RESEARCH SCIENTIST DEVELOPMENT AWARD **Federal Award Date:** 05/18/2020

Department of Health and Human Services
National Institutes of Health

NATIONAL CANCER INSTITUTE

Grant Number: 1K01CA237748-01A1
FAIN: K01CA237748

Principal Investigator(s):
Jennifer C Erves, PHILOSOPHY

Project Title: A tailored, health communication intervention for HPV vaccine hesitant families

MR. GAMALIEL L. BALLARD
DIRECTOR/GRANTS MANAGEMENT
MEHARRY MEDICAL COLLEGE
OFFICE OF THE RESEARCH
1005 DR. D.B. TODD JR. BOULEVARD
NASHVILLE, TN 372083501

Award e-mailed to: gballard@mmc.edu

Period Of Performance:
Budget Period: 06/01/2020 – 05/31/2021
Project Period: 06/01/2020 – 05/31/2024

Dear Business Official:

The National Institutes of Health hereby awards a grant in the amount of $134,887 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to MEHARRY MEDICAL COLLEGE 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 grantee when funds are drawn down or otherwise obtained 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 K01CA237748. 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 contact the individual(s) referenced in Section IV.

Sincerely yours,

Kimery Griffin
Grants Management Officer
NATIONAL CANCER INSTITUTE

Additional information follows

SECTION I – AWARD DATA – 1K01CA237748-01A1

Award Calculation (U.S. Dollars)

Salaries and Wages	$76,500
Fringe Benefits	$20,028
Personnel Costs (Subtotal)	$96,528
Other	$28,680
Federal Direct Costs	$125,208
Federal F&A Costs	$9,679
Approved Budget	$134,887
Total Amount of Federal Funds Obligated (Federal Share)	$134,887
TOTAL FEDERAL AWARD AMOUNT	$134,887
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$134,887

SUMMARY TOTALS FOR ALL YEARS		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
1	$134,887	$134,887
2	Future Costs, Recommended	
3		
4		

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

Fiscal Information:

CFDA Name:	Cancer Research Manpower
CFDA Number:	93.398
EIN:	1620488046A1
Document Number:	KCA237748A
PMS Account Type:	P (Subaccount)
Fiscal Year:	2020

IC	CAN	2020	2021	2022	2023
CA	8481720	$134,887	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: BWMB / **OC**: 41033 / **Released**: GRIFFINK 05/11/2020
Award Processed: 05/18/2020 12:16:14 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 1K01CA237748-01A1

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 – TERMS AND CONDITIONS – 1K01CA237748-01A1

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

This award has been assigned the Federal Award Identification Number (FAIN) K01CA237748. 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 Special Terms and Conditions – 1K01CA237748-01A1

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 PAR18-365, "NCI Mentored Research Scientist Development Award to Promote Diversity (K01 - Clinical Trial Required)", NIH Guide to Grants and Contracts, 11/17/17, 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: The clinical trial(s) supported by this award is subject to the plan dated 3/15/19 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: Mentored career award recipients are eligible to receive concurrent support in the last two years of the career award. Concurrent support must be in accordance with : NOT-OD-18-157, "Career Award (K) Policy Update: Concurrent Support from a Mentored K Award and a Research Grant."

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 grantee responsibilities related to the protection of human subjects, which are applicable to and are a term and condition of this award.

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

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

INFORMATION: This award, including the budget and the budget period, has been discussed between Ms. Kimery B. Griffin of the National Cancer Institute and Mr. Gamaliel L. Ballard on 5/7/20.

STAFF CONTACTS

The Grants Management Specialist is responsible for the negotiation, award and administration of this project and for interpretation of Grants Administration policies and provisions. The Program Official is responsible for the scientific, programmatic and technical aspects of this project. These individuals work together in overall project administration. Prior approval requests (signed by an Authorized Organizational Representative) should be submitted in writing to the Grants Management Specialist. Requests may be made via e-mail.

Grants Management Specialist: Kimery Griffin
Email: griffink3@mail.nih.gov **Phone**: (240) 276-6315

Program Official: Mulualem Enyew Tilahun
Email: mulualem.tilahun@nih.gov **Phone**: 240 276 6170

SPREADSHEET SUMMARY
GRANT NUMBER: 1K01CA237748-01A1

INSTITUTION: MEHARRY MEDICAL COLLEGE

Budget	Year 1	Year 2	Year 3	Year 4
Salaries and Wages	$76,500	Future Costs, Recommended		
Fringe Benefits	$20,028			
Personnel Costs (Subtotal)	$96,528			
Other	$28,680			
TOTAL FEDERAL DC	$125,208			
TOTAL FEDERAL F&A	$9,679			
TOTAL COST	$134,887			

Facilities and Administrative Costs	Year 1	Year 2	Year 3	Year 4
F&A Cost Rate 1	8%	Future Costs, Recommended		
F&A Cost Base 1	$120,990			
F&A Costs 1	$9,679			

PI: **Erves, Jennifer C**	Title: A tailored, health communication intervention for HPV vaccine hesitant families	
Received: 03/12/2019	FOA: PAR18-365 Clinical Trial:Required	Council: 10/2019
Competition ID: FORMS-E	FOA Title: NCI Mentored Research Scientist Development Award to Promote Diversity (K01)	
1 K01 CA237748-01A1	Dual:	Accession Number: 4284084
IPF: 5050201	Organization: MEHARRY MEDICAL COLLEGE	
Former Number:	Department: Internal Medicine	
IRG/SRG: NCI-J	AIDS: N	Expedited: N
Subtotal Direct Costs (excludes consortium F&A) Year 1: 125,208 Year 2: Future Costs Year 3: Year 4:	Animals: N Humans: Y Clinical Trial: Y Current HS Code: 30 HESC: N	New Investigator: Early Stage Investigator:
Senior/Key Personnel:	*Organization:*	*Role Category:*
Jennifer Erves Ph.D	MEHARRY MEDICAL COLLEGE	PD/PI
CONSUELO WILKINS	VANDERBILT UNIVERSITY MEDICAL CENTER	Other (Specify)-Primary Mentor
Pamela Hull	Vanderbilt University Medical Center	Other (Specify)-Co Primary Mentor
Amanda Dempsey	University of Colorado	Other (Specify)-Co-Mentor

Appendices

AppendixF

Reference Letters

Nataliya Ivankova	University of Alabama at Birmingham	03/15/2019
Stephania Miller-Hughes	Meharry Medical College	03/12/2019
Laura Forbes	University of Alabama at Birmingham	03/15/2019
Velma Murry	Vanderbilt University	03/15/2019

Additions for Review

Accepted Publication Erves PSM.pdf

OMB Number 4040-0001
Expiration Date 10/31/2019

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
CA237748

b. Agency Routing Number

2. DATE SUBMITTED | **Application Identifier**

c. Previous Grants.gov Tracking Number

5. APPLICANT INFORMATION

Organizational DUNS*: 0414381850000

Legal Name*: MEHARRY MEDICAL COLLEGE
Department: Internal Medicine
Division: School of Medicine
Street1*: MEHARRY MEDICAL COLLEGE
Street2: 1005 Dr. D. B. Todd Jr. Boulevard
City*: NASHVILLE
County: Davidson
State*: TN: Tennessee
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: 372083501

Person to be contacted on matters involving this application
Prefix: Mr. First Name*: Gamaliel Middle Name: L. Last Name*: Ballard Suffix:
Position/Title: Director, Grants Management Office
Street1*: 1005 Dr. D.B. Todd Jr. Blvd.
Street2:
City*: Nashville
County: Davidson
State*: TN: Tennessee
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: 372083501
Phone Number*: 6153276738 Fax Number: 6153276716 Email: gballard@mmc.edu

6. EMPLOYER IDENTIFICATION NUMBER *(EIN) or (TIN)** 1620488046A1

7. TYPE OF APPLICANT* T: Historically Black Colleges and Universities (HBCUs)

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*
A tailored, health communication intervention for HPV vaccine hesitant families

12. PROPOSED PROJECT
Start Date* Ending Date*
12/01/2019 11/30/2023

13. CONGRESSIONAL DISTRICTS OF APPLICANT
TN-005

SF 424 (R&R) APPLICATION FOR FEDERAL ASSISTANCE

14. PROJECT DIRECTOR/PRINCIPAL INVESTIGATOR CONTACT INFORMATION

Prefix: Dr. First Name*: Jennifer Middle Name: C Last Name*: Erves Suffix: Ph.D

Position/Title: Assistant Professor
Organization Name*: MEHARRY MEDICAL COLLEGE
Department: Internal Medicine
Division: School of Medicine
Street1*: 1005 Dr. D.B. Todd Jr Boulevard
Street2:
City*: Nashville
County: Davidson
State*: TN: Tennessee
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: 372083501
Phone Number*: 615-327-5692 Fax Number: Email*: jerves@mmc.edu

15. ESTIMATED PROJECT FUNDING

a. Total Federal Funds Requested*	$519,399.00
b. Total Non-Federal Funds*	$0.00
c. Total Federal & Non-Federal Funds*	$519,399.00
d. Estimated Program Income*	$0.00

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

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

DATE:

b. NO ● PROGRAM IS NOT COVERED BY E.O. 12372; OR

○ PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW

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

● I agree*

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

18. SFLLL or OTHER EXPLANATORY DOCUMENTATION File Name:

19. AUTHORIZED REPRESENTATIVE

Prefix: Dr. First Name*: Maria Middle Name: F. Last Name*: Lima Suffix: Ph.D

Position/Title*: Vice President of Research
Organization Name*: Meharry Medical College
Department: Office of the President
Division: Office for Research
Street1*: 1005 Dr. D.B. Todd Jr. Boulevard
Street2:
City*: Nashville
County: Davidson
State*: TN: Tennessee
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: 372083501
Phone Number*: 6153276407 Fax Number: 6153212933 Email*: mflima@mmc.edu

Signature of Authorized Representative*
Gamaliel Ballard

Date Signed*
03/12/2019

20. PRE-APPLICATION File Name:

21. COVER LETTER ATTACHMENT File Name:Cover_Letter_F.pdf

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

OMB Number: 4040-0010
Expiration Date: 10/31/2019

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:	Meharry Medical College
Duns Number:	0414381850000
Street1*:	1005 Dr. D. B. Todd Jr. Blvd.
Street2:	Department of Internal Medicine
City*:	Nashville
County:	Davidson
State*:	TN: Tennessee
Province:	
Country*:	USA: UNITED STATES
Zip / Postal Code*:	372083501
Project/Performance Site Congressional District*:	TN-005

Additional Location(s) File Name:

Funding Opportunity Number: PAR-18-365. Received Date: 2019-03-12T11:51:54.000-04:00

OMB Number: 4040-0001
Expiration Date: 10/31/2019

RESEARCH & RELATED Other Project Information

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

1.a. If YES to Human Subjects

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

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

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

IRB Approval Date:

Human Subject Assurance Number 00003675

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: Meharry Medical College is a historical black college.

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*	AbstractF.pdf
8. Project Narrative*	ProjectNarrativeF.pdf
9. Bibliography & References Cited	ReferencesF.pdf
10.Facilities & Other Resources	FacilitiesANDResourcesF.pdf
11.Equipment	EquipmentF.pdf
12. Other Attachments	LetterofInstitutionalCertificationF.pdf

Funding Opportunity Number: PAR-18-365. Received Date: 2019-03-12T11:51:54.000-04:00

Abstract

The human papillomavirus (HPV) causes 90% of cervical cancers and is implicated in multiple other cancers. The HPV vaccine can prevent the vast majority of these cancers, but it is underused in adolescents, especially among those within vaccine hesitant (VH) parents. Dr. Erves, an Assistant Professor in Research at Meharry Medical College and Adjunct Assistant Professor at Vanderbilt University, is poised to become a leader in behavioral cancer prevention research. This Mentored Research Scientist Development Award (K01) will complement her in-depth training in public health research methods, statistical analysis, patient centered outcomes research, and community engagement obtained during her doctoral, post-doctoral, and early career experiences. It will provide the training she needs to further her current cancer prevention research program, characterizing preferences and perceived needs of African American adolescents and parents when deciding about HPV vaccination for cancer prevention. Dr. Erves short-term goals are to become proficient in behavioral intervention development, an expert in conducting clinical trials, and knowledgeable of implementation science by engaging in didactic, clinical research training activities; conducting a pilot, randomized clinical trial; submitting an R01 in Year 3 of this award; increasing manuscript publications; and advancing leadership through scientific presentations. Her mentors include highly-qualified experts in community engagement and clinical trials (Dr. Consuelo Wilkins), HPV vaccination and behavioral interventions (Dr. Pamela Hull), and vaccine hesitancy, clinical interventions, and implementation science (Dr. Amanda Dempsey). State-of-the-art facilities and vast resources at Meharry Medical College and Vanderbilt University provide the environment needed to promote her career development, and complete the proposed research successfully. The proposed research is to develop and pilot test a tailored, health communication intervention aimed to increase HPV vaccination among VH parents. The research will add knowledge on how tailored education provided before a doctor's visit can play a role in improving HPV vaccination rates among underserved, VH parents. The study aims to develop a tailored, health communication intervention for HPV VH parents (AIM 1); conduct a pilot study of the intervention and study protocol on a small scale to demonstrate feasibility of a future full-scale randomized control trial (RCT) (AIM 2); and examine acceptability of the protocol and intervention among parents and providers (AIM 3). The proposed research is innovative because no evidence-based health communication interventions target HPV VH parents, and we will use stakeholder engagement throughout this study. The knowledge, experience, and pilot data provided by this award will prepare Dr. Erves to secure subsequent R01 funding to assess the intervention's efficacy in a well-powered RCT and advance her multidisciplinary, research program on behavioral interventions to increase HPV vaccine rates. This award will allow her to establish an independent, long-term career focused more broadly on cancer prevention behaviors.

Public Health Relevance Statement/Project Narrative

Improving HPV vaccine rates among adolescents in vaccine hesitant parents is key to improving HPV vaccine rates among poor, underserved adolescents, a population with a higher incidence of HPV-associated cancers of the cervix, vagina, vulva, penis, and anus. This proposed research is innovative because it provides tailored education prior to the medical visit and applies stakeholder engagement at each stage of the research process. The proposed training and research will prepare the candidate to further the field of cancer prevention behaviors through reducing HPV-associated cancers among underserved populations, while promoting a future career in the broader field of public health oncology.

References

1. Cunningham J, Wilkinson LL, Talbott LL. Human Papilloma Virus Vaccine acceptance among commuter college students:: The role of Health Insurance Coverage. *IJSCH.* 2014;2(4):204-222.
2. Cunningham-Erves J, Talbott LL, O'Neal MR, Ivankova NV, Wallston KA. Development of a Theory-based, Sociocultural Instrument to Assess Black Maternal Intentions to Vaccinate Their Daughters Aged 9 to 12 Against HPV. *J Cancer Educ.* 2015.
3. Cunningham-Erves J, Joosten Y, Bruce MA, et al. Comprehensive strategy for capturing and integrating community input into community research training curricula. *Journal of Clincal and Translational Science.* 2018;2(1):1-7.
4. Cunningham J, Miller ST, Joosten Y, et al. Community-Engaged Strategies to Promote Relevance of Research Capacity-Building Efforts Targeting Community Organizations. *Clin Transl Sci.* 2015;8(5):513-517.
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6. Cunningham J, Wallston KA, Wilkins CH, Hull PC, Miller ST. Development and Psychometric Evaluation of the HPV Clinical Trial Survey for Parents (CTSP-HPV) Using Traditional Survey Development Methods and Community Engagement Principles. *Clin Transl Sci.* 2015;8(6):702-709.
7. Miller ST, Cunningham-Erves J, Akohoue SA. Diabetes Education, Specialty Care, and Self-Care Advice among Obese African American Women with Type 2 Diabetes. *Ethn Dis.* 2016;26(2):229-234.
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10. Centers for Disease Control and Prevention. How many cancers are linked with HPV each year? 2017; https://www.cdc.gov/cancer/hpv/statistics/cases.htm. Accessed January 16, 2018.
11. National Cancer Institute. Accelerating HPV vaccine uptake: Urgency for Action to Prevent Cancer. A report to the President of the United States from the President's Cancer Panel. 2014; http://deainfo.nci.nih.gov/advisory/pcp/annualReports/HPV/PDF/PCP_Annual_Report_2012-2013.pdf.
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14. Gilkey MB, Calo WA, Marciniak MW, Brewer NT. Parents who refuse or delay HPV vaccine: Differences in vaccination behavior, beliefs, and clinical communication preferences. *Hum Vaccin Immunother.* 2017;13(3):680-686.
15. Dorell C, Yankey D, Jeyarajah J, et al. Delay and refusal of human papillomavirus vaccine for girls, national immunization survey-teen, 2010. *Clinical pediatrics.* 2014;53(3):261-269.
16. Perkins RB CJ, Apte G, Vercruysse JL, Sumner JJ, Wal-Haas CL, Rosenquist AW, Pierre-Joseph N. Missed opportunities for HPV vaccination in adolescent girls: A qualitative study. *Pediatrics.* 2014.
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FACILITIES & OTHER RESOURCES

I am currently an Assistant Professor in the Department of Internal Medicine located at Meharry Medical College. I am currently funded under [redacted] Private Support [redacted] Together, the Department of Internal Medicine and the MVA provide administrative support, and [redacted] Pr. Supp. [redacted] provides funding. As part of my current position, I have a multidisciplinary Mentorship Committee that guides my career development. I also have access to the many educational activities and resources that support research available at Meharry Medical College and Vanderbilt University such as research seminars, works-in-progress, and the Vanderbilt Institute for Clinical and Translational Research. Other relevant resources include the Participant Clinical Interactions Resource, The Meharry Translational Research Center, and The MVA.

MEHARRY MEDICAL COLLEGE – Facilities and Resources
Street address: 1005 Dr. D.B. Todd Jr. Blvd.
City, county, state, & ZIP code: Nashville, Davidson, TN 37208
Congressional district:

Meharry Medical College (MMC): is a national leader in health, healthcare and research among minority and underserved populations. Meharry has degreed programs in medicine (MD, MD/PD), dentistry (DDS), and biological sciences (PhD, MSPH). It also has a Masters of Science in Clinical Investigation (MSCI) program, described elsewhere in this application. The biological sciences are represented by 4 basic science departments: Cancer Biology, Immunology, Physiology, and Neuroscience. The Schools of Medicine, Dentistry and Graduate Studies had a total of 802 students in residence in 2013, 91% of whom were underrepresented minorities. In the same year, a total of 235 full-time faculty members served the College, of which 62% were underrepresented minorities.

Meharry's teaching hospital is Nashville General Hospital (NGH), a 127-bed county hospital staffed by Meharry physicians. MMC also serves as the home to The Journal of Health Care for the Poor and Underserved as well as the Robert Wood Johnson Foundation Center for Health Policy at Meharry. MMC's annual research portfolio of ~$60 million largely focuses on basic and translational studies related to health disparities. It has several major Research Centers, including the Women's Health Research Center, the Center for AIDS Health Disparities Research, and the Center for Molecular & Behavioral Neuroscience. A separate facility on campus, the Elam Mental Health Center, has both inpatient and outpatient services, and focuses many of its efforts on mental health and substance abuse.

Office: I have adequate office support, private office, as well as a conference room if meetings need to be held in the Department of Internal Medicine at Meharry Medical College. The office is located in a suite, which is locked unless members of the suite are available. Only the PI has access to her private office. There is a storage space (i.e., locked file cabinet) to store interview transcripts, surveys, and audio recorders. Both are in the George W. Hubbard Hospital, an excellent environment for me to execute the proposed study.
Computer: Meharry Medical College continues a tradition of innovation by offering and maintaining the latest networking technologies to the faculty, staff and students. These include networking services, computer desktop management, server management, client systems integration and support, clinical workstation integration and support, website development, technical procurement services, data security and computer repairs. The IT department also offers staffing and consultation to Meharry departments and a Help Desk. Within the private office, I have one desktop computer, which is connected to the internet through a secure server.
Participant Clinical Interactions Resource (PCIR): The PCIR is located on the fourth floor of the former Hubbard Hospital, and includes rooms for patient waiting, intake and counseling; three examining rooms; a procedures room; a dental suite dedicated to AIDS patients; a staff office, a staff lounge, a records room; and a conference room. The unit also houses a nursing station, a sample processing lab, freezers and refrigerators, for storage of samples or supplies and rooms for biohazardous materials and radioactive materials. The PCIR operates a 2,300 square-foot core laboratory which encompasses (1) a tissue culture laboratory with a class II biosafety cabinet, two CO_2 incubators an inverted scope, and a chemical hood; (2) an instrument room with a Coulter counter, HPLC, autoclave, ultracentrifuge, high temperature oven, nephelometer, spectrophotometer,

ELISA reader, slide maker, lyophilizer, and protein concentrator; and (3) an endocrinology core facility for the assay of gonadal steroids, circulating steroid binding proteins, and other related measures. Dr. John Murray is the PCIR director. This resource has an associate director as well as 3 RNs and several medical technicians to assist clinical and translational researchers. Staff also provide regulatory assistance, and advice regarding recruitment and/or conduct of studies.

Meharry Medical College Library: The Meharry Medical College Library (MMCL) serves as a central repository of information to support the college's missions of providing exemplary healthcare education with a focus on minority and underrepresented students, conducting research that fosters improved health outcomes and the elimination of health disparities, and delivering high-quality patient- and community-oriented health services. The Meharry library is open more than 100 hours a week, with 24-hour electronic access to journals and books. Services include interlibrary loan, information management training, database searching, library orientation, clinical librarian services and information filtering. The "research librarian," who also serves as Assistant Director for Informatics, facilitates the use of technology in support of teaching and learning. The library's Microcomputer Learning Lab provides access to computers and computer training. MMCL's print collection includes essential resources for healthcare scholarship and research, with a focus on health disparities and minority health. Users can locate library holdings via MMCL's online catalog. MMCL also participates in consortium agreements to offer its users interlibrary loan access to print resources not held at Meharry. Targeted training sessions covering MMCL resources are available to users upon request. The library also offers orientation sessions for new students and upon request. The library's electronic classrooms contain 20 networked computers to promote interactive teaching and learning. Library users also have access to 13 computers in the MMCL's computer lab, 13 public access computers throughout the library and five circulating laptop computers for in-library use. Wireless access is enabled throughout all three floors of the library. MMCL staff is available 86 hr/wk during the academic year to assist users with computer applications, databases, and other resources. Additionally, asynchronous assistance is available through two online features within the Digital Library: the "Ask A Librarian" and "The Information Desk." Under the auspices of the library, the Meharry Medical College Archives also collects, preserves, and disseminates information on black medical history and the history of the college.

