy and Management, UNC-CH
2012 International Cancer Screening Network (ICSN) Young Investigator, NCI ICSN Meeting Sydney
2014 Lancet and Consortium of Universities for Global Health (CUGH) Best Student Abstract, CUGH
2015 Future Faculty Fellowship Program, Center for Faculty Excellence, UNC-CH
2015 Harry T. Phillips Award for Outstanding Teaching by a Doctoral Student, UNC-CH

C. Contributions to Science

1. Patient acceptability and preferences for new cancer screening services. Much of my work focuses on understanding the patient experience and ensuring that medical and public health interventions are patient-centered. I led formative research to inform the intervention content, design, and delivery options using both qualitative and quantitative methods to gain in-depth understandings of patients' views. My expertise in preference elicitation techniques mainly involves discrete choice experiments (DCEs), which I have developed and applied across various populations and health interventions, including HPV self-sampling, cancer early detection services, smoking cessation, and pre-exposure prophylaxis (PrEP) for HIV prevention. I have conducted and analyzed interviews and focus groups, employing user-centered approaches, to evaluate future needs and experiences with existing interventions.

a. **Kohler RE**, Lee CN, Gopal S, Reeve BB, Weiner BJ, Wheeler SB. Developing a discrete choice experiment in Malawi: eliciting preferences for breast cancer early detection services. Patient Preference and Adherence 2015 Oct;9:1459-72. PMCID: 4612134
b. **Kohler RE,** Miller AR, Gutnik L, Lee CN, Gopal S. Experiences and perceptions regarding clinical breast exam screening by trained laywomen in Malawi. Cancer Causes and Control 2017 Feb;28(2), 137-43. PMCID: 5419072
c. **Kohler RE**, Gopal S, Lee CN, Weiner BJ, Reeve BB, Wheeler SB. Breast cancer knowledge, behaviors, and preferences in Malawi: Implications for early detection interventions from a discrete choice experiment. Intervention implications from a discrete choice experiment for early detection. Journal of Global Oncology 2017 Oct; 3(5):480-489. PMCID: 5646878
d. **Kohler RE**, Elliott T, Monare B, Moshashane N, Ramontshonyana K, Chatterjee P, Ramogola-Masire D, Morroni C. HPV self-sampling acceptability and preferences among women living with HIV in Botswana. International Journal of Gynecology and Obstetrics 2019 Dec;147(3):332-338. PMCID: 6944206

2. Multilevel determinants of delayed cancer behaviors. Complex factors that span multiple social ecological levels of influence contribute to disparate health outcomes and behaviors. My completed Nodal Award study among women experiencing homelessness found that many of the participants had experienced sexual violence and delayed or refused Pap screening for multiple years or decades. Homeless women have multiple competing health and social needs, which also contributed to women de-prioritizing screening. I have also assessed barriers to cancer diagnosis. Part of my dissertation research described how low knowledge and fatalistic beliefs influenced breast cancer diagnosis in Malawi. I outlined the breast cancer help-seeking pathway explaining how patients decide to seek help for symptoms and identified intervention opportunities at multiple ecological levels along the pathway. Similarly, during my postdoctoral fellowship, I advised a doctoral student on an analysis of patient interviews that explored delays in accessing cancer care in Botswana. Poor knowledge of cancer symptoms among patients and frontline health workers contributed to delays in care and late diagnosis.

a. **Kohler RE**, Gopal S, Miller AR, Lee CN, Reeve BB, Weiner BJ, Wheeler SB. A framework for improving early detection of breast cancer in sub-Saharan Africa: a qualitative study of help-seeking behaviors among Malawian women. Patient Education and Counseling. 2017 Jan;100(1):167-73. PMCID: 5301948
b. Brown CA, **Kohler RE**, John O, Motswetla G, Mmalane M, Tapela N, Grover S, Dryden-Peterson S, Lockman S, Dryden-Peterson SL. Multi-level Factors Affecting Time to Cancer Diagnosis and Care Quality in Botswana. The Oncologist 2018 Dec;23(12):1453-60. PMCID: 6292540
c. **Kohler RE,** Aguiar AM, Roncarati JS, Chatterjee P, Henry C, Viswanath K. Barriers and facilitators to cervical cancer prevention among homeless women. 2020. American Public Health Association Annual Meeting. Philadelphia, PA.

In Press

3. Disparities in cancer prevention behaviors and outcomes. Throughout my training and research experiences, I have analyzed large datasets from cancer registries, survivorship cohorts, and population-based surveys from the US and multiple countries in Southern Africa. I led the first study characterizing breast cancer clinical outcomes in Malawi, which found that most cases were diagnosed with advanced disease after long symptom durations. I also examined cervical cancer in Malawi, noting particularly poor outcomes among women living with HIV, which was awarded the *Lancet* and Consortium of Universities for Global Health Best Student Abstract in 2014. I mentored an Epidemiology PhD student on an analysis of delayed diagnosis among cancer patients in Botswana, which documented long delays from first presentation to treatment initiation and increased risk of advanced stage. Finally, clinical data analyzed as part of an inter-institutional Center for AIDS Research (CFAR) collaborative project I led during my postdoc demonstrated high prevalence of high-risk types of HPV among women living with HIV.

a. **Kohler RE**, Moses A, Krysiak R, Liomba NG, Gopal S. Pathologically confirmed breast cancer in Malawi: a descriptive study; clinical profile of breast cancer. Malawi Medical Journal 2015 Mar;27(1): 10-2. PMCID: 4478398
b. **Kohler RE**, Tang J, Gopal S, Chinula L,Hosseinipour MC, Liomba TG, Chiudzu G. High rates of cervical cancer among HIV-infected women at a referral hospital in Malawi. International Journal of STD and AIDS 2016 Aug;27(9):753-60. PMCID: 4870149
c. Iyer HS, **Kohler RE**, Ramogola-Masire D, Brown C, Molebatsi K, Grover S, Kablay I, Bvochora-Nsingo M, Efstathiou JA, Lockman S, Tapela N, Dryden-Peterson SL. Explaining disparities in oncology health systems delays and stage at diagnosis between men and women in Botswana: A cohort study. PLoS ONE 2019 Jun;14(6): e0218094. PCMID: 6553768
d. **Kohler RE**, Elliott T, Monare B, Moshashane N, Ramontshonyana K, Muthoga C, Wynn A, Howett R, Luckett R, Morroni C, Ramogola-Masire D. Performance of vaginal self-sampling for HPV testing among women living with HIV in Botswana. International Journal of STD & AIDS 2019 Oct;30(12):1169-1176. PMCID: 7179768

4. Cancer communication interventions for vulnerable populations. I have significantly contributed to projects identifying communication inequalities that can affect cancer prevention behaviors. Within the Viswanath lab, some of my postdoctoral work examined the information environment, including daily exposure to messages

that influence health information seeking, processing, and behaviors. I have also been involved in developing and testing multiple component interventions, including mHealth interventions for health workers and systems to communicate with patients and link them to follow-up care. I served as Co-Investigator on *Project ATICA* in rural Argentina where my main role was to determine information needs and develop the content and framing of messaging for an mHealth intervention to deliver results after women screen with HPV self-sampling. My work also includes developing, facilitating, and evaluating primary care provider training for counseling patients on cancer risks and prevention strategies for the *Potlako+* (meaning '*hurry'* in Setswana) intervention. Building off our published pilot work, I currently serve as Co-Investigator on the NCI-funded R01 in Botswana where I am leading the development of a community cancer awareness campaign.

a. **Kohler RE**, Ramanadhan S, Viswanath K. Intervening on the Information Environment to Address Cancer Disparities. in Chambers, Vinson, Norton (Eds.) Optimizing the Cancer Control Continuum: Advancing Implementation Research. NY, NY: Oxford University Press. 2018
b. **Kohler RE**, Revette A, Chatterjee P, Viswanath K. Building Public Agenda and Media Support for Public Health in India; Thematic Report of Interviews with Delhi Journalists 2019. Prepared for the India Office of the Bill and Melinda Gates Foundation
c. Sanchez Antelo V, **Kohler RE**, Szwarc L, Paolino M, Viswanath K, Arrossi S. Knowledge and Perceptions regarding triage among HPV-tested women: a qualitative study of perspectives of low-income women in Argentina. Women's Health 2020. Jan-Dec;16. PMCID: 7716054
d. Sanchez Antelo V, **Kohler RE**, Curotto M, Viswanath K, Paolino M, Thouyaret L, Arrossi S. Developing SMS content to promote Pap triage: a qualitative exploration. Journal of Medical Internet Research 2020. 4(3): e14652. PCMID: 7084289

5. Health system and structural factors influencing cancer service use and delivery. As a health services researcher, my work focused on understanding health system factors (at the physician, facility, and organization levels) of cancer outcomes. As new technologies increase delivery options for HPV screening, implementation science frameworks and systems thinking will be increasingly important to evaluate how facilities and organizations adopt new services and delivery models. My research analyzing Medicaid claims data has helped explain the role of delivery models, such as patient-centered medical homes, in cancer-related treatment outcomes among low-income women. Studies I contributed to suggest opportunities to improve treatment through innovative care models using patient navigators, lay health workers, and community health workers. Costs of new services and delivery models are also critical implementation measures to consider when scaling-up; I have conducted numerous micro-costing and cost-effectiveness analyses.

a. **Kohler RE**, Sheets NC, Wheeler SB, Nutting C, Hall E, Chera BS. Two-year and lifetime cost-effectiveness of intensity modulated radiation therapy versus 3-dimensional conformal radiation therapy for head-and-neck cancer. Int J Radiat Oncol Biol Phys. 2013 Nov 15;87(4):683-9. doi: 10.1016/j.ijrobp.2013.08.011. PMID: 24138916
b. Wheeler SB, **Kohler RE**, Goyal RK, Lich KH, Lin CC, et al. Is medical home enrollment associated with receipt of guideline-concordant follow-up care among low-income breast cancer survivors? Medical Care 2013 Jun;51(6):494-502. PMCID: 6067673
c. **Kohler RE**, Goyal RK, Hassmiller-Lich K, Domino ME, Wheeler SB. Association between Medical Home Enrollment and Health Care Utilization and Costs among Breast Cancer Patients in a State Medicaid Program. Cancer 2015. 121(22): 3975-81. PMCID: 5004988
d. Painschab MS, **Kohler RE**, Kasonkanji E, Zuze T, Kaimila B, Nyasosela R, Nyirenda R, Krysiak R, Gopal S. Microcosting Analysis of Diffuse Large B-Cell Lymphoma Treatment in Malawi. J Glob Oncol. 2019 Jul;5:1-10. doi: 10.1200/JGO.19.00059. PMCID: 6690619

Complete List of Published Work in My Bibliography:
https://www.ncbi.nlm.nih.gov/myncbi/1HG3h5bL5NfAM/bibliography/public/

D. Research Support

Ongoing Research Support

3P30CA072720-21S2 National Cancer Institute	Libutti (PI)	03/01/2021-02/28/2022

Vaccine hesitancy related to uptake of the HPV vaccine in regions with low adolescent HPV vaccination rates
This supplement will analyze 2020 Rutgers Cancer Institute catchment area survey data to identify sociodemographic characteristics associated with parent-reported HPV vaccination uptake, delays, refusals, and reasons for non-vaccination. Formative research in the Greater Newark area will explore social determinants of HPV vaccine hesitancy.
Role: Project Leader

Private Support — Narayanan (PI) — 02/16/2021-02/15/2026

COVID-19 and Vaccine Confidence
To evaluate knowledge, attitudes, and perceptions of the COVID-19 pandemic and its health system response in relation to vaccine confidence and hesitancy among underserved communities in New Jersey. We will conduct survey research among patients, pharmacists, and pharmacy staff and identify opportunities for education, promotion and distribution of novel COVID-19 vaccines and routine immunizations.
Role: Co-Investigator

Private Support — Hudson, Kohler (MPI) — 07/01/2020-06/30/2021

Development of a Health Enhancement Resource System (HERS) to address urban, cervical cancer disparities
The pilot study will adapt an efficacious, barriers-focused, tailored counseling intervention that increased adherence to colposcopy among urban, underserved women, from phone delivery to text message. We will conduct interviews with providers and patients to adapt messages and determine usability.
Role: Co-Principal Investigator

R01 CA236546 — Dryden-Peterson (PI) — 09/19/2019-08/31/2024
National Cancer Institute
A multilevel intervention (Potlako+) to improve timely cancer detection and treatment initiation
Development and implementation of a complex intervention including a community awareness campaign, patient education, provider training and support, and SMS-based navigation for suspected cancer patients in a pair-matched, community-randomized study involving 20 communities in Botswana.
Role: Co-Investigator

Completed Research Support

R01 CA218306 — Arrossi (PI) — 09/01/2017-08/31/2020
National Cancer Institute
Evaluation of mHealth intervention to increase triage adherence of HPV+ women who self-collected
This cluster randomized hybrid implementation-effectiveness trial includes mixed methods research to develop and test an mHealth intervention for improving cervical cancer Pap triage adherence in Argentina.
Role: Co-Investigator

Private Support — Viswanath, Kohler (MPI) — 09/01/2016-09/30/2019

Improving HPV testing and triage for underserved women
This project evaluates the feasibility of HPV self-sampling as a primary screening method and explores the clinical performance of novel epigenetic markers as triage approaches among homeless women in Boston.
Role: Co-Principal Investigator

R25 CA057711 — Viswanath (PI) — 09/01/2015-08/31/2018
National Cancer Institute
Harvard-Dana Farber Cancer Prevention Training Program
Postdoctoral fellowship with coursework and mentored research experiences focused on cancer risks, assessment, intervention, prevention, and evaluation. The goal is to prepare fellows to become independent scientists who can excel in interdisciplinary team science research on cancer prevention and control.
Role: Postdoctoral Fellow

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

BIOGRAPHICAL SKETCH

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

NAME: Manuel E. Jimenez, MD, MS

eRA COMMONS USER NAME (credential, e.g., agency login): [redacted] eRA Commons User Name

POSITION TITLE: Assistant Professor

EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
Rutgers University, New Brunswick, N.J.	B.A.	6/2003	Biological Sciences
Rutgers Robert Wood Johnson Medical School, New Brunswick, NJ	M.D.	6/2006	Medicine
University of Pennsylvania Perelman School of Medicine, Philadelphia, PA	M.S.	6/2012	Health Policy Research

A. Personal Statement

I am a physician-scientist with board certification in developmental and behavioral pediatrics and research training in health policy research. I am an Assistant Professor of Pediatrics and Family Medicine and Community Health at Rutgers Robert Wood Johnson Medical School. My faculty appointment comes with the designation of Chancellor's Scholar. I am also the Director of Developmental and Behavioral Pediatrics Education at the Boggs Center on Developmental Disabilities and Attending Developmental and Behavioral Pediatrician at Children's Specialized Hospital. My research has largely focused on developing and testing interventions that promote health equity among underserved populations, particularly low-income Latino families with limited English proficiency and literacy. As PI/MPI of multiple UL1 and R01 grants, I have conducted randomized trials in community health centers serving racially/ethnically diverse low-income families aimed at improving parent attitudes, behaviors and child language and socio-emotional developmental outcomes. Several of my studies have used psychosocial, behavioral, and clinical measures of parent-child dyads in effectiveness-implementation hybrid randomized trials among underserved populations.

This application is well-aligned with my clinical specialty as a developmental and behavioral pediatrician working with families of vulnerable children as well as my methodological expertise developing and testing parent-targeted texting interventions. As a collaborator, I will lend my expertise on how to design tailored psycho-educational interventions for assessing and changing parents' attitudes and intentions. I have experience recruiting specific racial/ethnic minorities from safety-net clinics similar to Dr. Kohler's K22 application, which will facilitate logistical and planning aspects of the proposed pilot trial. Dr. Kohler and I are both actively involved with the Rutgers dissemination and implementation working group and I look forward to collaborating with her on this project. I have demonstrated my ability to work successfully as part of an interdisciplinary team focused on improving parent-child socio-emotional outcomes and behaviors through tailored texting interventions in underserved populations, which will contribute to this study's success.

1. **Jimenez ME**, Crabtree BF, Hudson SV, Mendelsohn AL, Lima D, Shelton PA, Veras J, Lin Y, Pellerano M, Morrow L, Strom BL. Enhancing Reach Out and Read with a Video and Text Messages: A Randomized Trial in a Low-income Predominantly Latino Sample. Acad Pediatr. 2021 Feb 19:S1876-2859(21)00067-X. doi: 10.1016/j.acap.2021.02.011. Epub ahead of print. PMID: 33618060.
2. Coffield CN, Harris JF, Janvier YM, Lopez M, Gonzalez N, **Jimenez ME**. Parental Concerns of Underserved Young Children at Risk for Autism. J Health Care Poor Underserved. 2020;31(2):742-755. doi: 10.1353/hpu.2020.0058. PMID: 33410805.

3. **Jimenez ME,** Hudson SV, Lima D, Crabtree BF. Engaging a Community Leader to Enhance Preparation for In-Depth Interviews With Community Members. Qual Health Res. 2018 Aug 12:1049732318792848. doi: 10.1177/1049732318792848. [Epub ahead of print] PubMed PMID: 30101661.
4. **Jimenez ME**, DuRivage NE, Bezpalko O, Suh A, Wade R, Blum NJ, Fiks AG. A Pilot Randomized Trial of a Video Patient Decision Aid to Facilitate Early Intervention Referrals From Primary Care. Clin Pediatr (Phila). 2017 Mar;56(3):268-277. doi: 10.1177/0009922816677038. Epub 2016 Nov 12. PubMed PMID: 27834191.

B. Positions and Honors

Positions and Employment

2006-2007	Intern in Pediatrics, Children's National Medical center, Washington, D.C.
2007-2009	Residence in Pediatrics, Children's National Medical Center, Washington, D.C.
2009-2010	Joseph P. Kennedy, Jr. Foundation Public Policy Fellow, US Senator Jeanne Shaheen (NH)
2010-2012	Robert Wood Johnson Foundation Clinical Scholar, University of Pennsylvania Perelman School of Medicine
2010-2014	Fellow in Developmental & Behavioral Pediatrics, Children's Hospital of Philadelphia, Philadelphia, PA
2014-	Assistant Professor of Pediatrics & Family Medicine and Community Health, Tenure Track, Rutgers Robert Wood Johnson Medical School
2014-	Chancellor's Scholar, Rutgers Robert Wood Johnson Medical School
2015-	Director, Developmental Behavioral Pediatrics Education, The Boggs Center on Developmental Disabilities, Rutgers Robert Wood Johnson Medical School

Honors

2003	Phi Beta Kappa, Rutgers University
2006	Gold Humanism Honor Society, UMDNJ- Robert Wood Johnson Medical School, Piscataway, NJ
2006	Leonard Tow Humanism in Medicine Award Presented by the Arnold P. Gold Foundation, UMDNJ- Robert Wood Johnson Medical School, Piscataway, NJ
2006	Robert Wood Johnson Medical School Alumni Association- Alumni Award
2006	Robert Wood Johnson Medical School Academic Excellence in Pediatrics Award
2007	Children's National Medical Center Resident Teaching Award
2008	American Academy of Pediatrics (AAP) Community Pediatrics Training Initiative (CPTI) – Advocacy Training Grant
2012	Academic Pediatric Association Research Award for Best Abstract by a Fellow
2013	Children's Hospital of Philadelphia Barbara Brodsky Endowed Fellow in Neurodevelopmental Disabilities
2013	American Academy of Pediatrics - Bright Futures Early Childhood Expert Panel
2015	Eastern Society for Pediatric Research Meritorious Poster Award
2015	Rutgers Robert Wood Johnson Pediatric Research Day Excellence Award
2016	Rutgers Robert Wood Johnson Pediatric Research Day Excellence Award
2018	Participant, Program for Early Career Excellence, Rutgers University
2018	Rutgers Robert Wood Johnson Pediatric Research Day Excellence Award
2019	Robert Wood Johnson University Hospital Service and Advocacy for Latinos United for Development (SALUD) Star

Professional Societies

2006	American Academy of Pediatrics
2010	Academic Pediatric Association
2014	NJ Chapter of the American Academy of Pediatrics
2014	Society of Developmental and Behavioral Pediatrics
2016	Society for Pediatric Research

C. Contributions to Science

1. While stakeholder engagement in research is a growing national priority much work is needed to understand how to meaningfully engage stakeholders in developing and answering research questions and setting research priorities. To date, I have applied my training in community based participatory research, qualitative and quantitative research, and engagement to engage diverse stakeholders, understand barriers to care and identify sustainable strategies to overcome these barriers. As a medical student I co- led a group of students that partnered with a local soup kitchen to conduct a needs assessment among their clients and start a student run clinic in response to their needs that has now been in operation for 15 years. Later as a RWJF Clinical Scholar and developmental pediatrics fellow I led a series of studies to understand barriers to early intervention therapy receipt among young children identified with developmental concerns from the perspective of parents, pediatricians and early intervention service providers. I then partnered with the early intervention agency, pediatric health care providers, and parents to develop an intervention to facilitate the early intervention referral process for families. I have also applied ethnographic research methods to engage stakeholders in identifying the research topic, developing the interventions, and disseminating findings.
   a. **Jimenez ME,** Hudson SV, Lima D, Crabtree BF. Engaging a Community Leader to Enhance Preparation for In-Depth Interviews With Community Members. Qual Health Res. 2018 Aug 12:1049732318792848. doi: 10.1177/1049732318792848. [Epub ahead of print] PubMed PMID: 30101661.
   b. **Jimenez ME,** DuRivage NE, Bezpalko O, Suh A, Wade R, Blum NJ, Fiks AG. A Pilot Randomized Trial of a Video Patient Decision Aid to Facilitate Early Intervention Referrals From Primary Care. Clin Pediatr (Phila). 2017 Mar;56(3):268-277. doi: 10.1177/0009922816677038. Epub 2016 Nov 12. PubMed PMID: 27834191.
   c. **Jimenez ME**, Fiks AG, Ramirez-Shah L, Gerdes M, Ni A, Pati S, Guevara JP: Factors associated with early intervention referral and evaluation: A mixed methods analysis. Academic Pediatrics 14(3): 315-323, 2014. PMID: 24767785
   d. **Jimenez ME**, Tan- Billet J, Babineau J, Jimenez JE, Billet T, Flash C, Levin S, West B, Tallia A: The Promise Clinic: A Service Learning Approach to Increasing Access to Health Care. Journal of Health Care for the Poor and Underserved 19(3): 935-943, 2008.

2. My work has examined strategies to leverage primary care to promote equity in school readiness for children from vulnerable backgrounds. I have used quantitative and qualitative research methods to identify barriers to primary care based literacy promotion, identify stakeholder prioritized research questions and outcomes, and develop and test outreach strategies to enhance an existing primary care literacy promotion program for low-income Latinx families. Ongoing work includes a randomized clinical trial testing the extent to which videos and text messages increase shared reading among low-income Latinx parents and conducting qualitative interviews to contextualize our findings. We have also used qualitative methods to explore how pediatricians are trained regarding literacy promotion. Currently I am the PI on a NICHD R01 that tests distinct approaches to literacy promotion in collaboration with a community based agency focused on maternal-child health. I am also leading cross sector health-education partnership to reduce inequities in school readiness for dual language learners.
   a. Kinney JE, **Jimenez ME**, Mandel Morrow L, Pai S. Training Pediatric Residents in Literacy Promotion: Residency Directors' Perspectives. Teach Learn Med. 2019 Apr 19;:1-8. doi: 10.1080/10401334.2019.1598866. [Epub ahead of print] PubMed PMID: 31002003.
   b. **Jimenez ME**, Hudson SV, Lima D, Mendelsohn AL, Pellerano M, Crabtree BF. Perspectives on shared reading among a sample of Latino parents. Child Care Health Dev. 2018 Nov 24. doi: 10.1111/cch.12634. [Epub ahead of print] PubMed PMID: 30471139.
   c. **Jimenez ME,** Hudson SV, Lima D, Crabtree BF. Engaging a Community Leader to Enhance Preparation for In-Depth Interviews With Community Members. Qual Health Res. 2018 Aug 12:1049732318792848. doi: 10.1177/1049732318792848. [Epub ahead of print] PubMed PMID: 30101661.
   d. Mayne J, Pai S, Morrow L, Lima D, **Jimenez ME**. Understanding Barriers to Literacy Promotion Among New Jersey General Pediatricians. Clin Pediatr (Phila). 2018 Jun;57(6):667-671. doi: 10.1177/0009922817734360. Epub 2017 Oct 13. PubMed PMID: 29027479.

3. My work has identified and proposed strategies for overcoming barriers to early intervention service receipt among children identified with developmental concerns in primary care. I led a series of studies on why children referred to early intervention are not always evaluated. This work was recognized with 2 national awards: a Young Investigator Award from the Academic Pediatric Association and an award for Best Abstract by a Fellow at the 2012 Pediatric Academic Societies Meeting. Building on this work I received a foundation grant to engage parents, pediatric health care clinicians, and early intervention providers to develop and pilot test a video on developmental delay and early intervention with a text message reminder. Recently I led a mystery shopper study to understand national wait times for diagnostic evaluations for developmental and behavioral concerns

and explore differences based on whether an appointment is requested in English or Spanish. Ongoing work explores barriers to service receipt among Latino families whose children were diagnosed with autism spectrum disorder.

a. **Jimenez ME**, Barg FK, Guevara JP, Gerdes M, Fiks AG: Barriers to evaluation for early intervention services: parent and early intervention employee perspectives. Academic pediatrics 12(6): 551-7, Nov 2012. PMID:23159037
b. **Jimenez ME,** DuRivage NE, Bezpalko O, Suh A, Wade R, Blum NJ, Fiks AG. A Pilot Randomized Trial of a Video Patient Decision Aid to Facilitate Early Intervention Referrals From Primary Care. Clin Pediatr (Phila). 2017 Mar;56(3):268-277. doi: 10.1177/0009922816677038. Epub 2016 Nov 12. PubMed PMID: 27834191.
c. **Jimenez ME**, Martinez Alcaraz E, Williams J, Strom BL. Access to Developmental Pediatrics Evaluations for At-Risk Children. J Dev Behav Pediatr. 2017 Apr;38(3):228-232. doi: 10.1097/DBP.0000000000000427. PubMed PMID: 28240650.
d. Mackie TI, Schaefer AJ, Ramella L, Carter AS, Eisenhower A, **Jimenez ME**, Fettig A, Sheldrick RC. Understanding How Parents Make Meaning of Their Child's Behaviors During Screening for Autism Spectrum Disorders: A Longitudinal Qualitative Investigation. J Autism Dev Disord. 2020 Apr 23. doi: 10.1007/s10803-020-04502-7. PMID: 32328857.