MMCL Digital Resources: The MMCL is increasingly focusing its collection on electronic resources to maximize the utility and accessibility of information across the campus and from home. MMCL makes over 1,175 electronic journals, 474 books, 245 databases, and 650 web resources available via an integrated digital library. The digital library provides fast access and multiple routes to electronic resources including tools to support evidence-based practice including synthesized topic reviews via UpToDate, a suite of evidence-based medicine Cochrane databases, the differential diagnosis tool DXPlain, eMedicine, a peer-reviewed clinical content repository, InfoRetriever/InfoPOEMs, the wealth of clinical textbooks and journals available in MDConsult and synthesized journal evidence via FirstConsult. The MMCL also provides access to over 70 full-text journals through the Ovid system as well as over 300 clinical and research-focused full-text journals through the ScienceDirect database. StatRef provides users with clinical textbooks including Harrison's Principles of Internal Medicine, Griffith's 5 Minute Clinical Consult, and Current Medical Diagnosis & Treatment. Derm101, a clinical diagnostic tool, provides an online atlas for management of dermatopathology issues plus board review preparation materials. Users can also access health-focused databases such as Health Reference Center and Health and Wellness Resource Center via the Tennessee Electronic Library.

Computing Capability: Meharry Medical College has a variety of networking components and services to support its computing systems. With a ten-megabit Internet connection, a high-speed Internet 2 connection, and a Gigabit Ethernet backbone to all buildings, all students, faculty, and staff have fast access to the internet. Campus-wide, computing systems consist of over 1,000 Pentium desktop computers and over 500 laptop computers. The network operating system for the PC and laptop environment is Windows 7. Approximately 10% of the systems are Mac, AS/400, OpenVMS or UNIX systems; these systems are used for research, specialized computing, clinical computing, and administrative computing. The standard desktop software for all users is Microsoft Office; Microsoft Outlook for e-mail, calendar, tasks, and contact lists; Internet Explorer web browser; Adobe Reader and Acrobat Professional (9.0); and AVG antivirus software. Most of the campus has wireless networking technology installed. This technology, coupled with IP videoconferencing, permits greater flexibility and interactive learning for faculty and students. An Access Grid conferencing system has been installed and Meharry has converted to IP telephones. The Information Technology Division has a staff of 21, housed in the Meharry Computer Center. Included in this staff are Help Desk technicians, programmers, server administrators, network specialists, web administrators, and trainers. SCT Banner is the primary administrative software platform. There are more than 40 Windows 2007 servers operating in the Computer Center, many connected to

Meharry's new Storage Area Network (SAN). The SAN provides a shared storage facility for research, teaching and learning, electronic mail and administrative functions. It also supports secure backup for these functions.
Office of Information Technology (OIT) and Computer Center: The OIT is in the Computer Center, which is a stand-alone, two-story structure located on the north end of Meharry's campus. It has an internal server room that is environmentally adapted to contain campus servers and critical systems. The server room is equipped with a dedicated fire suppression system, primary and backup air conditioning, a 50-KVA uninterruptible power supply, and a 100-KVA generator. The Meharry Life Sciences & Research compute resources consists of 4 HP BL460cG6 Blade Servers. Each of these has 2 Intel Xeon X5670 (2.93GHz/6-core/12MB/95W) processors, and 2 SAS 6G 600 Gigabyte 10K-RPM local disk drives. Each server has 2 Embedded NC532i Dual Port Flex-10 10GbE Multifunction Server Adapters for 10G bit network connectivity. The redundant network interconnect modules are HP Virtual Connect Flex-10 Gigabit Ethernet modules. The Operating System for the Life Science servers is Red Hat Enterprise Linux for High Performance Computing (HPC). The HPC Compute Cluster provides a total of 48 CPU cores with 384 Gigabytes of memory that can be expanded at any time to provide additional compute capacity. The college also maintains a SGI Altix3700 (Altix) super computer cluster with (64) Itanium2 1.5GHz/4MB CPUs and 512GB shared RAM.
Storage for the Life Sciences HPC Cluster is provided as NAS (Network Attached Storage) via the 10 Gigabit network infrastructure of dual 10Gig connections on HP A5800 LAN Swtiches. The NAS storage is a HP X9720 Network Storage System reconfigured with 246TB RAW/192TB Useable, 3-82TB Storage Blocks, 2 Blade Servers (one dedicated as a management server, and two as file serving nodes and configured as a High Availability pair). Network connectivity for the X9720 is provided by redundant HP Virtual Connect Flex-10 10gB Ethernet Modules. The database server for this project will be stored in the computer center.

Robert Wood Johnson Foundation (RWJF) Center for Health Policy at Meharry Medical College

In February 2009, the Robert Wood Johnson Foundation (RWJF) awarded Meharry Medical College a multi-million dollar endowment to establish the Robert Wood Johnson Foundation Center for Health Policy at Meharry Medical College. Meharry is the nation's largest private historically black academic health center, and RWJF is the largest philanthropy devoted solely to improving the health and health care of all Americans. The Center for Health Policy aims to provide leadership in health policy education along with research and reform on national, state, and local levels, while continually supporting Meharry Medical College's historic mission of improving the health and health care of minority and underserved communities.

The mission of the Robert Wood Johnson Foundation (RWJF) Center for Health Policy at Meharry Medical College is to increase the diversity of health policy leaders in the social, behavioral, and health sciences, particularly sociology, economics, and political science, who will one day influence health policy at the national level.

The Center accomplishes its mission through six aims:

- Recruiting and matriculating African American and Hispanic social scientists into the field of Health Policy;
- Developing a strong, collaborative environment that supports health policy education and partnership among faculty, fellows, scholars, and leadership that spans across Meharry Medical College and Vanderbilt University College of Arts and Science;
- Cultivating a thriving academic partnership and culture among faculty, fellows, and visiting scholars at Meharry Medical College and Vanderbilt University;
- Supporting research and scholarly development among faculty, fellows, and scholars;
- Creating a national reputation and image for the RWJF Center for Health Policy at Meharry Medical College, as a leading source for health policy, analysis, and research; and
- Sustaining the RWJF Center for Health Policy by acquiring external funding for research and research infrastructure

Research and Resources at RWJF Center

RWJF Center for Health Policy at Meharry maintains many online resources for those interested in our mission and efforts. We offer an online archive of lectures from our distinguished National Scholars, Scholars-in-Residence, Associates, and others. We also make available online articles and presentations from those

associated with the center, along with conference presentations and professional information regarding educational and career opportunities

RWJF Programs, Scholars, and Fellows

Among its many duties addressing health policy issues, RWJF Center for Health Policy at Meharry Medical College conducts its mission through several programs regarding education, awareness, and professional development in the arena of health policy. Those programs include:

Health Policy Fellows Program
The Health Policy Fellows Program is a prestigious doctoral fellowship program for students with educational and research interests that include health and health policy analysis and research. Vanderbilt University, in collaboration with MMC, accepts qualified applicants to one of their Ph.D. programs in economics, political science, and sociology. Accepted Ph.D. candidates will earn a doctorate degree from Vanderbilt University while participating in additional coursework, seminars and research activities at Meharry Medical College. Fellows will receive five years of funding support including paid tuition, a $32,000 annual stipend, and health insurance.

Health Policy Scholars Program (Certificate in Health Policy)
The Health Policy Scholars Program offers MMC students in the School of Medicine, School of Dentistry, and School of Graduate Studies & Research, who have educational and research interests in health policy and social science research, the opportunity to participate in coursework, seminars and research activities leading to the completion of a Certificate in Health Policy to be awarded in conjunction with the student's declared academic program degree.

Pilot Project Mini-Grant Program
The Pilot Project Mini-Grant Program awards MMC and Vanderbilt University faculty funding for pilot projects relative to health policy that will contribute toward the improvement of minority health and/or the elimination of health disparities. The intent of the funding, in the amount of $20,000-$25,000 for 18 months, is to intensify investigator-initiated research, to attract new investigators to the field and to encourage trans-disciplinary research that will advance health policy and social science research.

Scholars-in-Residence Visiting Professor Program
The Scholars-in-Residence Visiting Professor Program invites nationally-renowned health policy and social science experts to campus to serve as visiting professors who mentor, educate, and train Health Policy Fellows and Scholars, as well as faculty members at MMC and in health policy, analysis, and research.

Health Policy Associates Program
The Health Policy Associates Program is designed to provide MMC and Vanderbilt University faculty with a distinct affiliation and role with the RWJF Center for Health Policy in order to encourage and enhance purpose, training, collegiality, commitment to, and support of health policy and social science research.

Summer Externship Program
The Summer Externship Program is designed for Health Policy Fellows and Scholars to augment the health policy studies that take place in the classroom with experiential, real-world, experience in a policy work environment. The Externs have paid, external, learning opportunities during the summer months at some of the nation's most noted health policy organizations, academic research institutions, and governmental agencies such as the Inter-University Consortium for Political and Social Science Research, National Institutes of Health, National Dental Association, Institute of Medicine, Association of American Medical Colleges as well as a host of others.

Health Policy Professional Development Program
The Health Policy Professional Development Program is intended for Health Policy Fellows and Scholars (and faculty) and provides a variety of training and development opportunities, such as quantitative and qualitative research training, academic writing workshops, etc., for the enhancement of professional and technical skills.

Health Policy Social Events Program
The Health Policy Social Events Program gives Health Policy Fellows and Scholars the opportunity to participate in activities and events to network across disciplines, departments, and institutions, thus promoting collaboration and building mutually beneficial relationships.

Health Policy Alumni Program
The Health Policy Alumni Program provides career development and advancement opportunities in health policy for graduates of the Health Policy Scholars and Fellows Programs and encourages their continued work with the Center on policy initiatives and research

MEHARRY'S RESEARCH CENTERS

Whether in a laboratory or a clinic, looking through a microscope or listening though a stethoscope, Meharry's investigators are translating research into cures.

Center for Women's Health Research (CWHR): This center addresses diseases unique to women, particularly those experienced at higher rates among minority populations. Current and future research studies at the CWHR are in the areas of reproductive health, cardiovascular disease, HIV/AIDS, breast cancer, and social and environmental factors in women's health, as well as health care access and quality.

Center for AIDS Health Disparities Research (CAHDR): This center engages in research that unravels the biology of HIV/AIDS as well as seeks remedies for the populations most affected. The CAHDR has three major areas of focus: biology, behavioral, and community outreach. Researchers at the CAHDR study new mechanisms of HIV infection, pathogenesis, immunity, and development of novel means for intervention. The members of the center include scientists, MD clinicians and DDSs from the three schools of Meharry who are working on various aspects of HIV/AIDS with the goal to eliminate health disparities. The CAHDR members hold faculty appointments in the Departments of Internal Medicine, Microbiology and Immunology, Biochemistry and Cancer Biology, Oral Biology and in the School of Graduate Studies. The CAHDR faculty members are members of the TN CFAR, a partnership between Vanderbilt University, Meharry Medical College, and the TN Department of Health, which is aimed to have a transformative impact locally, nationally and globally to reduce the burden of HIV/AIDS.

The Meharry Translational Research Center (MeTRC): The center is involved in research, training and collaborations through the translational research infrastructure that serves as an incubator for Meharry scientists conducting translational research. MeTRC's scientists are focused on advancing research and health care related to diseases and disorders that disproportionately impact underrepresented minority populations. MeTRC is currently funded by U54 grant from NIMHD. During the first cycle of NIH funding, MeTRC's investigators were engaged in translational research at the T1/T2 levels. In the current (second cycle funding) the overreaching goal of the center is to enhance clinical translational research on health disparities by promoting the T2/T3/T4 levels of translational research continuum. The center has 12 Key Activity Functions/Cores for supporting translational research. The center nurtures collaborations among Meharry's investigators as well as foster establishment of partnerships between Meharry's investigators and outside investigators. The center has strong collaborations with the Vanderbilt CTSA through which Meharry's population-based investigators have access to the Community Engagement Research Core (CERC). This center will assist in my transition into an independent researcher, and long-term career development.

Center for Molecular and Behavioral Neuroscience: This center focuses on understanding the brain's circuitry/chemistry as it relates to human behavior and thereby treating dementia, Parkinson's, addictions, and other psycho-social disorders. The mission of the Center for Molecular and Behavioral Neuroscience is to conduct research in all phases—basic, translational, clinical, social, and behavioral—that will generate new knowledge and perhaps reduce health disparities in neurological disease and mental health

PERTINENT RESOURCES AVAILABLE THROUGH JOINT EFFORTS OF VANDERBILT/ MEHARRY
Meharry-Vanderbilt Alliance (MVA, 1999-present). The Alliance was created in 1999 by an MOU signed by the then President Maupin of MMC and the then VC of Health Affairs Dr. Jacobson at Vanderbilt U Medical

Center (VUMC); it continues to be supported by the current leaders at Meharry and VUMC, President Dr. James Hildreth and VC of Health Affairs Dr. Jeff Balser, respectively. The MVA administrative offices are located on Meharry's campus; Dr. Consuelo Wilkins (primary mentor) recently took over as Executive Director of the MVA, a post previously held by Dr. Clifton Meador. The MVA was created to facilitate collaborative working relationships between clinicians, researchers and students on both campuses, thereby enhancing the range and diversity of healthcare delivery services, research endeavors and educational opportunities that each institution is able to provide. In practical terms, this effort has opened libraries and research cores to users on both campuses, courses and clerkships to students, and resulted in multiple joint research and research training activities. Some examples of resources associated with joint grants are given below.

The Community Outreach and Health Disparities Core (COHDC): This core is at Meharry (Margaret Hargreaves, PhD, Director), but exists as a joint effort of the Center for Diabetes Translational Research (CDTR) at VUMC, Tom A. Elasy, MD, PI (5P30DK092986-02). The purpose of the core is to provide Meharry with its own resources for the advancement of local translational research projects related to diabetes. The core has 3 aims: create effective investigator-community based research teams; help develop and evaluate community-based interventions; and to evaluate projects through process and outcomes data using appropriate measurement tools. It has several service components including a CBPR unit that will help develop research teams and protocols, a behavioral intervention unit that will advise on the conduct, clinical management (including the promotion of adherence) and an assessment and evaluation unit (including assistance with surveys and community needs assessments).

The Vanderbilt Institute for Clinical & Translational Research (VICTR). This Vanderbilt / Meharry CTSA award (2UL1TR000445-06, Gordon R. Bernard, MD, PI) has Meharry as a collaborating partner (Duane Smoot, MD, Meharry PI of record). Resources available to both Vanderbilt & Meharry faculty (and students as appropriate) include the following:

- *Studios.* On a rolling basis, investigators can arrange to meet with a small group of separate experts at Vanderbilt who will help with: Hypothesis generation, Study design, Implementation, Analysis & interpretation, Translation, and Manuscript development.

- *Mock Study Section pre-review of to-be submitted R01s and if time permits, K awards*. This occurs 3x/yr about 1 month prior to regular grant deadlines. The expert mock study section provides written comments in the same format provided by a regular NIH study section. This allows investigators an opportunity to improve their grants prior to submission.

- *REDCap.* This user-friendly Research Electronic Data Capture software provides a secure program for data entry and management for teams involved in collaborative clinical and translational research.

- *REDCap Survey.* A similar program for the entry of data or information collected directly from research subjects. Both software products include full audit-trails in compliance with HIPPA security requirements.

- *Vouchers.* To facilitate the ability to obtain preliminary data for translational research grants, vouchers are available ($2K max) to purchase core resources and/or supplies. Both faculty & students may apply.

- *Community Engagement Research Core (CERC) and Community Review Board.* CERC can provide consultative assistance with study design and implementation, data collection/analyses, translation and dissemination of findings. The Review Board will help provide buy-in from community stakeholders.

- *CRC.* For those clinical research projects requiring space, hospitalization costs, equipment, laboratories and supplies, the CRC also has outpatient procedure rooms as well as special procedure capabilities, such as a bionutrition unit with a metabolic kitchen.

- *Synthetic Derivative (SD) Database.* This database contains de-identified clinical information from Vanderbilt's EMR, labeled with a unique ID that is no longer linked to the EMR. The SD can be used alone, or in conjunction with the VU DNA Databank to identify patient sets for genome-phenome analyses. Use of the SD requires IRB approval.

MEHARRY COMMUNITY WELLNESS CENTER

The Meharry Community Wellness Center includes a wide range of early intervention services and focuses on expanding access to and retention into high quality care, reducing health disparities, and improving health outcomes. The target population (African Americans in north Nashville) are characterized by high rates of non-insurance (43%), poverty (87.5%), incarceration (20%), low education (86%), and family breakdown (85%). Among HIV/AIDS clients seen at MCWC, the primary mode of transmission is heterosexual contact (56%) but the MSM category is increasing (23%). The primary goals of this program are 1) to reduce the rate of HIV/AIDS and 2) to improve the health outcomes of low-income and medically underserved African Americans living with HIV/AIDS primarily in North Nashville. The Center is a Ryan White Part C outpatient EIS program administered by Vladimir Berthaud, M.D., M.P.H., F.A.C.P., vberthaud@mmc.edu.

Meharry - Clinical and Translational Research Center (CTRC)
Supported by NIH U54
Leader: John J. Murray, MD, PhD

Building upon successes, the Clinical and Translational Research Center (CTRC) represents an expansion and an evolution of the Meharry Medical College's GCRC and PCIR model predecessors in providing an environment that promotes participation in and facilitates clinical and translational research by serving as the anchor of the clinical and translational research program at Meharry. To this end, the CTRC not only encompasses the physical space, personnel, equipment, and facilities within Meharry, but also reaches beyond the institution to support community research. It seeks to provide cost-effective resources where the scientific effort to understand health and disease converges with direct participant contact. The CTRC has been built on the mission to promote the advancement of clinical research and improve the health and welfare of disadvantaged and minority populations through participation in clinical studies and to promote an environment that encourages, stimulates, and attracts clinical research by providing leadership and support for conducting clinical and translational research.

CTRC Function:

- promote participation of underrepresented minorities in clinical research protocols;
- offer resources with plans for prioritization, readily available, well managed, and tracked;
- ensure that all studies utilizing these resources will meet the highest standards for quality of science, statistical rigor, ethical evaluation, robust design, participant safety, and strict implementation, analysis and reporting;
- implement and maintain Good Clinical Practices;
- address under-utilization and poor performance;
- anticipate and respond to the changing needs of the clinical and translational research communities;
- evaluate studies to justify an investigator's continued access to resources;
- recover costs from funded investigators, where appropriate.
- Enhance institutional and translational research infrastructure, capacity, and accountability
- Provide an outpatient clinical and translational research environment that fosters the participation of underrepresented minorities
- Foster intra-institutional and inter-institutional collaborations to increase the capacity to improve minority health and address minority health disparities.

The purpose of the CTRC is to provide the resources necessary to facilitate clinical research in a minority academic setting by expanding existing programs, nurturing new investigators, and encouraging full utilization of its services. This CTRC provides an environment that promotes participation in outpatient clinical and translational research, community outreach that fosters participation of underrepresented minorities, and in addition to providing resources for cost-effective research participant interactions.

MEHARRY INVESTIGATORS HAVE ACCESS TO ALL FACILITIES AND RESOURCES AT VANDERBILT UNIVERSITY THROUGH THE VANDERBILT- MEHARRY ALLIANCE.

VANDERBILT UNIVERSITY – Facilities and Resources
Street address: 2201 West End Ave.
City, county, state, & ZIP code: Nashville, Davidson, TN 37235
Congressional district:

Vanderbilt University
Vanderbilt University is an independent, privately supported university founded in 1873. The authority of the University resides in a self-perpetuating Board of Trust, and the Chief Executive Officer of the University is Chancellor Nicholas Zeppos. It is a private, independent university located on a 330-acre campus near downtown Nashville, TN, a metropolitan area with a population of over 1,000,000. There are 12,724 students and 4,417 full-time faculty in the 10 schools: College of Arts and Sciences, Blair School of Music, Divinity School, School of Engineering, School of Law, Owen School of Management, Peabody College of Education, Graduate School, School of Medicine, and School of Nursing. As a hub of the mid-south, some 40% of the United States population resides within 500 miles of Nashville. Government agencies, health care facilities, and institutions of higher education contribute a substantial portion to the city's economic base. These facilities, in combination with major manufacturing installations, multiple culture opportunities, and an extensive freeway system create an excellent environment for faculty and students. The computer and infrastructure resources at Vanderbilt are complex enough to support the various missions, including advanced research applications. The mission of Vanderbilt University is to be a leader in the quest for knowledge, in the dissemination of knowledge through teaching and outreach, and in creative experimentation with ideas and concepts. As a center for scholarly research, teaching, and service to the community and society, Vanderbilt values intellectual freedom that supports inquiry, equality, compassion, and excellence in all endeavors. Vanderbilt has hospitals, clinics, physician practices and affiliates in 172 countries.

Vanderbilt University Medical Center (VUMC)
Vanderbilt University Medical Center has built a strong reputation as a leader in medical education, research and patient care throughout the Southeast and the nation over the course of its history. At its heart the Vanderbilt Medical Center is driven by discovery and the immediate incorporation of new knowledge into innovation in patient care and physician and nurse education. Vanderbilt affiliations include 9 hospital systems and 48 hospital locations. Through the Vanderbilt Health Affiliated Network the reach expands throughout Tennessee to parts of Mississippi, Arkansas, Missouri, Kentucky and regions of North Carolina and Virginia.

The School of Medicine began as the University of Nashville in 1850, approximately 23 years before Vanderbilt University was established. The Medical School affiliated with Vanderbilt in 1874 and awarded the first Vanderbilt medical degrees in 1875. Since that time, a Vanderbilt medical education has been held in high esteem among its peer institutions; the current dean is Dr. Jeffrey R. Balser. The mission of the School of Medicine is to matriculate a diverse group of academically exceptional students whose attributes and accomplishments suggest that they will be future leaders and/or scholars in medicine. The School of Medicine placed 15th among 146 medical schools in U.S. News & World Report's 2011 survey, "America's Best Graduate Schools." VUMC was recently ranked the best hospital in Tennessee from the 2014 US News and World Report and is nationally ranked in six specialties.

As an integral member of the University, the Medical Center assists in financially supporting university-wide programs. VUMC is located on the campus of Vanderbilt University and consists of the School of Medicine, the School of Nursing, and the 834 bed Vanderbilt University Hospital, which includes the Vanderbilt Psychiatric Hospital and the Vanderbilt Stallworth Rehabilitation Hospital. The 271 bed Children's Hospital, Monroe Carell Jr. Children's Hospital, was opened January 1, 2004 with state-of-the-art treatment facilities for ill children and their families. The School of Medicine has a student enrollment of 630 and VUMC employees 19,600 staff and faculty, and has been awarded $616 million in research funds annually.

The Vanderbilt campus is composed of 300 acres and was designated as a national arboretum in 1988. Buildings on the original campus date to 1873, the year Vanderbilt was founded, and the Peabody section of campus has been a registered historic landmark since 1966. Vanderbilt University Medical Center is located between the undergraduate and Peabody campuses and has approximately 7.2 million square feet of building space. The close proximity of Vanderbilt University and Vanderbilt Medical Center promotes interactions, sharing of resources, and collaboration.

Institute of Medicine and Public Health
The Vanderbilt Institute of Medicine & Public Health, under the leadership of director Dr. Robert Dittus and deputy director Dr. Katherine E. Hartman, is another important resource. The mission of the institute is to improve personal and public health through discovery, training and service programs designed to protect against threats to health, promote healthier living, improve the quality of health services and prepare leaders to advance health and health care. The institute, which emerged from the medical center's new strategic plan to strengthen its research enterprise, will be an umbrella organization, coordinating and supporting rapidly growing areas of epidemiology, health services research and behavioral health research. It will provide structure and support for recruiting and strategic efforts encompassing nearly 30 percent of the Medical Center's research strategic plan. The Institute provides important access to research space, statistical support, database management, & other resources.

Vanderbilt Center for Health Services Research
The Vanderbilt Center for Health Services Research was formally created in 2000 under the leadership of Robert Dittus, Dr. Russell Rothman, is the current Director. The Center currently has more than 100 faculty members with more than $150 million in total awarded funding. The Center has an overall program emphasis on improving healthcare outcomes. Research is conducted in several programs: (1) Clinical epidemiology and biostatistics, (2) Clinical Improvement and operations research, (3) Clinical economics and decision science, (4) Behavioral medicine, (5) Health policy, and (6) Chronic disease and molecular epidemiology. Center faculty members have methodological expertise and experience in each of these disciplines.

Comprising more than 40,000 square feet of space on the sixth floor of Medical Center East, the VA Medical Center, and 2525 West End, the space provides the ideal environment within which research can flourish. The Center houses a portion of the HSR faculty and their affiliated research staff. A large conference room holds research seminars, journal clubs, and work-in-progress meetings. Smaller conference rooms are designed for small group research meetings. A break room provides an opportunity for investigators to gather over lunch and discuss their work. All offices are connected to the central information center providing quick access to the Internet, library resources, and electronic mail system. A central computer server is supported within the center, as are statisticians, programmers and administrative support.

Qualitative Research Core: The Qualitative Research Core directed by Dr. David Schlundt (Collaborator) is a new resource provided through the Center for Health Services Research that offers consultative services to support investigators planning to conduct qualitative studies. Assistance is available for design, implementation and analysis. Services relevant to the current proposal include conducting of qualitative interviewers, recording of interviews, consultation on coding data, coding and thematic analysis. We will use this core to transcribe and code our qualitative data.

The Vanderbilt Institute for Clinical & Translational Research (VICTR):
The Vanderbilt CTSA award (2UL1TR000445-06, Gordon R. Bernard, MD, PI) has Meharry as a collaborating partner. One of the primary goals of VICTR and CTSAs as a whole is to provide resources to clinical and translational researchers to support their research. Resources available to both Vanderbilt & Meharry faculty (and students as appropriate) include the following:

- Studios. On a rolling basis, investigators can arrange to meet with a small group of separate experts at Vanderbilt who will help with: Hypothesis generation, Study design, Implementation, Analysis & interpretation, Translation, and Manuscript development.
- Mock Study Section pre-review of to-be submitted R01s and if time permits, K awards. This occurs 3x/yr about 1 month prior to regular grant deadlines. The expert mock study section proivdes written comments in the same format provided by a regular NIH study section. This allows investigators an opportunity to improve their grants prior to submission.
- REDCap. This user-friendly Research Electronic Data Capture software provides a secure program for data entry and management for teams involved in collaborative clinical and translational research. *We will use REDcap as our primary database for this project.*
- REDCap Survey. A similar program for the entry of data or information collected directly from research subjects. Both software products include full audit-trails in compliance with HIPPA security requirements. *We will use REDcap to collect quantitative survey data for this project.*

- Vouchers. To facilitate the ability to obtain preliminary data for translational research grants, vouchers are available ($2K max) to purchase core resources and/or supplies. Both faculty & students may apply.
  Clinical Research Center (CRC). For those clinical research projects requiring space, hospitalization costs, equipment, laboratories and supplies. The CRC also has outpatient procedure rooms as well as special procedure capabilities, such as a bionutrition unit with a metabolic kitchen. For this project, the CRC provides training opportunities, professional support, and informatics tools/applications including weekly Research Skills Workshops and the Elliot Newman Society, which I currently attend now for career development purposes.
    - Research-Skills Workshops: The weekly CRC Research-Skills Workshops offer basic instruction and practical advice on commonly encountered clinical research topics. Sessions are typically demonstration oriented and provide an informal setting to learn new skills. Sessions are available at no charge and are available to anyone without registration.
    - The Elliot Newman Society is a professional organization for all physician-scientists and Ph.D. scientists supported by career development awards. Society members meet annually with the Associate Dean for Clinical and Translational Scientist Development to review the scholar's career and mentorship plan. In addition, this society provides a career development lecture series tailored to junior investigators and a forum for peer support.
- Synthetic Derivative (SD) Database. This database contains de-identified clinical information from Vanderbilt's EMR, labeled with a unique ID that is no longer linked to the EMR. The SD can be used alone, or in conjunction with the VU DNA Databank to identify patient sets for genome- phenome analyses. Use of the SD requires IRB approval.
- ResearchMatch (RM) is a disease-neutral, national participant recruitment and engagement platform serving over 73,000 volunteers across all 50 states. To date, volunteer activity records show that 51.3% of volunteers contacted have responded "yes" to a study invitation and been matched with a research team. The volunteer population is currently growing at an average of 70 new participants each day, or over 25,500 each year. Approximately 11% are African Americans and 7% are Latinos/Hispanics. We will use RM to recruit for this study.

The Meharry-Vanderbilt Community Engaged Research Core (CERC): The Community Engaged Research Core (CERC), a focused partnership between Meharry Medical College and the Vanderbilt University Medical Center, brings academic and community partners together to improve community health and healthcare through research. CERC shapes and supports innovative and translational community-engaged research by preparing scientists to impact the public's health; energizing communities to engage in research, and build transformative strategies and structures to support academic-community partnerships.

CERC is directed by *Consuelo H. Wilkins, the Primary Mentor for this proposal*. With input from community partners and academics, CERC has developed infrastructure to create and sustain community engaged research partnerships. CERC consists of a diverse team of faculty and staff, and an advisory council (including community health centers, public health, non-profit service providers, faith-based organizations, and grassroots community coalitions) with considerable experience in Community Engaged Research (CEnR). The services currently offered by CERC include:

- Expert Consultation offered for all phases of CEnR, including refining research questions, optimizing recruitment, developing research protocols that work in community settings, appropriate methodologies.
- Mini-grants. Awards up to $10,000 to support activities that promote development of academic- community research partnerships.
- Website and Newsletter: www.communityresearchpartners.net helps community organizations and academics connect with potential partners who share research interests. Community ResearchPartners eNews is an electronic newsletter with local, regional and national news of interest to CEnR partners. The biweekly newsletter currently reaches over 600 academic and community members.
- Monthly Works in Progress Meetings provide a public forum to showcase academic-community

research partnerships; share information about on-going academic-community research; learn about resources to support community-engaged research, and network.

- Professional Development Studios prepare junior investigators to maximize the benefits of the Translational Research Studios. The Translational Research Studios are intended to enhance research quality; improve funding success; foster advances in clinical practice and improvements in health, healthcare and community practice; increase publications; and generate new hypotheses.
  Professional Development Studios are structured guidance sessions in which faculty advisors engage the junior researcher in a dialogue to develop a research conceptual model, articulate research questions and highlight potential pitfalls and barriers to the identified scope of research. Four modules are offered to clarify research emphasis: Career development, Idea refinement, Research question development and Preparing for a Studio. The service is available to junior faculty at Meharry, TSU, Fisk, and Vanderbilt.
- Qualitative Research Core provides assistance with qualitative data collection and analysis.
- Training is offered to researchers and community members on community engaged research topics such as ethics, building sustainable partnerships, conducting focus groups, and translating evidence
  into policy. Training modules are available live or online.
- State Health Report Cards are produced annually in partnership with state and local government, academic groups and the community. These reports grade health indicators for specific groups (men, women), and offer an assessment of leading causes of death, modifiable risk behaviors and barriers to health.
- Community Engagement Studios (CES) provides a structured forum for academic researchers to gain valuable patient or community insight on their research and has the potential to transform the way community and academic investigators work together. In a CES, members of the researcher's population of interest serve as experts. The researcher gives a brief presentation about the research project and poses specific questions to the community experts. The discussion is guided by a neutral facilitator to elicit honest and constructive feedback. To optimize community participation, CES sessions are scheduled at a time and location convenient to community experts, and the community experts are compensated for their time. Feedback from researchers and community members who have participated in past CESs indicates that the experience increases the researcher's understanding of, and sensitivity to, the community and creates an awareness of community priorities and needs and provides an opportunity to build a relationship with community partners and deepen the understanding of the community of interest. CESs also provide immersion into the community's cultural nuances and possible historical issues, allows researchers to assess the feasibility and appropriateness of the project for the community, and gets buy-in from key community stakeholders. For researchers who do not have experience engaging community stakeholders in this process can open the door to a more participatory approach to their work. We will use these studios to gain feedback from parents to inform this intervention research in this proposal.

Vanderbilt AHRQ Effective Health Care Program: In 2003, AHRQ's Effective Health Care Program was created from the Medicare Prescription Drug Improvement and Modernization Act (MMA), which authorizes AHRQ to conduct and support research with a focus on comparing the outcomes and effectiveness of different treatments and clinical approaches as well as communicate its findings widely to a variety of audiences. In doing so, the Effective Health Care Program partners with designated networks of researchers and clinical teams, through the DEcIDE Network(Developing Evidence to Inform Decisions about Effectiveness), the Evidence-based Practice Centers (EPCs) and the Centers for Education & Research on Therapeutics (CERTs). Participation in each of these research networks is extremely competitive, and Vanderbilt is privileged to be one of only a few institutions that have been funded to participate in all three.

1. **Vanderbilt DEcIDE (Developing Evidence to Inform Decisions about Effectiveness):** AHRQ recently funded a new network of 14 Developing Evidence to Inform Decisions about Effectiveness research centers (referred to as DEcIDE) to carry out accelerated studies, including research aimed at filling knowledge gaps about treatment effectiveness. Operating under strict procedures to guarantee privacy and security, DEcIDE centers use de-identified data available through insurers, health plans and

other partner organizations to answer questions about the use, benefits and risks of medications and other therapies. Collectively, the DEcIDE centers have access to de-identified medical data for millions of patients, including Medicare's 42 million beneficiaries. The DEcIDE network assists health care providers, patients, and policymakers seeking unbiased information about the outcomes, clinical effectiveness, safety, and appropriateness of health care items and services, particularly prescription medications and medical devices. The Vanderbilt site of the DecIDE network, led by Dr. Marie Griffin, includes a diverse range of health services researchers, epidemiologists, biostatisticians, and physician-scientists investigating the effectiveness of therapeutics. The focus of the Vanderbilt DEcIDE is the study of comparative effectiveness of treatment for chronic illness in the Tennessee Medicaid population and in the veteran population both in the Southeast and nationally. The Vanderbilt DEcIDE is currently conducting a series of analyses to fully understand the effectiveness and drivers of effectiveness of oral anti-diabetic medications. Vanderbilt investigators will determine whether choice of initial antidiabetic drug influences long-term health outcomes, including cardiovascular disease and kidney function. They also study the factors including specific drug choice associated with adherence and persistence to medication use, and the effect of persistence on outcomes of interest. A focus on methods for comparative effectiveness research is also a priority.

2. **Vanderbilt Evidence Based Practice Center (EPC)**: The Vanderbilt Evidence-based Practice Center is one of fourteen centers in the United States and Canada funded by the AHRQ to conduct systematic evidence reviews and produce technical briefs on a variety of clinical topics and therapies of high importance to patients and providers. In particular, this work is intended to provide evidence where there is clinical uncertainty and to suggest directions in future research. Dr. Melissa McPheeters, PhD, MPH, is Director of the EPC, and also leads stakeholder engagement and dissemination efforts for the Vanderbilt DEcIDE site. Dr. Katherine Hartmann, MD, PhD, is the founding Co-Director and a Senior Fellow of the EPC and also serves as Deputy Director of Vanderbilt's Institute for Medicine and Public Health. The core staff members of the EPC have been involved in systematic reviews and comparative effectiveness research for more than a decade, both within and outside of AHRQ's Effective Healthcare Program. They successfully competed in 2007 to be designated an EPC, and since then have expanded the Center to involve more than 30 faculty members, 13 staff and eight trainees. The leadership team has more than 3 decades of total methodologic expertise in the conduct of systematic reviews, particularly in new and emerging technologies. The program offers resources and hands-on opportunities to learn the conduct of systematic evidence reviews and meta-analyses. The program's projects provide patients, clinicians, and policy makers with high-quality evidence to inform their healthcare decision making. The program also has significant experience in stakeholder development and dissemination of scientific findings. They have also been key participants in methods groups across the EPC program, developing and disseminating advancing methods for comparative effectiveness research. They regularly engage national and international stakeholders in the development of future research recommendation documents intended to provide guidance and support in particular to emerging and evolving fields of research. Recent reviews have garnered substantial interest from lay, clinical and policy arenas and the staff are frequently invited to present their work to policy making bodies at state, federal and local levels.

3. **Vanderbilt Center for Education and Research on Therapeutics (CERT)**: The CERTs work to translate clinical research advances into better clinical practice by conducting "research and provider education that will advance the optimal use of drugs, medical devices, and biological products". To achieve that mission, three key threats to optimal therapeutics are addressed: (1)Gaps in the therapeutics knowledge base that impede rational clinical decision-making;(2) Suboptimal provider practices that do not reflect the best available evidence; and (3) Counterproductive policies that pose barriers to appropriate clinical decisions. Certain populations are particularly vulnerable to suboptimal therapeutics as the result of intrinsic sensitivity to drug effects, under-representation in traditional research studies, or elevated burden of disease. These populations include the developing fetus, children and adolescents, minorities, persons with mental illness, persons with serious chronic diseases or who use multiple medications, and older patients. The theme of the Vanderbilt CERT is Promoting Optimal Pharmacotherapy in Medicaid and Veterans' Health Administration Populations.

Vanderbilt Center for Health Services Research: (See page 2 of Vanderbilt Facilities and Resources)

Program on Effective Health Communication: Dr. Russell Rothman serves as the Director of the Vanderbilt Program on Effective Health Communication. The Program encompasses research, education, and practice in a number of fields that relate to health communication. These include health literacy, numeracy, risk communication, medical decision making, patient centered communication, cross-cultural communication, and limited English proficiency. As Director, Dr. Rothman has access to a multidisciplinary group of researchers including physicians, nurses, health and social psychologists, education researchers, nutritionists, health educators, and biostatisticians.

Vanderbilt Department of Biomedical Informatics (DBMI): Vanderbilt's DBMI is the largest academic department of biomedical informatics in the country, with more than 65 faculty members, a graduate training program, and a portfolio of research and development projects that spans from computational biology and bioinformatics applied to the understanding of biological molecules, through advanced clinical information systems that care for hundreds of thousands of patients at Vanderbilt, to regional health information projects that span many states.

The Vanderbilt Informatics Center: Unique among academic health centers, Vanderbilt University Medical Center entrusts its Informatics Center with the responsibility for: a) providing the essential information infrastructure for patient care, management, research and education — including the support for informatics-related research and education in clinical informatics and the emerging field of bioinformatics (including new initiatives in genomics and proteomics); and, b) fusing scholarly research in biomedical informatics with the dissemination of the resultant knowledge to individuals through its education programs and into operation through the infrastructure.

Vanderbilt Institute for Clinical and Translational Research Clinical Research Center: The Clinical Research Center (CRC) is a central, physical research hub within the Vanderbilt Institute for Clinical and Translational Research, providing a full service clinical research center that is open 24 hours per day, 7 days per week. Current facilities include 14 inpatient licensed hospital beds and an additional 3 hospital beds. All 17 are used for both inpatient and outpatient research visits. We have 6 general outpatient research exam and procedure rooms, a metabolic kitchen, a CAP/CLIA certified laboratory, and other specialized core labs. The CRC infrastructure and resources provide support to investigators for the efficient conduct of investigations of compelling quality, most of which would not have been possible otherwise. The CRC encompasses closely integrated adult and pediatric inpatient and outpatient facilities, with 23 full time nurses and 14 technical support staff. These resources have supported 548 studies over the past 4 years, involving both adult and pediatric participants, conducted by approximately 233 investigators. These users come from the Vanderbilt Medical School, School of Nursing, Peabody School of Education and Human Development, School of Engineering, the Lipscomb School of Pharmacy, and the Meharry Medical and Dental Colleges. In fact, since 1994, we have hosted all inpatient investigator-initiated clinical research protocols from Meharry, and many outpatient/ community protocols from Meharry investigators. The CRC is highly productive, initiating approximately 130 new protocols each year. Each protocol is executed, managed, and overseen by a trained team of investigators and care providers. These include protocols which are resource intensive and of high acuity, such as investigations requiring glucose clamp or insulin clamp, studies of hypertension mechanisms with intravenous ganglionic blocking agents, or intensive Phase I studies of pharmacodynamics with and without controlled diet interactions. All investigators have access to these resources on a competitive basis, with rolling submissions. Studies are led by expert teams in a dedicated, sophisticated facility designed with the capability to support a broad spectrum of investigation. The presence at Vanderbilt of one of the nation's largest and most active Clinical Pharmacology divisions ensures a vibrant portfolio of advanced, mechanistic patient-oriented research and a full range of drug studies encompassing every stage of the process of drug development from new target identification to compound discovery through Phase 1 studies, and beyond. PK/PD studies which require very precise timing of drug administration, blood draws and processing, and constant monitoring for the highest standard of safety, are a particular strength.

CRC OPERATIONS: The CRC is broadly utilized, and available to all. It has been utilized by investigators from 56 divisions. To ensure that all studies utilizing CRC resources meet the highest standards for quality, science, and safety, a Scientific Review Committee (SRC) evaluates the quality of science, feasibility of the study design

andstatistical plan, data and safety monitoring plans, and prioritizes requests for support. This committee is anindependent review body responsible for allocation of all pilot and research funding and other resources of VICTR. The centrality of prioritization by one robust SRC with experienced investigators drawn from many disciplines, with a common mandate for rigorous scientific evaluation, ensures equivalent treatment of all proposals. The SRC has successfully used this model over the past four years to review more than 417 projects.

Vanderbilt Ingram Cancer Center: Vanderbilt Ingram Cancer Center (VICC) is a designated comprehensive cancer center in Nashville, Tennessee under the direction of Jennifer A. Pietenpol, PhD.; Executive Director, Lauren Hackett, M.P.A.; Deputy Director, Dan Beauchamp,M.D.;and Chief Medical Officer, Michael N. Neuss, MD; and a team of 16 other Associate Directors and Key Leaders. VICC is guided by a Board of Overseers and an external scientific advisory board. While the primary location is central to downtown Nashville, three other locations also exist in surrounding communities which include, One Hundred Oaks, Green Hills, Cool Springs/Franklin, and Clarksville.

Vanderbilt Ingram Cancer Center is the only National Cancer Institute-designated Comprehensive Cancer Center in Tennessee and a member of the non-profit alliance of the world's leading cancer centers, National Comprehensive Cancer Network (NCCN). Blue Cross Blue Shield has designated the Ingram Cancer Center as a Blue Distinction Center for complex and rare cancers. The center encompasses a clinical oncology program, cancer-related research, education, and outreach activities. Types of research include basic, translational, clinical, population-based, and cancer prevention and control. The cancer center is ranked among the top 10 according to the National Cancer Institute (NCI) and boasts close to 300 research and physician-scientists in seven research programs generating more than $160 million in annual research funding from public and private sectors.

Vanderbilt Ingram Cancer Center supports approximately 5,400 new cancer patients each year and more than 111,000 outpatient visits annually. The center offers a wide-range of promising new therapies through clinical trials. Unique to VICC is the comprehensive program for cancer survivors regardless of age, type of cancer or where they received their oncology treatment. The Office of Patient and Community Education (OPACE) has multiple resources including; the patient resource center, patient advocacy opportunities, community outreach, the cancer information program, and the Vanderbilt Cancer Wellness Program. Thus, VICC provides a supportive environment to conduct cancer prevention research.

List of Designations and Accreditations:
Comprehensive Cancer Center, National Comprehensive Cancer Network, Blue Distinction Center for Complex and Rare Cancers, Joint Commission on Accreditation of Healthcare Organization, American College of Surgeons Commission on Cancer, American Nurses Credentialing Center Magnet Recognition Program, National Marrow Donor Program affiliate, American Association of Cancer Institutes, Foundation for the Accreditation of Cellular Therapy (blood and bone marrow transplant program), Clinical Laboratory Improvement Amendment (blood and bone marrow transplant program), NCI program for Phase I and Phase II clinical trials, Three NCI Specialized Programs of Research Excellence (lung, colon, and breast cancer), and Association for the Accreditation of Human Research Protection Programs.

Research:
Ingram Cancer Center supports seven research programs: Breast Cancer, Cancer Epidemiology, Prevention and Control, Gastrointestinal, Genome Maintenance, Host-Tumor Interactions, Signal Transduction and Cell Proliferation, and Thoracic/Head and Neck Cancer. These programs are highly collaborative with over 250 members from the center that belong to one of the seven programs. Together, the programs generate approximately $130 million dollars in research support from both the public and private sectors.

Vanderbilt Ingram Cancer Center has three Specialized Programs of Research Excellence (SPOREs) in Breast Cancer, Gastrointestinal Cancer, and Lung Cancer. This funding supports laboratory and clinical scientists in planning, designing, and implementing research programs that could potentially impact cancer prevention, detection, diagnosis, and treatment. In addition to outside sources, institutional pilot funding is also available to researchers and faculty from the American Cancer Society and NCI for proof-of-concept research

and cutting edge discoveries. Vanderbilt Ingram Cancer Center research is also supported by donors such as the Frances Williams Preston Laboratories, A.B. Hancock Jr. Memorial Laboratory for Cancer Research, The Robert J. Kleberg Jr. and Helen C. Kleberg Foundation, and the Ayers Institute.

VICTR Design, Biostatistics and Clinical Research Ethics:

VICTR provides biostatistical and ethical supportive resources to investigators to improve research quality and rigor is another important goal of VICTR and the NIH funded Clinical and Translational Science Award (CTSA). Currently there are four biostatisticians and four ethicists who provide support, consultation, project review and training for VICTR research/researchers. These personnel support both the investigator and the VICTR Scientific Review

Committee through individual consultation and pre-review of VICTR Resource Requests, providing proactive biostatistical input to minimize bias, improve study designs, assure recording of appropriate data and confounding factors, avoid common research obstacles, assure appropriate sample size, produce sound and safe study design and apply advanced methods of reproducible statistical analysis and reproducible reporting. Investigators may request biostatistical and ethical consultation services using a VICTR Resource Request.

VICTR biostatisticians and ethicists also support investigators by participation in VICTR Studios. VICTR Studios are a series of integrated, dynamic, and interactive roundtable discussions that bring relevant research experts from diverse academic disciplines together to focus on a specific research project at a specific stage.