4. I am leading a series of studies to understand associations between adverse childhood experiences and developmental and behavioral problems. My work identified associations between early adverse childhood experiences and poor academic and behavioral outcomes in Kindergarten as well as associations between adverse childhood experiences in middle childhood and ADHD diagnosis at age 9 above and beyond early adversity and previous ADHD diagnosis. Another study examined association of poor infant health and adverse childhood experiences. Recently we documented how early shared reading is associated with less harsh parenting an important aspect of the parent-child relationship which can help buffer adversity. We have also examined how reactive alleles moderate associations between early exposure to shared reading and child developmental outcomes.

a. **Jimenez ME**, Reichman NE, Mitchell C, Schneper L, McLanahan S, Notterman DA. Shared Reading at Age 1 Year and Later Vocabulary: A Gene-Environment Study. J Pediatr. 2019 Aug 8;. doi: 10.1016/j.jpeds.2019.07.008. [Epub ahead of print] PubMed PMID: 31402141.
b. **Jimenez ME,** Mendelsohn AL, Lin Y, Shelton P, Reichman N. Early Shared Reading Is Associated with Less Harsh Parenting. J Dev Behav Pediatr. 2019 May 16;. doi: 10.1097/DBP.0000000000000687. [Epub ahead of print] PubMed PMID: 31107765.
c. **Jimenez ME,** Wade R Jr, Schwartz-Soicher O, Lin Y, Reichman NE. Adverse Childhood Experiences and ADHD Diagnosis at Age 9 in a National Urban Sample. Acad Pediatr. 2016 Dec 18. pii: S1876-2859(16)30549-6. doi: 10.1016/j.acap.2016.12.009. [Epub ahead of print] PubMed PMID: 28003143
d. **Jimenez ME**, Wade R, Lin Y, Morrow LM, Reichman NE. Adverse experiences in early childhood and kindergarten outcomes. Pediatrics. 2016;137(2):e20151839

Complete list of published work in MyBibliography:

http://www.ncbi.nlm.nih.gov/sites/myncbi/1xYQxqYFQhHQk/bibliography/49370590/public/?sort=date&direction=ascending

D. Research Support

Ongoing Research Support

R01HD099125-01A1 Jimenez (PI) 05/15/2020-03/31/2025

Addressing Disparities in Language and Social-emotional Skill Acquisition through Literacy Promotion in Primary Care

This study tests the extent to which tailored outreach text messages that provide a cue to action and an intervention that enhances access to poverty-reducing resources, in combination with standard primary care literacy promotion, can improve child language and social- emotional skill acquisition among low-income Latino children.

Role: Principal Investigator

1UL1TR003017-01 Hudson, Panettieri, Barrett, Blaser, Jimenez, Hill (MPI) 09/01/2020-08/31/2022
NJ HEROES TOO
This RADxUP supplement, through ongoing follow-up of identified under-represented minority members in existing healthcare worker cohorts, will advance COVID-19 testing in their communities by providing access to testing for their households and extended families. We will compare this outreach approach with other more conventional means of stimulating testing. In light of the continuing COVID-19 pandemic, this research will help us to find better ways to reach members of vulnerable under-represented minority communities to lessen the impact of COVID-19.
Role: MPI

Private Support Jimenez (PI) 06/15/2020 – 05/30/2021
A Cross-Sector Partnership to Promote Equity in School Readiness
This community engaged research study builds on a cross-sector education health partnership between Rutgers RWJMS and a local charter school to study an online family literacy program that uses health topics to introduce basic literacy skills to dual language learners entering Kindergarten and their families.
Role: Principal Investigator

Private Support Spitalnik (PI) 07/01/2017 - 06/30/2021
As an interdisciplinary, clinical leadership and research education program, NJLEND integrates family-centered, culturally competent, life course and social determinants and public health perspectives to address ASD and related neurodevelopmental disabilities.
Role: Co-Investigator

UL1 TR003017-01 Panettieri (PI) 03/11/2019 – 02/29/2024
NJACTS capitalizes on the unique resources that the state of New Jersey brings to translational science. The Community and Collaboration Core enhances and encourages community engagement and team science addressing critical health and healthcare issues in the population of New Jersey.
Role: Core Advisor for Community and Collaboration

Select Completed Research Support
Private Support Jimenez (PI) 07/01/2018 – 06/30/2019
Promoting school readiness through developmental monitoring and language promotion
This community based participatory research study develops and pilot tests an intervention to help parents monitor their children's developmental milestones and foster their early language development in collaboration with local community partners
Role: Principal Investigator

Private Support Jimenez (PI) 01/01/2016 - 06/30/2020
Assuring patient-centered literacy promotion for underserved children to promote school readiness
This is a 4 year career development award that develops and tests a video and text messaging intervention to enhance Reach Out and Read and encourage shared reading between parents and young children seeking extensive input from parents and stakeholders which culminated in a effectiveness implementation hybrid design randomized trial.
Role: Principal Investigator

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

BIOGRAPHICAL SKETCH

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

NAME: Kathryn L. Greene

eRA COMMONS USER NAME (credential, e.g., agency login): [redacted] eRA Commons User Name

POSITION TITLE: Professor of Communication

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 Georgia, Athens GA	B.A.	06/1987	Communication
University of Georgia, Athens, GA	M.A.	12/1989	Communication
University of Georgia, Athens GA	Ph.D.	12/1992	Communication

A. Personal Statement

Broadly, my research focuses on health communication and related decision-making with an emphasis on developing messages and interventions to engage participants in risk prevention and communication of risk information within social networks. A portion of my research program has been to increase involvement in message processing and to explore prevention message features, especially with adolescents. I began work on developing interventions that address media influences on behavior in an effort to better understand and integrate message processing and active involvement in brief interventions that leverage emerging technology and are easy to disseminate. My communication expertise has led to identifying and implementing community-grounded engaging components of interventions. I have served as Principal Investigator/MPI on NIH-funded R21, R41, and R42 grants to develop and test media literacy interventions. Additionally, I have served or am serving as a Co-Investigator, researcher, advisor/mentor, or consultant on other grants including R01s.

I am well-qualified to contribute to Dr. Kohler's proposed study. I have experience with all phases of intervention research including identifying efficacious intervention messaging, pilot testing intervention materials with target users, conducting intervention feasibility tests, and refining intervention materials based on iterative user feedback. I have collaborated on intervention development research with attention to health literacy and user-centered strategies previously with colleagues at Rutgers Cancer Institute of New Jersey on various types of cancer studies. I will utilize my experience in online and mHealth intervention development and pre-testing as the messages are drafted and revised, leveraging adult learning strategies, instructional design, and message processing while focusing on health literacy. I will advise on how to incorporate various factors to tailor messages to enhance participant engagement. I have been working with Drs. Kohler and Btoush on the vaccine hesitancy administrative supplement and am excited to continue collaborating on this and future projects.

1. **Greene, K.**, Choi, H. J., Glenn, S. D., Ray, A. E., & Hecht, M. L. (2021). The role of engagement in effective, digital prevention interventions: The function of engagement in the REAL media substance use prevention curriculum. Prevention Science, 22, 247-258. https://doi.org/10.1007/s11121-020-01181-9
2. **Greene, K.**, Carpenter, A., Catona, D., & Magsamen-Conrad, K. (2013). The Brief Disclosure Intervention (BDI): Facilitating African Americans' disclosure of HIV. *Journal of Communication, 63*, 138-158. doi: 10.1111/jcom.12010
3. **Greene, K.** (2013). The Theory of Active Involvement: Processes underlying interventions that engage adolescents in message planning and/or production. *Health Communication, 28*, 644-656. doi: 10.1080/10410236.2012.762824

4. Ray, A. E., **Greene, K.**, Hecht, M. L., Barriage, S. C., Miller-Day, M., Glenn, S. D., & Banerjee, S. C. (2019). An e-learning adaptation of an evidence-based media literacy curriculum to prevent youth substance use in community groups: Development and feasibility of REAL media. *Journal of Medical Internet Research (JMIR): Formative Research, 3*(2). doi:10.2196/12132

B. Positions and Honors

Positions and Employment

1992-2000 Assistant/Associate Professor, East Carolina University
1999-2000 Visiting Associate Professor, University of Wisconsin, Madison
2000-present Professor, Department of Communication, Rutgers University
[former: Associate Professor, Department of Communication, Rutgers University]
2012-present Member, Rutgers Cancer Institute of New Jersey (Associate Member to 2016)
2015-2018 Senior Editor, *Health Communication*
2016-present Joint Appointment, Rutgers University School of Public Health, Department of Social and Behavioral Health Sciences
2017-present Affiliate, Rutgers Center for Tobacco Studies (CTS)

Other Experience and Professional Memberships (selected)

Society for Prevention Research
International Communication Association
National Communication Association
Health Communication Division of the National Communication Association (2002 Chair)
Coalition for Health Communication

Honors

1991 10 top paper/panel awards at International, National, and Regional Conferences
1992 Recipient of the Bostrom Young Scholars Award of SSCA (Southern States, Comm. Theory)
1993 Recipient of the G. R. Miller Outstanding Dissertation Award of SCA (Speech Comm. Assoc.)
1994 Recipient of the joint Outstanding Dissertation Award for the Health Divisions of the International (ICA) & Speech Communication Associations (SCA)
1994 Recipient of New Professional Paper Award of the Family Health section of the National Council on Family Relations
1995 Recipient of the East Carolina University College Research Award
1997 Early Career Research Award from SSCA
2003 Department of Communication Excellence in Research Award, Rutgers University
2003 School of Communication, Information, & Library Science Excellence in Research Award
2009 NCA Applied Communication Division Distinguished Scholarship Award for Scholarly Journal Article
2011 Eastern Communication Association's Article of the Year Award
2013 School of Communication and Information, "Friend of the Program" for outstanding contributions to doctoral education, Rutgers University

C. Contributions to Science

My research program explores health decision-making, or the central role of communication in preventing and maintaining health and wellness, increasing involvement in message processing and exploring prevention message features. Most broadly, my research focuses on developing messages and interventions to engage target audiences in prevention. This research has focused on 4 main areas including identifying active involvement intervention features, developmental factors affecting adolescents' message processing, narrative messages in health interventions, and the relation between media viewing and risk-taking behaviors.

1. My first contribution has been to identify features that lead to actively engaging audiences in message processing. Much of this work has focused on media literacy, where my research is the only to date to separate components of media literacy interventions to assess which features produce the active involving

effects. This research has also contributed to improved measurement of engagement and involvement and utilizes community grounded and community engaged iterative approaches to intervention development.

a. **Greene, K.** (2013). The Theory of Active Involvement: Processes underlying interventions that engage adolescents in message planning and/or production. *Health Communication, 28*, 644-656. doi: 10.1080/10410236.2012.762824
b. Ray, A. E., **Greene, K.**, Hecht, M. L., Barriage, S. C., Miller-Day, M., Glenn, S. D., & Banerjee, S. C. (2019). An e-learning adaptation of an evidence-based media literacy curriculum to prevent youth substance use in community groups: Development and feasibility of REAL media. *Journal of Medical Internet Research (JMIR): Formative Research, 3*(2). doi:10.2196/12132
c. **Greene, K.**, Choi, H. J., Glenn, S. D., Ray, A. E., & Hecht, M. L. (2021). The role of engagement in effective, digital prevention interventions: The function of engagement in the REAL media substance use prevention curriculum. *Prevention Science, 22*, 247-258. https://doi.org/10.1007/s11121-020-01181-9
d. **Greene, K.**, Ray, A. E., Choi, H. J., Glenn, S. D., Lyons, R. E., & Hecht, M. L. (2020). Short-term effects of the REAL media e-learning media literacy substance prevention curriculum: An RCT of adolescents disseminated through a community organization. *Drug and Alcohol Dependence, 214*. https://doi.org/10.1016/j.drugalcdep.2020.108170

2. My research has also focused on health disparities, with an emphasis on developing tailored interventions that are community grounded and accessible. This research has spanned varied contexts including HIV and cancer.
   a. Venetis, M. K., **Greene, K.**, Checton, M. G., & Magsamen-Conrad, K. (2015). Decision making in cancer-related topic avoidance*. Journal of Health Communication, 20*, 306-313. doi: 10.1080/10810730.2014.965364 PMID: 25584820
   b. **Greene, K.**, Carpenter, A., Catona, D., & Magsamen-Conrad, K. (2013). The Brief Disclosure Intervention (BDI): Facilitating African Americans' disclosure of HIV. *Journal of Communication, 63*, 138-158. doi: 10.1111/jcom.12010
   c. Elwood, W. N., & **Greene, K.** (2003). Desperately seeking skeezers: Downward comparison theory and the implications for HIV/STD prevention among African-American crack users. *Journal of Ethnicity in Substance Abuse, 2*, 15-33. doi: 10.1300/J233v02n01_02
   d. Checton, M. G., Venetis, M. K., Catona, D., Bontempo, A. C., **Greene, K.**, Buckley de Meritens, A., & Devine, K. A. (2019). Patients' with gynecologic cancer and supporters' reports of sharing (and holding back) cancer-related information during oncology visits. *Oncology Nursing Forum*, 45, 676-685. doi: 10.1188/19.ONF.676-685

3. My research has additionally explored the role of narrative messages in prevention interventions. This research has compared how audiences process narrative (anecdotal) evidence and statistical evidence. My work is some of the first to document that these forms of evidence in messages can have varied paths of effects. This research has compared effects in a variety of contexts including indoor tanning, alcohol prevention, and drug prevention messages.
   a. **Greene, K.**, & Brinn, L. S. (2003). Messages influencing college women's tanning bed use: Statistical versus narrative evidence format and a self-assessment to increase perceived susceptibility. *Journal of Health Communication, 8,* 443-461. doi:10.1080/713852118
   b. **Greene, K.**, Campo, S., & Banerjee, S. C. (2010). Comparing normative, anecdotal, and scientific risk evidence to discourage tanning bed use. *Communication Quarterly, 58*, 111-132. doi: 10.1080/01463371003773366
   c. Banerjee, S. C., & **Greene, K.** (2012). Role of transportation in the persuasion process: Cognitive and affective responses to anti-drug narratives. *Journal of Health Communication, 7,* 564-581.
   d. Banerjee, S. C., & **Greene, K.** (2013). Examining narrative transportation to anti-alcohol narratives. *Journal of Substance Use*, *18*, 196-210. doi: 10.3109/14659891.2012.661020

4. Another line of research explores the role of personality and developmental factors in targeting prevention messages. Prior to my research, little attention was paid in message design to how audience developmental facets could be used in tailoring messages. This research includes both egocentrism (imaginary audience and personal fable) in addition to sensation seeking, both of which peak during adolescence. Based on this research, I have been able to develop more engaging prevention interventions (as described above).

a. **Greene, K.**, Rubin, D. L., & Hale, J. L. (1995). Egocentrism, message explicitness, and AIDS messages directed toward adolescents: An application of the theory of reasoned action. *Journal of Social Behavior and Personality, 10,* 547-570.
b. **Greene, K.**, Rubin, D. L., Walters, L. H., & Hale, J. L. (1996). The utility of understanding adolescent egocentrism in designing health promotion messages. *Health Communication, 8,* 131-152. doi: 10.1207/s15327027hc0802_2
c. **Greene, K.**, Krcmar, M., Walters, L. H., Rubin, D. L., & Hale, J. L. (2000). Targeting adolescent risk-taking behaviors: The contributions of egocentrism and sensation seeking. *Journal of Adolescence, 23*, 439-461. doi: 10.1006/jado.2000.0330
d. **Greene, K.**, Krcmar, M., Rubin, D. L., Walters, L. H., & Hale, J. L. (2002). Elaboration in processing adolescent health messages: The impact of egocentrism and sensation seeking on message processing. *Journal of Communication, 52*, 812-831. doi: 10.1111/j.1460-2466.2002.tb02575.x

5. A final contribution of my research has been to explore how media viewing is associated with risk taking behaviors. This research includes both surveys and content analyses.
   a. Krcmar, M., & **Greene, K.** (1999). Predicting exposure to and uses of violent television. *Journal of Communication, 49,* 25-45. doi: 10.1111/j.1460-2466.1999.tb02803.x
   b. Krcmar, M., & **Greene, K.** (2000). Connections between violent television exposure and adolescent risk taking. *Media Psychology, 2,* 195-217. doi: 10.1207/S1532785XMEP0203_1
   c. Banerjee, S. C., **Greene, K.,** Krcmar, M., & Bagdasarov, Z. (2009). Who watches verbally aggressive shows? An examination of personality and other individual difference factors in predicting viewership. *Journal of Media Psychology: Theories, Methods, and Applications, 21*, 1-14. doi: 10.1027/1864-1105.21.1.1
   d. Bagdasarov, Z., **Greene, K**., Banerjee, S. C., Krcmar, M., Yanovitzky, I., & Ruginyte, D. (2010). I am what I watch: Voyeurism, sensation seeking and television viewing patterns. *Journal of Broadcasting and Electronic Media, 54*, 299-315. doi: 10.1080/08838151003734995

Complete List of Published Work https://www.ncbi.nlm.nih.gov/myncbi/kathryn.greene.1/bibliography/public/

D. Research Support

Ongoing Research Support

R37CA222002-01A1 Wackowski (PI) 04/01/2018 - 03/31/2022
Perceptions and Impact of Modified Risk Tobacco Product Communication Messages
This project aims to better our understanding of how to communicate about reduced risk tobacco products, such as e-cigarettes and snus, relative to traditional cigarettes. It investigates where and how these messages should be placed, how consumers might perceive them, and what their effects might be.
Role: Researcher

R01CA218068 Stapleton (PI) 07/15/2017 - 05/31/2022
Randomized trial of a social media-delivered intervention targeting indoor tanning users
This project involves developing and testing a novel behavioral intervention delivered via Facebook that is designed to reduce high-risk indoor tanning behaviors among young adult women. If effective, the intervention may be widely disseminated and has the potential to help reverse concerning melanoma trends observed among young women.
Role: Co-Investigator

Private Support Heinert (PI) 07/01/2021-06/30/2023
A youth-led digital education intervention to improve blood pressure for hypertensive adults who present to the emergency department.
Private Support involves developing and testing a novel behavioral intervention delivered via digital badges in collaboration with adolescents that is designed to improve blood pressure management for hypertensive adults. If effective, the intervention could be used to leverage youth technology use for assisting family members.
Role: Co-Mentor

3P30CA072720-21S2 Libutti (PI) 03/01/2021-02/28/2022
Vaccine hesitancy related to uptake of the HPV vaccine in regions with low adolescent HPV vaccination rates.
This administrative supplement involves analyzing survey and qualitative data with HPV vaccine hesitant parents. The goal is to identify sociodemographic characteristics associated with parent-reported HPV vaccination uptake, delays, and refusals.
Role: Co-Investigator

Completed Research Support

R01CA190444 Delnevo & Steinberg (MPI) 06/01/2015 - 05/31/2020
Physicians' Perceptions, Attitudes, and Communication of E-Cigarettes (PACE)
The purpose of this research project is to provide an understanding of physicians' knowledge and attitudes toward e-cigarettes. The relevance of the proposed research to public health is to provide information about current tobacco harm reduction beliefs and practices that may impact public health on the frontline, and to identify impactful ways of communicating about these products with physicians in the future.
Role: Collaborator

R42DA039595S1 Hecht & Greene (MPI) 05/01/2018 - 04/30/2020
Interactive technology for media literacy drug prevention in community groups: Marijuana Legal States
The goal of this supplement was to evaluate a media literacy intervention to reduce substance use and compare the effects among youth in adult legal and non-legal marijuana states.
Role: MPI

R42DA039595 Hecht & Greene (MPI) 05/01/2017 - 04/30/2020
Interactive Technology for Media Literacy Drug Prevention in Community Groups
This Phase II STTR project tests the efficacy of a web-based media literacy substance prevention intervention through collaboration with U.S. 4-H clubs. This intervention develops critical perspective taking about peer substance use decisions and confers resistance to pro-drug messages through youth analysis of pro-drug (alcohol, cigarette, smokeless tobacco) media messages combined with interactive media manipulation and active involvement of youth in planning substance use prevention messages.
Role: MPI

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

BIOGRAPHICAL SKETCH

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

NAME: **Btoush, Rula** *(formerly Rula Wilson)*

eRA COMMONS USER NAME (credential, e.g., agency login): [redacted: eRA Commons User Name]

POSITION TITLE: Associate Professor

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

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
University of Jordan, Amman, Jordan	BS	06/1992	Nursing
Georgetown University, Washington, DC	MS	12/1994	Oncology Nursing
Columbia University, New York, NY	PhD	05/2004	Nursing

A. Personal Statement

I am a health disparities researcher with a background in clinical nursing. I have led multiple studies examining HPV vaccination among low-income, Black and Hispanic populations in New Jersey (NJ). My work has included [redacted: Private Support] to understand HPV vaccination practices and attitudes among mothers in the Greater Newark area, one of several communities in NJ with cervical cancer incidence rates nearly two times higher than the national average. I also conducted a two-year study funded by [redacted: Private Support] [redacted: Private Support] to examine the prevalence and correlates of HPV vaccination in the Greater Newark area using electronic health record data from Newark Community Health Center, a large multi-site, federally qualified community health center (FQHC). I have developed multiple ongoing research collaborations with CINJ faculty to address multilevel influences of HPV vaccination and cervical cancer prevention. For example, recent pilot work analyzes New Jersey Immunization Information System (NJIIS) data from 2010-2017 to understand HPV vaccination trends across population subgroups and geographies. I was also a Co-Investigator on a Rutgers CINJ pilot award to examine provider-related knowledge, beliefs, and perceived barriers for HPV vaccine recommendation and to develop strategies to engage providers in improving HPV vaccine uptake among low-income adolescents. I was also a study section member of the NCI special emphasis panel for “Linking the Provider Recommendation to Adolescent HPV Vaccine Uptake” (PAR-18-008).

For the proposed application, I bring experience conducting qualitative and quantitative studies through FQHCs across New Jersey as well as ongoing relationships with NJ Department of Health. Dr. Kohler co-authored a [redacted: Under Review]

I also serve as a member of the New Jersey HPV Roundtable workgroup, which Dr. Kohler joined upon starting her Rutgers faculty position in 2019, where we promote HPV prevention and control strategies with various stakeholders across the state. As Collaborator on the proposed study, I will work with Dr. Kohler and the research team to contribute my expertise in mixed methods HPV vaccination studies and clinical care for safety-net populations. I will connect Dr. Kohler to various local advocacy and professional organizations to support the stakeholder engagement portion of the award. I will contribute to all aspects of the study, including development of data collection tools, analysis, interpretation, manuscript preparation, and dissemination of study findings to stakeholders.

[redacted: In Press]

2. **Btoush R,** Brown DR, Tsui J, Toler L, Bucalo J. Knowledge and attitudes toward human papillomavirus vaccination among Latina mothers of South American and Caribbean descent in the Eastern US. *Health Equity*. 2019; 3(1): 219-230. doi: 10.1089/heq.2018.0058.
3. **Btoush R**, Brown DR, Fogarty S, Carmody D. Initiation of HPV vaccination among female and male adolescents in low-income urban areas. *American Journal of Public Health*. 2015; 105(11): 2388-96. doi:10.2105/AJPH.2015.302584.
4. **Wilson R**, Brown DR, Boothe MAS, Harris, C. Knowledge and acceptability of the HPV vaccine among ethnically diverse Black women. *Journal of Immigrant and Minority Health*. 2013; 15(4): 747-757. doi: 10.1007/s10903-012-9749-5.

B. Positions and Honors

Positions and Employment

1992-1993	Staff Registered Nurse, Amman Surgical Hospital, Amman, Jordan
1993-1994	Research Assistant, Georgetown University School of Nursing, Washington, DC
1994-1999	Oncology Clinical Nurse Specialist, Al-Amal Center, Amman, Jordan.
1995-1999	Director, Outpatient Services and Women's Center, Al-Amal Center, Amman, Jordan
1999-2000	Teaching and Research Assistant, University of South Carolina, Columbia, SC
2000-2003	Teaching and Research Assistant, Columbia University, New York, NY
2001-2005	Nurse Manager, Trinitas Hospital (currently Trinitas Regional Medical Center), Elizabeth, NJ
2001-2002	Fellow, Women's International Leadership program, International House of New York
2002-2003	Doctoral Fellow, American Association of University Women
2005-2012	Assistant Professor, University of Medicine and Dentistry of New Jersey - UMDNJ (currently Rutgers University), School of Nursing
2011-	Research Member, Rutgers Cancer Institute of New Jersey (CINJ) - Cancer Prevention and Control (CPC) program
2012-	Associate Professor, Rutgers University, School of Nursing
2014-	Adjunct Associate Professor, Rutgers University, School of Public Health

Other Experience and Professional Memberships

2005-	Member, Oncology Nursing Society
2006-	Member, American Association of University Women
2010-	Member, Omicron Pi Chapter of Sigma Theta Tau
2011-	Member, American Public Health Association
2012-	Member, American Nurses Association

Honors

2010	Excellence in Scholarship Award from Sigma Theta Tau International, Omicron Pi Chapter
2012	Global Health Services Award from Sigma Theta Tau International, Omicron Pi Chapter
2013	Excellent in Research Award from the Foundation of the UMDNJ

C. Contributions to Science

1. Intimate Partner Violence. My early publications addressed intimate partner violence (IPV) in the US and globally. My doctoral dissertation examined the patterns of emergency department utilization among IPV victims in the US. The findings of this work demonstrate lack of screening, treatment, and referral to needed services for victims of violence. Later, I was involved in three international collaborative projects on IPV outside the US. The findings of these projects indicate the need to work closely with communities to prevent IPV perpetration and to address the health and psychosocial needs of IPV victims. These publications show the complex contexts that influence women's health and the influence of social and behavioral factors in health disparities.

a. **Btoush R,** Campbell JC, Gebbie KM. Characteristics of coded intimate partner violence victims and the health care delivery system in a national survey of emergency departments. *Journal of Emergency Nursing*, 34(5): 419-427, 2008. doi:10.1016/j.jen.2007.10.015
b. **Btoush R**, Haj-Yahia MM. Attitudes of Jordanian society toward wife abuse. *Journal of Interpersonal Violence*, 23(11): 1531-1554, 2008. doi:10.1177/0886260508314313

c. **Btoush R**, Campbell JC, Gebbie KM. Care provided in visits coded for intimate partner violence in a national survey of emergency departments. *Women's Health Issues*, 19(4): 253-262, 2009. doi:10.1016/j.whi.2009.03.004
d. **Btoush R**, Campbell JC. Ethical conduct in intimate partner violence research: challenges and strategies. *Nursing Outlook*, 57(4): 210-216, 2009. doi:10.1016/j.outlook.2008.10.005

2. Cervical Cancer Screening and Prevention. My work in 2011 shifted towards investigating cancer disparities as they related to cervical cancer screening and prevention. This began with a project that examined the knowledge, practices, and attitudes towards cervical cancer screening and prevention among ethnically diverse Black women. The findings from this and other HPV vaccination publications show severe lack of information about HPV infection and prevention as well the importance of health care providers in decision-making processes. These projects took place in collaboration with the Newark Community Health Centers (NCHC), where we recruited participants and conducted the focus group meetings. The proposed study will expand on our successful collaboration with NCHC. Also, my early research interest in IPV has connected with my recent interest in cervical cancer through a study examining the association between exposure to domestic violence and cervical cancer risk among women in low-income areas. The results show significant associations between exposure to domestic violence (childhood and IPV) and cervical cancer risk, directly and through the interaction of IPV with smoking and risky sexual behavior.

a. Brown DR, **Wilson R**, Boothe MAS, Harris, C. Cervical cancer screening among an ethnically diverse black population: Knowledge, attitudes, beliefs and practices. *Journal of the National Medical Association*, 103(8): 719-728, 2011. doi:10.1016/s0027-9684(15)30411-9
b. Hindin P, **Btoush R,** Brown DR, Munet-Vilaro F. Intimate partner violence and risk for cervical cancer. *Journal of Family Violence*. 2015; 30 (8): 1031-1043; doi:10.1007/s10896-015-9733-7.
c. Hindin P, **Btoush R,** Carmody D. History of childhood abuse and risk for cervical cancer among women in low-income areas. *Journal of Women's Health.* 2019; 28 (1): 23-29. doi:10.1089/jwh.2018.6926.
d. **Wilson R**, Brown DR, Boothe MAS, Harris, C. Knowledge and acceptability of the HPV vaccine among ethnically diverse black women. Journal of Immigrant and Minority Health, 15(4): 747-757, 2013. doi:10.1007/s10903-012-9749-5

3. HPV Vaccine Uptake in High Risk, Underserved Populations. My recent publications focused on HPV vaccine uptake in high-risk and underserved populations, particularly the Greater Newark area, which has high morbidity rates for cervical cancer. In this work, I have collaborated with a large multi-site FQHC to examine HPV vaccination among 3,690 adolescents. The results show dramatically low rates of HPV vaccine initiation and completion as well as dosing intervals that are much longer than those recommended by the CDC. I have also conducted two studies that examined the views of ethnically-diverse Black mothers as well as Latina mothers of diverse Hispanic backgrounds. Further, I have collaborated on a CINJ project to examine local barriers of healthcare providers' recommendation of the HPV vaccine. The findings of these projects show a critical need to develop provider-targeted interventions to improve HPV vaccine recommendation, which consequently improves HPV vaccine uptake. Lastly, I am conducting an analysis of HPV vaccine uptake using the New Jersey Immunization Information System (NJIIS) data for 2010-2017, which was presented at APHA in 2019. Findings will provide insights for targeting low uptake sub-groups for the proposed project.

In Press

b. **Btoush R,** Brown DR, Tsui J, Toler L, Bucalo J. Knowledge and attitudes toward human papillomavirus vaccination among Latina mothers of South American and Caribbean descent in the Eastern US. *Health Equity*. 2019; 3(1): 219-230. doi:10.1089/heq.2018.0058.
c. **Btoush R**, Brown DR, Fogarty S, Carmody D. Initiation of HPV vaccination among female and male adolescents in low-income urban areas. American Journal of Public Health. 2015; 105(11): 2388-96. doi:10.2105/AJPH.2015.302584.
d. **Wilson R**, Brown DR, Carmody D, Fogarty S. HPV vaccination completion and compliance with recommended dosing intervals among female and male adolescents in an inner-city community health center. Journal of Community Health. 2015; 40(3): 395-403, doi:10.1007/s10900-014-9950-7.

Complete List of Published Work in My Bibliography:
http://www.ncbi.nlm.nih.gov/sites/myncbi/1TW75rfwvevkv/bibliography/49095436/public/?sort=date&direction=ascending

D. Research Support

Ongoing Research Support

3P30CA072720-21S2 Libutti (PI) 03/01/2020-02/28/2022
Vaccine hesitancy related to uptake of the HPV vaccine in regions with low adolescent HPV vaccination rates
This administrative supplement will analyze 2020 Rutgers Cancer Institute catchment area survey data to identify sociodemographic characteristics associated with parent-reported HPV vaccination uptake, delays, refusals, and reasons for non-vaccination. Formative research in the Greater Newark area will explore reasons for HPV vaccine hesitancy to inform future communication interventions.
Role: Co-Investigator

Completed Research Support

[redacted] Btoush (PI) 06/04/2016 – 06/03/2018
Engaging Healthcare Providers to Reduce Disparities in HPV Vaccination among Low-Income Adolescents in the Greater Newark Area
The purpose of this study is to develop and pilot test strategies to engage healthcare providers (HCPs) in improving HPV vaccination among low-income adolescents in the Greater Newark area. The objectives of the proposed study are to 1) examine provider-related knowledge, beliefs, and perceived barriers for HPV vaccine recommendation; 2) develop strategies to engage HCPs in improving HPV vaccine uptake among low-income adolescents in the Greater Newark area; and 3) pilot-test the feasibility of implementing these strategies to reduce barriers for and improve HCP recommendation for the HPV vaccine.
Role: Principal Investigator

RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 1

ORGANIZATIONAL DUNS*: 078728091

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: Rutgers, The State University of New Jersey, RBHS-CINJ

Start Date*: 12-01-2021 **End Date*:** 11-30-2022 **Budget Period: 1**

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.		Racquel		Kohler		PD/PI	0.00	[redacted]			100,000.00	53,610.00	153,610.00

Calendar Months

Total Funds Requested for all Senior Key Persons in the attached file **0.00**

Additional Senior Key Persons: File Name: **Total Senior/Key Person** **153,610.00**

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)	**153,610.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 1

ORGANIZATIONAL DUNS*: 078728091

Budget Type*: ● Project ❍ Subaward/Consortium

Organization: Rutgers, The State University of New Jersey, RBHS-CINJ

Start Date*: 12-01-2021 **End Date*:** 11-30-2022 **Budget Period: 1**

C. Equipment Description	
List items and dollar amount for each item exceeding $5,000	
Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	**0.00**
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		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other:		
Number of Participants/Trainees	**Total Participant Trainee Support Costs**	

RESEARCH & RELATED Budget {C-E} (Funds Requested)

Funding Opportunity Number: PAR-18-466 . Received Date: 2021-03-10T15:05:11.000-05:00

RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 1

ORGANIZATIONAL DUNS*: 078728091

Budget Type*: ● Project ❍ Subaward/Consortium

Organization: Rutgers, The State University of New Jersey, RBHS-CINJ

Start Date*: 12-01-2021 **End Date*:** 11-30-2022 **Budget Period: 1**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	16,733.00
2. Publication Costs	1,500.00
3. Consultant Services	8,965.00
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 . TBD – Research Assistant	15,877.00
9 . INCENTIVES	6,250.00
10 . SHARED RESOURCES	675.00
Total Other Direct Costs	**50,000.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**203,610.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1 . MTDC	8	203,610.00	16,289.00
		Total Indirect Costs	**16,289.00**

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number): DHHS, Ryan McCarthy, 212-264-2069

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**219,899.00**

J. Fee	Funds Requested ($)*
	0.00

K. Total Costs and Fee	Funds Requested ($)*
	219,899.00

L. Budget Justification* File Name: Budget_Justification.pdf
(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 2

ORGANIZATIONAL DUNS*: 078728091

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: Rutgers, The State University of New Jersey, RBHS-CINJ

Start Date*: 12-01-2022 **End Date*:** 11-30-2023 **Budget Period: 2**

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.		Racquel		Kohler		PD/PI	0.00	[redacted]			100,000.00	53,610.00	153,610.00

Calendar Months

Total Funds Requested for all Senior Key Persons in the attached file **0.00**

Additional Senior Key Persons: File Name: **Total Senior/Key Person** **153,610.00**

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)	**153,610.00**

RESEARCH & RELATED Budget (A-B) (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 2

ORGANIZATIONAL DUNS*: 078728091

Budget Type*: ● Project ❍ Subaward/Consortium

Organization: Rutgers, The State University of New Jersey, RBHS-CINJ

Start Date*: 12-01-2022 **End Date*:** 11-30-2023 **Budget Period: 2**

C. Equipment Description	
List items and dollar amount for each item exceeding $5,000	
Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	**0.00**
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	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant Trainee Support Costs**	

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 2

ORGANIZATIONAL DUNS*: 078728091

Budget Type*: ● Project ❍ Subaward/Consortium

Organization: Rutgers, The State University of New Jersey, RBHS-CINJ

Start Date*: 12-01-2022 **End Date*:** 11-30-2023 **Budget Period: 2**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	14,057.00
2. Publication Costs	1,500.00
3. Consultant Services	7,880.00
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 . TBD – Research Assistant	16,353.00
9 . INCENTIVES	5,750.00
10 . SHARED RESOURCES	4,460.00
Total Other Direct Costs	**50,000.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**203,610.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1 . MTDC	8	203,610.00	16,289.00
		Total Indirect Costs	**16,289.00**

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number): DHHS, Ryan McCarthy, 212-264-2069

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**219,899.00**

J. Fee	Funds Requested ($)*
	0.00

K. Total Costs and Fee	Funds Requested ($)*
	219,899.00

L. Budget Justification*	File Name: Budget_Justification.pdf (Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 3

ORGANIZATIONAL DUNS*: 078728091

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: Rutgers, The State University of New Jersey, RBHS-CINJ

Start Date*: 12-01-2023 **End Date*:** 11-30-2024 **Budget Period: 3**

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.		Racquel		Kohler		PD/PI	0.00	[redacted]			100,000.00	53,610.00	153,610.00

Calendar Months

Total Funds Requested for all Senior Key Persons in the attached file **0.00**

Additional Senior Key Persons: File Name: **Total Senior/Key Person** **153,610.00**

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)	**153,610.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 3

ORGANIZATIONAL DUNS*: 078728091

Budget Type*: ● Project ❍ Subaward/Consortium

Organization: Rutgers, The State University of New Jersey, RBHS-CINJ

Start Date*: 12-01-2023 **End Date*:** 11-30-2024 **Budget Period: 3**

C. Equipment Description	
List items and dollar amount for each item exceeding $5,000	
Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	**0.00**
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		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other:		
Number of Participants/Trainees	**Total Participant Trainee Support Costs**	

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 3

ORGANIZATIONAL DUNS*: 078728091

Budget Type*: ● Project ❍ Subaward/Consortium

Organization: Rutgers, The State University of New Jersey, RBHS-CINJ

Start Date*: 12-01-2023 **End Date*:** 11-30-2024 **Budget Period:** 3

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	11,481.00
2. Publication Costs	4,000.00
3. Consultant Services	9,065.00
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 . TBD – Research Assistant	16,844.00
9 . INCENTIVES	2,250.00
10 . SHARED RESOURCES	6,360.00
Total Other Direct Costs	**50,000.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**203,610.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1 . MTDC	8	203,610.00	16,289.00
		Total Indirect Costs	**16,289.00**

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number): DHHS, Ryan McCarthy, 212-264-2069

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**219,899.00**

J. Fee	Funds Requested ($)*
	0.00

K. Total Costs and Fee	Funds Requested ($)*
	219,899.00

L. Budget Justification* File Name: Budget_Justification.pdf (Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

BUDGET JUSTIFICATION

KEY PERSONNEL

Racquel Kelly Kohler, PhD, MSPH – Principal Investigator, Percentage of Effort [redacted] Calendar Months [redacted] in years 1-3

Dr. Kohler is a Resident Member in the Center for Cancer Health Equity at Rutgers Cancer Institute of New Jersey and an Instructor in the Department of Health Behavior, Society and Policy at Rutgers School of Public Health. Her cancer control work draws from health services research methods, social behavioral science theories, and communication science to promote effective and equitable cancer prevention and control programs in vulnerable populations. Dr. Kohler's work involves understanding the causes and consequences of delayed cancer prevention behaviors and use of diagnostic services, specifically for HPV-associated cancers. She has been Co-Investigator on multiple cancer disparities studies focused on developing and evaluating interventions with primary care provider training, patient-direct communication materials, and mHealth interventions. Dr. Kohler will carry out all aspects of this K22, including career development, training activities, and the research plan. She will assemble an advisory committee after securing a tenure track faculty position to guide her career development and track progress. She will work closely with collaborators and be primarily responsible for the design, data collection tools, implementation, analysis, and dissemination of all proposed activities.

FRINGE BENEFITS

The Rutgers Cancer Institute of New Jersey fringe benefits rate is 38.55% for full-time faculty and staff positions of salary requested per the agreement dated December 13, 2019 with the University's Cognizant Audit Agency, the Department of Health and Human Services. This rate is expected to increase by 7.41% for 2021. In addition to fringe benefits, actual Social Security FICA (6.20%) and Medicare (1.45%) taxes are charged as direct costs. Total effective fringe rate is 53.61% for full-time staff. A copy of the agreement is available upon request.

OTHER DIRECT COSTS-RESEARCH DEVELOPMENT SUPPORT

TBD – Research Assistant, 20% effort, 2.4 Calendar Months in years 1-3

The Research Assistant trained in social sciences will work closely with Dr. Kohler to support the development and implementation of study-specific tasks including 1) recruitment, data collection, participant communications, and participant incentives; 2) development and implementation of moderator and interview guides and surveys; 3) managing study data, facilitating transcription and translation services; 4) assist with development of codebook and structural coding of transcripts for thematic analysis reports; 5) coordinating with survey management team for trial. S/he will prepare study materials and reports, assist with regulatory processes including Rutgers Cancer Institute of New Jersey Scientific Review Committee, Institutional Review Boards, NCI and other entities as needed. COST-OF-LIVING ADJUSTMENT: Salary requested includes annual cost-of-living adjustment (COLA) for expected salary increases per Rutgers University policy.

TRAVEL

International travel:

Travel to Scientific Meetings Funds are requested for Dr. Kohler to attend at least one scientific meeting per year (e.g., International Papillomavirus Society Conference, International Social and Behavior Change Communication Summit). Funds are requested for training at Maastricht University Intervention Mapping Summer Course in year 1. Travel expenses include airfare/train, accommodation, registration fees, per diem, and local ground transportation.

Domestic travel:

Travel to Scientific Meetings Funds are requested for Dr. Kohler to attend annual scientific meetings (e.g., National Immunization Conference, American Society of Preventive Oncology, Society of Behavioral Medicine Annual Meeting, HPV Roundtable). Travel expenses include airfare/train, accommodation, registration fees, per diem, and local ground transportation.

Local transportation Support is requested for local mileage, parking, and transportation reimbursement for planning meetings, recruitment, and data collection at community and clinical partner sites.

Travel and Training Activities Funds are requested for Dr. Kohler to participate in training institutes and workshops outlined in the Career Development Plan (e.g., Rutgers Family Systems and Child/Adolescent Health continuing education certificate courses, Columbia University PI Skills Crash Course in year 1; University of

Tennessee CBPR training workshop, NCI DCCPS MLTI Institute, NIH OBSSR Randomized Behavioral Trials Summer Institute in year 2). Travel expenses include airfare, accommodation, registration fees, per diem, and local ground transportation.

MATERIALS AND SUPPLIES

Computer costs Funds are requested for a study tablet/laptop in Year 1.

Software costs Funds are requested for a study software licensing for Atlas.ti for qualitative analyses in years 1 and 3.

Program Supplies Funds are requested for office supplies, as well as study-specific phone charges, consumable supplies, stakeholder meeting refreshments, generation and shipping print materials to distribute study related recruitment materials and final reports through clinical and community partners.

Books The training plan includes formal and informal training in new areas of research, for which the purchase of textbooks will be required in year 1.

Publication Costs

Dissemination and Publication Funds are requested for publication fees associated with open access to increase accessibility of findings, poster presentations, and additional community dissemination in year 3.

CONSULTANT SERVICES

Community and Clinical Partner Stipend Funds in the amount of $2,000 per year are requested to provide stipends to our community and clinical partner organizations for their collaboration with the project. This will include their input on the project from the community perspective on protocol development, assisting with developing communication materials, including email distributions and print materials to distribute study related materials for participant recruitment, and dissemination of findings to the local communities.

Stakeholder Advisory Board (SAB) Participants stipend Funds are requested for electronic gift certificates as incentives for the 10 stakeholder advisory board members who will be recruited to participate in meetings to develop and refine the intervention ($150 x 10 participants x 2 semi-annual meetings) in years 1-3.

Qualitative Data Transcription Rutgers Cancer Institute will coordinate transcription services to be provided from our established vendor for the SAB and Delphi meetings and 8, 90-minute focus groups (8 in English $2.75/minute transcription and 2 non-English groups $8.25/minute transcription and translation) in year 1, 60-minute pre-testing sessions (10 participants x 60-minutes ($1.80/minute) in year 2, and 60 minute 15 provider/staff and 15 participant interviews ($1.80/minute) in year 3.

TigerText Services TigerText is a HIPAA-compliant, fully encrypted secure message platform that can be accessed via mobile app or the web. Fees are requested to cover the two-way messaging, as well as archive all data to analyze the content and frequency of messages.

INCENTIVES

Parent Incentives Funds are requested for electronic gift certificates as incentives for each parent participant of formative research (6-10 participants x 8 groups, $50 per participant) in year 1, for refining the intervention ($50 x 10 participants) and the pilot feasibility trial ($75 x 70) in year 2, and evaluation interviews ($50 x 15 participants) in year 3.

Pediatric, Primary Care, and Family Medicine Providers and Staff Incentives Funds are requested for electronic gift certificates as incentives for the 15 public health and health care team members and staff who will be recruited to participate in multiple rounds of modified Delphi methods in year 1 ($150 x 15) and for clinic staff interviews to evaluate the intervention in year 3 ($100 x 15 participants).

SHARED RESOURCES

Biometrics Shared Resource Biostatistical support from Rutgers Cancer Institute will assist Dr. Kohler in the following tasks for: 1) statistical consultation and planning for trial design, methodology, monitoring, and

analyses; 2) oversee data management, linkage, and cleaning; 3) perform descriptive analyses; 4) provide expert advice on model specification; 5) assist with generating figures and tables and statistical language for reports and dissemination of study findings on abstracts and manuscripts. $108 x 20 hrs. year 2, $112 x 30 hrs. year 3)

Population Science Shared Resource Rutgers Cancer Institute Shared Resource will: 1) Provide an automated HIPAA compliant, cloud-based relational database to facilitate participant recruitment, tracking, and overall study management using advanced software (i.e., Datstat); 2) develop the automated study workflow to allow tracking of consenting, survey completion, disbursement of incentives, randomization, and automated messages (emails and SMS) to study participants; and 3) develop the surveys and data dictionary; 4) create weekly and overall study progress (e.g., recruitment, response and retention rates, completion of study activities).

INDIRECT COSTS

The allowable indirect cost rate is 8% of modified total direct costs per the sponsor guidelines.

RESEARCH & RELATED BUDGET - Cumulative Budget

	Totals ($)	
Section A, Senior/Key Person		460,830.00
Section B, Other Personnel		0.00
Total Number Other Personnel	0	
Total Salary, Wages and Fringe Benefits (A+B)		460,830.00
Section C, Equipment		0.00
Section D, Travel		0.00
1. Domestic	0.00	
2. Foreign	0.00	
Section E, Participant/Trainee Support Costs		0.00
1. Tuition/Fees/Health Insurance	0.00	
2. Stipends	0.00	
3. Travel	0.00	
4. Subsistence	0.00	
5. Other	0.00	
6. Number of Participants/Trainees	0	
Section F, Other Direct Costs		150,000.00
1. Materials and Supplies	42,271.00	
2. Publication Costs	7,000.00	
3. Consultant Services	25,910.00	
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 1	49,074.00	
9. Other 2	14,250.00	
10. Other 3	11,495.00	
Section G, Direct Costs (A thru F)		610,830.00
Section H, Indirect Costs		48,867.00
Section I, Total Direct and Indirect Costs (G + H)		659,697.00
Section J, Fee		0.00
Section K, Total Costs and Fee (I + J)		659,697.00

PHS 398 Cover Page Supplement

OMB Number: 0925-0001

Expiration Date: 02/28/2023

1. Vertebrate Animals Section

Are vertebrate animals euthanized? ○ Yes ● No

If "Yes" to euthanasia

Is the method consistent with American Veterinary Medical Association (AVMA) guidelines?

○ Yes ○ No

If "No" to AVMA guidelines, describe method and provide scientific justification

2. *Program Income Section

*Is program income anticipated during the periods for which the grant support is requested?

○ Yes ● No

If you checked "yes" above (indicating that program income is anticipated), then use the format below to reflect the amount and source(s). Otherwise, leave this section blank.

*Budget Period	*Anticipated Amount ($)	*Source(s)

PHS 398 Cover Page Supplement

3. Human Embryonic Stem Cells Section

*Does the proposed project involve human embryonic stem cells? ❍ Yes ● No

If the proposed project involves human embryonic stem cells, list below the registration number of the specific cell line(s) from the following list: http://grants.nih.gov/stem_cells/registry/current.htm. Or, if a specific stem cell line cannot be referenced at this time, check the box indicating that one from the registry will be used:

Specific stem cell line cannot be referenced at this time. One from the registry will be used.

Cell Line(s) (Example: 0004):

4. Human Fetal Tissue Section

*Does the proposed project involve human fetal tissue obtained from elective abortions? ❍ Yes ● No

If "yes" then provide the HFT Compliance Assurance

If "yes" then provide the HFT Sample IRB Consent Form

5. Inventions and Patents Section (Renewal applications)

*Inventions and Patents: ❍ Yes ● No

If the answer is "Yes" then please answer the following:

*Previously Reported: ❍ Yes ❍ No

6. Change of Investigator/Change of Institution Section

❑ Change of Project Director/Principal Investigator

Name of former Project Director/Principal Investigator

Prefix:

*First Name:

Middle Name:

*Last Name:

Suffix:

❑ Change of Grantee Institution

*Name of former institution:

Tracking Number: GRANT13318726 Funding Opportunity Number: PAR-18-466 . Received Date: 2021-03-10T15:05:11.000-05:00

PHS 398 Career Development Award Supplemental Form

OMB Number: 0925-0001
Expiration Date: 02/28/2023

Introduction	
1. Introduction to Application (for Resubmission and Revision applications)	Introduction_10March.pdf
Candidate Section	
2. Candidate Information and Goals for Career Development	Candidate_10March.pdf
Research Plan Section	
3. Specific Aims	Aims_10March_final.pdf
4. Research Strategy*	Strategy_10March_final.pdf
5. Progress Report Publication List (for Renewal applications)	
6. Training in the Responsible Conduct of Research	Training_in_RCR.pdf
Other Candidate Information Section	
7. Candidate's Plan to Provide Mentoring	
Mentor, Co-Mentor, Consultant, Collaborators Section	
8. Plans and Statements of Mentor and Co-Mentor(s)	Kohler_K22_Statement_of_Mentor.pdf
9. Letters of Support from Collaborators, Contributors, and Consultants	Combined_LOS.pdf
Environment and Institutional Commitment to Candidate Section	
10. Description of Institutional Environment	Institutional_Environment.pdf
11. Institutional Commitment to Candidate's Research Career Development	Kohler_K22_LOIS_revision_030421.pdf
12. Description of Candidate's Contribution to Program Goals	
Other Research Plan Section	
13. Vertebrate Animals	
14. Select Agent Research	
15. Consortium/Contractual Arrangements	
16. Resource Sharing	data_sharing_plan.pdf
17. Authentication of Key Biological and/or Chemical Resources	
Appendix	
18. Appendix	

Tracking Number: GRANT13318726
Funding Opportunity Number: PAR-18-466. Received Date: 2021-03-10T15:05:11.000-05:00

PHS 398 Career Development Award Supplemental Form

Citizenship*:

19. U.S. Citizen or Non-Citizen National?* Personal Information

If no, select most appropriate Non-U.S. Citizen option

Personal Information

With a Permanent U.S. Resident Visa

With a Temporary U.S. Visa

Not Residing in the U.S.

Personal Information

Response to Grant Critique

A. CANDIDATE BACKGROUND

I am a cancer disparities researcher committed to improving cancer prevention and control for vulnerable populations. Through this Transition Career Development Award, I will build on my experience detailed below and develop new expertise in designing and evaluating multilevel interventions, including vaccination behavior change interventions. The proposed research and training will provide me with skills, experience, and preliminary data to help me achieve my goal of becoming an NIH-funded independent investigator with a research program committed to improving cervical cancer control and achieving health equity through multilevel interventions.

My interest in cancer prevention dates back to when I was an undergraduate student at the University of Central Florida, and I became involved with cancer community outreach and awareness campaigns. I co-chaired the Orlando Relay for Life in 2006 and 2007. After receiving my Bachelor's in Molecular Biology and Microbiology, I worked as a consultant for a women's leadership organization. It was in that role, advocating for women's empowerment and promoting sexual and reproductive health services, that I realized how social and policy factors influence women's health outcomes. Eager to learn more about public health policy, I earned a Master of Science in Public Health from the University of North Carolina (UNC)-Chapel Hill. I developed expertise in quantitative methods, including econometrics and cost-effectiveness modeling, which I used to estimate the social, economic, and health outcomes of chemotherapy and radiotherapy for multiple types of cancers, including human papillomavirus (HPV)-related head and neck cancers.[1,2]

A1. Predoctoral training

Personal Information, Redacted Per Agreement

For my doctoral dissertation, I expanded my disparities lens to the global cancer burden affecting low- and middle-income countries. For 1.5 years I lived and worked in Malawi as a Fogarty Global Health Fellow (PI Van Der Horst, R25 TW009340) under the mentorship of Satish Gopal, MD, MPH. I developed a mixed methods protocol to understand advanced breast cancer diagnosis. I outlined the breast cancer help-seeking pathway,[6] described the burden of late diagnosis[7] and developed a community survey with a discrete choice experiment to elicit preferences about breast and cervical cancer early detection services.[8,9] My time in Malawi confirmed my passion for eliminating health disparities and underscored the need to improve cancer control in resource-limited settings, especially cervical cancer, which I found was mostly diagnosed at late stage among Malawian women.[10]

A2. Postdoctoral training

I went on to complete a postdoctoral fellowship in cancer prevention at Harvard T.H. Chan School of Public Health and Dana-Farber Cancer Institute (PI Viswanath, R25 CA057711). I was mentored by K. Vish Viswanath, PhD, and Jane Kim, PhD, on behavioral implementation science and HPV decision sciences. I wrote and co-authored two chapters in Chambers' book *Advancing the Science of Implementation across the Cancer Continuum*, outlining opportunities and challenges related to implementation research. I established collaborations on multiple projects to improve screening services and link patients to diagnostic tests and treatment. My contribution to *Project ATICA* (PI Arrossi, R01 CA218306), was largely to help develop text messages to notify women about HPV results and motivate Pap triage adherence for women testing HPV-positive in rural Argentina.[11,12] The other international collaboration is in Botswana, where I am currently creating cancer education materials for a randomized community trial of *Potlako+* (meaning "hurry up" in Setswana), which is a multilevel intervention to improve early diagnosis of the six most common cancers in Botswana (PI Dryden-Peterson, R01 CA236546). The trial expands a successful pilot intervention where we trained primary care providers on cancer symptoms, provide nurse navigation services, and send reminder texts to patients.[13]

I also led studies to evaluate cervical cancer screening behaviors and novel HPV testing interventions. I conducted an inter-institutional Center for AIDS Research (CFAR) pilot study with colleagues from Botswana-UPenn Partnership on a new screening modality – HPV self-sampling – among women living with HIV.[14,15] Results were presented to the Ministry of Health in 2018, and informed the next National Cervical Cancer

Prevention Program in Botswana. Qualitative analyses on women's HPV and cervical cancer knowledge were presented at the International Papillomavirus Conference in July 2020, and two first-authored manuscripts on HPV knowledge and screening barriers are under review at *Journal of Cancer Education* and *BMC Public Health*.