MEHARRY VANDERBILT ALLIANCE – Facilities and Resources
Street address: 1005 Dr. D.B. Todd Jr. Blvd.
City, county, state, & ZIP code: Nashville, Davidson, TN 37208
Congressional district:

Meharry-Vanderbilt Alliance (MVA): The Alliance was created in 1999 by an Memorandum of Understanding (MOU) signed by the then President Maupin of MMC and the then VC of Health Affairs Dr. Jacobson at Vanderbilt U Medical Center (VUMC); it continues to be supported by the current leaders at Meharry and VUMC. The MVA administrative offices are located on Meharry's campus; Dr. Consuelo Wilkins, primary mentor, took over as Executive Director of the MVA in June of 2012, a post previously held by Dr. Clifton Meador. The MVA was created to facilitate collaborative working relationships between clinicians, researchers and students on both campuses, thereby enhancing the range and diversity of healthcare delivery services, research endeavors and educational opportunities that each institution is able to provide. In practical terms, this effort has expanded resources, developed research cores available to users on both campuses, developed educational programs and resulted in multiple joint research and research training initiatives.

The collaboration has generated positive and productive outcomes for both institutions including more than 160 collaborative grants and 300 joint publications. Additionally, more than 50% of the publications are either clinical or community-engaged, compared to 1995 when nearly 100% were basic science. The Alliance has consistently brought together the research community at Meharry and Vanderbilt to successfully develop a multitude of jointly led translational and clinical research projects. Primary among these are the Vanderbilt Institute for Clinical and Translational Research (CTSA) and the Southern Community Cohort Study, an NCI-funded cohort of 90,000 volunteers (60,000 African-American and 30,000 non-African-American volunteers).

Research Resources: Provides access to experienced grant writers and materials supporting the grant application process. Provides grant support including proposal editing and writing, budget preparations, biosketch formatting, and letters of intent. The Alliance facilitates grant writing workshops and IRB application assistance.

Meeting Space:
Three conference rooms:

- Capacity for 40-50 in large conference room
- Capacity of 25 in formal Board Room
- Capacity for 8 in smaller conference room

Administrative, tech support & photography services available upon request. Each meeting room is equipped with high quality conference telephones, Meharry Wi-Fi, Vanderbilt Wi-Fi, and guest Wi-Fi. PowerPoint projectors, computers with Skype video conferencing, TV and DVD are all available on sight. (http://www.meharry-vanderbilt.org/)

UNIVERSITY OF COLORADO DENVER – Facilities and Resources
Street address: 1600 Broadway
City, county, state, & ZIP code: Denver, CO 80202
Congressional district:

The University of Colorado Denver (UCD), Anschutz Medical Campus is an academic health sciences center that encompasses four professional schools, a graduate school, and three teaching hospitals. The UCD consists of seven major organizational units: the Schools of Medicine, Nursing, Dentistry, and Pharmacy, the Colorado School of Public Health, University Hospital, Central Services, and Administration. The UCD Anschutz Medical Campus has a full-time faculty of approximately 4,023 individuals and a clinical faculty of 2,220 individuals. Nearly 4,000 students are enrolled in the dental, pharmacy, medical and nursing schools, as well as other graduate degree programs. Graduate programs at the UCD enroll approximately 1,245 students.

The UCD-affiliated clinical organizations include the University of Colorado Hospital, Denver Veterans Affairs Medical Center, National Jewish Health, Children's Hospital Colorado (CHC), and Denver Health and Hospital Authority (DHHA). These organizations all provide direct care and have community-based ambulatory care sites.

The UCD Health Sciences Library, a major resource for Colorado and the Rocky Mountain region, is housed in a new facility at the Anschutz Medical Campus in Aurora, Colorado. The Library boasts a staff of forty librarians and paraprofessionals, more than thirty collaborative meeting and study spaces, wireless "coffee house" style Internet access, and a Computer Commons with fifty computer workstations providing access to MS Office, SAS, SPSS, EndNote, and various instructional software, plus audio/visual resources in online streaming and more traditional formats. In addition to an extensive print journal and book collection, affiliated students, faculty, and staff have on and off campus access to online course reserve readings, more than 23,000 online journals, hundreds of electronic books and databases, and resources such as MEDLINE, Web of Science, The Cochrane Library, and FirstConsult/MDConsult/NursingConsult. A one-stop service desk provides assistance with questions about library services, research consultations, professional search services, book checkout and return, and instructional software, computing, email, and technology troubleshooting. A chat and email "Ask A Librarian" service provides remote assistance. Resources can be used by the public within the Library. More information can be found at the Library's website: http://hslibrary.ucdenver.edu/. The office of education is another resource that serves to support, enhance, and enrich the educational effectiveness of the faculty at the UCD Anschutz Medical Campus. Resources include faculty development education and training; consultation and/or collaboration on instructional planning and development; designing instructional materials; teaching methods; student assessment; curriculum evaluation/revision and educational research.

Adult and Child Center for Health Outcomes Research and Delivery Science (ACCORDS)
Previously titled Colorado Health Outcomes Program (COHO), the Adult and Child Center for Health Outcomes Research and Delivery Science (ACCORDS) is a program within the UCD School of Medicine. COHO was established in 1998 with support from the Dean of the University of Colorado School of Medicine and has faculty with primary appointments in the departments of Medicine, Family Medicine, General Internal Medicine, Cardiology and Pediatrics, the Colorado School of Public Health and the School of Pharmacy. COHO merged administrative and scientific functions in April 2004 with the Children's Outcomes Research Program (COR), led by Dr. Allison Kempe, and funded by The Children's Hospital Research Institute to provide expertise in child health outcomes research. ACCORDS serves as a "Center" within the University of Colorado community, and as such, serves as a nexus for multi-disciplinary health services research across the various schools (i.e., Medicine, Pharmacy, Nursing, Public Health, etc.), and for the Departments of the School of Medicine (Family Medicine, Medicine Pediatrics, etc.). ACCORDS

has been the development and organization center for over 100 large-scale awards since inception, totaling over $50 million.

ACCORDS is a health services research organization which provides infrastructure support and expertise via a team of experienced research scientists in practice-based research, pragmatic clinical trial, health information technology, mixed-methods evaluation, data center management, and biostatistics. Scientific collaboration occurs among a team of scientists that work across disciplines and interests to form a vital and thriving scientific community. The mission of ACCORDS is to contribute to improving health, both locally and nationally, by conducting state-of-the-art outcomes and community translational research that will impact clinical practice and health policy and by developing researchers to further this work. To accomplish this mission, ACCORDS has developed expertise in five methodological "core" areas: 1) Qualitative Science; 2) Practice-based Research Networks (PBRNs); 3) Biostatistics and Analysis; 4) Health Information Technology (HIT) and mobile health and 5) Dissemination and Implementation Science. Topic areas of particular strength in ACCORDS are primary care, immunization delivery, obesity, cardiovascular disease, diabetes, cancer, asthma, depression, and surgical outcomes. ACCORDS is also organized along four interdependent programmatic areas: 1) Research (Adult and Child Programs and Dissemination/Implementation (D/I) Program; 2) Education; 3) Research Training Programs; 4) Community Engagement and Outreach.

Children's Outcomes Research (COR)
A subset of ACCORDS research focuses on child outcomes research (COR), which is sponsored by Children's Hospital Colorado, and is part of the existing framework of outcomes research at UCD. The mission of the COR program is to contribute to an improvement of child health, both locally and nationally, by conducting state-of-the-art pediatric outcomes research that can be translated into clinical practice and child health policy. COR staff members participate in the education of fellows and faculty, consultations about methodological and analytical issues, and development of collaborative projects in the area of outcomes research. A particular area of emphasis at COR is the delivery of preventive services, including immunizations, to children. Dr. Allison Kempe is director of COR. COR and COHO share office space and research and administrative resources.

Equipment:
The Children's Hospital Colorado (CHC) and UCD information system consists of OC3 digital internet connections, microwave WAN connections between the campuses, switched packet networking and Cisco routers. The computing infrastructure is based on an Ethernet local area network (LAN,) which is a part of the wide area network (WAN). The campus provides Internet access to all members of the WAN via a T3 trunk. The entire campus WAN is behind a firewall that blocks direct outside access to all servers for FTP or direct logon without a designated hole created by the campus IS group. These holes are IP-to-IP specific. The campus, through six super servers, provides all users a central repository for e-mail/calendar functions. The entire campus uses Microsoft products and maintains site licenses for Microsoft Office and NT/2000. Microsoft Outlook is used for e-mail, and all Outlook functions can be accessed via the web or over the WAN. The campus supports dial-up networking for all faculty, or faculty can access web-based functions through their own Internet service provider. All campus servers and workstations are protected by anti-virus software. Statistical software available for faculty use includes SAS (Enterprise Guide 4.3). A number of other software products (including AtlasTi) are also available through site licenses from various members of the wider University campuses. All research workstations are password protected to further limit unauthorized user access. All personnel have access to a series of high-speed network laser printers, including a color printer.

All staff have Pentium PCs and office furniture, with many offices containing personal printers. Additionally, the following equipment is available to all staff in the suite: three large-capacity HP LaserJet printers, two fax machines, and two heavy-duty copiers, one with color and scanning capability.

Offices:
ACCORDS occupies 17,584 square feet in the University Physicians, Inc. building on the Anschutz Medical Campus. Within this research suite, we have 49 private offices and 28 workstations accommodating work

space for 95 individuals. Additionally, we have an onsite archive room and three meeting rooms accommodating meetings and trainings for up to 40 persons. All offices are wired for University network and telecommunications support. All UCD institutional support services are available including mail center, copy center, computer support services, etc.

EQUIPMENT

No major equipment will be needed.

Maria F. Lima, Ph.D.
Dean, School of Graduate Studies and Research
Sr. VP for Research and Innovation

February 26, 2019

National Institutes of Health
(NIH) 9000 Rockville Pike
Bethesda, Maryland 20892

Re: Eligibility Certification for NCI Mentored Research Scientist Development Award to Promote Diversity (K01-Clinical Trial Required) application for Jennifer Cunningham Erves, Ph.D.

Dear Colleagues:

I am writing this letter to certify eligibility criteria for Dr. Jennifer Erves for the *NCI Mentored Research Scientist Development Award to Promote Diversity (K01-Clinical Trial Required)*. Dr. Erves belongs to [redacted] Personal Information a member of the underrepresented groups in biomedical research.

If there are any additional questions, please contact me at mflima@mmc.edu or 615-327-6533.

Maria F. Lima, Ph.D.
Professor and Dean, School of Graduate Studies and Research
VP for Research and Innovation

OMB Number: 4040-0001
Expiration Date: 10/31/2019

RESEARCH & RELATED Senior/Key Person Profile (Expanded)

PROFILE - Project Director/Principal Investigator

Prefix: Dr. First Name*: Jennifer Middle Name C Last Name*: Erves Suffix: Ph.D

Position/Title*: Assistant Professor
Organization Name*: MEHARRY MEDICAL COLLEGE
Department: Internal Medicine
Division: School of Medicine
Street1*: 1005 Dr. D.B. Todd Jr Boulevard
Street2:
City*: Nashville
County: Davidson
State*: TN: Tennessee
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 372083501

Phone Number*: 615-327-5692 Fax Number:

E-Mail*: jerves@mmc.edu

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

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

Degree Type: Degree Year:

Attach Biographical Sketch*: File Name: ErvesBioF.pdf

Attach Current & Pending Support: File Name:

Tracking Number: GRANT12814098 Funding Opportunity Number: PAR-18-365 . Received Date: 2019-03-12T11:51:54.000-04:00

PROFILE - Senior/Key Person

Prefix: Dr. First Name*: CONSUELO Middle Name HOPKINS Last Name*: WILKINS Suffix:

Position/Title*: Associate Professor
Organization Name*: VANDERBILT UNIVERSITY MEDICAL CENTER
Department:
Division:
Street1*: 2525 West End Ave
Street2: Suite 600
City*: Nashville
County:
State*: TN: Tennessee
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 372030000

Phone Number*: 6159632820 Fax Number:

E-Mail*: consuelo.h.wilkins@vanderbilt.edu

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

Project Role*: Other (Specify) Other Project Role Category: Primary Mentor

Degree Type: MD,MS,BS Degree Year: 1996,2002,1992

Attach Biographical Sketch*: File Name: Wilkins_Biosketch.pdf

Attach Current & Pending Support: File Name: Wilkins_Meharry__OS.pdf

PROFILE - Senior/Key Person

Prefix: Dr. First Name*: Pamela Middle Name Carmen Last Name*: Hull Suffix:

Position/Title*: Asst Professor
Organization Name*: Vanderbilt University Medical Center
Department:
Division:
Street1*: Division of Epidemiology
Street2: 2525 West End, Suite 800
City*: Nashville
County:
State*: TN: Tennessee
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 370130000

Phone Number*: 615-343-3247 Fax Number:

E-Mail*: pam.hull@vanderbilt.edu

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

Project Role*: Other (Specify) Other Project Role Category: Co Primary Mentor

Degree Type: PHD,MA,BA Degree Year: 2004,2000,1995

Attach Biographical Sketch*: File Name: Hull_biosketch_.pdf

Attach Current & Pending Support: File Name: HullOSF.pdf

PROFILE - Senior/Key Person

Prefix: Dr. First Name*: Amanda Middle Name F Last Name*: Dempsey Suffix:

Position/Title*: Associate Professor
Organization Name*: University of Colorado
Department:
Division:
Street1*: 13199 E Montview Blvd
Street2: Suite 300
City*: Aurora
County:
State*: CO: Colorado
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 800450000

Phone Number*: 303-724-6679 Fax Number:

E-Mail*: amanda.dempsey@ucdenver.edu

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

Project Role*: Other (Specify) Other Project Role Category: Co-Mentor

Degree Type: MD,PHD,MPH Degree Year: 2000,2000,2005

Attach Biographical Sketch*: File Name: Dempsey_BiosketchF.pdf

Attach Current & Pending Support: File Name: OS_-_Dempsey__Feb_2019.pdf

OMB No. 0925-0001 and 0925-0002 (Rev. 09/17 Approved Through 03/31/2020)

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: **Cunningham Erves, Jennifer**

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

POSITION TITLE: **Assistant Professor**

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

INSTITUTION AND LOCATION	DEGREE (if applicable)	END DATE MM/YYYY	FIELD OF STUDY
Tuskegee University, Tuskegee, Alabama	BS	05/2006	Biology
Tuskegee University, Tuskegee, Alabama	MS	05/2008	Biology
University of Alabama at Birmingham (UAB), Birmingham, Alabama	MA	12/2013	Health Education
UAB, Birmingham, Alabama	PhD	12/2013	Health Education and Health Promotion
UAB, Birmingham, Alabama	Certificate	12/2013	Nonprofit Management
Meharry Vanderbilt Community Engaged Research Core, Nashville, TN	Postdoctoral Fellow	03/2015	Community Engagement
National Commission for Health Education Credentialing	Certificate	03/2015	Health Education Specialist
Albany State	Other training	03/2015	Public Health Certificate

A. Personal Statement

My long-term career goal is to become a productive, independent researcher in public health oncology focused on cancer prevention behaviors. I have a strong background in public health, biology, community engagement, and research methodology (quantitative, qualitative, and mixed methods). This makes me exceptionally poised to pursue a research career to investigate the impact of behavioral interventions focused on cancer prevention behaviors. My goals in seeking this NCI Mentored Research Scientist Development Award to Promote Diversity (K01- Clinical Trial Required) are to extend my training to seek knowledge and training to: 1) develop behavioral interventions using innovative, health communication strategies to promote cancer prevention behaviors and reduce cancer disparities for underserved populations; 2) design and conduct a pilot clinical trial to establish feasibility of the behavioral intervention; and 3) gain insight on the role of implementation science in cancer prevention for future work beyond this K award. I will leverage established educational opportunities and mentor support relevant to this research and my long-term career goal.

I completed my Bachelors and Masters degree in Biology at Tuskegee University with a focus on the application of biological principles in public health research to promote cancer prevention through HPV vaccine uptake in African American female college students. Subsequently, I completed a second Masters and Ph.D. at the University of Alabama at Birmingham in Health Education and Health Promotion. This training gave me a strong foundation in behavioral theory, research design, survey development, partnership development, and statistical, qualitative, and mixed methods. My next position was a post-doctoral fellow in Community Engagement for the Meharry-Vanderbilt Community Engaged Research Core. There I learned how to apply community engaged research principles to investigate factors influencing parental decision-making regarding their adolescent participation in cancer prevention behaviors (e.g., HPV vaccine clinical trials). My next position as an Assistant Professor at Meharry Medical College and an adjunct instructor at Vanderbilt University gave me the opportunity to use a diversity supplement and internal funding (K12) with the guidance of mentors to obtain didactic training in patient-centered outcomes research, community engagement, and advanced qualitative and quantitative research methods. My research findings pointed to the need for the proposed intervention; thus, I seek the knowledge and training to develop, implement, evaluate, and adopt interventions into health care and public health settings.

The proposed K01 award is the next logical step in my career development and will allow me to advance my research agenda in cancer prevention behavioral interventions. Specifically, I will develop and pilot test a tailored health communication intervention delivered to HPV vaccine hesitant (VH) families prior to their next physician visit to increase HPV vaccine uptake among underserved adolescents. The K01 will provide the opportunity for me to gain mentored training on intervention development using individually-tailored education to promote cancer prevention behaviors, as well as training on designing and implementing clinical trials to assess the efficacy of behavioral interventions. I am well-prepared to take full advantage of this mentored research scientist development award, and will use it to advance the rigor and dissemination of evidence-based behavioral interventions in the area of cancer prevention. The K01 will place me in an optimal position to secure future R01 funding necessary to establish an independent, multidisciplinary research program focused more broadly on cancer prevention behavioral interventions and reducing cancer disparities, starting with a focus on HPV vaccination in adolescents.

B. Positions and Honors

Positions and Employment

2006 - 2006	Activity Director, Salem Nursing and Rehab Center, Tuskegee, AL
2007 - 2007	Science Instructor, Tuskegee University Upward Bound Program, Tuskegee, AL
2007 - 2008	Graduate Research and Teaching Assistant, Tuskegee University, Tuskegee, AL
2008 - 2015	Adjunct Professor, University of Alabama at Birmingham, Birmingham, AL
2011 - 2013	Graduate Student Trainee, University of Alabama at Birmingham, Birmingham, AL
2013 - 2014	Methods Consultant (qualitative data analysis, interview protocol development), Meharry Vanderbilt Alliance, Nashville, TN
2013 - 2015	Post-Doctoral Fellow, Meharry-Vanderbilt Community Engaged Research Core, Nashville, TN
2014 - 2015	HPV Content Consultant, University of Alabama at Birmingham, Birmingham, AL
2016 -	Assistant Professor, Meharry Medical College, Nashville, TN
2016 - 2017	Adjunct Instructor, Vanderbilt University Medical Center, Nashville, TN
2017 -	Adjunct Assistant Professor, Vanderbilt University Medical Center, Nashville, TN

Other Experience and Professional Memberships

2005 - 2006	Member, Sigma Xi
2008 - 2013	Member, Eta Sigma Gamma
2008 - 2013	Ora Quick Counselor and Sexual health awareness through peer education (S.H.A.P.E) educator, University of Alabama at Birmingham
2009 - 2013	Member, American Alliance for Health, Physical Education, Recreation, and Dance
2009 - 2013	Reviewer, Journal of Health Care for the Poor and Underserved
2010 - 2013	Member, Kappa Delta Pi
2011 - 2013	Member, American College Health Association
2012 - 2013	Faculty Search and Hiring Team, University of Alabama at Birmingham
2013 -	Member, Mixed Methods International Research Association
2013 -	Member, Cervical Cancer Free Tennessee
2013 -	Member, Meharry Medical College/Vanderbilt Ingram Cancer Center/Tennessee State University Cancer Partnership Community Advisory Board
2015 -	Member, International Papillomavirus Society
2015 -	Member, Vanderbilt Ingram Cancer Center/Vanderbilt University Medical Center/Vanderbilt Health Affiliated Network HPV workgroup
2015 -	Reviewer, Trials (Journal)
2016 -	Reviewer, Journal of Cancer Education (Journal)
2016 -	Reviewer, Journal of Health Psychology

Honors

2002 - 2006	Recipient, Presidential Scholarship, Tuskegee University

2003	The Alabama Louis Stokes Alliance for Minority Participation Summer Research Conference-Biology Competition: 3rd Place, University of Alabama at Birmingham
2003	J.H.M. Henderson Outstanding Freshman Academic Achievement Award, Tuskegee University
2003	Inductee, Beta Kappa Chi Scientific Honor Society
2004	Tuskegee University Honor Roll, Tuskegee University
2005	Sigma Xi National Honour Society Conference-3rd Place, Tuskegee University
2005	Inductee, Golden Key International Honour Society
2006 - 2008	Recipient, Bridge to the Doctorate Fellowship, Tuskegee University
2008 - 2011	Recipient, Comprehensive Minority Faculty and Student Development Program Fellowship, University of Alabama at Birmingham
2011 - 2013	Graduate Student Trainee, University of Alabama at Birmingham
2012	American College Health Association 2012 Annual Meeting Scholarship, American College Health Association
2014	Recipient, 2014 Outstanding Student for Health Education Doctoral Award, University of Alabama at Birmingham
2016 – 2017	Leading Emerging and Diverse Scientists to Success (LEADS) Fellow in Translational Research, University of Pittsburgh
2017	Expanding National Capacity in PCOR through Training (ENACT) Program Fellow, University of Pittsburgh

C. Contribution to Science

Note: Manuscripts published under Jennifer Cunningham, Jennifer Cunningham Erves and Jennifer Erves.

1. **Cancer Prevention in Adolescents:** During my graduate studies, I developed an instrument and collected data using a cross-sectional study design. I found that subjective norms (i.e., physicians), perceived barriers, and perceived susceptibility associated with AA mothers' intent to obtain HPV vaccine for their daughters aged 9 to 12 to improve cervical cancer disparities. This dissertation work led to two publications. As a postdoctoral fellow, I applied community-engaged research principles to develop a survey and study design. I identified that child's age, perceived advantages of HPV vaccination, parental trust in medical researchers, and level of ease in understanding clinical trial information influenced parental willingness to allow their children aged 9 to 15 to participate in HPV vaccine clinical trials. This resulted in two publications. Upon transition to an Assistant Professor, I secured funding for a pilot study under a diversity supplement from the National Center for Advancing Translational Sciences. I sought to identify the role that alternative settings (i.e., pharmacies, health departments, and schools) could play in improving HPV vaccine rates among AA adolescents. I was later approved for K12 funding as a V-POCKET scholar (Vanderbilt Patient-centered Outcomes Research Career Knowledge, Education and Training) scholar. This research extended my community-engaged research training to gather input from AA families and key stakeholders regarding needs for a patient-centered educational intervention that could help to increase HPV vaccination. Findings from these studies indicated that families (parent-child dyads) preferred to receive the HPV vaccine in the medical home rather than alternative settings. Further, families varied in their educational needs and preferences regarding cancer, HPV, and the vaccine to influence their decision-making regarding HPV vaccination. In addition, I recently published an article as first-author that highlighted the important role of culture in influencing AA mother's likelihood of accepting a physicians' recommendation to get their daughter the HPV vaccine. Specifically, future time orientation, perceived barriers and benefits of HPV vaccination, and perceived susceptibility to HPV were association with increased likelihood of accepting the vaccine.

   a. **Cunningham-Erves J**, Forbes L, Ivankova N, Mayo-Gamble T, Kelly-Taylor K, Deakings J. Black mother's intention to vaccinate daughters against HPV: A mixed methods approach to identify opportunities for targeted communication. Gynecol Oncol 2018; PubMed PMID: 29588103.
   b. **Cunningham-Erves JL**, Kelly-Taylor KD, Mayo-Gamble TL, Deakings JA, Talbott LL. A Physician's Recommendation for HPV Vaccination: What Makes African American Mothers Compliant? Pediatr Infect Dis J. 2018 Jan 11;PubMed PMID: 29329167.
   c. **Erves JC**, Mayo-Gamble TL, Hull PC, Duke L, Miller ST. Adolescent Participation in HPV Vaccine Clinical Trials: Are Parents Willing?. J Community Health. 2017 Oct;42(5):894-901. PubMed PMID: 28321649; PubMed Central PMCID: PMC5594038.

d. **Cunningham-Erves J**, Talbott LL, O'Neal MR, Ivankova NV, Wallston KA. Development of a Theory-based, Sociocultural Instrument to Assess Black Maternal Intentions to Vaccinate Their Daughters Aged 9 to 12 Against HPV. J Cancer Educ. 2016 Sep;31(3):514-21. PubMed PMID: 26081311.

2. **Cancer Prevention in College Students:** My thesis research at Tuskegee University identified risk behaviors associated with HPV in Black female college students which led to two publications. At UAB, I work with colleagues to identify HPV vaccine rates and factors (e.g., health insurance status, OB-GYN visits) influencing HPV vaccine uptake among college students at UAB, which are presented in two publications. This work led to my selection as a HPV content consultant for a HPV vaccination program to increase HPV vaccine uptake at UAB student health center. We have one paper under review.

   a. [redacted] Forthcoming

   b. **Cunningham J,** Forbes L. HPV vaccination of college males: Strategizing against HPV infection in college students. College student journal. 2015; 49(4):565. [Indexed in PsycINFO]

   c. **Cunningham J,** Wilkinson LL, Talbott LL. Human Papilloma virus Vaccine acceptance among commuter college students: The role of Health Insurance Coverage. *Internal Journal of Science, Commerce, and Humanities*. 2014; 2(4):204-222.

   d. **Cunningham J,** Carter V, Troy R, Davis C. Risk factors associated with the Human Papillomavirus among African American Female College Students. Alabama State Association for Health, Physical Education, Recreation, and Dance Journal. Summer 2012; 32(2):18-27.

3. **Community-Engaged Research:** I have applied community engaged research (CEnR) approaches in most of my own research focused on cancer prevention. In addition, I also collaborated with members of the Meharry-Vanderbilt Community Engaged Research Core (CERC) as a post-doctoral fellow and Assistant Professor on other CEnR efforts as part of my training. For example, I worked with my post-doctoral mentor, Dr. Stephania Miller-Hughes, on a study that showed that receipt of diabetes education and some specialty care among AA women with Type 2 diabetes is below national benchmarks. I also worked with the capacity building team of CERC to identify needs of community members and organizations to build their research capacity. These findings led to the development of research curricula for both the community organization and community members. This work resulted in one publication, and one under review. We also identified research barriers (e.g., lack of cultural competence among researchers) and priorities of underrepresented groups in research via community listening sessions. My work resulted in become a qualitative methods expert, providing trainings and research skills workshops.

   a. **Cunningham J**, Wallston KA, Wilkins CH, Hull PC, Miller ST. Development and Psychometric Evaluation of the HPV Clinical Trial Survey for Parents (CTSP-HPV) Using Traditional Survey Development Methods and Community Engagement Principles. Clin Transl Sci. 2015 Dec;8(6):702-9. PubMed PMID: 26530324; PubMed Central PMCID: PMC5351134.

   b. **Erves JC**, Mayo-Gamble TL, Malin-Fair A, Boyer A, Joosten Y, Vaughn YC, Sherden L, Luther P, Miller S, Wilkins CH. Needs, Priorities, and Recommendations for Engaging Underrepresented Populations in Clinical Research: A Community Perspective. J Community Health. 2017 Jun;42(3):472-480. PubMed PMID: 27812847; PubMed Central PMCID: PMC5408035.

   c. Miller ST, **Cunningham-Erves J**, Akohoue SA. Diabetes Education, Specialty Care, and Self-Care Advice among Obese African American Women with Type 2 Diabetes. Ethn Dis. 2016 Apr 21;26(2):229-34. PubMed PMID: 27103774; PubMed Central PMCID: PMC4836904.

   d. **Cunningham J**, Miller ST, Joosten Y, Elzey JD, Israel T, King C, Luther P, Vaughn Y, Wilkins CH. Community-Engaged Strategies to Promote Relevance of Research Capacity-Building Efforts Targeting Community Organizations. Clin Transl Sci. 2015 Oct;8(5):513-7. PubMed PMID: 25951171; PubMed Central PMCID: PMC4626308.

Complete List of Published Work in my bibliography
https://www.ncbi.nlm.nih.gov/sites/myncbi/14qRcnwPnf-Q2/bibliography/47746808/public/?sort=date&direction=ascending

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

Ongoing Research Support

6K12HS022990-03, Agency For Healthcare Research And Quality, David Penson (PI) 10/01/16-07/31/18
The Vanderbilt PCOR Career Knowledge, Education, and Training Program (V-POCKET)
The purpose of this grant is to develop a PCOR mentored career development program to train new investigators that demonstrate a commitment to conducting CER as applied to PCOR. I am a scholar using patient-centered approaches to understand factors influencing HPV vaccination rates among AA adolescents.
Role: FEL

[redacted], Cunningham Erves, Jennifer (PI); Mayo-Gamble, Tilicia (Co-PI)
06/01/17-05/31/18
Use of a Multimodal Strategy for Community-Engaged Dissemination of Community Research Needs, Priorities, and Recommendations
We will disseminate research findings from 11 community listening sessions (CLSs) on priorities and barriers to research participation of those underrepresented in research to CLS participants and the community.
Role: PI

Completed Research Support

[redacted], Russell Rothman (PI) 06/01/14-06/01/15
Identifying factors influencing parental willingness of their adolescent girls' participation in HPV vaccine clinical trials utilizing a Community Engaged Approach
This funding will help to grow a clinical data research network across the Vanderbilt Health Affiliated Network, and practices across the nation in collaboration with Greenway Medical Technologies. Creation of the network will focus on data integration and interoperability, clinical decision support, and patient-facing informatics tools. Specifically, my survey gained patient/parent feedback on HPV vaccine clinical trials in adolescents.
Role: Post-Doctoral Scholar

UL1-TR000445, NIH, Gordan Bernard (PI) 06/01/14-06/01/15
CTSA: The Vanderbilt Institute for Clinical and Translational Research (VICTR)
VICTR provides next-generation support to faculty working to translate fundamental scientific discoveries into clinical practice. My post-doctoral project gained parent feedback on their adolescents' participation in HPV vaccine clinical trials.
Role: Post-Doctoral Scholar

5U54MD007593-07, NIH, Samuel Adunyah (PI) 06/01/14-06/01/15
Meharry Clinical and Translation Research Center (MeTRC)
A Scientific Working Group to 1) identify novel research, 2) recruit investigators, 3) create working structure, and 4) support investigator teams. Specifically, I was a post-doctoral fellow that received funding to conduct research to identify parent/patient feedback on their adolescents' participation in HPV vaccine clinical trials.
Role: Post-Doctoral Scholar

3UL1TR000445-11S1, NCATS, Gordan Bernard (PI) 07/21/17-09/30/17
Assessing views of the immunization neighborhood to improve HPV vaccine rates
VICTR focuses on removing impediments to research translation, creating new infrastructure, training new C&T scientists, and engaging and involving the local community to improve health. I initiated training in clinical and translational science and research the role of alternative settings in HPV vaccination in AA adolescents.
Role: FEL

BIOGRAPHICAL SKETCH

NAME: Wilkins, Consuelo Hopkins

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

POSITION TITLE: Associate Professor of Medicine, Vanderbilt University School of Medicine and Executive Director, Meharry-Vanderbilt Alliance

EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
Howard University, Washington, DC	B.S.	05/92	Microbiology
Howard University, Washington, DC	M.D.	05/96	Medicine
Duke University Medical Center, Durham, NC	Residency	06/99	Internal Medicine
Washington Univ/Barnes-Jewish Hospital, St. Louis	Fellowship	06/00	Geriatric Medicine
Washington University, St. Louis, MO	M.S.C.I.	05/02	Clinical Investigation

A. Personal Statement

I am pleased to serve as Dr. Erves primary mentor- providing expertise and mentorship in translational, comparative effectiveness, and community and stakeholder engaged research along with responsible conduct of research. I am committed to the success of Dr. Erves, and will meet with her weekly to provide expertise and research support to ensure her early career success. My background makes me highly qualified to serve in this role. I have mentored more than twenty trainees at varying periods in their careers and have contributed to their success as researchers, clinicians, and instructors. I have conducted extensive research in developing and accessing interventions related to cognitive impairment, frailty, and depression along with community and stakeholder engagement which has been reported in peer review articles. I am widely recognized for my work in stakeholder engagement with an emphasis on underrepresented populations in research, and more recently in precision medicine. In my role as Vice President for Health Equity at Vanderbilt University Medical Center, I provide oversight for the newly established Office of Health Equity and I continue to lead the Meharry-Vanderbilt Alliance (MVA), in the interim. At the MVA, my responsibilities include developing and supporting collaborative initiatives and programs in biomedical research, community engagement and interprofessional learning. I successfully direct the research enterprise and have experience mentoring teams of researchers. I hold appointments as Associate Professor of Medicine at both Vanderbilt University Medical Center and Meharry Medical College. As Associate Director of the Meharry-Vanderbilt Community-Engaged Research Core in the Vanderbilt Institute for Clinical and Translational Science, I bring together academic researchers and community members to improve community health and healthcare through community-engaged research. I am Principal Investigator of two NIH-funded centers, the Vanderbilt-Miami-Meharry Center of Excellence in Precision Medicine and Population Health, and the Center for Improving Clinical Trial Education Recruitment and Enrollment at CTSA Hubs. These roles allow me to provide support related to data collection and research that engages the community, and I will leverage my resources to ensure Dr. Erves success.

Positions and Honors

2000-2009 Assistant Professor, Internal Medicine, Division of Geriatrics and Nutritional Science, School of Medicine, Washington University, St. Louis, MO
2000-2012 Medical Director, Barnes-Jewish Extended Care, Clayton, MO
2001-2012 Geriatric Consultant, Rehabilitation Institute of St. Louis, St. Louis, MO
2007-2009 Assistant Professor, Psychiatry, School of Medicine, Washington University, St. Louis, MO
2007-2012 Health Editor, *St. Louis American* newspaper, St. Louis, MO
2009-2012 Associate Professor of Medicine and Psychiatry, Washington University School of Medicine
2009-2012 Faculty Scholar, Institute for Public Health, School of Medicine, Washington University
2009-2012 Director, Our Community, Our Health Program, St. Louis, MO

2010-2012 Co-Director, Center for Community Engaged Research in the Institute of Clinical and Translational Science, Washington University School of Medicine, St. Louis, MO
2010-2012 Community Outreach Program Director, Nutrition Obesity Research Center, School of Medicine, Washington University, St. Louis, MO2011-2012 Associate Professor of Surgery (Public Health Sciences), School of Medicine, Washington University, St. Louis, MO
2012-present Executive Director, Meharry-Vanderbilt Alliance, Nashville, TN
2012-present Associate Professor of Medicine, Vanderbilt University School of Medicine, Nashville, TN
2013-present Associate Professor of Medicine, Meharry Medical College, Nashville, TN
2017-present Associate Director, Vanderbilt Institute for Clinical and Translational Research, Nashville, TN
2013-2017 Co-Director, Vanderbilt Institute for Clinical and Translational Research, Nashville, TN
2017-present Director, Meharry-Vanderbilt Community Engaged Research Core, Nashville, TN
2013-2017 Co-Director, Meharry-Vanderbilt Community Engaged Research Core, Nashville, TN
2019 Vice President for Health Equity, Vanderbilt University Medical Center and Associate Dean for Health Equity, Vanderbilt University School of Medicine

Other Experience and Professional Memberships

2010-2012 Transdisciplinary Research in Energetics and Cancer, Faculty Mentor, Washington University School of Medicine, St. Louis, MO
2010-2012 Program for the Elimination of Cancer Disparities (PECAD), Advisory Board, Siteman Cancer Center, Washington University School of Medicine, St. Louis, MO
2010-2012 Comparative Effectiveness Research (CER) Career Development Program (KM1) Steering Committee, Washington University School of Medicine, St. Louis, MO
2012 NIH Reviewer, Neurological, Aging and Musculoskeletal Epidemiology (NAME) Study Section
2012-present Member, American College of Physicians
2012-present Internal Advisory Board, Vanderbilt Institute of Clinical and Translational Research
2012-present Board of Directors, Safety Net Consortium of Middle Tennessee
2013-2016 Senior Research Program Mentor, Research 2 Curriculum, Vanderbilt Univ School of Med
2014-present Member, PCORI Midsouth CDRN Operations Council and MS-CDRN Oversight Council
2014-present Member, Cancer Health Outcomes and Control Research Program, VICC
2014-2015 Workgroup Member, PCORnet ENgagement ACTivity Inventory (ENACT) Tool
2014-2016 Member, PCORnet Patient & Consumer Engagement (PCE) Task Force (Workgroup Chair, 2014-present)
2014-present Member, PCORI Advisory Panel on Clinical Trials (CTAP), Subcommittee on Recruitment, Accrual, and Retention (RAR)
2014-present Executive Committee, V-POCKET
2014-2016 Research Area Director, Vanderbilt Univ School of Medicine
2015-present NIA Task Force for Diversity in Scholar Development in Aging/ Neurocognitive Disease and Research Recruitment
2015 Panelist, Participant Engagement and Health Equity - President's Precision Medicine Initiative Working Group of the Advisory Committee to the NIH Director
2016-present Member, NashvilleHealth Hypertension Working Group
2016-present Member, United Way of Metropolitan Nashville, Strategic Leadership Group
2016-present Advisory Committee, Building Interdisciplinary Research Careers in Women's Health (BIRCWH)
2016-present Member, AcademyHealth
2017-2020 Advisory Committee, AcademyHealth Translation and Dissemination Institute
2017-present National Library of Medicine Strategic Planning Panel
2017-2018 Member, National Academies of Sciences, Engineering, and Medicine, Committee on the Return of Individual-Specific Research Results Generated in Research Laboratories
2018-2019 NEJM Catalyst Thought Leader
2018-2019 Scientific Advisory Board, Alzheimer's Association, U.S. POINTER Study
2018-2022 Member, National Human Genome Research Institute (NHGRI) Genomics and Society Working Group
2018-present Executive Committee, All of Us Research Program | The Precision Medicine Initiative Steering Committee, All of Us Research Program | The Precision Medicine Initiative

Clinical and Translational Science Award Consortium Activities

2012-2015 Community Engagement Key Function Committee, Operations Workgroup, Community Partners Integration Workgroup, Co-Chair

2011-2013 Added Value of Community Partners in the CTSA Subgroup, Co-Leader
2015-2017 Collaboration/Engagement Domain Task Force Lead Team
2015-present Collaboration/Engagement Domain Task Force
2015-present External Advisory Committee, Translational Research Institute, Univ of Arkansas
2016-present External Advisory Board, Georgetown-Howard Universities Center for Clinical and Translational Science
2017-present External Advisory Committee, Center for Clinical and Translational Science, Univ of Cincinnati
2017-present Indiana CTSI Scientific Advisory Board
2017-present External Advisory Board, Harvard Catalyst Clinical and Translational Science Center
2017-present Frontiers: University of Kansas Clinical and Translational Science Institute
2017-present External Advisory Committee, Northwestern Univ Clinical and Translational Sciences Institute (NUCATS)

Honors

2013-2014 Association of American Medical Colleges Learning Health System Challenge Award
2014-2015 Fellow, Hedwig van Ameringen Exec. Leadership in Acad. Med. (ELAM) Program for Women

B. Contribution to Science

1. I have contributed to the health disparities literature and overall science by focusing on African Am. population and their health outcomes. Much of my research has concentrated on older adults and cognitively impaired African Am. An observational study in a community-based setting showed that Dementia is often underdiagnosed in the African Am. population and affects instrumental activities of daily living. A subsequent cross-sectional study found that vitamin deficiency results in worse cognitive impairment and lower bone density in older African Am.
   a. Umeukeje E, Wild M, Maripuri S, Davidson T, Rutherford M, Abedel-Kader K, Lewis J, **Wilkins CH**, Cavanaugh K. Black Americans' Perspectives of Barriers and Facilitators of Community Screening for Kidney Disease. Clinical Journal of the American Society of Nephrology. 2018: Apr 6;13(4):551-559. PMID: 29545381 PMCID: PMC5969459
   b. **Wilkins CH,** Grant EA, Schmidt SE, McKeel D, and Morris JC. The Neuropathology of Alzheimer's Disease in African American and white individuals. Archives of Neurology 2006: 63(1): 87-90. PMID: 16401740 (manuscript was accepted for publication prior to April 7, 2008)
   c. **Wilkins CH**, Wilkins KL, Meisel M, Depke M, Williams J, and Edwards DF. Dementia Undiagnosed in Poor Older Adults with Functional Impairment". Journal of the American Geriatrics Society 2007: 55: 1771–1776. PMID: 17916120 (manuscript was accepted for publication prior to April 7, 2008)
   d. **Wilkins CH,** Birge SJ, Sheline YI, Morris JC. Vitamin D deficiency is associated with worse cognitive performance and lower bone density in older African Americans. JNMA, 2009; 101:349-354. PMCID: PMC2801439
2. My efforts towards community engagement have focused on developing and implementing innovative methods of engaging patients and communities in research. Identifying improved methods of integrating community members into the research process, in areas such as decision-making, hypothesis generation, and dissemination may change the paradigm of how research is conducted and lead to new insights into community health. The community engagement studios, is a valuable platform to actively engage individuals of different communities into the research enterprise. The opportunity for community members to serve as co-authors and co-investigators provides a unique and meaningful method of involvement and decision-making when it comes to community health.
   a. Selker H, **Wilkins CH**. From Community Engagement, to Community–Engaged Research, to Broadly Engaged Team Science. J Clin Trans Sci. 2017; 1(1), 5-6. DOI: 10.1017/cts.2017.1.
   b. Joosten YA, Israel TL, Williams NA, Boone LR, Schlundt DG, Mouton CP, Dittus RS, Bernard GR, **Wilkins CH**. Community Engagement Studios: A Structured Approach to Obtaining Meaningful Input From Stakeholders to Inform Research. Acad Med. 2015 Dec;90(12):1646-50. PMCID: PMC4654264
   c. **Wilkins CH**, Spofford M, Williams N, McKeever C, et al. Community Representatives' Involvement in Clinical and Translational Science Awardee Activities. Clinical and Translational Science. 2013 Aug; 6(4): 292-296. DOI: 10.1111/cts.120729. PMCID: PMC2884765
   d. Johnson DA, Joosten Y A, **Wilkins, CH** and Shibao CA. (2015), Case Study: Community Engagement and Clinical Trial Success: Outreach to African American Women. Clinical And Translational Science. 2015 Aug; 8(4): 388-90 doi:10.1111/cts.12264. PMCID: PMC4553110
3. My research has also focused on the physical function of older adults and aging. Dementia of the Alzheimer's type (DAT) is the most common cause of cognitive impairment in older adults. I conducted a

study to assess the association of impaired physical function and the development of dementia. Mild physical impairment in cognitively older adults was associated with the onset of DAT. Vitamin D deficiency is also prevalent in the older adult population which effects bone density and is implicated as a cause or consequence of Alzheimer Disease (AD). In a cross-sectional study I showed that Vitamin D deficiency was associated with low mood and cognitive impairment.

a. **Wilkins CH**, Skinner JS, Boyer AP, Morrow-Howell N, Smith JM, Birge SJ. A Community-Based Collaborative Care Model to Improve Functional Health in Underserved Community-Dwelling Older Adults. J Aging Health 2017; Nov 1:898264317731427. doi: 10.1177/0898264317731427. [Epub ahead of print] PMID: 29254408
b. **Wilkins CH**, Mathews J, Sheline YI. Late Life Depression with Cognitive Impairment: Evaluation and Treatment. Clinical Interventions in Aging. 2009:4 51-57. PMCID:PMC2685224
c. **Wilkins CH,** Roe CM, Morris JC. A brief clinical tool to assess physical function: The Mini-Physical Performance Test. Archives of Geriatrics and Gerontology, 2010; 50:96-100. PMCID: PMC2787987
d. **Wilkins, CH**, Roe, CM, Morris, JC, Galvin, J E. Mild Physical Impairment Predicts Future Diagnosis of Dementia of the Alzheimer's Type. Journal of the American Geriatrics Society. 2013 Jul;61(7). PMCID: PMC3809089

Complete List of Published Work in My Bibliography:
https://www.ncbi.nlm.nih.gov/sites/myncbi/1R3CqulZLjukz/bibliography/47575820/public/?sort=date&direction=ascending

D. Research Support

Ongoing Research Support

5U54MD010722-02 NIH/NIMHD Wilkins, Cox, Lima, Weiss (MPI, Contact PI) 05/19/2016 - 03/31/2021
The Vanderbilt-Miami-Meharry Center of Excellence in Precision Medicine and Population Health will bring together institutions and faculty with substantial expertise in precision medicine and health disparities research among African Americans and Latinos/Hispanics. The Center's aims are: 1) To foster transdisciplinary research collaborations that focus on using precision medicine approaches to eradicate health disparities; 2) Develop novel methods to integrate individual, contextual and environmental data (including genomic, social, cultural, environmental and clinical) to accurately identify precise groups at risk for disparities, and to explain mechanisms for disparities; 3) Propel novel health disparities research leveraging genomic and phenotypic data to a) examine differences in drug therapy outcomes; b) identify effective person-specific treatments that enhance therapeutic outcomes among racial and ethnic minorities; c) study genomic variations that impact the specificity and response of drugs; and d) develop valid predictive models (person-specific) for preventing, screening and treating conditions and 4) Develop ethical, deliberate, socially and culturally acceptable methods for engaging racial and ethnic minorities and vulnerable populations in precision medicine research.

1U24TR001579-02 NIH/NCATS Harris, Wilkins (MPI) 07/01/2016 - 06/30/21
Improving Clinical Trial Education, Recruitment, and Enrollment at CTSA Hubs (I-CERCH)
The specific aims of the program are as follows: 1) Provide a national home and collaborative 'storefront' for the creation, storing, and sharing of recruitment education, programs, and best practices; 2) Catalyze enrollment by developing and disseminating novel technical and procedural approaches to support *researchers* in recruiting participants; 3) Enhance national awareness of research through patient education, and facilitate participant identification of studies with novel online patient facing tools; and 4) Conduct rigorous studies on methods to enhance recruitment efficacy/efficiency and make modifications based on these data.