Cervical cancer disparities also persist in the United States (US). Black women have disproportionately higher cervical cancer incidence and mortality compared to non-Hispanic White women. Similarly, women with low socioeconomic position have increased mortality and low screening.[16] To understand drivers of disparities, I successfully competed for a Dana-Farber/Harvard Cancer Center pilot award to assess barriers and facilitators of screening in an FQHC through a partnership with the local health care for the homeless program. Some of the findings were that histories of sexual violence,[17] low perceived risk of HPV or cervical cancer, and competing health and social issues[18] were key factors in women's decisions to delay and refuse Pap screening. Low knowledge influenced women's perceived HPV risk, and few understood that HPV causes cervical cancer. Several women talked about HPV being a disease of young girls, not something older women needed to be screened for. They had seen TV ads and HPV vaccine information with images of adolescents, so they did not think they were at risk.[18]

A3. Mentored, non-tenure track position

I joined Rutgers Cancer Institute of New Jersey (Rutgers Cancer Institute) and School of Public Health (SPH) as a mentored, non-tenure track Instructor of Social and Behavioral Sciences in September 2019. I have continued my collaboration in Botswana and am building a local research program in underserved communities in New Jersey (NJ). I was drawn to Rutgers because of the growing health equity and community engagement initiatives at Rutgers Cancer Institute under Anita Kinney, PhD, Director of the Center for Cancer Health Equity (CCHE) and Associate Director for Population Sciences and Community Outreach, and Director of ScreenNJ, a statewide cancer prevention and screening program. I was also drawn to the commitment to social justice research and practice by SPH Dean Perry Halkitis, PhD, MS, MPH. Rutgers University is an outstanding environment in which I can pursue my training and research goals. Rutgers Biomedical and Health Sciences (RBHS) offers junior scholars exceptional academic and research resources that I need to develop into a successful independent investigator, including faculty seminars on grant writing, research working groups, works in progress meetings, and opportunities for collaboration with internationally regarded senior colleagues.

Since joining Rutgers, I quickly became engaged in local and regional, collaborative HPV prevention research. I am Project Director of an administrative supplement (P30CA072720-21S2) awarded in September 2020, focused on vaccine hesitancy in communities with low HPV vaccination in NJ. I am actively collaborating with Kathryn Greene, PhD, and Rula Btoush, PhD, on this award. Preliminary survey findings support the underlying rationale for this current study. We are actively recruiting for the qualitative phase of the supplement. I participate in monthly virtual meetings with other HPV supplement grantees facilitated by NCI, further expanding my professional network. I am also MPI on a Rutgers Cancer Institute pilot award to adapt and pilot test a text message version of an efficacious, tailored counseling phone intervention for underserved women needing colposcopy after abnormal screening. The pilot study is underway at a Rutgers-affiliated safety-net clinic and a co-authored manuscript is in preparation. As a of CCHE member, I am actively involved with community outreach and engagement (COE) and disparities research initiatives, and serve as co-leader of the Cervical Cancer Working Group, which is part of the Governor's Task Force to develop the 2025 New Jersey Cancer Control Plan. I am also part of NJ HPV Roundtable. Both groups enable me to work with stakeholders across the state.

B. CAREER GOALS AND OBJECTIVES

B1. Needs assessment

To date I have been successful in obtaining a unique array of skills and research experiences. My training in health services research, behavioral science, and implementation science at leading NCI-designated Comprehensive Cancer Centers and top ranked Schools of Public Health has provided me with a strong theoretical and analytical foundation to build upon. I have been a productive trainee and early career scientist in breast and cervical cancer prevention and control research for the past 10 years, underscoring my commitment to cancer research. Furthermore, I am highly collaborative as Co-Investigator on NCI-funded studies. I have 12 first-authored publications with 6 additional first-authored publications under review or revision. I also have 19 co-authored publications and 4 under review. An additional 4 first- and 5 co-authored manuscripts are in preparation. I will be senior author of 2 medical students' research manuscripts examining health system barriers to cervical cancer and a community cancer needs assessment in Belize.

For the last 6 years I have been working in cervical cancer screening and follow-up behaviors. All my HPV studies highlight how HPV knowledge across settings is generally low, barriers to prevention services persist, and counseling about the infection and potential cancer risk is complex. To move towards elimination of cervical cancer, as the WHO aims to do, a comprehensive action-oriented approach with multilevel interventions is needed to promote primary and secondary prevention across the life course. The addition of HPV vaccination in my research agenda is a logical progression from my prior HPV screening experience and complements both

my behavioral and health services background. Moving more upstream to primary prevention behaviors will give me expertise to comprehensively reduce the HPV-related cancer burden among underserved communities.

Although I have a strong foundation in HPV prevention, I require training in HPV vaccination and clinical exposure to pediatric provider-parent communication. I collaborate on multilevel and multiple-component interventions, but my work thus far has not involved parents/families. My experience with mixed methods study designs using qualitative and survey data collection involves diverse populations in domestic and global settings, however, I have yet to develop and implement an intervention through a stakeholder-engaged process and employing intervention mapping concepts. My postdoctoral training provided valuable experience conducting single-arm pilot intervention studies, but I have not designed and led a randomized controlled trial. To achieve independence, I need practical experience in the design, implementation, oversight and reporting of intervention trials. Given my longstanding focus on assessing barriers to care and health-seeking behaviors using primarily observational study designs, moving into this new direction of vaccination behavior change and addressing vaccine hesitancy closely aligns with my current focus on delays in HPV screening and my career goals.

B2. Long-term career goals (after K22).

My main goal in seeking this K22 is to further refine my mixed methods skills and transition to leading randomized controlled trials that apply community-engaged methods to behavioral interventions to reduce disparities in HPV prevention (**Figure 1**). This training is essential for me to become an independent investigator and leader in the field of community-engaged interventions that reduce HPV disparities.

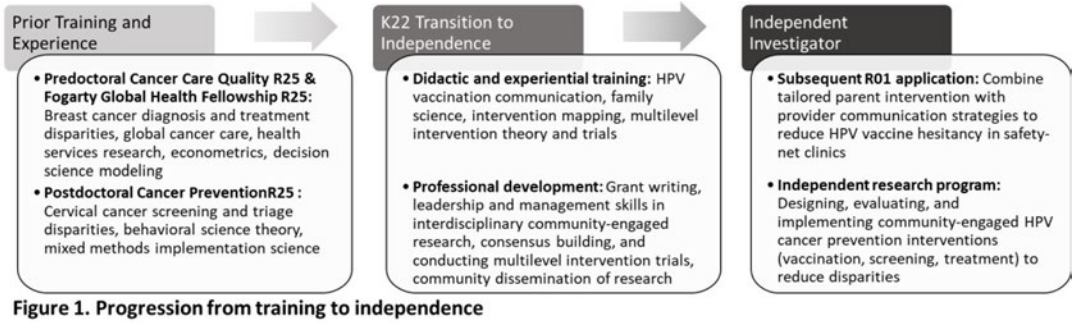


Figure 1. Progression from training to independence

My long-term career goals are to:

1. **Become an expert in implementation of comprehensive cervical cancer prevention strategies to promote equity.**
2. **Cultivate interdisciplinary, community-engaged research collaborations to develop and disseminate cancer prevention strategies responsive to underserved communities' needs.**
3. **Lead randomized trials as an independent investigator specializing in cancer disparities research at the intersection of health behavior, health service delivery, and implementation science.**

The refined skills and research experience I will gain and findings from the proposed research aims will support and inform future applications I plan to submit to reduce HPV cancer disparities and prevent cancer. For example, multiple evidence-based interventions (EBIs), including R/R and follow-up navigation, increase HPV vaccination, HPV screening, and fast follow-up treatment; however, implementation varies, particularly in clinics serving racial/ethnic minorities. Future grants may: (1) identify barriers and facilitators to safety-net clinics adapting EBIs to their context and implementing them, and (2) determine what combination of EBIs have optimal HPV prevention uptake. This award is also timely and will give me unique expertise in vaccine hesitancy and disparities to submit additional grants to examine vaccine hesitancy determinants, consequences, and messaging related to other vaccines such as the links between general vaccine hesitancy, COVID vaccine hesitancy, and HPV vaccine hesitancy. I am already collaborating on multiple COVID vaccine hesitancy studies in safety-net clinics and among providers. These experiences will be brought to bear in my cancer disparities research.

B3. Short-term objectives (during K22)

My long-term goals will be facilitated through the following short-term objectives to:

1. **Gain in-depth knowledge on evidence-based strategies for HPV vaccination communication.**
2. **Advance skills in community-engaged intervention planning and development.**
3. **Develop expertise in theory-based multilevel interventions and methods expertise in the design, implementation, analysis, and reporting of randomized behavioral trials focused on underserved communities.**

These objectives, and the focus of this K22, are to use a community-engaged approach to co-create and pilot test a tailored intervention for Black families to demonstrate the feasibility and acceptability of supplementing reminder/recall (R/R) systems and to generate preliminary efficacy estimates on vaccine confidence and

intentions to inform a larger randomized trial. This K22 award will give me the time, additional training, and leadership experience I need to continue making progress towards my long-term career goals. I will apply for an R01 to rigorously evaluate the culturally relevant tailored intervention developed through this proposal to determine whether increases in vaccine confidence and intention translate to changed behavior. My vision for the R01 is to conduct a multiple component intervention combining evidence-based provider training (provider level) and the tailored text intervention (parent and clinic levels) which is responsive to NOT-MD-21-008: *Research to Address Vaccine Hesitancy, Uptake, and Implementation among Populations that Experience Health Disparities*. Additionally, future comparisons could determine whether the intervention content could be adapted for other racial/ethnic minority groups or adolescents themselves.

C. CAREER DEVELOPMENT AND TRAINING ACTIVITIES DURING AWARD PERIOD

C1. Career Development

The rigorous plan outlined below will extend my HPV knowledge to new prevention approaches and advance my leadership and technical skills through hands on experiences in developing interventions using bidirectional community-engaged intervention planning, implementation, evaluation and dissemination of results as well as designing, conducting, analyzing, and reporting randomized controlled multilevel intervention trials aimed at reducing disparities. **Table 1** outlines didactic training, applied experiences, and continued professional development during the award to help me accomplish my research aims and move towards independence.

Table 1. Proposed Career Development Activities	Y1	Y2	Y3
Coursework, Training Institutes, Workshops			
Rutgers Family Systems and Child/Adolescent Health (3, 2-hr workshops)	X		
Pediatric, Family Medicine shadowing	X	X	
Maastricht University Intervention Mapping Summer Course (1 week)	X		
Univ of Tennessee Community Based Participatory Research (2 days, 1-year remote grant writing)		X	
NCI DCCPS Multilevel Intervention Training Institute (online 4 months, 1 day in person)		X	
NIH OBSSR Randomized Behavioral Trials Summer Institute (1 week)		X	
Columbia University Principal Investigator Skills Crash Course (2 days)	X		
Rutgers ESI RCT writing cohort sponsored by CTSA (10, 1-hr sessions)		X	
Scientific Conferences, Meetings, Working Groups			
National Immunization Conference, ASPO, Cancer Health Disparities Special Interest Group		X	X
Society of Behavioral Medicine Annual Meeting, International Papillomavirus Society Conference	X		X
Local symposia (Annual Cancer Retreat, HPV Roundtable meeting)			
CPC, Cancer Health Equity, Implementation Science, Communication meetings and working groups	X	X	X
Scientific Productivity			
Monthly, ad-hoc meetings with Collaborators	X	X	X
Semi-annual Advisory Committee Meetings	X	X	X
Research Project IRB, protocol preparation, renewal	X	X	X
Convene Stakeholder Advisory Committee meetings (2 per year)	X	X	X
Conduct Aim 1: Co-create tailored vaccine hesitancy intervention	X	X	
MS1: Intervention mapping to address vaccine hesitancy and increase vaccination among Black families		X	
MS2: Modified Delphi process identifying key elements of HPV vaccine hesitancy messaging		X	
Conduct Aims 2 & 3: Conduct pilot trial to assess feasibility, preliminary efficacy		X	X
MS3: A mixed methods feasibility evaluation of a tailored intervention to address HPV vaccine concerns of Black families			X
MS4: HPV vaccine concerns and confidence among Black families: A pilot trial			X
Prepare and submit R01 proposal for multilevel HPV prevention intervention in Botswana to NCI	X		
Prepare and submit R01 proposal testing multiple component tailored text intervention and provider training to NCI			X
Responsible Conduct of Research			
Ethical Scientific Conduct at Rutgers (15 hours)	X		

C2. Didactic and Experiential Training Activities

C2.1 Objective 1: HPV vaccination communication. The CDC has multiple online training courses through the Immunization Education & Training portal on Vaccine Communication, including *Foster a Culture of Immunization, You Are the Key to HPV Cancer Prevention*, and *Routinely Recommending Cancer Prevention*, which I will complete. CDC resources include summaries of parent-provider and community-facing strategies and materials that providers, clinics, or community organizations can use to promote the HPV vaccine.

To gain knowledge on vaccine hesitancy, I attended the virtual National Academies of Sciences Engineering Medicine Vaccine Hesitancy workshops (May and August 2020). The International Papillomavirus Conference (IPVC), has a pre-conference workshop on HPV Vaccination. There is a specific conference tract for HPV vaccination behavior, which will allow me to expand my current HPV research network.

To better understand the nuances of HPV vaccination communication and parent-provider interactions related to HPV vaccine recommendations, I will seek clinical exposure opportunities by shadowing pediatricians and

other primary care providers to observe the real-world communication challenges of HPV recommendations to witness how parents express concerns and how providers respond to racial/ethnic minority families. As a researcher without clinical training, the Department of Pediatrics at Robert Wood Johnson Medical School (RWJMS) ambulatory clinics, Grand Rounds, journal clubs and seminars will provide important insights into my proposed work. My collaborator, Manuel Jimenez, MD, MS, FAAP, will connect me with his pediatric and family medicine colleagues. The clinical shadowing will complement my participation in Rutgers School of Communication and Information (SCI) Health Communication and (mis)Information working group, of which Dr. Greene is a member. Similarly, Rutgers Cancer Institute has a patient-provider communication working group, with various clinicians (doctors, advanced practice nurses, pharmacists) and social science researchers.

I will pursue training in adolescent development and family science to increase my understanding of theory-based approaches for interactions with parents and families. I will participate in Bowen Family Systems Theory and Child/Adolescent Health workshops through Rutgers School of Social Work. The workshops include small group meetings and 1.5 hour-long webinars on Understanding Child Development through a Cultural Lens, Nuclear Family Emotional Process, and Societal Emotional Process.

C2.2 Objective 2: Community-engaged intervention planning. I will enroll in *Intervention Mapping: Designing Theory-based and Evidence-based Programs*, a course organized by the Applied Social Psychology faculty at Maastricht University. This weeklong in-person course will help refine my skills to develop theory- and evidence-based health promotion interventions. Intervention Mapping is rooted in Community-Based Participatory Research (CBPR) and emphasizes ecological approaches to behavior and environmental change. This training will help me select and combine interventions to address vaccine hesitancy across multiple levels.

To further enhance my health disparities skills for developing and adapting tailored and equitable interventions, I will enroll in a 2.5-day workshop at the University of Tennessee Health Science Center on CBPR. After the course, participants remain in an NIH-funded National Research Mentoring Network for a year after the workshop, through which a grant application is developed. This feedback will be critical as I develop my R01.

The Rutgers Cancer Institute CCHE has a strong and highly committed Community Cancer Action Board (CCAB) that fosters partnerships between researchers, outreach staff, providers, and communities throughout the state. Members of CCAB provided input through a Work in Progress meeting for this application. I will present to the CCAB to engage in dialogue and solicit feedback each year and work with COE leadership and staff to further enhance my skills for developing community-driven, equitable interventions and consensus building. Dr. Kinney has deep connections to Black communities and safety-net providers and organizations across the state with multiple studies focused on improving cancer prevention and care among high-risk Black families and ScreenNJ initiatives. I will assemble a study-specific Stakeholder Advisory Board (SAB) and convene meetings twice per year, working closely with Dr. Btoush to ensure local community groups are represented on SAB.

C2.3 Objective 3: Multilevel intervention trials. I will participate in the NIH Division of Cancer Control and Population Sciences (DCCPS)-hosted Multilevel Intervention Training Institute (MLTI), which includes online training over 4 months. The focus of MLTI is to provide a foundation in theory, study designs, methods, and funding opportunities for multilevel intervention research.

I will participate in the Summer Institute on Randomized Behavioral Clinical Trials sponsored by the NIH Office of Behavioral and Social Sciences Research (OBSSR). This weeklong Institute will increase my understanding of how to apply translational research models and intervention optimization frameworks as well as planning, designing, conducting, analyzing, and reporting clinical trials. And with guidance from my advisory committee, I will gain practical experience conducting a randomized pilot trial (Research Aims 2 and 3). I will participate in the clinical trial grant writing cohort sponsored by the NJ Alliance for Clinical and Translational Science (NJ ACTS, UL1TR003017) to develop my R01 proposal advancing the work of this proposal.

C3. Professional Development

Throughout the award period I will continue developing other essential professional skills, including leadership development, grant writing, and scientific networking and presentations to researchers and lay public.

I will continue participating in Rutgers OASIS Leadership & Professional Development Program, which is a year-long, university-wide cohort program with mentoring, professional coaching, and peer groups to enhance strategic planning, communication, and productivity for female faculty members. I will also continue my leadership role on the steering committee of Rutgers University Health Equity Academic Research (RU-HEAR), a special interest group sponsored by the Office of the Senior Vice President for Academic Affairs. I will attend Columbia University's PI Skills Crash Course: Skills for Future or New Leaders. This two-day intensive course includes lectures with interactive workshop sessions to put common "survival skills" into practice: staffing, leading, mentoring, managing people, managing time, and managing projects. My advisors and Rutgers Cancer Institute mentors and colleagues will assist in nominating me to editorial boards and national committees.

In addition to the grant writing workshops mentioned above, my participation in OASIS leadership development also provides a writing accountability group through the Office of Faculty Affairs, which will help me to develop grant applications and supporting manuscripts. Building on my pilot work in Botswana, I will submit an R01 grant application to assess the implementation of community-based self-sampling in Botswana. Other grant opportunities include, pilot funding through the Cancer Prevention and Control (CPC) Program, Cancer Health Equity, and Global Health Seed Pilot Awards at Rutgers, and NJ Commission on Cancer Research grants.

I will attend local symposia and conferences as well as annual retreats and seminars on community engagement and translational science methods hosted by Rutgers Cancer Institute, CCHE, and NJ ACTS to expand my scientific network and present my work. For example, Rutgers Cancer Institute and the NJ Commission on Cancer Research jointly sponsor an Annual Retreat to connect researchers from across the state. I will attend at least 2 national and international professional conferences each year to present findings and expand my network, including American Society of Preventive Oncology, Society of Behavioral Medicine, and IPVC.

I will complete the Rutgers University mandatory Responsible Conduct of Research (RCR) Program required for faculty engaged in NIH-sponsored training and career development award programs. This program is designed to fulfill the NIH RCR requirements. I will also maintain my CITI certification and Good Clinical Practice (GCP) training to stay up to date with guidelines as outlined in Training in the Responsible Conduct of Research.

C4. Collaborators

The interdisciplinary team of NIH-funded collaborators will enable the success of this proposal.

1. Manuel Jimenez, MD, MS, FAAP, a developmental and behavioral pediatrician, is an expert in parent and family behavioral interventions, specifically socio-emotional outcomes.
2. Kathryn Greene, PhD, a health communication expert, has extensive experience with prevention message processing and information sharing within social networks, specifically related to increasing engagement with digital and mHealth interventions.
3. Rula Btoush, PhD, a nursing researcher, has expertise in community-based studies on HPV vaccination knowledge, attitudes, and behaviors among Black and Hispanic parents and pediatric providers.

I will continue to meet monthly with Drs. Btoush and Greene. Dr. Jimenez and I will meet every month. All collaborators will be available for ad-hoc meetings (Letters of Support and Preliminary Studies). The content and methods expertise of the Collaborators is distinct but pairs well with the skills of my proposed advisory committee.

C5. Advisory Committee

I will assemble a strong interdisciplinary team for my research advisory committee, including senior investigators who have a strong track record of NIH funding with content expertise and methodological skills directly related to my goals. I will leverage my professional network and work with current and past mentors (i.e., Kinney, Viswanath, Wheeler) to identify and connect with experts in these areas to establish a formal K22 advisory committee upon receipt of this award. I will establish semi-annual meetings with all advisors, which will be held in-person or via Zoom, to provide feedback on project progress and my overall career trajectory from experts in:

1. Pediatric/adolescent vaccination: Guidance from a clinician scientist will facilitate my understanding of real-world challenges of conducting practice change research in pediatric and family medicine clinics.
2. Community-engaged research: A behavioral scientist with CBPR expertise will provide important insights on working with diverse community partners and practical tips for assembling and leading SAB meetings and engaging them in all phases of intervention design, dissemination of findings, and next steps.
3. Multilevel intervention trials: The trialist will advise on practical and methodological issues related to trial planning, randomization, implementation, analysis, and reporting.

C6. Summary

This Transition Career Development Award will provide protected time for me to gain more advanced skills and hands-on experience in HPV vaccination communication, community-engaged intervention planning, and intervention trials. My extensive mentored disparities research experiences in relevant mixed methods study designs and analyses will allow me to further refine my skills and apply these methods in behavioral clinical trials as I build an independent cancer prevention research program with a focus on cervical cancer disparities. I will commit at least 80% of my time to research and career development during the award period. This career development plan is linked to specific research aims and my career goals, which will help facilitate my independence by the end of the award period and propel my career as an emerging leader in cancer disparities research.

SPECIFIC AIMS

Vaccination against human papillomavirus (HPV) can prevent multiple types of cancer that disproportionately affect Black and Hispanic populations. Despite the availability of a safe and effective vaccine that can prevent up to 90% of cervical cancers, the most recent vaccination rates in the United States show that less than half of adolescents aged 13-15 years were fully vaccinated, with **Blacks having the greatest disparity in completion**.

HPV vaccine hesitancy is associated with under-vaccination and refusal. An estimated 23% of parents with adolescents are hesitant about the HPV vaccine, but parents' questions and concerns vary based on a myriad of individual, interpersonal, and sociocultural factors. Despite the literature on knowledge, attitudes, and beliefs to HPV vaccination, interventions to address hesitancy remain elusive, especially for Black families. Although receiving a provider recommendation is an important predictor of vaccination, it may not be sufficient to convince Black families whose vaccination decisions are strongly shaped by attitudes and beliefs. On top of low confidence in vaccine safety, Black families' low perceived HPV risk, lack of HPV knowledge, reliance on shared family decisions, high medical mistrust, and racial discrimination experiences influence motivation to vaccinate.

Multilevel interventions can increase vaccination, but no effective interventions exist to address Black vaccine hesitant parents' (VHPs') unique needs and concerns. Systematic reviews show reminder/recall (R/R) messages increase HPV vaccination among Black adolescents, but generic approaches are not enough to overcome hesitancy. R/R systems are increasingly using text messages, which can be tailored and enhanced with personalized features to provide education, address hesitancy concerns, link to credible sources, and increase self-efficacy to overcome barriers. **Supporting Black VHPs after the initial recommendation with a tailored text intervention has potential to overcome disparities in vaccine confidence and vaccination.**

My career goal is to be an independent investigator implementing effective and equitable interventions to improve cervical cancer disparities. The objectives of this proposal are to use a community-engaged approach to develop and pilot-test a tailored intervention for Black families. The overall hypothesis is that follow-up text messages tailored to parents' information needs will increase vaccine confidence and motivation to vaccinate. This K22 leverages a recently funded mixed methods study (P30CA072720-21S2) examining social and behavioral determinants of vaccine hesitancy. Preliminary catchment area survey findings indicate Blacks have lower HPV vaccine awareness and vaccination in addition to low vaccine confidence compared to other racial/ethnic groups in New Jersey. The rationale for this project is that community stakeholder input is critical to overcome vaccine hesitancy determinants specific to Black families and that R/R text messaging is a scalable strategy that is ideal for delivering tailored messages. To accomplish my long-term career goal and these research objectives, I require additional training and research experience in HPV vaccination communication with hesitant families as well as intervention mapping and trial implementation to enhance my cancer disparities expertise. I propose to:

Aim 1: Co-create a tailored text intervention to address HPV vaccine hesitancy and vaccination barriers among Black families using a community-engaged approach. First, I will draft a message bank using research-tested message framing on common concerns mapped to hesitancy determinants and barriers that were identified specifically by Black VHPs from preliminary data. Through stakeholder advisory board guidance, focus groups with parents, and a modified Delphi process with experts, I will refine the interactive intervention with content tailored to individual parent needs. *Aim 1 Hypothesis: The prototype intervention will include a higher proportion of vaccine hesitancy determinants compared to practical barriers.*

Aims 2 & 3: Conduct a two-arm pilot randomized controlled trial of an individually tailored intervention for Black families in a safety-net clinic to demonstrate feasibility (Aim 2) and explore preliminary efficacy (Aim 3) to inform a larger randomized trial. Seventy Black parents of adolescents aged 9-13 years will be randomized to receive either (1) tailored messages on hesitancy determinants and barriers or (2) untailored messages. Surveys will be conducted immediately after initial vaccination recommendation and post intervention (~2 weeks) to assess changes in vaccine confidence and intentions; vaccination status will be extracted at 8 months from EMR. Recruitment, retention, and intervention use will determine feasibility. Key informant interviews with a purposive sub-sample of patients (n~15) and providers and clinic staff (n~12) will be conducted to assess acceptability, appropriateness, and possible barriers to the implementation of the intervention. *Aim 2 Hypotheses: ≥50% of eligible parents will enroll with ≥70% retention. Aim 3 Hypotheses: Parents receiving tailored messages will have greater vaccine confidence and intentions compared to parents who receive untailored message.*

Results will provide critical insights on messages designed for Black VHPs and essential preliminary estimates on the feasibility and potential effects of a tailored text intervention in safety-net clinics. Findings will inform an R01 application for an adaptive trial combining interventions to reduce HPV vaccine hesitancy in line with existing funding opportunities (e.g., NOT-MD-21-008). This K22 is a logical progression from my research on women's screening decisions and complements my HPV testing work in underserved communities in the US and Southern Africa. The proposed development plan will propel my career as an independent investigator who leads high-impact, community-engaged research on multilevel interventions that reduce cervical cancer disparities.

RESEARCH STRATEGY

D. Significance

D1. Despite the availability of a safe and effective vaccine, HPV causes over 34,800 cancers in the US each year.[19-21] Significant racial/ethnic disparities in human papillomavirus (HPV) exist: Black women have the highest prevalence of HPV infection in the US.[22] Black women also have higher incidence and mortality rates of cervical cancer compared to non-Hispanic white women. The Advisory Committee on Immunization Practices recommends routine HPV vaccination for females and males aged 11-12 years though vaccination can start at 9 years.[23] Although HPV is recommended at the same time as other adolescent vaccines (i.e., tetanus, diphtheria, pertussis (Tdap) and meningococcal), HPV vaccination lags behind.[24] Only 48% of adolescents aged 13-15 years receive recommended doses, with significantly lower (12% less) completion among Black adolescents.[25] Increasing HPV vaccination among Black adolescents has potential to reduce cancer disparities.