3U24TR001579-01S1 NCATS Harris, Wilkins (MPI) 01/01/2017 – 06/30/2021
Improving Clinical trial Education, Recruitment, and Enrollment at CTSA Hubs (ICERCH)
Supplement goals: 1) develop innovative culturally tailored messaging and evaluate the overall impact on recruitment and retention in clinical trials within and across different racial/ethnic groups; 2) create clinical trial recruitment plans with input from underrepresented minority communities and to test the effectiveness of recruiting those groups in trials; 3) develop and test a training module on approaches to engaging underrepresented minorities and marginalized communities in clinical trials; and 4) build a web-based portal to disseminate innovations in minority recruitment, catalogue materials, and engage stakeholders from underrepresented communities.

1R13TR001694-01A1 NCATS Wilkins (PI) 09/01/2017 – 08/31/2018
Advancing the Science of Community Engaged Research
Overarching project goal: expand the scientific basis for the community engaged research field by convening a diverse stakeholder group including researchers, community partners, patient advocacy organizations, and others to share innovative methods and strategies.

Private Support [redacted] Rothman (PI) 03/11/2014 - 09/09/2018
The Mid-South CDRN Phase II
This award will support the continued development of infrastructure for patient-centered clinical research across multiple partnered health care systems, including data aggregation and development of information technology tools. Role: Investigator; Dr. Wilkins leads the stakeholder engagement team and oversees the refinement and implementation of its activities. She will have an active role in the leadership of MS-CDRN.

UL1TR002243-01 NIH/NCATS Bernard (PI) 06/17/2012 – 05/31/2022
Vanderbilt Institute for Clinical and Translational Research (VICTR)
VICTR was created to provide next-generation support to faculty working to translate fundamental scientific discoveries into clinical practice. Role: Associate Director, VICTR and Director, Meharry-Vanderbilt Community Engaged Research Core.

5P30CA068485-22 NCI Pietenpol (PI) 09/01/2016 - 08/31/2020
Cancer Center Support Grant
The Vanderbilt-Ingram Cancer Center Support Grant provides the infrastructure support to facilitate basic, clinical and population-based research relevant to our mission to alleviate cancer death and suffering through pioneering research, innovative patient care, evidence-based prevention, education and communication. Role: Special Populations Staff Investigator and Program Director of Community Health Educator Program

U54MD007593 NIH Adunyah (PI) Wilkins (subcontract PI) 07/01/2014 - 04/30/2019
Meharry Clinical and Translation Research Center (MeTRC)
Co-Leader – Oversee and lead Scientific Working Group to identify novel research; recruit investigators; create working structure; and support investigator teams

5P30AI110527-03 NIH/NIAID Mallal (PI) 05/01/2016 - 03/31/2020
Tennessee Center for AIDS Research (TN-CFAR) - Patient Record Reducing the overall burden of HIV/AIDS in Tennessee By forging a unique three-way partnership between VU, MMC, and TDH, the Tennessee CFAR (TN-CFAR) is building a research infrastructure toward having an impact on the overall burden of HIV diseases in our state. Role: Co-Investigator

Private Support [redacted] Rothman (PI) 09/29/2015 - 09/28/2019
Private Support [redacted]
Private Support will focus on clinical goals that are concordant with current efforts related to PQRS, VBRS, the Choosing Wisely Campaign, and a planned shared saving agreement for commercially insured patients. Clinical outcomes will focus on improving care for patients with diabetes, hypertension, coronary artery disease, heart failure, and asthma.

6-OT2-OD-023132-02 NIH/OD Denny (PI) 04/30/16 – 02/23/2017
PMI Participants Preparatory/Prototyping Initiative
Project goals: 1) Create the (non-governmental) national home and storefront for the Precision Medicine Initiative (PMI), 2) Develop and test prototypes of infrastructure for the collection, organization, storage, and security of biospecimens and health data, and 3) Develop data-driven reports for transmission to future awardees. Role: Investigator

5RM1HG009034-02 NIH/NHGRI Clayton, Malin (MPI) 05/16/2016 – 04/30/2020
Genetic Privacy and Identity in Community Settings – GetPreCiSe
Project goals: 1) enhance our understanding of the impact of threats to privacy and identity in genomic data, 2) measure the efficacy of efforts to protect privacy and identity, 3) develop models to quantify the probability of genomic data re-identification and harm, and 4) address concerns by developing interventions that provide certainty and enhance institutional trust.

1U2COD023196-02 NIH/OD Denny (PI) 07/06/2016 – 06/30/2021
Partnership in Learning around Engagement, Data, Genomics, and Environment (PLEDGE)
The Precision Medicine Initiative's (PMI's) overarching goal is to transform our understanding of the factors that contribute to health and disease, and ultimately, to leverage this understanding to information how we prevent and treat disease.

5K12HS022990-04 AHRQ Penson (PI) 08/01/2016 – 07/31/2019
The Vanderbilt PCOR Career Knowledge, Education and Training Program
This proposal will establish a PCOR mentored career development program at Vanderbilt University to train the next generation of PCOR investigators.

BIOGRAPHICAL SKETCH

NAME: **Hull, Pamela Carmen**

eRA COMMONS USER NAME: [redacted]

POSITION TITLE: **Assistant Professor of Medicine**

EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE	Completion Date	FIELD OF STUDY
Duke University, Durham, NC	BA	05/1995	Sociology
Universidad Mayor de San Simón, Cochabamba, Bolivia	--	09/1996	Gender & Development
Vanderbilt University, Nashville, TN	MA	08/2000	Sociology
Vanderbilt University, Nashville, TN	PHD	12/2004	Sociology

A. Personal Statement

I am pleased to serve as co-mentor for Dr. Jennifer Erves on her K01 application to NCI. I will contribute content-area expertise related to prevention and control of HPV-associated cancers, development and evaluation of behavioral interventions to increase HPV vaccination, and cancer disparities. My research focuses on cancer prevention and behavior, specifically focused on HPV vaccination, nutrition, and physical activity. Much of my research has focused on disparities among Hispanic and African American populations. I lead an NCI-funded R01 study with 21 community-based pediatric practices to compare the clinical effectiveness and cost-effectiveness of two modalities for delivering a multi-component practice facilitation intervention to increase HPV vaccination initiation and completion. I will provide Dr. Erves opportunities to be involved with this study for training experience and for collaborating on manuscripts. I previously co-led studies of two HPV vaccine interventions, one with community health centers and another targeting parents. I also lead the USDA-funded (R01-equivalent) Children Eating Well (CHEW) grant, which focused on early childhood obesity prevention. Under this grant, I am building on our previously development prototype smartphone application ("app") to adapt, disseminate, implement, and evaluate version 2.0 of the CHEW app through a public health nutrition program. I previously co-led a randomized clinical trial of a community-based, culturally-targeted childhood obesity intervention (Healthy Families Study) for Hispanic families.

Sanderson M, Canedo JR, Khabele D, Fadden MK, Harris C, Beard K, Burress M, Pinkerton H, Jackson C, Mayo-Gamble T, Hargreaves M, **Hull PC**. Pragmatic trial of an intervention to increase human papillomavirus vaccination in safety-net clinics. *BMC Public Health*. 2017; 17(1):158. PMID: 28153042; PMCID PMC5290601.

[redacted] In Press

Hull PC, Emerson JS, Quirk ME, Canedo JR, Jones JL, Vylegzhanina V, Schmidt DC, Mulvaney SA, Beech BM, Briley C, Harris C, Husaini BA. A Smartphone App for Families with Preschool-Aged Children in a Public Nutrition Program: Prototype Development and Beta-Testing. *JMIR mHealth uHealth*. 2017; 5(8):e102. PMID: 28768611; PMCID: PMC5559651.

Weber SJ, Dawson D, Greene H, **Hull PC**. Mobile phone apps for low-income participants in a public health program for women infants and children (WIC): Review and Analysis of Features. *JMIR mHealth uHealth*. 2018; 2018; 6(11):e12261. PMID 30455172; PMCID PMC6277824.

B. Positions and Honors

Positions and Employment

1996 - 1997	Consultant, Bureau of Gender Affairs, Bolivian Government, Cochabamba, Bolivia
1997 - 2001	Teaching Assistant, Vanderbilt University, Department of Sociology, Nashville, TN
2000	Instructor, Vanderbilt University, Department of Sociology, Nashville, TN
2001 - 2004	Research Associate, Center for Prevention Research, Tennessee State University (TSU), Nashville
2004 - 2011	Associate Director, Center for Prevention Research, TSU, Nashville, TN
2011-Present	Assistant Professor of Medicine, Division of Epidemiology, School of Medicine, Vanderbilt University Medical Center (VUMC), Nashville, TN
2013-Present	

2017-Present	Member, Cancer Health Outcomes and Control Program, Vanderbilt-Ingram Cancer Center (VICC)
2018-Present	Affiliated Faculty, VUMC Center for Clinical Quality and Implementation Research
2018-Present	Affiliated Faculty, VUMC Center for Effective Health Communication
2018-Present	Affiliated Faculty, VUMC Institute for Infection, Immunology, and Inflammation
2018-Present	Affiliated Faculty, VUMC Center for Child Health Policy
2019	Associate Director of Community Outreach and Engagement, VICC Associate Professor of Medicine, Division of Epidemiology, School of Medicine (expected 8/19)

Other Experience and Professional Memberships

2011-2017	Co-Chair (2011-2016), Past Co-Chair (2017), Southeastern Health Equity Council, National Partnership for Action to End Health Disparities, in partnership with the Office of Minority Health, US Department of Health & Human Services
2011-Present	Ad Hoc Reviewer, Scientific Review Committee, Meharry Translational Research Center (MeTRC)
2013-Present	Statewide Co-Chair, HPV Cancer Free Coalition
2015-Present	Associate Editor, *BMC Cancer*; Epidemiology, Prevention and Public Health Section
2015-2017	Lead Guest Editor, *Biomedical Informatics Insights*, Supplement issue on "Use of biomedical informatics for improving vaccine uptake and adherence"
2017	Ad Hoc Reviewer for Lister Prize Fellowship, Scientific Review Committee, Lister Institute

Honors

1991-1995	Albert G. Myers Scholarship, First Gaston Foundation
1995	Dean's List with Distinction, Duke University
1995	Graduated magna cum laude, Duke University
1995-1996	Rotary International Ambassadorial Scholarship (to study in Bolivia)
1997-2001	Graduate Teaching Assistantship, Vanderbilt University
1997-2001	University Graduate Fellowship, Vanderbilt University
2001	Special Dissertation Grant, Graduate School, Vanderbilt University
2006-2010	Health Disparities Research Loan Repayment Program Award, National Center for Minority Health and Health Disparities (NCMHD/NIH)
2011	Million Dollar Researcher Club Award, Tennessee State University

C. Contribution to Science

1. **Increasing uptake of HPV vaccine:**
The central goal of my research focused on HPV vaccination is to identify optimal approaches to implement evidence-based intervention strategies for the uptake and completion of HPV vaccine among adolescents, guided by implementation science theories. I lead an NCI-funded study (R01 CA207401) that uses a Type 2 hybrid implementation-effectiveness design to assess implementation outcomes and compare the clinical effectiveness and cost-effectiveness of two implementation strategies for delivering a multi-level, multi-component practice facilitation intervention (also called quality improvement coaching) to increase HPV vaccination initiation and completion in 21 community-based pediatric practices. The trial is currently ongoing. This study emerged from several years of formative research to develop culturally-sensitive bilingual patient education materials using a social marketing approach (see educational video and website at www.get3shots.org, English and Spanish), conduct surveys and key informant interviews with pediatric providers and other key stakeholders, build partnerships, and pilot test practice facilitation strategies. Evaluation of the patient education materials in a diverse sample of parents demonstrated that significantly more parents in the intervention arm planned to talk to the pediatrician about HPV vaccine after the workshop and more children received the first HPV vaccine dose by follow up, compared to a control group (manuscript in preparation). [redacted] Manuscript In Preparation [redacted]. I previously co-led a study with Dr. Maureen Sanderson (PI) at Meharry Medical College to develop and test an intervention in federally-qualified health centers (FQHCs) in Nashville, Tennessee, which aimed to train providers and staff to recommend HPV vaccine and use patient education materials that we developed to be culturally-appropriate for African American and Hispanic patients. The intervention

was effective at increasing provision of patient education materials and provider recommendation, although vaccine uptake did not differ across study sites after adjusting for patient's age, and over one-third of intervention arm mothers cited our materials as motivating HPV vaccination.

a. **Hull PC**, Williams EA, Khabele D, Dean C, Bond B, Sanderson M. HPV vaccine use among African American girls: qualitative formative research using a participatory social marketing approach. *Gynecol Oncol.* 2014 Mar;132 Suppl 1:S13-20. PMID 24491412; PMCID: PMC3966189.

b. Moore KL, Fankhauser MK, **Hull PC**. Tennessee's 3-Star Report: Using available data systems to reduce missed opportunities to vaccinate preteens. *Biomed Inform Insights*. 2016; 8(Suppl 2):15–21. doi:10.4137/BII.S40207. PMID: 27980415; PMCID: PMC5138065

c. Odoh C, Sanderson M, Williams EA, **Hull PC.** Operationalizing outcome measures of HPV vaccination among adolescents. *Public Health*. 2018, 159:129-132, PMID: 29609838; PMCID: 5984163.

d. Selove R, Foster M, Mack R, Sanderson M, **Hull PC**. Using an implementation research framework to identify potential facilitators and barriers of an intervention to increase HPV vaccine uptake. *Journal of Public Health Management & Practice.* 2017; 23(3):e1-e9. PMID: 27902559; PMCID: PMC5373968

2. **Childhood obesity prevention:**
I have led or co-led several studies in which we developed and tested behavioral interventions for parents aimed at promoting healthy weight gain in children. In the Nashville Children Eating Well for Health (CHEW) grant, I led the research project to gather formative research with African American and Hispanic mothers and input from stakeholders to develop and test a prototype of a smartphone app designed for low-income mothers of 2-4 year-old children receiving benefits from the federal WIC (Women, Infants, and Children) Supplemental Nutrition Program. The prototype app included WIC shopping tools and nutrition education features that focused on improving the availability of healthy food in the home and improving child feeding practices related to snacks and beverages (www.nashvillechew.org/tutorial.html). I am now lead the 5-year continuation of that grant, in which I am adapting version 2.0 of the CHEW app, and next I will conduct a Type 2 hybrid implementation-effectiveness study to assess use of the app as a dissemination strategy for get evidence-based nutrition education tools out to WIC participants, as well as an implementation strategy increasing retention in the WIC program. The app will be disseminate through all of the WIC clinics across the state of Tennessee using a wait-list control design, and we will evaluate its impact on implementation outcomes and effectiveness outcomes (WIC family benefit redemption, diet quality, and other obesity risk factors) among preschool-aged children. We will also examine the cost effectiveness of using the app in the WIC program. In the Healthy Families Study, as Co-PI, I led adaptation of a family-based intervention to target Hispanic parents with 5-7 year-old children based on formative research. We conducted a randomized controlled trial (N=272 families) of a 12-month intervention consisting of eight group classes followed by booster information by mail and phone, with an emphasis on parental modeling and experiential learning for children. While the intervention did not lead to significant differences in body mass index growth trajectories for the overall sample, dose response analysis indicated a significant effect among obese children who attended more class sessions. I am also senior author on a systematic review of childhood obesity prevention interventions in childcare settings.

a. **Hull PC**, Buchowski M, Canedo JR, Beech BM, Du L, Koyama T, Zoorob R. Childhood obesity prevention trial for Hispanic families: Outcomes of the Healthy Families Study. *Ped Obes*. 2016; e-pub ahead of print, DOI 10.1111/ijpo.12197. PMID: 27884047; PMCID: PMC5443700.

b. Zoorob R, Buchowski MS, Beech BM, Canedo JR, Chandrasekhar R, Akohoue S, **Hull PC**. Healthy Families Study: Design of a childhood obesity prevention trial for Hispanic families. *Contemp Clin Trials*. 2013 Jul;35(2):108-21. PMID: 23624172; PMCID: PMC3749297.

c. Zhou YE, Emerson JS, Levine RS, Kihlberg CJ, **Hull PC**. Childhood obesity prevention interventions in childcare settings: systematic review of randomized and nonrandomized controlled trials. *Am J Health Promot*. 2014 Mar-Apr;28(4):e92-103. PMID: 24200332.

d. Schlundt DS, Briley C, Canada B, Jones JL, Husaini BA, Emerson JS, **Hull PC.** Availability of low-fat milk and produce variety small- and mid-sized grocers after 2014 WIC final rule changes, Tennessee. *Chronic Disease Prevention*. 2017; 14(E70):1-8. PMCID: PMC5573198.

3. **Community-engaged research:**
Most of my research has utilized community-engaged research approaches in collaboration with community partners, stakeholders, and coalitions. I have published several articles in collaboration with the Nashville Latino Health Coalition, documenting some of the early stages of participatory needs assessment

and planning research that we conducted to inform the development of interventions to address community-identified needs. These findings led to my focus on childhood obesity prevention and HPV vaccination. In addition, for the Healthy Families Study described above, we developed an intervention focused on oral health education for the attention-control arm of the trial, given that oral health was one of the top community-identified priorities.

a. **Hull PC**, Canedo J, Aquilera J, Garcia E, Lira I, Reyes F. Assessing community readiness for change in the Nashville Hispanic community through participatory research. *Prog Community Health Partnersh*. 2008 Fall;2(3):185-94. PMID: 20208197.

b. **Hull PC**, Canedo JR, Reece MC, Lira I, Reyes F, Garcia E, Juarez P, Williams E, Husaini BA. Using a participatory research process to address disproportionate Hispanic cancer burden. *J Health Care Poor Underserved*. 2010 Feb;21(1 Suppl):95-113. PMID: 20173287; PMCID: PMC3831608.

c. **Hull PC**, Reece MC, Patton M, Williams J, Beech BM, Canedo JR, Zoorob R. A community-based oral health self-care intervention for Hispanic families. *Int J Public Health*. 2014 Feb;59(1):61-6. PMID: 23612890; PMCID: PMC3884052.

d. Emerson JS, Towns DR, Jones JL, Cain VA, **Hull PC**. Racial/ethnic and Weight Status Differences in Food Preparation among WIC Participants. *J Health Care Poor Underserved*. 2015;26(2):335-44. PMID: 25913333.

4. **Health disparities:**
Prior to starting my tenure-track faculty position at Vanderbilt, I worked in a research center at Tennessee State University, which is a historically-black university, in which I gained more experience in studying the causes and consequences of health disparities, including neighborhood context, healthcare access, and quality of care. I also collaborated on the development and testing of culturally-targeted health promotion interventions focusing on reducing health disparities experienced by African Americans. Much of my own research in recent years has continued to include a focus on health disparities among African Americans, Hispanics, and low-income populations.

a. **Hull PC**, Kilbourne B, Reece M, Husaini B. Community involvement and adolescent mental health: Moderating effects of race/ethnicity and neighborhood disadvantage. *Journal of community psychology*. 2008; 36(4):534-551.

b. **Hull PC**, Husaini BA, Tropez-Sims S, Reece M, Emerson J, Levine R. EPSDT preventive services in a low-income pediatric population: impact of a nursing protocol. *Clin Pediatr*. 2008 Mar;47(2):137-42. PubMed PMID: 17873239.

c. Emerson JS, **Hull PC**, Cain VA, Novotny ML, Larson CO, Levine RS. Challenges and strategies in serving the uninsured in Nashville, Tennessee. *J Ambul Care Manage*. 2012 Oct-Dec;35(4):323-34. PubMed PMID: 22955092.

d. Selove R, Foster M, Wujcik D, Sanderson M, **Hull PC**, Shen-Miller D, Wolff S, Friedman D. Psychosocial concerns and needs of cancer survivors treated at a comprehensive cancer center and a community safety net hospital. *Support Care Cancer*. 2017; 25(3):895**–**904. PMCID: PMC5269536

Complete List of Published Work in My Bibliography:
http://www.ncbi.nlm.nih.gov/myncbi/pamela.hull.1/bibliography/47984021/public/?sort=date&direction=ascending

D. Research Support

Ongoing Research Support

R01 CA207401, National Cancer Institute, Hull (PI) **12/2016-11/2021**
Increasing HPV Vaccination in Community-Based Pediatric Practices
This study aims to compare the clinical effectiveness and cost-effectiveness of two modalities for delivering a multi-component practice facilitation intervention to increase HPV vaccination initiation and completion in community-based pediatric practices, as well as examining possible mediating and moderating factors.
Role: PI

2017-68001-26352, U.S. Department of Agriculture, AFRI, Hull (PI) **4/2017-4/2022**
Children Eating Well (CHEW) Smartphone Application for WIC Families
We will adapt, disseminate, and evaluate CHEW smartphone application, aimed to increase WIC benefit redemption and improve obesity risk among preschool-aged children, while training future obesity researchers.

Role: PI

R01 CA232743, National Cancer Institute, Cólon-López (PI) 12/2018-11/2023
Implementation of School-Entry Policies for Human Papillomavirus Vaccination
This study aims to examine geographic variation in the dissemination and implementation of HPV vaccine policies across US states and territories, and to study the implementation and outcomes of the new school-entry HPV policy in Puerto Rico in depth.
Role: PI

P30 CA068485, National Cancer Institute, Pietenpol (PI) 09/2015-08/2020
Cancer Center Support Grant
The primary goals are: 1) coordinate and integrate cancer and cancer-related activities of VICC; 2) conduct enhance cancer research and to integrate cancer-related activities; 3) integrate, develop and conduct cancer education programs; and 4) to coordinate and integrate the care of cancer patients at VICC.
Role: Associate Director of Community Outreach and Engagement

U54 CA163072, National Cancer Institute, Moses (PI) 9/2016-8/2021
Meharry-VICC-TSU Partners in Eliminating Cancer Disparities
Meharry-Vanderbilt-TSU Cancer Partnership aims to enhance the cancer disparities research and outreach activities at Meharry Medical College (MMC) and Tennessee State University (TSU) and VICC.
Role: Co-Leader of Cancer Outreach Core

U54 MD010722, NIMHD, Wilkins (M-PI) 5/2016-3/2021
Center of Excellence in Precision Medicine and Population Health
The Center will leverage unique assets and resources to develop novel methods and approaches to advance population health and precision medicine, while examining multilevel determinants that drive health disparities.
Role: Co-Investigator on Consortium Core

2015-70018-23332, U.S. Department of Agriculture, James Lutzweiler (PD) 4/2015-3/2019
Large Scale SNAP Incentives at a National Retailer and Farmers` Markets in Mississippi & Tennessee
This project aims to implement an incentive program (FreshSavings) for SNAP participants to purchase more fresh fruits and vegetables at Kroger stores and farmers' markets in Tennessee and Mississippi.
Role: Evaluator

Completed Research Support

2011-68001-30113, U.S. Department of Agriculture, AFRI, Husaini (PI) 2/2011-2/2017
Nashville Children Eating Well (CHEW) for Health
Role: Co-PI and Research Project PI

U54 CA153708, National Cancer Institute, Hargreaves (PI) 9/2010-8/2016
Meharry Medical College – CHC Community Networks Program Center II
Project: *Development of an HPV and cervical cancer screening provider intervention* (Sanderson, Project PI)
Role: Full Project Co-PI

P30 CA068485-18S3, National Cancer Institute, Pietenpol (PI) 9/2014-8/2015
A Strategic Research Partnership to Increase HPV Vaccination in Pediatric Settings
Administrative supplement to VICC Cancer Center Support Grant
Role: Leader/Cancer Control Coordinator

U54 CA163072-04S1, National Cancer Institute, Moses (PI) 9/2014-8/2015
Assessment of a Social Marketing Intervention to Increase HPV Vaccination
Administrative supplement to Meharry-Vanderbilt-TSU Cancer Partnership
Role: Leader/Evaluator

P20 MD003362, NIMHHD, Mouton (PI) 5/2009-11/2014
Culturally-Appropriate Childhood Obesity Prevention Program for Hispanic Families (Healthy Families Study) Project under Health Disparities Research Center of Excellence at Meharry. (Zoorob, Full Project PI)
Role: Full Project Co-PI

OMB No. 0925-0001 and 0925-0002 (Rev. 10/15 Approved Through 10/31/2018)

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: Dempsey, Amanda F

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

POSITION TITLE: Associate Professor of Pediatrics

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

INSTITUTION AND LOCATION	DEGREE (if applicable)	Completion Date MM/YYYY	FIELD OF STUDY
University of Rochester	BS	06/1991	Developmental Biology
Vanderbilt	PHD	05/1998	Cell Biology
Vanderbilt University	MD	05/2000	Medicine
Seattle Children's Hospital	OTH	06/2003	Residency in Pediatrics
University of Washington	OTH	06/2005	Robert Wood Johnson Clinical Scholars Program
University of Washington	MPH	06/2005	Health Services

A. Personal Statement

I am an Professor of Pediatrics at the University of Colorado [redacted], and a senior faculty member of the Adult and Child Consortium for Outcomes Research and Dissemination Science (ACCORDS) program. I also serve as the director of the Surgical/Subspecialist Clinical Outcomes Research (SCORE) fellowship at the University of Colorado that provides extensive mentoring and education in health services research for junior faculty over a two-year period. I have mentored 14 junior faculty since 2015, including Dr. Erves, and have served or am currently serving as a primary mentor for 4 other faculty involved in writing/receiving K awards. In terms of research expertise, have an extensive research background in immunization delivery, and am recognized internationally for this work, particularly as it relates to HPV vaccination. In this topical area, I have led numerous studies related to improving vaccine delivery in the primary care setting, and have been the PI on several large grants to support this work, receiving multi-million dollar [redacted], NIH, and CDC. Methodologically I have expertise in using qualitative and quantitative methods to examine barriers to implementing recommended, evidence-based procedures (in this case related to vaccination), survey design, large data base analysis, and the development and assessment of interventions to improve vaccine utilization in the outpatient setting. These experiences will be of direct relevance to Dr. Erves' project. I will bring both my methodological and topical expertise to the current application to assist Dr. Erves as a mentor on her project. This past record of academic research and mentoring success, plus my topical expertise in the field of HPV vaccination, will help to ensure the successful completion of the activities proposed in her application.

B. Positions and Honors

Positions and Employment

2003 - 2006	Instructor, Department of Pediatrics, University of Washington, Seattle, WA
2006 - 2008	Lecturer, General Pediatrics, University of Michigan, Ann Arbor, MI
2008 - 2011	Assistant Professor, General Pediatrics, University of Michigan, Ann Arbor, MI
2011 - 2012	Adjunct Assistant Professor, Health Management and Policy, School of Public Health, University of Michigan, Ann Arbor, MI
2012 – present	Associate Professor of Pediatrics, Adult and Child Center for Outcomes Research and Dissemination Science, University of Colorado Denver, Denver, CO.
2017-2017	Co-Director, Surgical/Subspecialist Clinical Outcomes (SCORE) Fellowship, University of Colorado Denver.
2017-present	

Director, Surgical/Subspecialist Clinical Outcomes (SCORE) Fellowship, University of Colorado Denver.

Other Experience and Professional Memberships

2003 -	Member, American Academy of Pediatrics
2003 -	Member, International Papillomavirus Society
2006 -	Member, Ambulatory Pediatrics Association
2008 -	Member, Society for Pediatric Research

Honors

1991	Cum Laude undergraduate graduation honors, University of Rochester

C. Contribution to Science

1. At the time of licensure of the human papillomavirus (HPV) vaccine, little was known about or had been considered regarding its acceptance among the general public. Indeed, history has in fact shown that the HPv vaccine is one of the most 'controversial' vaccines on the current vaccination schedule. Since the licensure of the vaccine in 2006 hundreds of articles have been published regarding HPV vaccine acceptability among parents, patients, and providers. One of the seminal articles in this field came from my early research that described parental acceptability of HPV vaccines for adolescents. Importantly, this work demonstrated a lack of influence on parental HPV vaccine acceptability with 'generic' educational materials - a finding that has since been replicated in numerous populations, and has provoked the need to identify novel and innovative educational methods to promote acceptance of the vaccine. Although the 2006 study was one of the first to examine parental acceptability of HPV vaccines, I have continued to work in this area for over a decade, furthering our understanding of facilitators and barriers to adolescent HPV vaccination, and examining the evolution of these factors over time.

    a. **Dempsey AF**, Zimet GD, Davis RL, Koutsky L. Factors that are associated with parental acceptance of human papillomavirus vaccines: a randomized intervention study of written information about HPV. Pediatrics. 2006 May;117(5):1486-93. PubMed PMID: 16651301.
    b. **Dempsey AF**, Abraham LM, Dalton V, Ruffin M. Understanding the reasons why mothers do or do not have their adolescent daughters vaccinated against human papillomavirus. Ann Epidemiol. 2009 Aug;19(8):531-8. PubMed PMID: 19394865; PubMed Central PMCID: PMC2880849.
    c. **Dempsey A**, Cohn L, Dalton V, Ruffin M. Patient and clinic factors associated with adolescent human papillomavirus vaccine utilization within a university-based health system. Vaccine. 2010 Jan 22;28(4):989-95. PubMed PMID: 19925899; PubMed Central PMCID: PMC2887043.
    d. **Dempsey AF**, Butchart A, Singer D, Clark S, Davis M. Factors associated with parental intentions for male human papillomavirus vaccination: results of a national survey. Sex Transm Dis. 2011 Aug;38(8):769-76. PubMed PMID: 21336230.

2. In recent years, significant focus has been on providing recommended vaccines to adolescents. Formalization of an "adolescent platform" of vaccines gained momentum in 2005, coincident with national recommendations for universal vaccination of all adolescents with the tetanus-diphtheria-acellular pertussis vaccine. Since that time, 3 additional vaccines have been added to the platform, and more are expected in the future. Much of my work has focused on describing current adolescent vaccine utilization patterns and identifying clinic, patient, and provider-level barriers to getting adolescents vaccinated. My work, along with that of many others, has laid the foundation for more recent studies undertaken by many groups aimed at identifying successful interventions to overcome these barriers. This particular set of studies also represents my work as a mentor with Dr. Charitha Gowda when she was completing a post-doctoral fellowship. Dr. Gowda's projects culminated in several other publications besides those listed here.

    a. Gowda C, **Dempsey AF**. Medicaid reimbursement and the uptake of adolescent vaccines. Vaccine. 2012 Feb 21;30(9):1682-9. PubMed PMID: 22226859.

b. Gowda C, Schaffer SE, Dombkowski KJ, **Dempsey AF**. Understanding attitudes toward adolescent vaccination and the decision-making dynamic among adolescents, parents and providers. BMC Public Health. 2012 Jul 7;12:509. PubMed PMID: 22768870; PubMed Central PMCID: PMC3406969.

c. Gowda C, Dong S, Potter RC, Dombkowski KJ, **Dempsey AF**. A population-level assessment of factors associated with uptake of adolescent-targeted vaccines in Michigan. J Adolesc Health. 2013 Oct;53(4):498-505. PubMed PMID: 24054080.

d. Gowda C, Dong S, Potter RC, Dombkowski KJ, Stokley S, **Dempsey AF**. A systematic evaluation of different methods for calculating adolescent vaccination levels using immunization information system data. Public Health Rep. 2013 Nov-Dec;128(6):489-97. PubMed PMID: 24179260; PubMed Central PMCID: PMC3804092.

3. Healthy people 2020 states a national goal of 80% coverage for the four vaccines recommended specifically for the adolescent population: the human papillomavirus (HPV) vaccine, the meningococcal vaccine, the tetanus-diphtheria-acellular pertussis (Tdap) vaccine, and the influenza vaccine. Yet, national studies demonstrate that among U.S. adolescents age 13-17 years, utilization is below this target level for three of these four vaccines, with HPV vaccination one of the lowest. Thus, there is a critical need to identify interventions to improve adolescent vaccine utilization, especially for HPV. As a direct response to this need, my research has recently focused on developing, implementing, and evaluating different types of interventions to increase adolescent vaccine acceptance within the primary care setting. Much of this work has focused on using modern technology such as "smart sites" and text messaging to achieve this goal. This work represents a cutting edge interface between technology, public health and primary care. If these interventions prove successful, the impact on improving public health could be significant.

   a. **Dempsey AF**, Maertens J, Beaty B, O'Leary ST. Characteristics of users of a tailored, interactive website for parents and its impact on adolescent vaccination attitudes and uptake. BMC Res Notes. 2015 Dec 1;8:739. PubMed PMID: 26625932; PubMed Central PMCID: PMC4665955.

   b. **Dempsey AF**, Zimet GD. Interventions to Improve Adolescent Vaccination: What May Work and What Still Needs to Be Tested. Am J Prev Med. 2015 Dec;49(6 Suppl 4):S445-54. PubMed PMID: 26272849.

   c. **Dempsey AF**, Maertens J, Beaty BL, O'Leary ST. Understanding how different recruitment strategies impact parent engagement with an iPad-based intervention to provide personalized information about adolescent vaccines. J Adolesc Health. 2015 May;56(5 Suppl):S7-13. PubMed PMID: 25863557.

   d. Small SL, Sampselle CM, Martyn KK, **Dempsey AF**. Using risk to target HPV vaccines in high-risk, low-resource organizations. Hum Vaccin Immunother. 2013 May;9(5):1146-52. PubMed PMID: 23324592; PubMed Central PMCID: PMC3899152.

4. Since 2015 I have increased my participation in formalized junior faculty development through my role in the SCORE fellowship. This has allowed me to expand my publication record into other topical domains based on my mentorship of these faculty. This diversification exemplifies my ability to successfully mentor researchers in a variety of health services research topics.

   a. [redacted] In Press [redacted]

   b. [redacted] In Press [redacted]

   c. [redacted] In Press [redacted]

   d. Tyler, A, Hyman, D, Beaty, B, **Dempsey, AF.** Variation in in patient croup management and outcomes. 2017 *Pediatrics,* Apr;139(4). Pubmed PMID: 28292873

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

Ongoing Research Support

R01 HD079457-03, National Institutes of Health, Eunice Kennedy Shriver National Institute of Child Health and Development
Dempsey, Amanda F (PI)
05/05/14-03/31/2020
The REDIVAC Study - Reducing Delay In Vaccination of Children Study
Role: PI
This study addresses the impact of a tailored messaging intervention on vaccination timeliness among infants.
Patient Centered Outcomes Research Institute

No grant number, [redacted]
Forrest (PI), Dempsey (Site PI)
10/15/18-10/13/20
PEDSNet CDRN
This study aims to develop a data base of clinical care information for 8 children's hospitals dispersed across the U.S. and to use this resource to perform retrospective and prospective studies on child health.
Role: Site PI

1U01 IP001070-01, Centers for Disease Control and Prevention
Dempsey, Amanda F (PI)
09/01/2018 – 08/31/2022
Understanding and Addressing Vaccination Disparities among Rural Adolescents
Role: PI
The goal of this randomized, controlled, pragmatic trial is to assess the impact of a community engagement method called "boot camp translation" on adolescent vaccination rates in rural Colorado

1R01 HD093628-01
O'Leary/Opel (PI)
Evaluation of the Presumptively Initiating Vaccines and Optimizing Talk with Motivational Interviewing (PIVOT with MI) Intervention
Role: Co-I
The goal of this project is to evaluate the impact of a novel and innovative provider communication strategy on vaccine acceptance among vaccine-hesitant parents.

Completed Research Support

[redacted]
Shlay (PI)
07/01/15-06/30/18
Denver Metro Alliance for HPV Prevention
This project grant seeks to develop and implement a multi-faceted approach to improving HPV vaccine uptake among adolescents in the 5 most populous counties in Colorado
Role: Co-Investigator

[redacted]
Borrayo (PI)
07/01/15-06/01/18
Multi-Level Intervention to Reduce Cervical Cancer Risks among Young Latinas

This project grant seeks to develop a patient navigator intervention for young adult Latinas to improve their uptake of HPV vaccines within a safety net clinical system in Metro Denver.
Role: Co-Investigator

U01 IP000801-01, Centers for Disease Control and Prevention
Dempsey, Amanda F (PI)
08/01/13-12/31/16
Strengthening Physician Communication about Adolescent Vaccines
Role: PI

[redacted]
Dempsey, Amanda F (PI)
03/01/13-12/31/16
Cultural Tailoring of Educational Materials to Minimize Disparities in HPV Vaccination
Role: PI

U01 IP000501-03, Centers for Disease Control and Prevention
Dempsey, Amanda F (PI)
09/01/11-08/31/15
Immunization Delivery in Obstetrics and Gynecology Settings
Role: PI

U01-IP000414, Center for Disease Control and Prevention
Dombkowski, Kevin (Formerly Dempsey, Amanda) (PI)
09/01/09-08/31/15
Improving Vaccination Coverage Among Adolescents
Role: Co-Investigator

OTHER SUPPORT

WILKINS, CONSUELO H.

ACTIVE

5U54MD010722-03,03S1(Wilkins, MPI) 05/19/2016 - 03/31/21 Calendar Months
NIH/NIMHD $2,398,048
Center of Excellence in Precision Medicine and Population Health
The goal of this project is to establish a Center of Excellence in Precision Medicine and Population Health in order to identify genetic and phenotype markers representative of lifetime risks and outcomes for asthma, pre-term birth, cancer and Body Mass Index in African American and Hispanics/Latino populations.

5U24TR001579-03 (Harris, Wilkins MPI) 07/01/2016 - 06/30/2021 Calendar Months
NIH/NCATS $1,923,495
Improving Clinical Trial Education, Recruitment, and Enrollment at CTSA Hubs (I-CERCH)
The specific aims of the program are as follows: 1) Provide a national home and collaborative 'storefront' for the creation, storing, and sharing of recruitment education, programs, and best practices; 2) Catalyze enrollment by developing and disseminating novel technical and procedural approaches to support *researchers* in recruiting participants; 3) Enhance national awareness of research through patient education, and facilitate participant identification of studies with novel online patient facing tools; and 4) Conduct rigorous studies on methods to enhance recruitment efficacy/efficiency and make modifications based on these data.

3U24TR001579-01S1(Harris, Wilkins MPI) 01/01/2017 – 06/30/2021 Calendar Months
NCATS $474,553
Improving Clinical trial Education, Recruitment, and Enrollment at CTSA Hubs (ICERCH)
The goals of this supplement are to, 1: Develop innovative culturally tailored messaging and evaluate the overall impact on recruitment and retention in clinical trials within and across different racial/ethnic groups; 2: Create clinical trial recruitment plans with input from underrepresented minority communities and to test the effectiveness of recruiting those groups in trials; 3: Develop and test a training module on approaches to engaging underrepresented minorities and marginalized communities in clinical trials; and 4: Build a web-based portal to disseminate innovations in minority recruitment, catalogue materials, and engage stakeholders from underrepresented communities.

Private Support (Wilkins) 07/15/2018 – 07/14/2020 Calendar Months
Private Support $109,117
Engendering Trust in Health Care: Incorporating gender, age and race in efforts to measure and increase trust among African American men
We propose to conduct a study of African American men's medical help-seeking that examines dimensions of trust and perceived mutual respect as key factors that shape their willingness to initially seek and return for care. Our study considers the historical and intergenerational context that shapes engagement in the health care system.

5P30CA068485-23 (Pietenpol) 04/30/16 - 08/31/20 Calendar Months
NIH/NCI $3,704,490
Cancer Center Support Grant
The Vanderbilt-Ingram Cancer Center Support Grant provides the infrastructure support to facilitate basic, clinical and population-based research relevant to our mission to alleviate cancer death and suffering through pioneering research, innovative patient care, evidence-based prevention, education and communication.

U54MD007593 (Adunyah) 07/01/14 - 04/30/19 Calendar Months
NIMHD/Meharry Medical College $11,376
Meharry Clinical and Translational Research Center (MeTRC)
Oversee and lead Scientific Working Groups that will work to 1) identify high-priority areas for novel research, 2) recruit investigators, 3) create a collaborative space and working structure, and 4) support and sustain investigator teams.

Private Support (Rothman) 11/01/2018 – 09/30/2020 Calendar Months
$1,468,998

Private Support

Private Support will allow us to: 1) expand our data research network from our existing network to our broader VHAN which will include 32 hospitals and over 500 ambulatory practices covering over 3 million lives in the mid-South; 2) expand our data research network to include Greenway, which includes over 24 million lives; 3) expand and optimize patient facing tools for direct collection of patient related data, including attitudes, behaviors, satisfaction, quality, adverse events, and outcomes; and, 4) improve our current tools for creating data integration and interoperability between the network's hospitals and ambulatory practices. (includes Diabetes and Obesity supplement)

Private Support (Rothman) 09/29/16 - 09/28/19 Calendar Months
$5,191,756
Transforming Clinical Practice Initiative (TCPI) – Year 4
The Mid-South PTN will focus on clinical goals that are concordant with our current efforts related to PQRS, VBRS, the Choosing Wisely Campaign, and a planned shared saving agreement for commercially insured patients. Clinical outcomes will focus on improving care for patients with diabetes, hypertension, coronary artery disease, heart failure, and asthma. We will also focus on preventive efforts including pediatric/adult vaccination and cancer screenings. Goals will be achieved through centralized data aggregation and reporting, centralized and local QI cycles, and other approaches that engage local clinicians, their practices, and the community.

5RM1HG009034-03 (Malin, Clayton MPI) 05/16/2016 – 04/30/2020 Calendar Months
NIH/NHGRI $641,924
Genetic Privacy and Identity in Community Settings – GetPreCiSe
The goals of this project are to: 1) enhance our understanding of the impact of threats to privacy and identity in genomic data, 2) measure the efficacy of efforts to protect privacy and identity, 3) develop models to quantify the probability of genomic data re-identification and harm, and 4) address concerns by developing interventions that provide certainty and enhance institutional trust, as well as policy solutions that could deter intrusions of privacy and misuse.

5U2COD023196-02 (Denny) 07/06/2016 – 12/31/2021 Calendar Months
NIH/OD $28,399,163
Partnership in Learning around Engagement, Data, Genomics, and Environment (PLEDGE)
The Precision Medicine Initiative's (PMI's) overarching goal is to transform our understanding of the factors that contribute to health and disease, and ultimately, to leverage this understanding to information how we prevent and treat disease. Dr. Wilkins is Program Director and Lead of the Engagement Core.

5UL1TR002243-02 (Bernard) 6/01/2017 – 2/28/2022 Calendar Months
NCATS $4,773,476
Vanderbilt Institute for Clinical and Translational Research (VICTR)
The VICTR Clinical and Translational Science Award (CTSA) represents a major component of Vanderbilt's infrastructure for patient-oriented research.

5U54MD007586-32(Miller-Hughes) 09/01/2017 – 06/30/2022 Calendar Months
NIMHD/Meharry Medical College $10,542
RCMI Community Engagement Core
The Community Engagement Core will employ an inclusive and participatory engagement philosophy to involve disparate communities in all aspects of the health disparities research at Meharry Medical College. A conceptual framework that recognizes the structural, social, cultural, behavioral, and biological factors that influence disparities will guide the Community Engagement Core's implementation of the specific aims.

PENDING

Pending Support

Pending Support

[redacted]

OVERLAP

There is no scientific or budget overlap. Institutional policy prevents overall effort to exceed 12 calendar months. As such, any potential overlap for the “pending” projects will be addressed/adjusted in compliance with Institutional policy and NIH/AHRQ policy.

OTHER SUPPORT
Hull, Pamela

ACTIVE:

5R01 CA207401-02 (Hull) 12/01/2016 - 11/30/2021 Calendar Months
NIH/NCI $426,426
Increasing HPV vaccine uptake in community-based pediatric practices
This study aims to determine the clinical effectiveness and cost-effectiveness of two modalities for delivering a multi-component practice facilitation intervention to increase HPV vaccination initiation and completion in community-based pediatric practices. In addition, the study aims to understand mechanisms of why the intervention may work better for some pediatric practices than others for HPV vaccination.

5U54 MD010722-03 (Wilkins) 05/19/2016-03/31/2021 Calendar Months
NIH/NIMHD $2,143,973
Center of Excellence in Precision Medicine and Population Health
The Center will leverage unique assets and resources to develop novel methods and approaches to advance population health and precision medicine, while examining multilevel determinants that drive health disparities.

2017-68001-26352 (Hull) 04/15/2017 - 04/14/2020 Calendar Months
USDA $644,636
Children Eating Well (CHEW) Smartphone Application for WIC Families
This study aims to adapt, implement, and evaluate a culturally-appropriate, smartphone application ("app") designed for use in the WIC program to maximize redemption of WIC benefits and promote healthy dietary and physical activity behaviors among preschool-aged children.

5U54 CA163072-09 (Moses) 09/22/2016-08/31/2021 Calendar Months
NIH/NCI $780,323
MMC, VICC & TSU: Partners in Eliminating Cancer Disparities
The Meharry-Vanderbilt-TSU Cancer Partnership grant aims to enhance the cancer research capability, training, education and outreach activities at Meharry Medical College (MMC) and Tennessee State University (TSU) and to improve the effectiveness of these activities at VICC for benefiting minority populations. Dr. Hull co-leads the Outreach Core.

Private Support 04/30/2016-03/31/2019 Calendar Months
$12,897
Evaluation of SNAP Incentives to Increase Fruit and Vegetable Purchase and Consumption in Tennessee and Mississippi
This project led by AARP Foundation aims to implement an incentive program (Fresh$avings) for SNAP participants to purchase more fresh fruits and vegetables at Kroger stores and farmers' markets in Tennessee and Mississippi. Dr. Hull serves as one of the evaluators.