D2. Health care providers play a critical role in HPV vaccination uptake, but many parents remain hesitant.[26-29] Evidence-based toolkits and communication trainings improve provider recommendations, but may not help providers sufficiently address parents' questions and concerns. The most recent 2018 National Immunization Survey-Teen (NIS-Teen) data show that 25% of parents did not accept the HPV vaccine despite receiving a provider recommendation.[24] HPV vaccine refusal and not completing the series are largely driven by vaccine hesitancy, independent of barriers.[30] Hesitancy, which many experts consider to be a motivational state, is influenced by complex individual, interpersonal, and sociocultural factors (**Figure 2**).[31] A parents' thoughts and feelings (mainly risk perceptions and vaccine confidence) in addition to social processes can motivate vaccination. Thus, parents who accept vaccination could still be hesitant. Practical barriers affect the ability to act on the motivation and get vaccinated.[32-34]

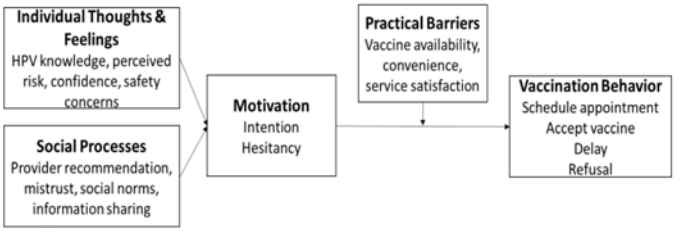


Figure 2. Increasing Vaccination Model adapted from WHO Behavioral & Social Drivers of Vaccination Working Group

D3. Parents express diverse concerns and Black families have unique reasons for refusals. Nearly half of all parents have at least one concern about HPV vaccination, with side effects and safety being the most prevalent.[30,35] Vaccine hesitant parents (VHPs) report low perceived risk of HPV and low confidence in vaccine effectiveness and benefits.[36-39] Among Black parents, refusals are often linked to shared family decisions,[36] which are complicated by perceptions of sexuality and religion.[40] Refusals are more common within social networks expressing medical mistrust and sharing misinformation.[41] Previous negative health care experiences also affect Black parents' decisions.[40,42] Cultural beliefs about vaccines are key drivers of vaccination among Black families.

D4. Provider recommendations are insufficient to convince many Black families to vaccinate. Trust is a key component of vaccine confidence but extends beyond trust in the HPV vaccine itself. Although provider trust is positively associated with HPV vaccination,[43] trust in the broader health system and government agencies or authorities making recommendations also influence Blacks' vaccine attitudes.[44-46] Medical mistrust is more prevalent among Blacks as a result of systemic racism.[47] Many Black families have personal experiences and intergenerational histories of medical abuse, mistreatment, and racial discrimination.[48] Medical mistrust is associated with difficulty talking to providers about vaccines, vaccine hesitancy, and vaccination.[49-51] Community-driven interventions are needed to build vaccine confidence and trust among Black families.

D5. Communication strategies to effectively address hesitancy remain unclear. Although brief, direct recommendations using an announcement approach ("Your child is due for three vaccines today") increase HPV vaccination,[52,53] this presumptive approach may not be effective among hesitant parents.[54] Conveying urgency can make VHPs feel rushed to decide and negatively affect provider trust,[55] which may be particularly harmful for Blacks. Motivational Interviewing, where providers help parents explore and identify motivating factors for vaccination,[56] improves communication with VHPs when they have questions.[57-59] Even with these evidence-based communication strategies, VHPs require longer conversations to address concerns and often want time to review and digest information before making a decision.[55] Provider/appointment time burden is a well-known barrier to vaccination conversations.[28] To avoid this, studies have tested pre-visit interventions, but differential effects on vaccination by race have been observed with no benefit for Blacks.[60] Pre-visit screening may prime parents and providers thus leading to more participatory conversations, which are associated with underimmunization.[61-63] Research on interventions for Black families *after* provider recommendation is needed.

D6. Health system interventions, including navigation and recall messages can increase vaccination. Secondary acceptance among those who initially refused is common when parents receive follow-up counseling to ease concerns, underscoring the importance of multiple opportunities to increase vaccine confidence. However, only half of parents report receiving follow-up counseling at subsequent appointments.[64] Navigation can address barriers and increase both initiation and completion, but is resource intensive.[65,66] Automated reminders for upcoming vaccine doses and recall messages for past-due vaccines (R/R) increase vaccination across various settings.[67-74] R/R effectively increases completion and has shown stronger effects for Black adolescents compared to other races.[75] However, generic R/R is not enough to tackle multiple determinants of

hesitancy.[76] Notably, R/R using standard announcement approaches in letters or calls was not effective among refusers.[60] The effects of tailored R/R to motivate Black VHP parents remains unclear.

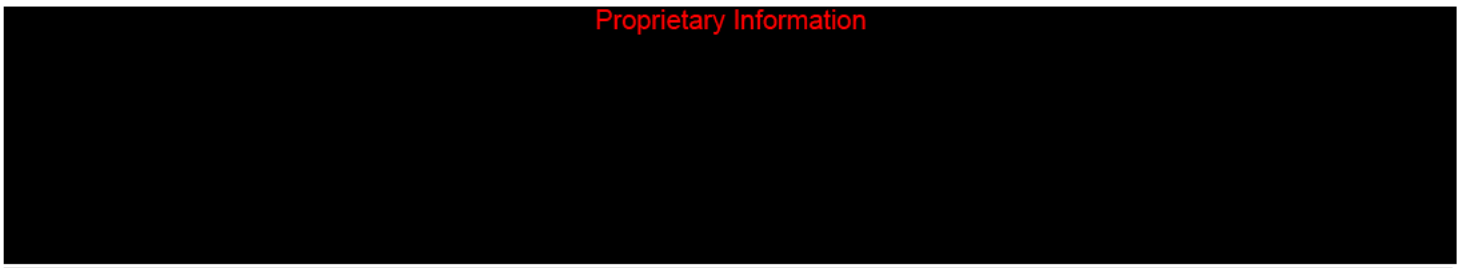
D7. A one-size-fits-all approach does not address the unique needs of Black VHPs. Tailored messages improve intentions[77,78] and may be more appropriate than segmenting parents based on unique needs and concerns.[79] The WHO recommends tailored strategies because messages that too strongly promote vaccination may be counterproductive and reinforce VHPs' worries.[34] VHPs tend to want multiple sources of information, though they distrust information from pharmaceutical companies and some advocacy groups.[80-83] Some Black parents rely on family and friends whereas others prefer online sources of information.[40,41] Preferences also vary regarding level of details.[84-88] Recent message testing on information desired by parents found that messages on HPV knowledge increased vaccine confidence and motivation.[55] Similarly videos tailored to parents' concerns increased intentions, though the strength of the main concern remained high.[35] These survey experiments did not tailor beyond concerns/desired information topic and did not consider racial/ethnic sociocultural determinants of hesitancy. Little research exists on tailored, scalable communication interventions for Black hesitant families.

D8. R/R texts tailored to concerns and barriers may increase VHPs' confidence. Parents are more responsive when R/R comes from a familiar source, such as the providers' office as it may be more appealing than state registry notices.[89] Simple personalization with the child's name and gender are helpful,[90] but further tailoring can increase relevance and behavior change.[91-93] Texts can be tailored to provide advice, goal setting, and navigation support.[94-96] Automated two-way texting allows more of a dialogue feel, which is recommended for communicating with hesitant parents.[34,83] Using multimedia message service (MMS) messaging (text and images) enables images or links to additional information to increase the effect of standard R/R texts.

D9. Summary of scientific premise. This study will fill knowledge gaps on effective HPV vaccine hesitancy communication specifically focusing on the youngest group of vaccine-eligible adolescents and under-vaccinated Black families who have unique needs and concerns. The design employs intervention mapping, which is a stakeholder-engaged approach informed by behavior change theories, to foster co-creation of a culturally-relevant and individually tailored intervention. The proposed intervention leverages R/R, which is an underutilized evidence-based strategy that has potential to increase vaccination among Black families. This study is highly responsive to the Cancer Moonshot Blue Ribbon Panel.[97] NCI's objective to develop, test, and scale-up effective multilevel interventions fits extremely well with my background, career development plan, and proposed research aims. Strategies to increase vaccine confidence are critical to increasing HPV vaccination and reducing HPV disparities. This study will generate an individually tailored intervention for Black families (Aim 1) and determine its feasibility (Aim 2) and preliminary efficacy on vaccine confidence, intentions, and vaccination (Aim 3).

E. Innovation

Vaccine hesitancy is an urgent public health challenge, but evidence-based strategies to address its complex, context-specific determinants and overcome concerns are lacking. This study is innovative in the following ways:



E3. Engages diverse stakeholders to develop messages addressing multiple determinants of hesitancy and low vaccination for Black families. Few studies have tested messages to address hesitancy specifically,[55,77] and fewer have been culturally-developed.[76] Previous research among Black families largely focused on knowledge, awareness, and structural barriers to acceptance without assessing or intervening on hesitancy determinants.[40] In addition, tailored interventions have previously targeted Hispanics or safety-net populations pre-visit with brochures or iPad.[101] One culturally developed video for Black adolescents increased vaccination, but it was not focused on parents or hesitancy.[102] Our diverse stakeholder input will prioritize community concerns and align messages with social norms among Black

families.[76] Through iterative intervention mapping steps, this pilot trial will be one of the first to assess feasibility of tailored hesitancy messages and preliminary effects of their exposure among Black VHPs.

F. Preliminary studies

F1. This strong interdisciplinary team has the requisite experience to contribute to my transition to independence and the project's success. My collaborators have expertise leading community-based HPV vaccination studies (Btoush[103,104]), developing tailored behavioral and psychosocial interventions among parent-child dyads (Jimenez[105-107]), and increasing engagement with digital and mHealth interventions (Greene[108-110]).

F2. We have experience collaborating on HPV vaccination studies. This proposal builds upon a series of preliminary studies to determine factors associated with low HPV vaccination in NJ. In two co-authored publications under review, we [redacted] Under Review [redacted]

Since the initial submission, Drs. Greene, Btoush, and I have been collaborating on an administrative supplement (P30CA072720-21S2) to analyze Rutgers Cancer Institute 2020 Catchment Survey data on vaccine confidence and collect qualitative data to identify social and behavioral determinants of HPV vaccine hesitancy. Data collection will be complete by summer 2021, providing rich insights to inform the proposed study. Preliminary survey results indicate Blacks have the lowest HPV vaccine awareness, lower vaccination compared to Hispanics, and lowest vaccine confidence among NJ residents, further justifying the need for a vaccine hesitancy intervention for Black families. Finally, Dr. Btoush's work found racial/ethnic minority mothers were interested in HPV vaccine text interventions and reminders.[104] Overall, we have demonstrated health care and community need for interventions to address vaccine hesitancy interventions and interest in texts for education and R/R.

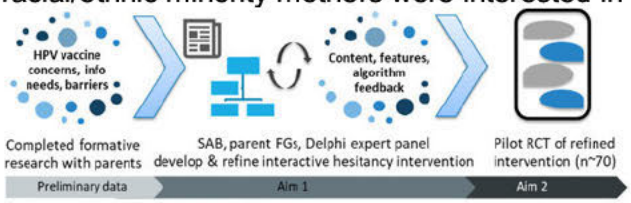


Figure 3. Overview of study design

G. Approach

G1. Research overview. This mixed-methods study employs a community-engaged, Intervention Mapping design guided by health behavior and communication theories.[112-115] The project includes the development, iterative feedback, and pilot testing of an interactive texting intervention designed to provide individually-tailored messages about Black families' HPV vaccine hesitancy determinants and vaccination barriers. We will convene a study-specific Stakeholder Advisory Board (SAB) to guide the project, employ user-centered design with parents, and elicit expert feedback through a modified Delphi process to ensure high priority determinants and appropriate change methods are included (**Figure 3**).[116] We will conduct a pilot RCT to demonstrate feasibility and key informant interview (KIIs) with clinic staff and participants to assess acceptability and appropriateness. Together, our strong community and clinical relationships will facilitate high-quality, participatory approaches throughout intervention planning and implementation, creating content that responds to individual parents' needs and can be linked to R/R systems. Once completed, we will have developed and refined a novel intervention with community-driven solutions to overcome vaccine hesitancy that will be ready for formal efficacy testing.

G2. Conceptual model. The interactive text intervention is based on the Increasing Vaccination Model[31] (**Figure 2** above) and rooted in behavioral constructs from the Health Belief Model and Social Cognitive Theory,[117-119] including knowledge, risk perception, vaccine confidence (vaccine benefits, harms),[120] social norms regarding vaccination information sharing,[41] and self-efficacy. [redacted] Proprietary Information [redacted] Proprietary Information [redacted] Proprietary Information [redacted] The intervention is designed to assess and address hesitancy determinants and vaccination barriers endorsed by individual parents with the ultimate goal of motivating Black parents to vaccinate their adolescents and overcome barriers to them acting on the motivation.

G3. Stakeholder Advisory Board (SAB). I will assemble and convene a study-specific SAB using our connections through ongoing HPV vaccination research projects and Rutgers Center for Cancer Health Equity (CCHE). The SAB will be comprised of Black parents, community leaders from racial justice and faith-based organizations, youth activity organizations, and advocacy groups, some of whom have served on our Community Cancer Action Board (CCAB). The SAB will also include an administrator and clinician from the enrolling clinic. The SAB will have 8-10 members and will meet twice per year throughout the award. Following Intervention Mapping steps, the SAB will advise on the development of a logical model mapping hesitancy determinants, change methods, objectives, and outcomes (**Table 2**).[115,116] As we design and create the intervention, they will also review moderator guides, FG results, and prototypes to provide input on cultural relevance and help plan

implementation of the intervention. As we plan to evaluate the intervention, the SAB will also help inform RCT data interpretation, dissemination, and delineation of next steps. SAB members will receive $150 per meeting.

G4. Aim 1. Co-create a tailored text intervention to address HPV vaccine hesitancy and vaccination barriers among Black families using a community-engaged approach.

G4.1. Rationale: Preliminary studies will be completed by the start of this K22 to provide rich insights into specific social and behavioral determinants of hesitancy among Black families. The intervention will be delivered after providers recommend vaccination to allow parents to process vaccine information on their preferred timeline, provide tailored information to address questions or concerns not addressed during the appointment, provide supportive information to local resources to help overcome barriers, and R/R about upcoming or past due vaccination. Clinics are increasingly using population health management lists and appointment reminder texts, allowing integration into EMRs. Asking parents about their main concern is encouraged through the announcement approach, and discrete EMR fields document vaccination and refusals.[53]

G4.2. Design and Development: During the initial months, I will review in-depth analyses of preliminary qualitative data on hesitancy determinants, focusing on common concerns, social processes, and barriers from the logic model developed with the Proprietary Information Proprietary Information Proprietary Information Proprietary Information Proprietary Information

G4.3. Recruitment: We will identify and recruit 6-10 parents for each FG. Eligibility includes: (1) be a parent or legal guardian of adolescent aged 9-13 years, (2) self-identify as Black/African American, and (3) speak and understand English. Black Hispanics and Black Caribbeans are eligible. In collaboration with the SAB and other partners, we will use purposive, snowball sampling to identify and select parents based on their vaccination experiences according to different subgroups (**Table 3**). We will rely on parent-reported HPV vaccination status of child. Based on the literature, we will aim to include perspectives with a variety of educational attainment, adolescent age, religious affiliation, and foreign-born parents.[40,128] We will use CCHE and ScreenNJ partners to recruit more broadly. To get expert input, we will identify a list of potential local practitioners to serve on the Delphi panel, including public health researchers and health care staff (immunization program managers, medical assistants, nurses, physician assistants, nurse practitioners, and physicians) through existing relationships with Greater Newark Health Care Coalition, NJ HPV Roundtable, NJ Immunization Coalition, and NJ chapter of American Academy of Pediatrics, ScreenNJ and RWJBarnabas Health pediatric, primary care, and family medicine practices. We will recruit 15 professionals for a modified Delphi technique to prioritize and reach consensus on assessment questions and messages.[129]

Table 3. FG vaccination subgroups

Unvaccinated	*Vaccinated*
Did not receive recommendation	Accepted initial recommendation
Refused initial recommendation	Secondary acceptance

G4.4. Procedures: Once the initial message bank is developed, we will conduct 2 rounds of the 4 FG subgroups comprised of 6-10 parents of 9-13 year old female and male children to revise and refine content iteratively between rounds. FG participants will complete a brief intake form on sociodemographic data and modified HPV vaccine hesitancy scale (VHS).[30,130] We will use a combination of participatory formative research techniques and user-centered approaches to determine acceptability, appeal and appropriateness of the messages. For example, pile sorting exercises and discussion prompts to elicit reactions to visuals/graphics and content; feedback on message length, delivery, timing; and brainstorming for building trust, identifying local resources, and linking to trusted websites. We will convene the SAB to review FG summaries before moving forward. In the modified Delphi technique, we will email an executive summary of the parent FGs and SAB feedback with a Delphi questionnaire for participants to rank candidate messages and sequencing on importance and helpfulness.[129,131] Participants will use 5-point Likert scales and explain ratings. One group meeting will be scheduled to discuss and resolve first round feedback and emergent themes from explanations. Intervention duration, delivery, and logic rules will be discussed before a second re-rating questionnaire. We anticipate 3-4 weeks between each round. Parents in FG and pretesting will receive $50; panel experts will receive $150.

G4.5. Prototype Refinement: Proprietary Information

Proprietary Information

Proprietary Information

G4.6. Analysis: Recordings of FGs, SAB and modified Delphi meetings, and pretesting sessions will be transcribed and all notes and transcripts will be uploaded into Atlas.ti to organize, code, and analyze qualitative data using qualitative interpretive analysis.[132] All data will be coded by two independent coders for thematic analysis to identify patterns within and across sub-groups. Based on the literature and past experience, we expect two rounds of FGs using the described sampling frame will be sufficient[133] to reach data saturation (i.e., no new themes emerging on the topic).[134] We will publish *Intervention mapping to address vaccine hesitancy and increase vaccination among Black families* to summarize FG and SAB feedback. All scores and comments from each Delphi round will be tabulated, using 70% rating in top two categories (essential or very important) as consensus. Consensus that an item was not important includes >80% rate in lowest categories.[135] Criteria may change by round; we will add an additional round if consensus is not reached, though the meeting helps avoid additional rounds and respondent burden.[131] We will examine all items not achieving consensus before advancing. We will publish: *Modified Delphi consensus identifying key elements of an HPV vaccine hesitancy texting intervention.*

G5. Aims 2 & 3: Conduct a two-arm pilot RCT of an individually tailored intervention for Black families in a safety-net clinic to demonstrate feasibility (Aim 2) and explore preliminary efficacy (Aim 3).

G5.1. Pilot RCT Design: This pilot RCT is designed to investigate feasibility, acceptability, and preliminary efficacy of the tailored intervention and inform a future definitive RCT of a multi-component intervention for VHPs.[136] We will recruit 70 Black parents of adolescents from a safety-net clinic to participate. Consenting parents will complete the baseline survey and be randomized to one of two arms, receive message prompts (week 1), and post-intervention survey (week 2). Standard practice in local clinics is to schedule dose 2 at earliest eligibility (6 months after dose 1). We will examine feasibility (Aim 2) through trial recruitment, retention, and intervention delivery assessments (**Table 4**). We use validated measures of vaccine confidence and intentions and vaccination assessed at 8 months from EMR to estimate preliminary effects (Aim 3).

G5.2. Recruitment: The pilot RCT involves recruiting Black parents from a safety-net clinic. Clinic staff have weekly EMR reports identifying unvaccinated adolescents and EMRs have vaccination prompts for both well and sick visits. The medical assistants and nursing staff will be trained on screening, inviting and consenting parents to participate in a project to improve satisfaction with care and vaccination delivery at the end of the visit to not prime parents about vaccination. Eligibility includes: (1) be a parent or legal guardian of adolescent aged 9-13, (2) Black/African American race, (3) no documented HPV vaccination or refusal in EMR before appointment, (4) have access to personal mobile phone and agree to send/receive messages, (5) speak and understand English.

G5.3. Procedures: Eligible participants providing informed consent will complete 2 brief online surveys (i.e., baseline, immediate post-intervention) using DatStat, a HIPAA-compliant electronic data tracking system. Upon completion of the baseline survey, parents will be randomized to the tailored intervention group or the untailored group. Randomization is built into the DatStat survey, so parents and investigators will be blinded by automated processes and will be stratified based on baseline vaccination status as we expect initial refusers will respond differently than accepters.[60] Participants will receive $25 after completing each survey.

Table 4. Pilot Randomized Trial Measures

	Source, Measure	Description
Survey, texting platform logs		
Aim 2	Recruitment	# eligible / # approached # parents recruited / # eligible Reasons for non-eligibility, non-participation
Aim 2	Retention	# parents completing post survey / # enrolled Reasons for dropout
Aim 2	Intervention delivery	# parents receive HPV message / # enrolled # undelivered messages/invalid phone numbers
Aim 2	Intervention use	# responses to prompts / # sent # requests to stop
Aim 2	Intervention response engagement	# parents click on links / # sent # parents complete all questions / # enrolled # unsolicited user texts (e.g., thank you, emojis)
Aim 2	*Provider/Staff KIIs*	
Aim 2	Acceptability	Acceptability of Intervention (4 items, α=0.89)[137]
Aim 2	Feasibility	Feasibility of Intervention (4 items, α=0.89)[137]
Aim 2	Appropriateness	Intervention Appropriateness (4 items, α=0.89)[137]
Aim 2	*Parent intake, follow-up survey, outcomes*	
Aim 2	Intervention acceptability	Perceived ease of use, likeability, helpfulness, impact of texts- Mobile App Rating Scale (8 items, α=0.9).[138]
Aim 3	Vaccine confidence	Vaccine Confidence Scale (4 items, α=0.84)[120]
Aim 3	HPV vaccination intention	Vaccination Intention in next 6 months[36]
Aim 3	*EMR*	
Aim 3	Vaccination	Dose(s), date, reason for non-vaccination

G5.4. Intervention: The tailored text intervention (described above) consists of brief, interactive questions on hesitancy determinants and vaccination barriers and individually tailored messages based on responses. If no or incomplete responses are logged

after 24 hours, parents will receive a prompt to begin or pick-up at the last question. The untailored group will also complete the surveys and questions but receive untailored messages.

G5.5. Intervention Feedback: Shortly after intervention completion, I will conduct semi-structured KIIs to assess perceptions of feasibility, acceptability, appropriateness, and possible barriers to the implementation of the intervention. I will re-contact up to 15 participants to assess whether the intervention was useful, relevant, and culturally appropriate, which messages were most helpful and feedback on supplemental resources and links. Parent KIIs will be purposefully sampled by intervention group, retention, and outcomes. Upon completion of all participants, at least 12 health care staff and providers from the enrolling site will be recruited to obtain feedback on protocol, processes, and linkage with EMR and R/R systems and guide future implementation. Parent KIs will receive $50 and clinic staff will receive $100 for completing the interview.

G5.6. Outcomes: Recruitment and retention will be tracked through Datstat and TigerText (**Table 4**). Perceived feasibility and acceptability will be measured through post-intervention KIIs with providers and staff using validated measures,[137] parent acceptability,[138] and open-ended questions for feedback on improvements and potential barriers. The pre/post surveys assess constructs from health behavior theories that have associations with HPV vaccine hesitancy and vaccination, including preliminary efficacy outcomes of vaccine confidence and intention to vaccinate. We will assess documented vaccination from the EMR for exploratory outcomes, including: receipt of any doses, secondary acceptance (vaccinated during study after enrolling with 0 doses), completion (received dose 2), date of dose(s), and/or reason for non-vaccination.

G5.7. Proposed Analyses: Similar to the approach in G4.6, I will employ mixed method research best practices[139-141] triangulating data from surveys, text platform delivery data, EMR records and interview results to evaluate and refine the intervention. I will apply CONSORT guidelines for pilot RCTs.[142, 143] For Aim 2, I will examine feasibility using recruitment, retention, delivery, and engagement. Descriptive analyses (frequencies, means, confidence intervals) will evaluate the hypotheses of enrollment (>50%) and retention (≥70%). I will summarize staff perceived intervention feasibility, acceptability, and appropriateness measures separately. I will publish a manuscript: *A mixed methods feasibility and acceptability evaluation of a tailored intervention to address HPV vaccine hesitancy among Black families.* For Aim 3, I will examine differences between tailored and untailored group in vaccine confidence, intention to vaccinate, and vaccination to assess whether the tailored intervention had a greater effect. I will describe prevalence of endorsed concerns, strength of main concerns, and barriers and conduct exploratory analyses of whether specific determinants are associated with intervention effects. We will publish: *HPV Vaccine confidence and intentions among Black parents: A randomized pilot trial.*

G5.8. Sample Size: We used SWOG Statistical Tools Calculators and local clinic volume. We can estimate a 95% CI for 50% recruitment rate to within 6%; anything less than 44% would be unacceptable to move to efficacy trial. We aim to recruit 70 participants allowing for 70% retention, so around 50. The preliminary efficacy outcome is change in confidence. Based on the literature, we expect the confidence in the untailored group to be 2.24 out of 4.0 (SD=1.08). With two-sided type I error of 0.05, we have 80% power to detect a difference of at least 0.76.

G5.9. Potential Limitations and Alternative Approaches: (1) Considering Black VHPs may be less willing to participate in research, we included both initial accepters and refusers. If we encounter difficulties, we will target parents who vaccinate against Tdap and meningococcal but refuse HPV as they may have more positive vaccine attitudes. (2) A small sample for a pilot feasibility trial is appropriate to provide important potential effect sizes for a larger definitive trial as well as rich qualitative data and critical sample size, and technology capability insights. (3) The nature of vaccine hesitancy is contextual, and the study will be conducted with a specific population, limiting generalizability somewhat. The future R01 will be in multiple safety-net clinics. (4) To not interfere with clinical care, we elected to randomize parents and will not restrict provider communication. We measure communication satisfaction. Automated text messages will help control for potential differences in provider characteristics and communication across and within groups, which helps minimize bias in either direction. We considered a post-only survey to assess the added value of untailored messages; however, pre/post surveys will assess changes and the mixed methods design captures parents' and clinics' experiences. (5) We plan to deliver the intervention over a short time period, but our other text studies showed parents wanted more texts.[105] Intervals may change based on stakeholder-driven timing preferences. Although 18 months follow-up would allow time for behavior change, 8 months is reasonable given the study timeline and preliminary effect estimates.

G6. Overall Impact. This K22 proposal employs rigorous mixed methods to develop an innovative personalized intervention that addresses an urgent public health problem: vaccine hesitancy among Black families. Achieving the aims of this project has potential to increase HPV vaccine motivation and vaccination as we progress to eliminate cervical cancer. Given the global interest in increasing vaccine confidence, findings from this study could also inform future interventions relevant to uptake of other vaccines, including novel COVID vaccines and boosters. This K22 will allow me to advance and apply my unique expertise in behavioral sciences and health services research toward the overarching goal of this project: developing and pilot testing a vaccine hesitancy intervention to be in a future R01 definitive trial and determine whether addressing Black families' concerns translates to behavior change and helps reduce HPV vaccination disparities.

TRAINING IN THE RESPONSIBLE CONDUCT OF RESEARCH

Previous Training: Through my graduate training at the University of North Carolina at Chapel Hill (UNC-CH), I completed the required training in ethical conduct of social and behavioral research, biomedical research, Good Clinical Practice, and conflicts of interest offered by the Collaborative Institutional Training Initiative (CITI). I have continued CITI refresher courses every 3 years. I completed a 3-day course in the Responsible Conduct of Research through the NIH CTSA at UNC-CH for my predoctoral fellowship in 2013. In 2016, I took the 8-hour Responsible Conduct of Research course at Harvard University for postdoctoral fellows. I have a strong background in ethical training, particularly with respect to conducting international health research among people living with HIV, research with vulnerable populations including individuals experiencing homelessness, and ethical and legal issues in research on sensitive topics and sexual behaviors. Since coming to Rutgers Cancer Institute of New Jersey, I have taken the required training for Conflict of Interest, annual Health Insurance Portability and Accountability Act (HIPAA) compliance, Rutgers Code of Conduct, and eIRB Training Workshop.

Formal Coursework: I will receive comprehensive training in the responsible conduct of research during the award period. I will complete the semester-long course ***Ethical Scientific Conduct*** **(16:115:556)** offered by the Rutgers Graduate School in the Spring of Year 1 and receive a certificate of completion. I will complete the ***Ethical Scientific Conduct*** Refresher course two years following the introductory course.

- **Format, frequency, and duration:** The course meets weekly for lectures and small group discussions (~10 students). The course duration is one semester for a total of 13, one-hour weekly hours. The Refresher course (8 hours) will be completed 2 years later to reinforce the topics from the first course through small group discussions led by faculty and a webinar on scientific rigor.
- **Subject matter:** The course covers: (1) mentor-mentee relationships; (2) plagiarism and copyright; (3) data acquisition, including management, sharing and ownership; (4) research misconduct and policies to handle misconduct; (5) responsible authorship and publication; (6) personal, professional, and financial conflicts of interest; (7) scientists as responsible members of society; (8) collaborative research; (8) peer review; (9) policies for human subjects research; (10) contemporary ethical issues in biomedical research; (11) contemporary ethical issues; (12) intellectual property; (13) policies for animal subjects research.
- **Faculty participation:** Faculty participate in both the large group lectures, which are led by an expert in the field who is affiliated with Rutgers University, and the small groups, which are facilitated by Rutgers faculty who are actively conducting research. As a K award recipient, I could lead a small group.

Ongoing Advisement: As I have done during past NIH-funded training, I will ensure time during regular study meetings with collaborators and my future advisory committee is dedicated to consider important ethical principles in human subjects research broadly and specifically in aspects of implementing the proposed research. Kathryn Greene, PhD, is an expert in adolescent health decision-making and will provide key insights into intervention research with minors. Rula Btoush, PhD, is a nurse with experience conducting community-based research with minority parents, so she will advise on community-engaged ethics. Manuel Jimenez, MD, MS, FAAP, is a board certified developmental and behavioral pediatrician, so he will provide guidance on ethical issues related to working with parent-child dyads and behavior change interventions. We will discuss issues including but not limited to involvement with research, data privacy; institutional review board (IRB) renewal; human subjects research; and authorship. My current supervisor, Anita Kinney, PhD, will advise on Rutgers Cancer Institute Scientific Review Board, eIRB processes, campus resources, and ethical considerations of conducting randomized trials. I will continue participating in monthly works-in-progress meetings and brown bag lunches through the Center for Cancer Health Equity and School of Public Health, where we discuss ethical issues specific to research on preventive screening, research with vulnerable populations, and racial disparities.

Ongoing Training: I will continue to take online CITI refresher courses as needed (every 3 years) and complete the online certification courses of HIPPA compliance and Rutgers Code of Conduct annually (~3.5 hours). I will attend 2-3 IRB forums, ethics-related conference workshops, and specialized trainings in ethical issues for my proposed work each year. Numerous other opportunities for discussing cutting-edge bioethical issues are offered across Rutgers, including international experts at annual seminars hosted by the Center for Population-Level Bioethics at Rutgers School of Public Health. The center offers workshops and trainings on ethical and legal issues of research on sensitive topics, adolescent autonomy, health promotion, priority setting for vulnerable populations, and human participants. Rutgers Office of Research Regulatory Affairs holds weekly IRB walk-in hours for the Health Science IRB and hosts brown bag lunch and learn sessions.

Summary: The proposed in-person formal coursework, advisement, and workshops will advance my training in ethical considerations specific to the proposed K22 research and benefit my long-term professional development.

THIS IS A TRANSITION AWARD WITH NO MENTOR OR CO-MENTOR

RUTGERS
Robert Wood Johnson
Medical School

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Manuel E. Jimenez, MD, MS, FAAP
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February 20, 2021

Dear Kelly,

I am happy to write this letter in strong support of your application for a Transition Career Development Award (K22). Your commitment to community-engaged research to address health disparities is impressive and your focus on HPV vaccine hesitancy is critically important. Your innovative proposal to address hesitancy concerns and practical barriers has great potential to not only increase vaccine confidence but also motivate vaccination behavior change. This is a timely public health issue and I was glad you proposed to leverage reminder/recall systems as reminder texts are increasingly being used to promote continuity of care and coordination.

As Director of Developmental and Behavioral Pediatrics Education at the Boggs Center on Developmental Disabilities, I have supervised and trained a number interdisciplinary trainees including pediatric residents and fellows. My work is centered on making health care systems more responsive to families' needs and promoting optimal developmental outcomes for vulnerable children, specifically socio-emotional and language skills. I have been funded to complete projects with similar methods to those you propose in your K22, including community-engaged behavioral intervention planning, tailored text messages, and implementation evaluations. My portfolio includes substantial community-based and mixed-methods research methods to address disparities among low-income Latino families, so I have expertise with the formative phases of behavior change intervention development, specifically in collaboration with clinical and community stakeholders. As the PI of an R01 focused on evaluating the implementation of tailored text messages paired with an evidence-based intervention to promote shared reading among low-income Latino parents (HD099125), I have considerable experience assessing barriers and facilitators of using text interventions through health systems.

In my role as a collaborator, I'll meet with you every 1-2 months during the project and will provide guidance on designing and testing theory-based behavioral interventions through meaningful stakeholder engagement. I will connect you with pediatric clinics and colleagues and provide expertise on provider communication with vulnerable families. I also have technology services and support at Rutgers Robert Wood Johnson Medical School for multiple texting platforms, which may be valuable as you develop and program the texting program and logic rules. I will also be available to you for ongoing consultation, particularly in the design phase of the culturally-tailored behavioral intervention for hesitant parents and planning aspects of conducting text interventions through pediatric and primary care settings.

I am looking forward to collaborating with you on this project and am confident the K22 award support your rapid development into an independent investigator. I would be glad to work with you on this project at Rutgers or if you obtain a tenure-track position at another institution. There is a great need for evidence to effectively overcome parents' vaccine hesitancy, mistrust, and structural barriers, especially among Black families. I am excited to join your interdisciplinary team of collaborators and believe this study will resonate with community needs, making a significant contribution to reducing HPV disparities.

Sincerely,

Manuel Jimenez, MD, MS, FAAP
Assistant Professor of Pediatrics & Family Medicine and Community Health
Director of Developmental and Behavioral Pediatrics Education, Boggs Center on Developmental Disabilities
Rutgers Robert Wood Johnson Medical School
Attending Developmental and Behavioral Pediatrician at Children's Specialized Hospital

Kathryn Greene, Ph.D.
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Rutgers, The State University of New Jersey
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Phone: (848) 932-8715
Email: klgreene@rutgers.edu

February 25, 2021

Racquel Kelly Kohler, PhD, MSPH
Re: Letter of Support for K22 Transition Career Development Award

Dear Kelly,

I am writing to express my strong enthusiasm and support for your NCI K22 application on developing a tailored intervention to reduce HPV vaccine hesitancy among Black families. I look forward to continuing our work together and agree to serve as a collaborator.

As you know, I am a professor in the Rutgers School of Communication and Information and an active member of the Cancer Prevention and Control Program at Rutgers Cancer Institute of New Jersey. I have been PI and MPI on multiple R-level grants from NIH/NIDA and NIH/NCI, and Co-I on various R01s with other Rutgers Cancer Institute faculty. My work focuses on patient engagement with mHealth and digital interventions, mainly around message processing and exploring features of prevention messages. I have expertise in developing communication interventions related to adolescent prevention behaviors and testing novel behavioral interventions delivered via SMS, social media, and online. My research focuses on the role of media literacy, personality, and narratives, and how these factors can be used in tailoring messages to enhance participant engagement and information sharing. I will provide expertise on message processing and tailoring features to increase engagement as well as broader behavior change communication advice as you develop and test the intervention.

I am happy to collaborate with you on another project and fully support this next study to develop and test a tailored text intervention on HPV vaccine hesitancy. The preliminary formative data highlighting low vaccine confidence and low HPV vaccine uptake among Black/African Americans in New Jersey further justifies this need for tailored communication strategies. It is important to meet the information needs of hesitant parents with sources they deem credible, especially given the current racial injustices and misinformation environments, which have been exacerbated by COVID-19. An important next step will be to get community feedback on potential messages to determine how parents perceive them and whether they address underlying vaccination concerns. I am impressed with your innovative approach to engage a variety of stakeholders throughout the project and believe it will help ensure success. I use testing facilities and data visualization and graphic design services at Rutgers School of Communication and Information to evaluate intervention materials, for which I will facilitate access for you. I will be actively involved in the developing and pilot testing and will meet with you monthly throughout the project.

Your background in disparities related to cancer screening delays and decision-making and the preliminary study on HPV vaccine hesitancy make this is a perfect project for a K22 award. I strongly support your application and am sure this will be a very successful project building on our collaboration with Dr. Rula Btoush. As we have discussed, there is a lot of misinformation and mistrust about vaccines that needs to be addressed and your proposed project will contribute timely, impactful findings for Black families and HPV vaccine hesitant parents. I am excited to contribute as this investigation may also provide insights into communication interventions applicable to other vaccines to address vaccine hesitancy more generally.

Sincerely,

Professor, Rutgers School of Communication and Information
Member, Rutgers Cancer Institute of New Jersey
Joint Appointment, Rutgers School of Public Health
Affiliate, Rutgers Center for Tobacco Studies

RUTGERS School of Nursing

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March 2, 2021

Racquel Kelly Kohler, PhD, MSPH
Instructor of Social and Behavioral Sciences
Rutgers Cancer Institute of New Jersey

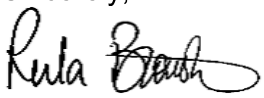
Dear Dr. Kohler,

I would like to express my full support for your application for the NCI Transition Career Development Award (K22) to address HPV vaccine hesitancy and HPV vaccination disparities. When you first came to Rutgers, I was glad to learn we shared a commitment to improving cervical cancer control among socially and economically vulnerable women. I have enjoyed our collaborative work thus far and believe the two manuscripts you co-authored with me demonstrate an urgent need for effective interventions to address hesitancy. Primary care providers face barriers in recommending the vaccine, especially in answering parents' questions about potential side effects and safety. Similarly, New Jersey's low uptake among young adolescents requires attention to maximize the benefits of the vaccine. I am excited you will move forward to develop and pilot an intervention based on the formative research we're collecting for the administrative supplement. Your proposal will launch a timely and innovative study to reduce HPV disparities among Black adolescents. Including community and clinical stakeholders in the development process is critical to consider the social contextual factors driving hesitancy among Black parents. Tailoring messages to be used as part of reminder/recall systems builds nicely on evidence-based strategies to increase vaccination and will help move the field forward toward scalable interventions that improve vaccination for those who are at high risk for HPV infection.

Regarding my experience, I am an Associate Professor of Nursing and have led and collaborated on multiple studies of HPV awareness and vaccination uptake, particularly among Hispanic mothers. Over the last few years, I have worked with the New Jersey Department of Health and Immunization Information System (NJIIS) to analyze data on HPV vaccination among teens and pre-teens. I also have deep expertise in barriers and facilitators to HPV vaccination and conducting qualitative studies in low-income neighborhoods, which makes me a strong collaborator for this project. I am well-connected with local HPV vaccination advocates, so I will provide local community and clinical insight to help foster relationships as you assemble the Stakeholder Advisory Board to develop messages to address parents' key concerns about HPV vaccine. I am confident you will be able to leverage our connections through the HPV Roundtable, regional Immunization Coalitions, the NJ Chapter of American Academy of Pediatrics, the NJ Primary Care Association, and of course RWJBarnabas Health system, to successfully conduct the proposed study. Given our recent collaboration, I anticipate that we will be in regular contact in between monthly meetings and throughout the award period as we continue to work on manuscripts. I believe I provide a strong complement to the other collaborators as I bring expertise in community-based HPV disparities research and a nursing perspective to your work.

I am committed to ensuring the success of this highly impactful project. I am glad to continue collaborating with you on this K22 proposal. I am confident our ongoing collaboration with Dr. Kathryn Greene will help you succeed, and I anticipate having many more opportunities as you establish your independent research program at Rutgers or another similar research institution.

Sincerely,



Rula Btoush, PhD, RN
Associate Professor
Rutgers School of Nursing

DESCRIPTION OF INSTITUTIONAL ENVIRONMENT

Dr. Kohler is based at **Rutgers Cancer Institute of New Jersey (Rutgers Cancer Institute)** and **School of Public Health (SPH)**. She will perform research activities at Rutgers Cancer Institute, which is part of **Rutgers Biomedical and Health Sciences (RBHS), Rutgers, The State University of New Jersey** and **RWJBarnabas Health**. This is an exceptional research environment with expertise in clinical, behavioral, and social sciences. RBHS has strong relationships with public health and community organizations to conduct impactful research.

RBHS has a robust research infrastructure to support Dr. Kohler through this award in a rich interdisciplinary, research-intensive environment. RBHS was awarded a **NIH CTSA** with Princeton University and NJ Institute for Technology, to support research and training for extramural funding and research infrastructure with links to the community. Dr. Kohler participated in a K writing cohort through the CTSA which provided feedback on this proposal. RBHS is particularly suited to the development of junior faculty, including resources for leadership and professional development programs, structured writing groups, center and institute-specific seminar series, symposia, and workshops. Dr. Kohler is on the steering committee of **RU Health Equity Academic Researchers**, a university-wide initiative from the Office of the Executive Vice President for Academic Affairs to bring together faculty conducting translational disparities research for seminars and networking. Rutgers Office of Research and Economic Development supports collaborative and individual faculty research programs through intramural funding, such as Seed Grants, Bridge Funds, and Collaborative "High Impact" Grants.

Rutgers Cancer Institute, the first and only NCI designated Comprehensive Cancer Center in New Jersey, benefits from being part of the largest integrated health network in the state - **RWJBarnabas Health** – which Dr. Kohler will leverage for the proposed project on HPV vaccine hesitancy. The **Center for Cancer Health Equity** is under the direction of **Anita Kinney, PhD**, Associate Director of Population Science and Community Outreach. The Center creates synergy among investigators across programs and disciplines to serve the most vulnerable through a community-engaged approach, including quarterly meetings, works-in-progress seminars, and outreach events. Dr. Kohler has opportunities to present research ideas, grants, and manuscripts for review and input from other faculty and **Community Cancer Action Board** members. There are several internationally recognized senior faculty members within Population Science with developmental psychology, mHealth and behavioral trials, and disparities expertise relevant to her research (**Drs. Carolyn Heckman, Katie Devine, Sharon Manne, Elisa Bandera, and Kinney**). The Division is a vibrant workplace with a long-standing track record in cancer epidemiology and intervention research and strong commitment to supporting junior faculty. Drs. Jerod Stapleton, Katie Devine, Bo Quinn, and Dena O'Malley received NCI career development awards and the early stage investigators meet frequently to discuss projects and grants. **Cancer Prevention and Control (CPC)** is one of five established Rutgers Cancer Institute research programs, all supported by peer-reviewed grants and shared resources. CPC meets monthly and is a collegial group where interdisciplinary collaboration is valued and encouraged. The program has over 30 interdisciplinary members from across the University, including **Kathryn Greene, PhD, and Rula Btoush, PhD,** collaborators on this application. The Center and CPC support internal, competitive funding for pilot awards. A range of opportunities to engage with other scholars is available through Distinguished Lecture Series, Cancer Center Grand Rounds, and an Annual Retreat on Cancer Research. The Governor's Conference on Effective Partnering in Cancer Research brings together experts from academia, clinics, industry, and government to discuss emerging cancer research issues. Rutgers Cancer Institute is committed to Dr. Kohler's success in becoming an independent investigator and in preparing this application, Drs. Kinney and Libutti have ensured that [redacted] Percentage of Effort and career development activities. Since beginning her Instructor position, Dr. Kohler has benefited from grant development, community connections, and sponsorship for OASIS faculty leadership and development program. Dr. Kinney has worked closely with Dr. Kohler as she develops her independent disparities research program. Dr. Kohler has access to Population Sciences Shared Resources, which assist with biostatistics, study design, project management, data collection, and analysis. The Office of Human Research Services ensures the responsible conduct of research and supports IRB submissions. Dr. Kohler also has administrative grant support.

Robert Wood Johnson Medical School Department of Family Medicine and Community Health (DFMCH) and **Department of Pediatrics** host Grand Rounds, journal clubs, monthly seminar series and working group meetings with international experts and local investigators. Ambulatory clinics will facilitate shadowing opportunities for Dr. Kohler's training objectives. The DFMCH Research Division is under the leadership of **Shawna Hudson, PhD**, who is Co-PI on a pilot award with Dr. Kohler. DFMCH faculty, including **Manuel Jimenez, MD, MS, FAAP**, a collaborator on this K22, have well-developed primary care research portfolios.

SPH aims to advance health equity and under the leadership of **Perry Halkitis, PhD**, SPH excels in cancer disparities, LGBTQ, sexual/reproductive health, HIV, and mental health research. Namely, Dean Halkitis and **Adana Llanos-Wilson** (HPV vaccination and testing), **Devin English** (racial discrimination EMAs), **Leslie Kantor** and **Slawa Rokicki** (maternal child health disparities) have well-funded intervention programs. Dr. Kohler is in the **Department of Health Behavior, Society, and Policy (HBSP)**, chaired by Paul Duberstein, a public health psychologist. HBSP has 24 policy and behavior science faculty who hold monthly brown bag lunches. SPH and NJ Department of Health host the **Annual NJ Immunization Conference** gathering Vaccine for Children programs, health centers, and academics. The Signature Seminar series features international experts in research, practice, and policy. Monthly luncheons for junior faculty promote networking with leadership.

RUTGERS
Cancer Institute
of New Jersey
RUTGERS HEALTH

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March 3, 2021

Dear Members of the Review Committee,

It is with great enthusiasm that I write in support of Dr. Racquel Kelly Kohler's NCI Transition Career Development Award (K22) application. We were excited when she joined Rutgers Cancer Institute of New Jersey (Rutgers Cancer Institute) in September 2019, and fully support her career development. Her strong background in cancer screening disparities makes her an ideal candidate for this K22 award that will develop a tailored intervention to increase HPV vaccine confidence among Black vaccine hesitant parents. Her proposal is responsive to community-identified priorities and addresses the urgent need for culturally-targeted interventions among Black families facing significant disparities in HPV cancers. Dr. Kohler's HPV cancer disparities research portfolio is aligned with our strategic priorities and is directly linked to our mission to achieve equitable access and improve health care quality. Her training, track record, and active Rutgers collaborations demonstrate her commitment to cancer disparities and outstanding potential to become an independent investigator.

Dr. Kohler is a resident member of the Center for Cancer Health Equity under the mentorship of Dr. Anita Kinney, Associate Director for Population Science and Community Outreach. Dr. Kohler is an Instructor of Social and Behavioral Sciences, a mentored position, at the School of Public Health. Based on her accomplishments at Rutgers thus far, I am excited about her future success. In her first year here, she published multiple first-author papers, presented her work at national and international conferences, joined state cancer control taskforces, received intramural pilot funding, and successfully submitted an administrative supplement for our Cancer Center Support Grant. She collaborates with Rutgers faculty on pilot projects, from which she has HPV vaccination publications under review. I am also impressed by Dr. Kohler's early involvement with our Community Outreach and Engagement (COE) activities, including our 2020 Catchment Area Survey, which provides additional rationale for the proposed research among Black families in New Jersey. I am confident she will continue to foster relationships with faculty and community collaborators to successfully conduct the proposed aims.

Personal Information

Rutgers Cancer Institute has a long history of behavioral and intervention research and supporting new investigators.

Personal Information, Redacted Per Agreement

[redacted]

Personal Information, Redacted Per Agreement

Dr. Kohler has an office in the main building, shared secretarial support, and dedicated grants administrative support. She has access to shared resources, including human subjects research protocol support, biostatistical expertise, and population science project management. Her community-engaged research will be enhanced through our COE, which gives her access to a large staff of Community Cancer Control Specialists, Community Cancer Action Board, and strong relationships with community organizations and safety-net clinics through ScreenNJ. Our partnership with RWJBarnabas Health Medical Group allows access to the large network of primary care and pediatric facilities across the state for recruiting diverse sites and participants. She has access to grants writing seminars and working groups. through Rutgers CTSA (New Jersey Alliance for Clinical and Translational Science) and various training opportunities as part of Rutgers Biomedical and Health Sciences (RBHS).

The research-intensive setting of Rutgers Cancer Institute and RBHS with its multidisciplinary centers, research facilities, community outreach, and training opportunities offers an ideal environment for Dr. Kohler's proposed research and career development. This K22 award has potential to address an urgent public health problem faced by communities across the globe - vaccine hesitancy. Dr. Kohler's extraordinary productivity of impactful cancer disparities research makes me confident that she is highly capable of conducting the proposed project and securing independent R01 funding.

Sincerely,

Steven K. Libutti, MD, FACS
Director, Rutgers Cancer Institute of New Jersey
Vice Chancellor for Cancer Programs, Rutgers Biomedical and Health Sciences
Professor of Surgery, Rutgers Robert Wood Johnson Medical School
Affiliated Distinguished Professor in Genetics, Rutgers School of Arts and Sciences
Rutgers, The State University of New Jersey
Senior Vice President, Oncology Services, RWJBarnabas Health

NCI Comprehensive Cancer Center

PHS Human Subjects and Clinical Trials Information

OMB Number: 0925-0001

Expiration Date: 02/28/2023

Use of Human Specimens and/or Data

Does any of the proposed research in the application involve human specimens and/or data *	● Yes ○ No
Provide an explanation for any use of human specimens and/or data not considered to be human subjects research.	human_data_LH_Edits_kk.pdf
Are Human Subjects Involved	● Yes ○ No
Is the Project Exempt from Federal regulations?	○ Yes ● No
Exemption Number	❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑ 6 ❑ 7 ❑ 8
Other Requested Information	

USE OF HUMAN SPECIMENS AND/OR DATA

All data in the proposed study is Human Subjects Data. No human specimen data will be collected in the proposed project.

1. HUMAN DATA AND ROLE

For Aim 1, adult parents of adolescents and expert practitioners will participate in focus group/interviews or surveys, therefore providing human data. The role of parents and experts is that of research subjects/participants. For Aims 2 and 3, parents and clinic staff will complete surveys and semi-structured interviews. The medical records of the enrolled parents' adolescents' will be accessed to confirm eligibility and extract vaccination information.

2. DESCRIPTION OF IDENTIFIERS

Personal identifiers, such as names and contact information, will be used for recruitment, participant tracking, and mobile phone numbers are required for text message intervention delivery (Aims 2 and 3) and study coordination. Upon completion, all identifiers will be removed; only de-identified data will be analyzed. A unique study identification code will be generated for each participant in all aspects of data collection. The database file will be password-protected, and this will be the only place where personal identifiers and study identification codes are linked.

3. ACCESS TO PARTICIPANTS' IDENTITIES

Only Dr. Kohler and research staff who are responsible for study coordination and whom have Institutional Research Board approval will have access to subjects' identities. Research staff will include Population Science Shared Resource and Behavior Science staff who will coordinate DatStat. The identifiable database will be stored on password-protected computer files on Dr. Kohler's password-protected computer and computers belonging to research staff. All computers are at the Rutgers Cancer Institute of New Jersey. Collaborators on this grant will have access to de-identified data files following Institutional Research Board approval.

4. PRIVACY OF RESEARCH PARTICIPANTS AND CONFIDENTIALITY OF DATA

All data collected from focus groups/interviews will be de-identified. All data files will use unique study identification codes to match data to a participant. All qualitative audio and transcripts will be de-identified. During the interviews and focus groups, participants, Dr. Kohler, and behavioral research staff will be encouraged to not use personal identifiers during discussions. In the event where an individual uses (a) personal identifier(s) during the interview, the particular text will be expunged prior to analysis. Regarding the trial, all analyses will be conducted on a de-identified dataset. Any documents with identifiable information will be stored in locked file cabinets in keycard-protected areas at the Rutgers Cancer Institute of New Jersey.

Human Subject Studies

Study#	Study Title	Clinical Trial?
1	Addressing HPV vaccination disparities through tailored messaging for hesitant families	Yes

Section 1 - Basic Information (Study 1)

OMB Number: 0925-0001

Expiration Date: 02/28/2023

1.1. Study Title *

Addressing HPV vaccination disparities through tailored messaging for hesitant families

1.2. Is this study exempt from Federal Regulations * ○ Yes ● No

1.3. Exemption Number ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑ 6 ❑ 7 ❑ 8

1.4. Clinical Trial Questionnaire *

1.4.a. Does the study involve human participants?	● Yes	○ No
1.4.b. Are the participants prospectively assigned to an intervention?	● Yes	○ No
1.4.c. Is the study designed to evaluate the effect of the intervention on the participants?	● Yes	○ No
1.4.d. Is the effect that will be evaluated a health-related biomedical or behavioral outcome?	● Yes	○ No

1.5. Provide the ClinicalTrials.gov Identifier (e.g. NCT87654321) for this trial, if applicable

Section 2 - Study Population Characteristics (Study 1)

2.1. Conditions or Focus of Study

- - Human Papillomavirus Vaccination - Vaccine hesitancy - Health communication - Reminder systems

2.2. Eligibility Criteria

Aim 1 Focus Group Participants (n: 80): Up to 10 participants will be recruited for up to 8 focus groups if they: 1) are between the ages of 18 and 80 years; 2) are parent or legal guardian of at least one child aged 9-13; 3) self-identify as Black/African American; 4) agree to participate in a recorded focus group; 5) speak and understand English; and 6) able to provide informed consent.

Aim 1 Pre-testing Participants (n: 10): Study participants will be recruited for brief individually moderated pre-testing with up to 10 participants in each group if they: 1) are between the ages of 18 and 80 years; 2) are parent or legal guardian of at least one child aged 9-13 years; 3) self-identify as Black/African American; 4) able to access personal mobile phone and agree to send/receive SMS/MMS messages; 5) agree to participate in a recorded interview; 6) speak and understand English; and 7) able to provide informed consent.

Aim 1 Modified Delphi Process Participants (n: 15): Experts will be recruited for modified Delphi surveys and group discussions if they: 1) are between the ages of 18 and 80 years; 2) are a physician, nurse practitioner, physician assistant, nurse, medical assistant, health care administrator, Vaccine for Children program staff, Immunization Information System staff, or public health researcher conducing work related to adolescent vaccinations; 3) agree to participate in a recorded group discussion and provide information for survey questionnaires; and 4) speak and understand English; 5) able to provide informed consent.

Aims 2-3 Randomized Trial Participants (n: 70): Study participants will be: 1) are between the ages of 18 and 80 years; 2) a parent or legal guardian of at least one child aged 9-13 years who has received 0 or 1 dose of HPV vaccine; 3) identify as Black/African American race; 4) able to access personal mobile phone and agree to send/receive SMS/MMS messages; 5) able to speak and understand English and able to provide information for survey questionnaires in English; and 6) able to provide informed consent. Further, participants who engaged in the Aim 1 focus groups or online pretesting are not eligible for the trial.

Aims 2-3 Key Informants (n: 12): Key informants will be recruited for semi-structured interviews and feasibility surveys if they: 1) are between the ages of 18 and 80 years; 2) are a physician, nurse practitioner, physician assistant, nurse, medical assistant, or administrator at the enrolling clinic; 3) agree to participate in a recorded interview and provide information for survey questionnaires; and 4) speak and understand English; 5) able to provide informed consent.

2.3. Age Limits	Min Age: 18 Years	Max Age: 80 Years
2.3.a. Inclusion of Individuals Across the Lifespan	individuals_across_lifespan.pdf	
2.4. Inclusion of Women and Minorities	women_and_minorities.pdf	
2.5. Recruitment and Retention Plan	recruitment_retention.pdf	
2.6. Recruitment Status	Not yet recruiting	
2.7. Study Timeline	Study_Timeline.pdf	
2.8. Enrollment of First Participant	12/01/2021	Anticipated

INCLUSION OF INDIVIDUALS ACROSS THE LIFESPAN

No children will be recruited or prospectively enrolled in the study to develop and pilot the tailored vaccine hesitancy text message intervention. Parent-reported child age, gender and vaccination status will be collected for Aim 1. However, child age, gender, and vaccinations will be extracted from the electronic medical record to determine parent eligibility for trial participant in Aims 2 and 3. Understanding that the adolescent's age may be an important determinant in parents' HPV vaccination beliefs, intentions, and behaviors, the study will recruit adults at least 18 years of age with children of varying ages (i.e., 9-13 years) based on Advisory Committee on Immunization Practices (ACIP) recommendations. Older adults up to age 80 years are eligible to include grandparents who are legal guardians of an adolescent.

INCLUSION OF WOMEN AND MINORITIES

1. Inclusion of Women

The proposed study is focused on parents and legal guardians/caregivers of adolescents engaged in health care decision-making. Understanding that most parents attending pediatric appointments are mothers, focus groups and the trial will likely recruit majority women. Eligibility for health care and immunization program staff and expert practitioner participants is not restrictive to biological sex or gender.

2. Inclusion of Minorities

This is a study focused on racial/ethnic disparities in HPV vaccination. All parents recruited will be Black/African American or Black as one of multiple races. We will not exclude Blacks identifying as Hispanic/Latinx. However, vaccine hesitancy is not homogenous within racial/ethnic groups but is shaped by sociocultural contexts. For health care and expert stakeholder input, we will not exclude participants based on race/ethnicity.

RECRUITMENT AND RETENTION PLAN

Recruitment

Aim 1 Focus Groups

We will use purposive, snowball sampling to identify and invite participants for 8 Focus Groups (FGs) with 6-10 participants in each group (n = 80). We will use our study specific Stakeholder Advisory Bord (SAB) and established community partners (e.g., Greater Newark Health Care Coalition, NJ HPV Roundtable, NJ Immunization Coalition, NJ chapter of American Academy of Pediatrics, NJ Primary Care Association), Rutgers Cancer Institute Community Cancer Advisory Board (CCAB), and ScreenNJ partners to identify and contact potential participants. Dr. Kohler will work with Behavior Science staff, Center for Cancer Health Equity (CCHE) navigators and Outreach Specialists to generate a list of potential participants and specific recruitment sites/events (e.g., health fairs, outreach events). Staff will make initial contact via e-mail, telephone, or in-person to invite potential participants to be in the study, determine the person's willingness to participate and collect initial eligibility information using a brief eligibility screener. Participants must self-identify as Black/African American, have an adolescent aged 9-13 years, and meet eligibility criteria explained in Human Subject. Parents will self-report their adolescent's age and vaccination status. Staff will explain the purpose, methods, and expectations for the study to prospective participants, who will be asked to read the informed consent form and ask questions prior to signing it. Study staff will then be required to ask potential participants whether he/she has understood the information. After consent is obtained, participants will be scheduled for a FG appropriate to their vaccination behavior. At the FG, staff and participants will briefly review the elements of consent relevant to the minimal risk study prior to beginning FGs or interviews. Verbal permission to participate and record the discussions will be obtained. Focus groups will last approximately 1.5 hours. We will conduct FGs until we reach thematic saturation. Participants will be offered a $50 incentive.

Aim 1 Prototype Refinement Pretesting Interviews

We will conduct 6-10 recorded pre-testing sessions of parents who have a child with 0 or 1 HPV vaccine doses (i.e., age-eligible and has not yet initiated the series or only received one dose and has not yet completed the series). We will use similar approach strategies to the initial in-person FGs above. Specific eligibility criteria is explained in Human Subjects. Sessions will be recorded for transcription. Pre-testing FGs may last 1-1.5 hours. Participants will be offered a $50 incentive. Participants in pre-testing groups will not be eligible to take part in the trial.

Aim 1 Modified Delphi Process Participants

Local experts will be identified and invited to participate in modified Delphi surveys and group discussions, including physicians, nurse practitioners, physician assistant, nurses, medical assistants, health care administrators, Vaccine for Children program staff, Immunization Information System staff, or public health researchers whose work relates to adolescent vaccinations. We will leverage relationships with Greater Newark Health Care Coalition, NJ HPV Roundtable, NJ Immunization Coalition, NJ chapter of American Academy of Pediatrics, NJ Primary Care Association, and RWJBarnabas Health pediatric, primary care, and family medicine practices to identify potential participants. We anticipate 3-4 weeks between each round with $50 offered for each round (survey, group discussion, survey).

Aims 2 and 3 Key Informant Interviews

We will conduct individual interviews with pediatric care team staff from the clinical site where the trial will take place (see Human Subjects). We will purposively recruit staff to assess the feasibility of scaling up for a larger trial in clinical settings and get feedback on linkages through existing systems (e.g., electronic medical records [EMR], IIS). We solicit feedback through a follow-up survey questionnaire with intervention feasibility and acceptability measures. A $100 incentive will be offered to staff participating in interviews and surveys.

Aim 3 Randomized Controlled Trial

Participants for the proposed study will be recruited from the enrolling site who have adolescents aged 9-13 years and have not received any doses of HPV vaccine as identified by weekly EMR reports and EMRs reminders for both well and sick visits. The research assistant, medical assistants and nursing staff will be trained on screening, inviting and consenting parents to participate in a project to improve satisfaction with care and vaccination delivery at the end of the visit to not prime parents about vaccination. During recruitment

conversations, parents will be offered the opportunity to participate in the proposed study and complete a brief screening in order to ensure eligibility requirements are met. The staff will explain the study, answer questions, and consent participants after confirming eligibility in EMR. This information is assessed by a staff member and entered directly into a secure database for processing and storage. If participants meet eligibility requirements (see Human Subjects Protections), they will be consented and asked to complete the baseline survey. Participants who engaged in the online pre-testing FGs are not eligible for the trial. In the event that this method of recruitment does not yield the necessary participants, or that an alternative strategy will be needed, we may rely on clinic staff to recruit before appointments or in the waiting area. Additionally we may use regular EMR checks of declinations to recruit over the phone after parents leave the clinic or to mail eligible parents a recruitment packet (introductory letter signed by Dr. Kohler, study information sheet, informed consent document, opt-out email/address/telephone number) immediately after the appointment. Participants will receive a $25 electronic gift certificate after enrolling and an additional $25 at completion of the follow-up survey to promote retention.

Retention

Using Dr. Kohler's, collaborators, and Rutgers Cancer Institute outreach and research staff's collective experiences in research with community members from diverse backgrounds and settings, we will maximize retention with a variety of methods. Drs. Kohler, Jimenez and Btoush have considerable experience working with diverse patients and community partners. Dr. Jimenez has an active R01 assessing a texting intervention for Latinx parents and has used similar recruitment approaches. Dr. Greene has expertise in recruiting adolescents and parents of adolescents. The CCHE, Behavioral Sciences, and Outreach Specialists have experience working with patients, family members, and community members. All study team members and Rutgers staff will be trained and supervised in best practices for interacting with participants and optimizing retention. All participants will receive clear and easy-to-follow, instructions about scheduling/attending FGs, or Interviews and completing/scheduling follow-up surveys. We will also provide prompts to remind trial participants of follow-up surveys using their preferred method of contact (e.g., text, email, phone call). We will monitor data collection and send prompt reminders to participants when assessments are not completed. A wide range of contact information will be collected from participants, including cell phone and home phone numbers, home and work addresses, and email address(s). Additional strategies include provision of electronic gift cards for additional follow-up surveys; repeated contacts; including flexible scheduling (i.e., evenings and weekends); and regular quality control meetings to review response rates and technical issues. These strategies have been shown to be effective in retaining participants in community-based research and our prior and ongoing research. Finally, we will follow all participants through the completion of the follow-up survey, regardless of poor compliance with the protocol. Given the short duration of the intervention and our excellent response rates from similar texting studies in safety-net clinics (80-90%), we do not anticipate significant challenges.

STUDY TIMELINE

Timeline of Research Activities by Aim Quarters:		Year 1				Year 2				Year 3			
	Pre-K22	1	2	3	4	1	2	3	4	1	2	3	4
Analyze existing qualitative data to identify determinants of vaccine hesitancy													
Prepare study documents, train staff, IRB approval, renew IRB													
Identify and convene study-specific Stakeholder Advisory Board													
Aim 1: Stakeholder engaged co-creation of tailored text intervention													
Adapt message bank from literature, mapped to concerns from preliminary data													
Conduct parent focus groups about message content, goals; analyze transcripts													
Modified Delphi process with clinical, public health, VFC, IIS experts													
Refine and pre-test prototype													
Refine and finalize interactive intervention based on Aim 1 activities and SAB input													
Aim 2: Demonstrate feasibility of tailored text intervention with two-arm pilot RCT													
Recruit parents for pilot trial, deliver intervention, post-intervention survey													
Conduct follow-up health care, parent participant semi-structured interviews													
Analyze recruitment, retention, message delivery and intervention engagement													
Aim 3: Assess preliminary efficacy of tailored text intervention													
Extract EMR vaccination documentation													
Analyze vaccine confidence, intention, vaccination													
Prepare and submit multilevel R01 to NCI													
Submit final report to NCI and send summary of results to research participants													

2.9. Inclusion Enrollment Reports

IER ID#	Enrollment Location Type	Enrollment Location
Study 1, IER 1	Domestic	
Study 1, IER 2	Domestic	
Study 1, IER 3	Domestic	
Study 1, IER 4	Domestic	

Inclusion Enrollment Report 1

1. Inclusion Enrollment Report Title* : Addressing HPV vaccination disparities through tailored messaging for hesitant families

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: We will recruit 15 public health and health care experts for modified Delphi process

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	2	2	2	2	8
More than One Race	1	0	0	0	1
Total	6	5	2	2	15

Cumulative (Actual)

Racial Categories	Ethnic Categories									Total
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			
	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	
American Indian/ Alaska Native	0	0	0	0	0	0	0	0	0	0
Asian	0	0	0	0	0	0	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0	0	0	0	0	0	0
Black or African American	0	0	0	0	0	0	0	0	0	0
White	0	0	0	0	0	0	0	0	0	0
More than One Race	0	0	0	0	0	0	0	0	0	0
Unknown or Not Reported	0	0	0	0	0	0	0	0	0	0
Total	0	0	0	0	0	0	0	0	0	0

Inclusion Enrollment Report 2

1. Inclusion Enrollment Report Title* : Addressing HPV vaccination disparities through tailored messaging for hesitant families

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: We will recruit Black parents for up to 8 focus groups with up to 10 parents per group and 10 parents for pre-testing interviews.

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	73	6	6	0	85
White	0	0	0	0	0
More than One Race	2	1	2	0	5
Total	75	7	8	0	90

Cumulative (Actual)

Racial Categories	Ethnic Categories									Total
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			
	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	
American Indian/ Alaska Native	0	0	0	0	0	0	0	0	0	0
Asian	0	0	0	0	0	0	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0	0	0	0	0	0	0
Black or African American	0	0	0	0	0	0	0	0	0	0
White	0	0	0	0	0	0	0	0	0	0
More than One Race	0	0	0	0	0	0	0	0	0	0
Unknown or Not Reported	0	0	0	0	0	0	0	0	0	0
Total	0	0	0	0	0	0	0	0	0	0

Inclusion Enrollment Report 3

1. Inclusion Enrollment Report Title* : Addressing HPV vaccination disparities through tailored messaging for hesitant families

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: We will recruit 12 health care staff and provider for key informant interviews post intervention

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	2	1	2	1	6
More than One Race	0	0	0	0	0
Total	5	4	2	1	12

Cumulative (Actual)

Racial Categories	Ethnic Categories									Total
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			
	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	
American Indian/ Alaska Native	0	0	0	0	0	0	0	0	0	0
Asian	0	0	0	0	0	0	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0	0	0	0	0	0	0
Black or African American	0	0	0	0	0	0	0	0	0	0
White	0	0	0	0	0	0	0	0	0	0
More than One Race	0	0	0	0	0	0	0	0	0	0
Unknown or Not Reported	0	0	0	0	0	0	0	0	0	0
Total	0	0	0	0	0	0	0	0	0	0

Inclusion Enrollment Report 4

1. Inclusion Enrollment Report Title* : Addressing HPV vaccination disparities through tailored messaging for hesitant families

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: We will recruit 70 Black parents to participate in the pilot feasibility randomized trail

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	58	4	4	0	66
White	0	0	0	0	0
More than One Race	2	1	1	0	4
Total	60	5	5	0	70

Cumulative (Actual)

Racial Categories	Ethnic Categories									Total
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			
	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	
American Indian/ Alaska Native	0	0	0	0	0	0	0	0	0	0
Asian	0	0	0	0	0	0	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0	0	0	0	0	0	0
Black or African American	0	0	0	0	0	0	0	0	0	0
White	0	0	0	0	0	0	0	0	0	0
More than One Race	0	0	0	0	0	0	0	0	0	0
Unknown or Not Reported	0	0	0	0	0	0	0	0	0	0
Total	0	0	0	0	0	0	0	0	0	0

Section 3 - Protection and Monitoring Plans (Study 1)

3.1. Protection of Human Subjects	human_subjects_kk_10mar.pdf
3.2. Is this a multi-site study that will use the same protocol to conduct non-exempt human subjects research at more than one domestic site?	❍ Yes ● No ❍ N/A
If yes, describe the single IRB plan	
3.3. Data and Safety Monitoring Plan	dsmp_LH_Edits_kk.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	study_team.pdf

PROTECTION OF HUMAN SUBJECTS

1. Risks to Human Subjects

a. Human Subjects Involvement, Characteristics, and Design

For this study we will employ a community-engaged, Intervention Mapping approach using established community and pediatric clinical partners (e.g., Greater Newark Health Care Coalition, NJ HPV Roundtable, NJ Immunization Coalition, NJ chapter of American Academy of Pediatrics, NJ Primary Care Association), Rutgers Cancer Institute Community Advisory Board, RWJBarnabas Health pediatric practice sites, and Screen NJ partners to assemble and convene a study-specific Stakeholder Advisory Board (SAB). The SAB will advise on the overall cultural relevance, design, implementation, data interpretation, dissemination of findings, and delineation of next steps.

This study involves developing and refining the initial intervention content message bank and components based on parent Focus Group (FG) focus group feedback, expert Delphi panel, pre-testing intervention materials and input from SAB. We will develop, refine, and test the feasibility of a novel intervention targeted at vaccine hesitant parents in order to ensure that context-specific factors are considered, including local concerns and motivations and determine appropriate delivery timing, duration. We plan to conduct randomized controlled trial (RCT) at a clinic participating in the Vaccine for Children (VFC) program because they are mandated to report HPV vaccination to the NJ Immunization Information System (NJIIS). RWJBarnabas Health has a wide network of pediatric and primary care facilities across the state, from which collaborators on the study have RCT enrollment experience. Rutgers Cancer Institute's Center for Cancer Health Equity (CCHE) and ScreenNJ program have Outreach Specialists maintain strong relationships with practices in every county of NJ to support recruitment and retention.

Focus Group Discussions

We will use purposive, snowball sampling to identify and recruit participants for 8 FGs with 6-10 participants in each group for a sample of 80. We will work with our SAB, community partners, RWJBarnabas Health pediatric practice sites, and Screen NJ Outreach Specialists to identify and contact potential participants. We will strive for a stratified sample, conducting 2 FGs with each vaccination behavior group (i.e., Did not receive recommendation, refused initial recommendation, accepted initial recommendation, secondary acceptance), while prioritizing sociodemographic characteristics. A moderator and notetaker will be present. All FGs will be recorded for transcription and translation (as needed). Participants will be offered a $50 incentive.

Eligibility Criteria

To participate in the FGs, individuals will be eligible if they: 1) are between the ages of 18 and 80 years; 2) are parent or legal guardian of at least one child aged 9-13; 3) self-identify as Black/African American; 4) agree to participate in a recorded focus group; 5) speak and understand English; and 6) able to provide informed consent. We will rely on parent-reported adolescent vaccination status and age.

Pre-testing Sessions

The same FG recruitment strategy will assist with identifying potential participants for 6-10 pre-testing sessions. Once the intervention prototype development is complete, we will conduct pre-testing to get feedback on the proposed intervention format and flow. The individually moderated session will be recorded. We will iteratively revise the texting algorithm and content as necessary in between sessions. Recordings will be transcribed for analysis. Participants will be offered a $50 incentive. Participants will not be eligible for the trial.

Eligibility Criteria

Parents will be recruited for pre-testing if they: 1) are between the ages of 18 and 80 years; 2) are parent or legal guardian of at least one child aged 9-13 years; 3) self-identify as Black/African American; 4) able to access personal mobile phone and agree to send/receive MMS messages; 5) agree to participate in a recorded interview; 6) speak and understand English; and 7) able to provide informed consent. We will rely on parent-reported adolescent vaccination status and age.

Modified Delphi Panel

We will create a list of local experts and invite them to participate in modified Delphi surveys and group discussions, including physicians, nurse practitioners, physician assistant, nurses, medical assistants, health care administrators, Vaccine for Children program staff, Immunization Information System staff, or public health researchers whose work relates to adolescent vaccinations. We will leverage relationships with Greater Newark Health Care Coalition, NJ HPV Roundtable, NJ Immunization Coalition, NJ chapter of American Academy of Pediatrics, NJ Primary Care Association, and RWJBarnabas Health pediatric, primary care, and family medicine practices to identify potential participants. We anticipate 3-4 weeks between each round with $50 offered for each round (survey, group discussion, survey).

Eligibility Criteria
Key informants will be recruited for in-depth interviews and feasibility surveys if they: 1) are between the ages of 18 and 80 years; 2) are a physician, nurse practitioner, physician assistant, nurse, medical assistant, health care administrator, Vaccine for Children program staff, Immunization Information System staff, or public health researcher conducing work related to adolescent vaccinations; 3) agree to participate in a recorded group discussion and provide information for survey questionnaires; and 4) speak and understand English; 5) able to provide informed consent.

Randomized Controlled Trial
We will conduct a pilot of a two-arm RCT in one primary care pediatric clinic. We will recruit parents from the participating clinic The research assistant, medical assistants and nursing staff will be trained on screening, inviting and consenting parents to participate in a project to improve satisfaction with care and vaccination delivery at the end of the visit to not prime parents about vaccination. A sub-sample of approximately 15 participants will be recruited for follow-up individual interviews. Participants will receive a $25 electronic gift certificate after enrolling and an additional $25 at completion of the follow-up survey to promote retention.

Eligibility Criteria
Trial participants will be: 1) are between the ages of 18 and 80 years; 2) a parent or legal guardian of at least one child aged 9-13 years who has received 0 or 1 dose of HPV vaccine; 3) identify as Black/African American race; 4) able to access personal mobile phone and agree to send/receive MMS messages; 5) able to speak and understand English and able to provide information for survey questionnaires in English; and 6) able to provide informed consent. Further, participants who engaged in the Aim 1 focus groups or online pretesting are not eligible for the trial.

Key Informant Interviews
We will conduct 12 semi-structured individual interviews with staff and providers at the enrolling primary care clinic to get feedback on protocol and intervention implementation. A $100 incentive will be offered to staff participating in interviews and surveys.

Eligibility Criteria
Interview participants will be: 1) are between the ages of 18 and 80 years; 2) are a physician, nurse practitioner, physician assistant, nurse, medical assistant, or administrator at the enrolling clinic; 3) agree to participate in a recorded interview and provide information for survey questionnaires; and 4) speak and understand English; 5) able to provide informed consent.

b. Study Procedures, Materials, and Potential Risks

Focus Groups and Key Informant Interviews
I will work with collaborators, SAB, and CCHE staff to develop FG moderator and key informant interview guides, as well as consent processes and documents. We will incorporate constructs from WHO's vaccine hesitancy matrix of multilevel influences of vaccine hesitancy and the Increasing Vaccination Model. FG participants will complete a brief intake form to collect parents' sociodemographics and vaccine hesitancy; we will also gather parent-reported information on adolescent age, vaccination status, and age at vaccination (if applicable). FGs guides will include topics on social processes, thoughts and feelings (HPV vaccine confidence, perceived disease risk) drives parents' motivations to vaccinate (or hesitancy to delay/refuse) as well as what factors influence each subgroup's vaccination behavior, including information needs and trusted sources. We will use

live polling and rating/ranking questions to get feedback on visuals/graphics, SMS content and framing. Interview guides will probe issues related to potential feasibility of intervention and trial protocol.

Once a list of potential participants and specific recruitment sites/events are developed, project staff will make initial contact via email, telephone, or in-person to invite them to participate in the study and schedule an in-person discussion for the FGs or interview for key informants. Study staff and participants will review the elements of consent relevant to the minimal risk study prior to beginning FGs or interviews. Verbal permission to participate and record the discussions will be obtained. We will conduct FGs until we reach thematic saturation.

All qualitative data collection will be conducted by Dr. Kohler or CCHE staff from Rutgers Cancer Institute. We will moderate up to 8 FG; they are each expected to take approximately 1.5 hours. We will conduct key informant semi-structured interviews with 12 men and women. The interviews are estimated to take no more than 60 minutes. Interviews and FGs will be audio-recorded. Recordings will be transcribed verbatim and translated as necessary. Transcripts will be managed using ATLAS.ti qualitative data analysis software. Data collection and data synthesis will be guided by our conceptual models and framework and will be based on the interview and FG guides.

Modified Delphi Panel

In the modified Delphi process, we will email an executive summary of the parent FGs and SAB feedback with a Delphi questionnaire for participants to rank feedback on importance and helpfulness of items to be included in the intervention. Participants will use 5-point Likert scales and explain ratings in free text. The PI and CCHE staff will compile and summarize the initial survey results. One group meeting will be scheduled to discuss first round feedback and content, message length, timing of intervention delivery and algorithm logic before a second re-rating questionnaire to reach consensus. We anticipate 3-4 weeks between each round. We use 70% rating in top 2 categories (essential or very important) as consensus. Consensus that an item was not important includes >80% rate in lowest categories. Criteria may change by round; we will add an additional round if consensus is not reached, though the meeting helps avoid additional rounds and respondent burden. We will examine all items not achieving consensus before advancing.

Expected Intervention

Guided by qualitative results, risk communication concepts, and behavior change theory, I will work with collaborators and information technology (IT) consultants to develop a series of text messages with HPV vaccination information to address specific concerns and motivations raised to address hesitancy. At the conclusion of this process, we will produce a prototype to be pre-tested and refined iteratively. We will develop messages to include information based off local information needs (e.g., perceived risk), specific hesitancy concerns (e.g., vaccine safety), and common motivators (e.g., cancer prevention), ensuring that risks and benefits are balanced, trusted sources are referenced, and facts are presented (i.e., content does not focus on dispelling myths). Based on current EMR capacity for R/R, we anticipate developing brief SMS or MMS messages and will tailor (e.g., adolescent's vaccination status, risk, concerns, credible sources) content desired by parents. Depending on formative work, we may alter intervention timing (~2 weeks after initial recommendation) and dose (1, 2, 3 R/R messages).

Pre-testing Session

Project staff will make initial contact via email, telephone, or in-person to invite them to participate in the study. Electronic consent to participate and record the session will be obtained. We will conduct 6-10 individually moderated sessions. We will assess delivery, formatting, and tailored algorithm logic of prototype. Following each session, we will review results and modify the texting program accordingly.

Randomized Controlled Trial

For the trial, we will recruit from one clinic to recruit parents attending routine appointments. Adolescent age and vaccination status will be confirmed by clinic staff in the EMR. Enrolled participants will complete the intake survey sent via email after the appointment, and a follow-up survey will be administered post intervention. Upon enrollment, parents will be randomized to one of two arms: tailored or untailored messages, which will be sent to participants' personal mobile phones dur the study period. Datstat provides data on whether messages were received and viewed, which will be used to assess successful delivery and completion. I will assess acceptability of intervention as well as secondary preliminary outcomes vaccine intentions, confidence and concerns through

self-reported baseline, post intervention survey administered by DatStat. Randomization is built into the survey, so parents and investigators will be blinded by automated processes. We have successfully used DatStat to implement secure and HIPAA-compliant electronic surveys in prior studies. To maximize retention, we will provide a $25 electronic gift certificate after enrolling and an additional $25 at follow-up. We will also send email reminders to complete the surveys. Providers and clinic staff (n~12) will be contacted to complete a semi-structured interview with brief survey questionnaire on implementation process outcomes. Parent participants (n~15) will be purposefully sampled to provide feedback after completing the intervention and provided $50 for completing an interview.

Materials

The sources of research material will include: 1) focus group sessions, recordings, and transcripts; 2) pre-testing online sessions, interviews, recordings and transcripts; 3) web-based self-report surveys; 4) Datstat intervention message tracking; and 5) EMR extracted vaccination status. Data collected through the internet will be obtained through secured means and stored on private servers (see Protections section below). Personal Health Information (PHI) will be stored separately from study data on a different HIPAA compliant server. Only study staff with the requisite IRB-approved Human Subjects Training will have access to participant data on password protected computers.

Potential Risks

The potential risks to human subjects are minimal. For the pre-testing and trial, messages shared or sent are similar in many ways to risks experienced by those who receive CDC Vaccine Information Sheets and IIS appointment R/R outside of a research study. Phone, SMS, and email reminders have become part of standard care for those receiving services at practices using EMR reminder systems. Although tailored follow-up is not part of standard care, we believe the risks would be similar to R/R or other appointment follow-up navigation.

A small group of parents may be strongly opposed to vaccination and react negatively to the discussions and/or intervention, which could also cause stress for other participants, enrolling site staff, and research staff. However, this study is not focused on anti-vaccination and we do not aim to recruit individuals who identify as such. All research staff will be trained to deal with these situations, and every effort will be made to address each participant's concerns or problems in the most supportive and empathic manner.

The staff interviews and surveys, mentioned above, pose minimal risk to staff because the instruments contain minimal personal information. It is possible that someone in the clinic could use information about a respondent's role (e.g., Medical Assistant) to identify that person and his or her responses. For this reason, our study team collects these data, and the data we collect is kept completely confidential and only used by the study team. If data is reported back to the clinic, we will report these data in aggregate so that it is not possible to link an individual to his or her responses. Health care, VFC, and IIS staff members may become distressed discussing their role in counseling extremely hesitant parents as they divulge their personal experiences.

There is a potential risk of loss of confidentiality, but that is protected against by limiting the use of the data to authorized study staff who have been trained in the protection of human subjects, HIPPA, and research integrity. All efforts will be taken to maintain privacy and confidentiality as described below. Also, because this study involves information about the participant's adolescent (age, gender, vaccination status), there are also concerns about the privacy and confidentiality of the adolescent. However, we are not directly recruiting or interacting with adolescents.

2. Adequacy of Protection Against Risks

a. Informed Consent

As stated above, trained research staff members will provide full informed consent about the procedures of the study to all potential participants. The consent form will be written at an 8th grade level and will emphasize that participants may decline to participate or withdraw from the study at any time. They will be assured that their decision to give, withhold, or retract consent will not in any way influence their present or future medical care or employment. The person obtaining consent will answer any questions that potential participants have. All participants will sign the informed consent prior to enrolling in the study. Participants will be given a copy of the

informed consent form. If they have any questions at a later time, they will be told that they can contact the PI. Participants will also be informed that if they have any questions regarding their rights as research participants, they may contact the Office of Research at Rutgers University; telephone numbers will also be on the informed consent form. Original signed copies will be kept in a locked file separate from study data.

b. Protection Against Risks

Several procedures will be implemented to protect against possible risks:

Our Rutgers Cancer Institute Community Cancer Action Board and study-specific SAB will weigh in on the study prior to implementation. Collaborators and clinical and community partners helping to recruit participants will also carefully review study procedures and materials, including contact letters and interventions, and provide feedback. We will incorporate their feedback, revise the materials in such a way to minimize risks and maintain confidentiality.

Because there is potential for discomfort due to the research topic and session content, we will make every effort to create a secure and trustworthy environment prior to conducting study visits. Participants will be reminded often that they may refuse to answer any question and that they may end their participation at any point during the interview. In the unlikely event that a participant experiences considerable distress, they will be offered a referral to services that could be helpful. All staff will receive training for identification and de-escalation of agitated or angry persons and are trained to appropriately evaluate and respond to these circumstances.

Every effort will be made to ensure that confidentiality is maintained. We are aware that data will contain demographic and personal health information, and consistent methods will be employed to protect the confidentiality of these data. This study will use identifiable information to deliver the intervention. Tracking, survey, and intervention data will be securely stored in a study database. A separate analytic dataset will be used including only de-identified variables necessary for the proposed analyses, and results will be reported in aggregate so that individuals are not identified. Study publications or presentations resulting from this research will not identify participants by name but will present only aggregate data.

Data entry and storage systems and procedures are in place at Rutgers Cancer Institute. With IRB approval, all participant demographic and parent-reported data will be stored in the Rutgers Cancer Institute database. These data will be maintained on a secure computing infrastructure behind the institutional firewall certified to store protected health information. We will take consistent measures to protect the confidentiality of these data. All investigators and project staff will be required to complete the online human subjects and good clinical practice training, which is mandated by the IRB. Study IDs will be assigned for individuals who participate to help maintain confidentiality. All identifying data will be stored in secured and password protected files separate from all other research information, which will be identified by study identification number alone. The records and data will be collected for this study following protocols that have been approved by the IRB. A DatStat study database will be hosted at Rutgers Cancer Institute in New Brunswick, NJ, on secure computing servers with secure data entry and submission. The DatStat study database, which includes participant contact and data from all surveys, will be restricted to only those individuals who are authorized to work on the study and have appropriate protection of human subjects' certification. Individual user accounts with passwords will be used to log and restrict access to the database. Specific privilege assignments within the database will also be employed to limit the types of functions that authorized users can perform to those functions that are appropriate for their role in the study. Access to individually identifiable private information about participants will be limited to Dr. Kohler and study team members involved in duties related to direct participant contact. Other research staff not involved directly in recruitment activities (e.g., research analyst) will not have access to identifiable participant or patient information. The use of network firewall technologies should prevent data security problems that include unauthorized internal access to data, external access to data, and malicious intent to destroy data and systems. Controlled user access will ensure that only appropriate and authorized personnel are able to view, access, and modify study data.

c. Vulnerable Subjects

This study focuses on Black families, so parents will all identify as Black/African American/African Caribbean. Black Hispanics are included. For the experts and provider/staff participants, no subject will be excluded from the study based on racial or ethnic origin. Both male and female staff (including pregnant staff) will be included in the study. We anticipate mostly female parents and legal guardians of adolescent patients (including pregnant parents) to enroll. As such, they will be included in analyses. This protocol involves parents of male and female adolescents ages 9 to 13 years. We will not enroll children, neonates, impaired adults, institutionalized individuals, or prisoners in this study. We will not collect information that would identify a woman as pregnant. The study poses minimal risk to pregnant women.

3. Potential Benefits of the Proposed Research to Research Participants and Others

The study may contribute benefits of new scientific knowledge about feasibility of interventions to increase HPV vaccination motivations and address concerns to improve HPV vaccination among Black families. Parent participants may benefit from the HPV information discussed in FGs and parents participating in the trial may benefit from the intervention materials. Staff participants may experience personal satisfaction for their contribution to research aimed at understanding how to address vaccine hesitancy and reduce HPV disparities; however, they will not directly benefit from their participation. The benefits of improving HPV vaccination communication, R/R processes, HPV vaccine motivation, and vaccination behaviors far outweigh the remote possibility of a breach in confidentiality.

4. Importance of the Knowledge to be Gained

The information gained from this study may provide critical information on how to reduce the burden of HPV-related cancer by increasing vaccination. It will also help determine behavioral determinants of HPV vaccine hesitancy, which may be useful to other areas of vaccine hesitancy research. Additionally, this study will help us understand what hesitancy concerns need to be addressed and potential strategies to do so.

DATA AND SAFETY MONITORING PLAN

The safety of participants in the study, including a small pilot randomized control trial of tailored text messages intervention about HPV vaccination, will be monitored directly by Dr. Kohler, the PI, in consultation with collaborators Drs. Jimenez, Greene and Btoush, and an internal Protocol Monitoring Committee. Dr. Kohler will meet with collaborators regularly as part of study team meetings to discuss any ethical issues that arise during the conduct of research. The trial will receive semi-annual reviews and annual internal audit reports by the Protocol Monitoring Committee.

We will utilize the following procedures for the reporting of adverse and serious adverse events to the Rutgers Cancer Institute's Protocol Monitoring Committee, Rutgers University IRB, and NCI as appropriate:

Adverse event assessment
Spontaneous reports by participants, observations by Population Science or Behavior Science research staff, reports to research staff will be investigated. The investigators will assess the relationship of the adverse event as not related, possibly related, or definitely related using standard criteria for clinical trials. Every adverse event will be evaluated by a staff affiliated with the study team and classified as adverse event, unexpected event, or serious (mild, moderate, severe) and reviewed by the PI, Dr. Kohler, in consultation with Drs. Jimenez, Greene and Btoush.

Adverse event definitions

Adverse Event: an undesirable and unintended result of therapy, intervention, or interaction experienced by a subject participating in a research study [adapted from Protecting Human Subjects: Institutional Review Board Guidebook, OPRR 1993, page 4.3].

Unexpected Adverse Event: any adverse event, the specificity, severity, frequency or nature of which is not consistent with the current investigator brochure, general investigational protocol, approved product labeling, or investigational protocol amendments [adapted from 21 CFR 312.32].

Serious Adverse Event: any adverse event that results in any of the following outcomes: death, a life-threatening adverse event, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect. Important medical events that may not result in death, may not be life-threatening, or may not require hospitalization could be considered serious adverse events when, based upon appropriate medical judgment, they may jeopardize the patient or subject.

Adverse event reporting
All serious adverse events must be reported in writing within 7 days of any member of the study team becoming aware of such an event. Unexpected adverse events must be reported in writing within 15 days of any study becoming aware of such an event. All serious and unexpected adverse events will be reported accordingly to NCI and Rutgers IRB guidelines. A copy of the report will be retained with the subject's research records. The investigators will ensure all appropriate resources are directed toward participant safety and well-being.

Additional adverse event monitoring
As adverse event reports are collected, they will be identified and reported to the PI, who is responsible for the review of all adverse event reports and determining whether any changes in the study protocol or informed consent are required to ensure subject safety and welfare. In order to ensure the safety of participants and the integrity of the study, a data safety and monitoring plan will be in put into effect. As part of this plan, all adverse events will be reported through Rutgers Cancer Institute for processing as per established policy. This policy includes specific timelines for reporting events that are stipulated by the Rutgers' Institutional Review Board (IRB). In addition to the IRB, Rutgers Cancer Institute's Protocol Monitoring Committee reviews all adverse events for investigator-initiated trials as they occur.

During regular study meetings, the research staff will address any issues with the research procedures and database, including: 1) recruitment, consent, enrollment and retention; 2) adverse events, serious adverse events, and any unexpected adverse events, even if minor, concluding with the safety procedures used to handle and minimize the occurrence of adverse events; 3) procedures for data collection, data entry, and data storage; 4) intervention implementation, if needed, procedures will be modified to enhance the integrity of the study. All

necessary steps will be taken to maintain subject safety. Any change to the procedures will be forwarded to the IRB for approval.

Data and Safety Monitoring

Prior to initiating this study, the proposed procedures will be reviewed for protection against risks by the Rutgers Health Sciences IRB. In addition, the Scientific Review Board will review the study procedures to ensure their scientific merit, safety, legality, and technical feasibility per established policy. Rutgers Cancer Institute's Protocol Monitoring (i.e., Data and Safety Monitoring) Committee will oversee the validity and integrity of the data by conducting periodic audits of study records. This committee is empowered to suspend or close studies with major deficiencies and provides direction to investigators in the development of corrective action plans to rectify and meet identified deficiencies. As part of the committee's function, accrual is monitored for clinical trials. All clinical trials undergo a semi-annual review at which time accrual figures are reviewed. Specific accrual rates for each trial are required under protocol monitoring policy. Rutgers Cancer Institute employs an internal audit program to address retention of participants, adherence to protocol, and data completeness. This audit program is reviewed and governed by the Protocol Monitoring Committee. All active trials not audited or monitored regularly by an external sponsor undergo a minimum of one internal audit annually. A specific function of the Protocol Monitoring Committee is to review and monitor gender and minority accrual for each study.

Further, the members of the Protocol Monitoring Committee as well as the Biometrics and Population Sciences research staff responsible for Datstat data and biostatistical analyses will oversee the safety monitoring of the study to ensure that the privacy of all participants in the study is protected; ensure that participants' interests are primary, that is, above the interests of the scientific investigation; and to ensure that all data collection is scrutinized for accuracy, privacy, and levels of protection. The committee will perform reviews of the data handling and confidentiality, communicate any breaches in data safety to the administration of Rutgers Cancer Institute Protocol Monitoring Committee and comply with recommendations to resolve such problems, and maintain written communication of the deliberations and recommendations that arise from their meetings. By examining adverse events information, the data and safety monitoring team will stay up-to-date of critical issues regarding recruitment and data integrity. Reports of all data and safety monitoring meetings and recommendations will be provided to the Rutgers IRB and as requested by NCI.

Data Confidentiality

Databases for participant recruitment and tracking, participant survey data, and intervention data will be developed and maintained by the Rutgers Cancer Institute Population Science Research Support Core using HIPAA-compliant DatStat software. Participant study IDs will also be stored in an Oncore database at Rutgers Cancer Institute according to institutional policies. Approval for use of DatStat and Oncore software in research studies has been provided by the Rutgers Health Sciences IRB. The approval process included: obtaining a Technology Professional Service Agreement and a Business Associate Agreement from DatStat and Oncore; the approval of a Third Party Security Questionnaire from the Rutgers Office of Information Technology; and the completion of a Security Risk and Assessment Tool by the Rutgers Cancer Institute Office of Information Technology. No personal identifiers will be stored in Oncore for this study (only subject IDs). These software packages allow for research study personnel to be assigned data access and privileges specific to their role on the study. Online surveys will be completed by participants using a secure website (hosted on DatStat servers) developed and maintained by the Rutgers Cancer Institute Population Science Research Support Core. DatStat secure servers are registered with site certificates provided by AddTrust that provide for advanced encryption over the wire. As each user moves through the survey form, his/her responses are encrypted while in-transit between the browser and DatStat's server using SSL (Secure Sockets Layer) and 40, 56, or 128-bit Public Key Encryption. All servers used for data collection are highly fault-tolerant and equipped with redundant, hot-pluggable power supplies, redundant network interfaces, and RAID 5 hot-swappable disk storage. All primary servers are plugged into a monitored, uninterruptible power supply (UPS). DatStat servers are stored in a locked server cabinet/rack, which are housed in a state-of-the-art, well-ventilated data center. Physical access to servers and data backup is restricted to a minimal number of information technology professionals. The servers are secured with physical and firewall security.

OVERALL STRUCTURE OF THE STUDY TEAM

Dr. Kohler will serve as the PI and project director for the study to develop and pilot the tailored vaccine hesitancy texting intervention and will execute the creation of the intervention as well as manage the project coordination with Rutgers Cancer Institute of New Jersey Population Sciences Shared Resources and Biometrics to oversee all aspects of recruitment, data collection, data management, data analysis, and manuscript development and dissemination. These activities will be done in collaboration with Manuel Jimenez, MD, MS, FAAP, Kathryn Green, PhD, and Rula Btoush, PhD, who will contribute to text intervention design and outcomes assessment (Dr. Jimenez), message framing and processing (Dr. Greene) as well as community and practice considerations of HPV vaccination (Dr. Btoush) throughout the data collection and intervention development.

Dr. Kohler will be supported with staff from Rutgers Cancer Institute resources:

1. Center for Cancer Health Equity will provide additional support with a master's level trained research assistant to assist in developing focus group moderator, Delphi surveys, and interview guides, participant recruitment, data collection, and assistance with focus groups and interviews. Dr. Kohler and the research assistant will conduct interviews and focus groups and manage interview data and transcripts, field notes. This will include ensuring that audio recorded interviews are appropriately transcribed, and that all qualitative data are imported properly into qualitative data analysis software. In addition, he/she will support Dr. Kohler with qualitative data coding and analysis to prepare thematic analysis reports.
2. Population Sciences Shared Resource staff will assist with project management and implementation through Datstat to track study workflow, surveys, randomization and incentive distribution. The Data Quality/Management team in the Population Sciences Shared Resource consists of a director and senior staff manager. They will ensure that study data are complete, accurate and submitted in a timely manner. Team members will review data entries and submissions and query the data as needed, develop and test electronic data collection platforms, and enter study data.
3. Biometrics will provide statistical consultation with a Research Analyst to plan for the trial design, methodology, and analytic aspects of Aims 2 and 3. The Research Analyst will oversee data management, cleaning, finalizing analytic datasets for analyses, and analytic support for model specification.

Section 4 - Protocol Synopsis (Study 1)

4.1. Study Design

4.1.a. Detailed Description

The objectives of this mixed methods study are to create an interactive tailored texting intervention to address determinants of vaccine hesitancy as it relates to HPV vaccination among Black families of adolescents and to pilot test the intervention in a pilot randomized controlled trial (RCT) to determine feasibility and preliminary effect sizes. The content and format of the intervention will be developed in an iterative and collaborative process with a Stakeholder Advisory Board, parents of young adolescents, experts, and the enrolling clinic staff. Guided by Intervention Mapping, we will get input from the Stakeholder Advisory Board, parent focus groups, and a modified Delphi process to develop and refine the intervention content and delivery. We will conduct a two-arm pilot RCT to demonstrate feasibility for a future definitive trial. We will recruit 70 Black parents of adolescents aged 9-13 years from a safety-net clinic and randomize them to receive either the tailored text intervention messages or untailored messages as reminder/ recall after receiving a provider recommendation to vaccinate. The trial will determine feasibility, acceptability, appropriateness, and preliminary effect estimates for vaccine confidence, intentions, and vaccination. Intervention content will target HPV vaccine knowledge (HPV disease prevention), concerns (vaccine safety, side effects), social processes (provider recommendation communication satisfaction, social information sharing), and practical barriers (appointment convenience and others as identified in qualitative data. Semi-structured interviews with participants and clinic staff post-intervention will provide additional implementation and intervention design feedback.

4.1.b. Primary Purpose: Health Services Research

4.1.c. Interventions

Type	Name	Description
Behavioral (e.g., Psychotherapy, Lifestyle Counseling)	Interactive Vaccine Hesitancy Texting	This will be an interactive texting intervention that be sent to participants personal mobile phones. The intervention will include several different text message prompts to help answer questions and provide information regarding HPV vaccination concerns. Message content may educate on HPV prevention, provide advice from a credible information source, ask parents to set goals to make appointments, and offer support to address practical barriers

4.1.d. Study Phase: N/A

Is this an NIH-defined Phase III Clinical Trial? ○ Yes ● No

4.1.e. Intervention Model: Single Group

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	Recruitment	Enrollment	This is a ratio of parents recruited to potential parents approached to participate.
Primary	Retention	Post Intervention	This is a ratio of parents completing post-intervention surveys to the number enrolled.
Primary	Intervention Delivery	2 weeks	This is a ratio of parents receiving HPV message to the number enrolled.

Primary	Intervention Use	2 weeks	This will be an assessment of how often participants opened and interacted with the prompts across the intervention period.
Primary	Intervention response	2 weeks	This will be an assessment of how often participants completed hesitancy questions across the intervention period.
Primary	Intervention Utility	Post-intervention	Perceived ease of use, likeability, helpfulness, impact of texts- Mobile App Rating Scale (8 items, α=0.9).133
Primary	Staff Acceptability	Completion	Assessment of Acceptability of Intervention (4 items, Cronbach's alpha: 0.85).
Primary	Staff Feasibility	Completion	Assessment of Feasibility of Intervention (4 items, Cronbach's alpha: 0.89).
Primary	Staff Appropriateness	Completion	Assessment of Intervention Appropriateness (4 items, Cronbach's alpha: 0.91).
Secondary	Parent Vaccine Intention	Baseline, post-intervention	Assessment of parent intention to vaccinate in next 6 months.
Secondary	Parent General Vaccine Confidence	Baseline, post-intervention	Assessment of benefits of vaccination, harms of vaccination, and trust in health care providers.
Secondary	Vaccination	Completion	Dose documentation and reason for non-vaccination
Secondary	Parent Immunization Attitudes and Beliefs	Baseline, post-intervention	Assessment of harms, effectiveness, and uncertainty adapted from Carolina HPV Immunization Attitudes and Beliefs Scale (10 items).
Secondary	Parent HPV vaccine concerns	2 weeks	Categorical assessment of top concerns about HPV vaccination based on formative data
Secondary	Strength of concern	2 weeks	Strength of main concern (5-point Likert scale)

4.3. Statistical Design and Power — statistical_design.pdf

4.4. Subject Participation Duration — Parent focus groups will be 1.5 hrs. Pretesting session will be 1 hr. Delphi panel experts will complete surveys within 3 months. Trial participation lasts 3 months; medical record review occurs at 8 months. Clinic staff interviews will be 1 hr.

4.5. Will the study use an FDA-regulated intervention? — ❍ Yes ● No

4.5.a. If yes, describe the availability of Investigational Product (IP) and Investigational New Drug (IND)/ Investigational Device Exemption (IDE) status

4.6. Is this an applicable clinical trial under FDAAA? — ❍ Yes ● No

4.7. Dissemination Plan — dissemination.pdf

STATISTICAL DESIGN AND POWER

Design

This is a mixed-method study using qualitative data collection and survey methods. Thus, power calculations and statistical analysis are not relevant for qualitative components. However, here we describe our analytic plans. Digital recordings will be transcribed verbatim and transcripts managed using ATLAS.ti qualitative data analysis software. Independent coding of data will be conducted by Dr. Kohler and Center for Cancer Health Equity (CCHE) staff with discrepancies reviewed at team meetings and resolved through consensus.[134] We will compare and contrast data within and across vaccination behavior subgroups as part of an iterative process of reading, summarizing, and re-reading the data using the five phases of qualitative interpretive analysis described by Miller and Crabtree: [124] 1) The *describing* phase begins with reading data to identify overarching, organizational themes. 2) Themes are used to create a codebook to apply to text, which is then sorted and summarized *using an editing style* to create an organizing scheme for interpretative analysis. 3) The *connecting phase* makes sense of the sorted data, summarizing themes and patterns of each vaccination subgroup. 4) The *corroborating/legitimating* phase uses additional data to confirm or refute initial insights. 5) The *representing the account phase*, shares and refines final findings with our Stakeholder Advisory Board in the form of summaries and visual presentations. To validate the accuracy of our findings, we employ mixed method research best practices[130-132] triangulating data from the focus groups, Delphi ratings and rationale, and pre-testing to develop and refine the intervention.

For the trial, we considered a single-arm study and a quasi-experimental design but elected to conduct a two-arm randomized controlled trial to develop and assess a strategy that will provide valuable information about tailored and untailored text reminder/recall. The sample of 70 parents of adolescents is powered primarily to determine acceptability, feasibility, and exploratory effect sizes for the brief messaging intervention. For Aim 2, feasibility and acceptability will be established through descriptive statistics on recruitment, retention, intervention delivery, use, response, and utility. We will assess undelivered messages, unsolicited user texts (e.g. thank you), requests to stop texts, reasons for not using the intervention as well as usability characteristics among those who use the intervention. The staff's perceptions of feasibility and acceptability will be assessed using validated measures and summarized descriptively and augmented open-ended questions in the follow-up survey (n=12). To evaluate the generalizability of our results, we will compare participants who agree to enroll to those who decline study participation on available demographic variables, noting reasons for nonparticipation. For Aim 3, preliminary effect estimates to be assessed are change in vaccine confidence, HPV vaccination intention, and vaccination. Statistical analyses will include all parents who were enrolled and randomized regardless of level of intervention use. We will calculate descriptive statistics for the sample overall and subgroups of interest, including means and standard deviations for continuous variables, and percentages for categorical variables. We will evaluate correlations between the changes (from baseline to post-intervention) in confidence and intention as continuous outcomes of interest, adjusting for covariates identified in bivariate analyses. We will also assess change in proportion of hesitant from baseline to post-intervention. We will describe changes in strength of main concern to assess whether the tailored intervention had a greater effect and prevalence of endorsed concerns and barriers and conduct exploratory analyses of vaccination and whether specific constructs are associated with the interventions effect.

Power

We used the SWOG Statistical Tools Calculators. We expect 50% of those contacted to enroll in our study. Given current clinic volume estimates for Black families with vaccine age-eligible children, we can estimate a 95% confidence interval for recruitment rate to within 6%. In order to achieve feasibility, anything less than 44% recruitment would be unacceptably low to move to efficacy trial. We conservatively estimate 70% of those recruited to be retained to the end of the study. Thus, we need to recruit around 70 participants so that we retain around 50. Our effect outcome is change in confidence between baseline and post-intervention. Based on the literature, we expect the primary outcome in the control group to be around 2.24 units (SD = 1.08). With a total of 50 participants retained to post-intervention, and two-sided type I error of 0.05, we have 80% power to detect a difference of at least 0.76 units, which would represent increasing to "moderately confident".

DISSEMINATION PLAN

The PI, collaborators, and Rutgers Cancer Institute are committed to collaboration with researchers, medical and public health communities, and other entities for rapid dissemination of findings to inform future research and practice. The PI will disseminate study findings locally through presentations at Rutgers Cancer Institute Community Cancer Action Board meetings, the study specific Stakeholder Advisory Board, clinical and community partner organizations, New Jersey Department of Health - Vaccine Preventable Disease Program as well as the staff at the New Jersey Immunization Information System, state cancer control and vaccine preventable disease meetings and symposia. Formal academic dissemination will occur through national or international conference presentations and peer-reviewed journals. In addition, manuscripts will be submitted to the digital archive of PubMed Central. Through program and center meetings at Rutgers Cancer Institute and working groups at Rutgers School of Public Health, the PI is exposed to local, national, and international researchers and has opportunities to present findings and disseminate work more widely. Given the importance of a community-engaged approach, I will also work with Rutgers Marketing and Communications to involve the lay press via news releases to publicize and disseminate findings.

Working closely with the Rutgers Cancer Institute Office of Human Research Services, the PI will be responsible for handling ClinicalTrials.gov requirements for this project. Dr. Kohler will register the trial prior to enrolling the first subject. Once a record is established, they will verify accuracy of record content, resolve problems, and maintain records, including content update and modifications in accordance with all applicable deadlines established in the Final Rule for Clinical Trials Registration and Results Information Submission (42 CFR § 11.64). The PI will also work with the Protocol Monitoring Committee to ensure aggregate results reporting and adverse event reporting is submitted within one year of the primary completion rate.

Delayed Onset Studies

Delayed Onset Study#	Study Title	Anticipated Clinical Trial?	Justification
The form does not have any delayed onset studies			

RESOURCE SHARING PLAN

Data Sharing Plan

Data sharing is essential to increase reproducibility, transparency, and translation of research into practice, leading to improved health outcomes and further reducing disparities. This trial will be registered on ClinicalTrials.gov and Rutgers Cancer Institute of New Jersey will continue to adhere to NIH Clinical Trials Reporting program requirements. Data generated from the proposed study will be shared through presentations at community scientific meetings and publications in peer reviewed journals. De-identified data, including the intervention, will be available to qualified researchers after the main findings are published in a peer-reviewed journal. All data sharing will comply with local, state, and federal laws and regulations, including HIPAA Privacy and Security Rules.

Sharing Model Organisms
Not applicable

Genome Data Sharing
Not applicable