P30 CA068485, Pietenpol (PI) 09/2015-08/2020 Calendar Months
National Cancer Institute $3,704,490
Cancer Center Support Grant
The primary goals are: Assess and monitor cancer-related needs and opportunities in the catchment area, Prioritize and align research and control strategies to address catchment area needs, Disseminate evidence-based cancer prevention and control practices , Enhance the impact of center research to reduce cancer burden and disparities within and beyond the catchment area

VUMC (Hull) 12/01/2018 - 11/30/2023 Calendar Months
NCI/Universidad de Puerto Rico $14,744

Implementation of School-Entry Policies for Human Papillomavirus Vaccination
This study aims to enhance understanding of geographic variation in HPV vaccine policies and outcomes across US states and territories, while taking advantage of the timely opportunity to study the implementation and impact of the new school-entry HPV vaccine policy in Puerto Rico. Dr. Hull will serve as a co-investigator.

PENDING

Pending Support

[redacted]

OVERLAP

(None) *There are no scientific and/or effort overlap issues.* ***Vanderbilt has an internal policy in place that restricts the potential for overlap of effort exceeding greater than 12 calendar months (100%).***

OTHER SUPPORT

DEMPSEY, A.

ACTIVE

R01 HD079457 (Dempsey) 05/05/2014 – 03/31/2020
NIH/NICHD $414,492
The REDIVAC Study – Reducing Delay in Vaccination of Children Study
Our intervention is designed to be delivered to mothers during the most critical time in their vaccination decision-making, without placing an increased burden on clinicians or the clinical encounter. Because of this, and the fact that our intervention is web-based, it has the capacity to be implemented on a large scale for relatively little cost, and could therefore become an important public health tool with a substantial potential to reduce the incidence of vaccine-preventable diseases.

[redacted] (Forrest) 10/15/2018 – 10/13/2020
$171,822 (subcontract only)
PEDSnet: a Pediatric Learning Health System
This study aims to develop a data base of clinical care information for 8 children's hospitals dispersed across the U.S. and to use this resource to perform retrospective and prospective studies on child health.

1U01 IP001070-01 (Dempsey) 09/01/2018 – 08/31/2021
CDC $317,403
Understanding and Addressing Vaccination Disparities among Rural Adolescents
The goal of this randomized, controlled, pragmatic trial is to assess the impact of a community engagement method called "boot camp translation" on adolescent vaccination rates in rural Colorado.

1R01 HD093628-01 (O'Leary/Opel) 09/01/2018 – 08/31/2023
NIH / NICHD $611,199
Evaluation of the Presumptively Initiating Vaccines and Optimizing Talk with Motivational Interviewing (PIVOT with MI) Intervention
The goal of this project is to evaluate the impact of a novel and innovative provider communication strategy on vaccine acceptance among vaccine-hesitant parents.

PENDING

[redacted]

OMB Number: 4040-0001
Expiration Date: 10/31/2019

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

ORGANIZATIONAL DUNS*: 0414381850000

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: MEHARRY MEDICAL COLLEGE

Start Date*: 12-01-2019 **End Date*:** 11-30-2020 **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 .		Jennifer	C	Erves	Ph.D	PD/PI	Institutional Base Salary	Calendar Months			76,500.00	20,028.00	96,528.00

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

Additional Senior Key Persons: File Name:

Total Senior/Key Person **96,528.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
1	Graduate Students	3.0			8,128.00	622.00	8,750.00
	Undergraduate Students						
	Secretarial/Clerical						
1	**Total Number Other Personnel**					**Total Other Personnel**	**8,750.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**105,278.00**

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

Funding Opportunity Number: PAR-18-365 . Received Date: 2019-03-12T11:51:54.000-04:00

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

ORGANIZATIONAL DUNS*: 0414381850000
Budget Type*: ● Project ❍ Subaward/Consortium
Organization: MEHARRY MEDICAL COLLEGE

Start Date*: 12-01-2019 **End Date*:** 11-30-2020 **Budget Period: 1**

C. Equipment Description		
List items and dollar amount for each item exceeding $5,000		
Equipment Item		**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file		
	Total Equipment	**0.00**

Additional Equipment: File Name:

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	3,000.00
2. Foreign Travel Costs	
Total Travel Cost	**3,000.00**

E. Participant/Trainee Support Costs		**Funds Requested ($)***
1. Tuition/Fees/Health Insurance		4,218.00
2. Stipends		
3. Travel		
4. Subsistence		
5. Other:		
Number of Participants/Trainees	**Total Participant Trainee Support Costs**	**4,218.00**

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

Tracking Number: GRANT12814098 Funding Opportunity Number: PAR-18-365 . Received Date: 2019-03-12T11:51:54.000-04:00

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

ORGANIZATIONAL DUNS*: 0414381850000
Budget Type*: ● Project ❍ Subaward/Consortium
Organization: MEHARRY MEDICAL COLLEGE

Start Date*: 12-01-2019 **End Date*:** 11-30-2020 **Budget Period: 1**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	1,940.00
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8 . incentives	1,400.00
9 . website	9,372.00
Total Other Direct Costs	**12,712.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**125,208.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1 . MTDC	8.0	120,990.00	9,679.00
		Total Indirect Costs	**9,679.00**

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number): DHHS, Darryl Mayes, 301 492 4855

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**134,887.00**

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	134,887.00

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

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

Tracking Number: GRANT12814098 Funding Opportunity Number: PAR-18-365 . Received Date: 2019-03-12T11:51:54.000-04:00

OMB Number: 4040-0001
Expiration Date: 10/31/2019

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

ORGANIZATIONAL DUNS*: 0414381850000

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: MEHARRY MEDICAL COLLEGE

Start Date*: 12-01-2020 **End Date*:** 11-30-2021 **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 .		Jennifer	C	Erves	Ph.D	PD/PI	Institutional Base Salary	Calendar Months			76,500.00	20,028.00	96,528.00

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

Additional Senior Key Persons: File Name:

Total Senior/Key Person **96,528.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
1	Graduate Students	3.0			8,128.00	622.00	8,750.00
	Undergraduate Students						
	Secretarial/Clerical						
1	**Total Number Other Personnel**					**Total Other Personnel**	**8,750.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**105,278.00**

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

Funding Opportunity Number: PAR-18-365 . Received Date: 2019-03-12T11:51:54.000-04:00

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

ORGANIZATIONAL DUNS*: 0414381850000
Budget Type*: ● Project ❍ Subaward/Consortium
Organization: MEHARRY MEDICAL COLLEGE

Start Date*: 12-01-2020 **End Date*:** 11-30-2021 **Budget Period: 2**

C. Equipment Description	
List items and dollar amount for each item exceeding $5,000	
Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	**0.00**

Additional Equipment: File Name:

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	3,000.00
2. Foreign Travel Costs	
Total Travel Cost	**3,000.00**

E. Participant/Trainee Support Costs		**Funds Requested ($)***
1. Tuition/Fees/Health Insurance		4,218.00
2. Stipends		
3. Travel		
4. Subsistence		
5. Other:		
1 Number of Participants/Trainees	**Total Participant Trainee Support Costs**	**4,218.00**

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

Tracking Number: GRANT12814098 Funding Opportunity Number: PAR-18-365 . Received Date: 2019-03-12T11:51:54.000-04:00

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

ORGANIZATIONAL DUNS*: 0414381850000
Budget Type*: ● Project ❍ Subaward/Consortium
Organization: MEHARRY MEDICAL COLLEGE

Start Date*: 12-01-2020 **End Date*:** 11-30-2021 **Budget Period: 2**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	375.00
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8 . incentives	4,410.00
9 . website	10,500.00
Total Other Direct Costs	**15,285.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**127,781.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1 . MTDC	8.0	123,563.00	9,885.00
		Total Indirect Costs	**9,885.00**

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number): DHHS, Darryl Mayes, 301 492 4855

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**137,666.00**

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	137,666.00

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

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

Tracking Number: GRANT12814098 Funding Opportunity Number: PAR-18-365 . Received Date: 2019-03-12T11:51:54.000-04:00

OMB Number: 4040-0001
Expiration Date: 10/31/2019

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

ORGANIZATIONAL DUNS*: 0414381850000

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: MEHARRY MEDICAL COLLEGE

Start Date*: 12-01-2021 **End Date*:** 11-30-2022 **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 .		Jennifer	C	Erves	Ph.D	PD/PI	Institutional Base Salary	Calendar Months			76,500.00	20,028.00	96,528.00

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

Additional Senior Key Persons: File Name:

Total Senior/Key Person **96,528.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
1	Graduate Students	3.0			8,128.00	622.00	8,750.00
	Undergraduate Students						
	Secretarial/Clerical						
1	**Total Number Other Personnel**					**Total Other Personnel**	**8,750.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**105,278.00**

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

Funding Opportunity Number: PAR-18-365 . Received Date: 2019-03-12T11:51:54.000-04:00

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

ORGANIZATIONAL DUNS*: 0414381850000
Budget Type*: ● Project ❍ Subaward/Consortium
Organization: MEHARRY MEDICAL COLLEGE

Start Date*: 12-01-2021 **End Date*:** 11-30-2022 **Budget Period: 3**

C. Equipment Description	
List items and dollar amount for each item exceeding $5,000	
Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	**0.00**

Additional Equipment: File Name:

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	3,000.00
2. Foreign Travel Costs	
Total Travel Cost	**3,000.00**

E. Participant/Trainee Support Costs		**Funds Requested ($)***
1. Tuition/Fees/Health Insurance		4,218.00
2. Stipends		
3. Travel		
4. Subsistence		
5. Other:		
1 Number of Participants/Trainees	**Total Participant Trainee Support Costs**	**4,218.00**

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

Tracking Number: GRANT12814098 Funding Opportunity Number: PAR-18-365 . Received Date: 2019-03-12T11:51:54.000-04:00

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

ORGANIZATIONAL DUNS*: 0414381850000
Budget Type*: ● Project ❍ Subaward/Consortium
Organization: MEHARRY MEDICAL COLLEGE

Start Date*: 12-01-2021 **End Date*:** 11-30-2022 **Budget Period: 3**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	600.00
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8 . website	5,000.00
Total Other Direct Costs	**5,600.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**118,096.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1 . MTDC	8.0	113,878.00	9,110.00
		Total Indirect Costs	**9,110.00**

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number): DHHS, Darryl Mayes, 301 492 4855

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**127,206.00**

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	127,206.00

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

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

Tracking Number: GRANT12814098 Funding Opportunity Number: PAR-18-365 . Received Date: 2019-03-12T11:51:54.000-04:00

OMB Number: 4040-0001
Expiration Date: 10/31/2019

RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 4

ORGANIZATIONAL DUNS*: 0414381850000

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: MEHARRY MEDICAL COLLEGE

Start Date*: 12-01-2022 **End Date*:** 11-30-2023 **Budget Period: 4**

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1 .		Jennifer	C	Erves	Ph.D	PD/PI	Institutional Base Salary	Calendar Months			76,500.00	20,028.00	96,528.00

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

Additional Senior Key Persons: File Name:

Total Senior/Key Person **96,528.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
1	Graduate Students	3.0			8,128.00	622.00	8,750.00
	Undergraduate Students						
	Secretarial/Clerical						
1	**Total Number Other Personnel**					**Total Other Personnel**	**8,750.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**105,278.00**

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

Funding Opportunity Number: PAR-18-365 . Received Date: 2019-03-12T11:51:54.000-04:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 4

ORGANIZATIONAL DUNS*: 0414381850000
Budget Type*: ● Project ❍ Subaward/Consortium
Organization: MEHARRY MEDICAL COLLEGE

Start Date*: 12-01-2022 **End Date*:** 11-30-2023 **Budget Period: 4**

C. Equipment Description		
List items and dollar amount for each item exceeding $5,000		
Equipment Item		**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file		
	Total Equipment	**0.00**

Additional Equipment: File Name:

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	3,000.00
2. Foreign Travel Costs	
Total Travel Cost	**3,000.00**

E. Participant/Trainee Support Costs		**Funds Requested ($)***
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other:		
Number of Participants/Trainees	**Total Participant Trainee Support Costs**	**0.00**

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

RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 4

ORGANIZATIONAL DUNS*: 0414381850000
Budget Type*: ● Project ❍ Subaward/Consortium
Organization: MEHARRY MEDICAL COLLEGE

Start Date*: 12-01-2022 **End Date*:** 11-30-2023 **Budget Period: 4**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	500.00
2. Publication Costs	2,000.00
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
Total Other Direct Costs	**2,500.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**110,778.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1 . MTDC	8.0	110,778.00	8,862.00
		Total Indirect Costs	**8,862.00**

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number): DHHS, Darryl Mayes, 301 492 4855

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**119,640.00**

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	119,640.00

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

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

Tracking Number: GRANT12814098 Funding Opportunity Number: PAR-18-365 . Received Date: 2019-03-12T11:51:54.000-04:00

BUDGET JUSTIFICATION

Overview

The requested funds will enable Dr. Jennifer Erves to engage research training activities during the 4-year award period. Dr. Erves will also have access to resources through the Meharry Medical College, Meharry-Vanderbilt Alliance, and Vanderbilt Institute for Clinical and Translational Institute as needed for accomplishing the objectives of her application.

A. Senior/Key Personnel

Jennifer Erves, PhD, Principal Investigator [redacted] **Years 1-4)**

Dr. Erves is an Assistant Professor in the Department of Internal Medicine at Meharry Medical College. She earned a Bachelor of Science and Master of Science in Biology from Tuskegee University. She received her Master of Arts and Doctor of Philosophy in Health Education and Health Promotion from the University of Alabama at Birmingham. Her background and experience in biology, health education and health promotion, and community engagement makes her an exceptional candidate for pursuing a long-term career goal of as independent researcher in public health oncology in cancer prevention. The primary focus of her research has been risk factors, vaccination, and clinical trial participation related to the Human Papillomavirus (HPV) among African Americans. Additionally, she has experience in survey development, application of mixed methods, and use of community engagement approaches to understand factors influencing vaccine uptake in a population disproportionately affected by HPV-associated cancers.

Responsibilities: Dr. Erves will work closely with her mentors to implement her career development plan and execute the research project. In order to evolve into an independent researcher, Dr. Erves will engage in didactic and experiential training in HPV vaccine clinical research, participate in professional development activities, and conduct the aims of this research proposal through the guidance of her mentoring team and scientific advisory committee. Dr. Erves will be responsible for maintaining communication with mentors and all stakeholders.

Total salary Year 1: $ 96,528 (Fringe benefit rate: 26.18%)
Total salary Years 1 - 4: $ 86,112

B. Other Personnel

Graduate Student (3.0 academic months, 10 hours per week in Years 1-4) The Research Assistant will assist the candidate in conducting the qualitative interviews and analyzing the data. The student will also assist in developing, pretesting, and evaluating the intervention for prefeasibility in Year 1. In Years 2, the implementation of the pilot study will be the primary responsibility of the research assistant. This student will also assist in the debriefing interviews for the study. In Years 3-4, the research assistant will assist in combining the survey and qualitative methods. This individual will also assist in the development of manuscripts in Years 2 through 4. The research assistant must be pursuing a master's degree in a public health related field with knowledge and/or experience in conducting literature searches, data collection and management, and intervention research. Having knowledge in HPV and related cancers is a plus.
Total Cost Graduate Student $8,750 per Year

Mentor and Co-Mentors

Under the mentoring team and scientific advisory committee that will advise and assist Dr. Erves through this career development award, she will strengthen and expand her knowledge and abilities related to public health oncology focused on cancer prevention behaviors.

Consuelo H. Wilkins, MD, MSCI, Primary Mentor (Meharry-Vanderbilt Alliance – no effort) Dr. Wilkins is Executive Director of the Meharry-Vanderbilt Alliance--a strategic partnership between Meharry Medical College and Vanderbilt University School of Medicine. She holds appointments as Associate Professor of Medicine at both Vanderbilt and Meharry. She is an expert in community and patient engagement. In addition, she has provided mentorship to over 25 faculty and fellows, including those with K awards. Dr. Wilkins will be instrumental in providing insight on patient and community engagement, as well as responsible conduct of research. Dr. Wilkins will meet with Dr. Erves weekly initially to oversee the status of her career development

and ensure her access to necessary resources, and bi-monthly starting year 3 as independence is being gained. She will also oversee her quarterly meetings with her co-mentors and her bi-annual meetings with her Scientific Advisory Committee.

Pamela Hull, PhD, Co-Primary Mentor (Vanderbilt University – no effort) Dr. Hull is a medical sociologist with expertise in the development and testing of behavioral interventions to promote cancer prevention behaviors (i.e., HPV vaccination) in youth. She co-leads the Cancer Outreach Core for the Meharry-Vanderbilt-TSU Cancer Partnership, in which they work closely with community partners through a Community Advisory Board to inform the development of community-engaged research studies and facilitate community involvement in each phase of the research process. She also is involved with HPV Cancer Free Tennessee Coalition being Statewide Co-Chair for four years. Dr. Erves will continue to participate in these activities with Dr. Hull to gain intervention development as well gaining feedback on this proposal. In addition, she will continue to observe and assist with Dr. Hull's R01 grant that aims to increase provider adherence to HPV vaccination guidelines in community-based pediatric practices, and her research project will build on Dr. Hull's R01. Dr. Erves will continue to meet with Dr. Hull bi-monthly.

Amanda Dempsey, MD, PhD, Co-Mentor (University of Colorado – no effort) Dr. Dempsey is an Associate Professor of Pediatrics and an Investigator in Children's Outcomes Research Program at the University of Colorado. She is an internationally recognized leader in examining barriers to adolescent vaccination and interventions to overcome them, with a focus on the HPV vaccine. Dr. Dempsey will work with Drs. Wilkins and Hull to provide a tailored mentoring plan for Dr. Erves. She will further provide data from a completed study to support Dr. Erves training in intervention development and evaluation, and granted Dr. Erves permission to attend her research meetings via Skype. She will continue to meet with Dr. Erves one-on-one monthly via videoconference throughout this award period.

Scientific Advisory Committee

Ronald Alvarez, MD, MBA (Vanderbilt University Medical Center – no effort). Dr. Alvarez is professor and chairman of the Department of Obstetrics and Gynecology and holds the Betty and Lonnie S. Burnett Endowed Chair of Obstetrics and Gynecology at Vanderbilt University Medical Center. He has over 20 years experience as an obstetrician gynecologist and researcher in oviarian and cervical cancers. Dr. Alvarez will be providing insight on cancer epidemiology and prevention (e.g., HPV vaccination for this proposal). Dr. Erves will meet with him biannually over 4 years with the other members of the scientific advisory committee, the monthly HPV-ACTIVE program meetings at VUMC, and as needed individually. Dr. Alvarez will not receive any financial compensation for his time.

Suzanne Tropez-Simms, MD, MPH (Meharry Medical College – no effort) Dr. Tropez-Simms is a Professor and Associate Dean of Academic Affiliations in Pediatric Medicine at Meharry Medical College who focuses on improving HPV vaccination uptake in underserved communities. Because Dr. Simms is a pediatrician, she has been providing insight for this proposals' development and will facilitate recruitment of parents and other physicians for this project through the Meharry Pediatric Clinic, as well as provide insight on intervention development. Dr. Erves will meet with her biannually over four years with the other members of the scientific advisory committee, and as needed individually. Dr. Tropez-Simms will not receive any financial compensation for her time.

Douglas Landsittel, PhD (University of Pittsburgh – no effort) Dr. Landsittel is a Professor of Biomedical Informatics and Director of Biostatistics for the Starzl Transplant Institute with extensive experience in advanced statistical analysis. Dr. Landsittel provided insight on the proposal and will provide insight on the design and conduct of advanced multivariable statistical analyses to evaluate preliminary efficacy of this study. Dr. Erves will meet with him biannually over four years with the other members of the scientific advisory committee. Dr. Landsittel will not receive any financial compensation for her time.

Lindsay Mayberry, PhD, MS. (Vanderbilt University – no effort) Dr. Mayberry is an Assistant Professor of Medicine and faculty within the Center for Effective Health Communication at Vanderbilt University. Dr. Mayberry has been informative for proposal development, and will assist in intervention development. Dr. Erves will meet with her biannually over four years with the other members of the scientific advisory committee,

and individually as needed. Dr. Mayberry will not receive any financial compensation for her time.

C. Equipment

D.Travel

Travel to Scientific meetings: As researchers collect data and discover new principles it is imperative that the information is disseminated at national conferences. We request funds for the travel for the Principal Investigator to attend two national conferences each year, such as the Annual Conference on the Science of Dissemination and Implementation and the American Public Health Association annual meeting (years 1-4). Conferences serve as an opportunity to expand the scientific knowledge of other colleagues in the field and as the chance to learn new methods and discoveries at workshops (i.e., clinical research, grant writing, career development, and networking) offered at these conferences. Dr. Erves will also receive Private Support [redacted] to support attending these conferences.
Total Costs: $6,000 ($1,500 per year in years 1-4)

Travel to Face-to-Face Mentor meetings: We request funds for Dr. Erves to meet face-to-face two times a year with Dr. Dempsey to observe her research meetings and research projects, and to discuss her research and her career development in Years 1-4. These trips will cost $750 each for two times a year ($1,500 per year).
Total Costs: $6,000 ($1,500 per year in years 1-4)

Total Travel Costs: $12,000 ($3,000 per Year for Years 1-4)

E. Participant Trainee Support Costs

Tuition
Tuition – The requested budget accounts for tuition costs three courses (3-hr Program Evaluation at $4,218 – Year 1, 3-hr Measurement and Analysis for Healthcare Improvement at $4,218 – Year 2, and 3-hr Model Strategies Course at $4,218 Year 3 at Vanderbilt University.
Total Tuition Costs- $12,654 ($4,218 Year 1; $4,218 Year 2; $4,218 Year 3)

F. Other Direct Costs

Materials and Supplies:

Books
Book costs for three courses taken during Years 1-3.
Total Costs: $300 ($100 Year 1; $100 Year 2; $100 Year 3). Supplies
The cost of office supplies related to study data collection and record-keeping, such as notebooks, folders, digital audio recorder, name tags, and pens.
Total Costs: $750 ($100 Year 1, $150 Year 2; $250 Year 3; $250 Year 4)

Laptop computer and software (MacBook Pro with Retina Display- Latest Model- 13.3" Display – 8GB Memory – 128GB Flash Storage - Silver) The Laptop will be used by the graduate student to collect data and analyze data. It will further be used to input, store, and analyze data.
Total Costs: $1,300 in Year 1

Tablets
The Samsung-Galaxy Tab E Lite 7" (8GB) will be used to gather surveys from adolescent parents in clinics. Each tablet will be equipped with appropriate protective cases (Insignia-FlexView Folio Case) and Insignia-Stylus. 2 tablets @ $129.99 each, 2 cases at $29.99 each, 2 stylus at $9.99 each.
Total Costs: 2 Tablets @ $129.99 each; 2 cases at 29.99 each, 2 stylus at 9.99 each or $340 in Year 1

Total supplies costs $2,690 ($1,840 Year 1, $250 Year 2, $350 Year 3, $250 Year 4)

Other Expenses

Printing
Printing cost will be needed to and will be used as a medium for recruitment flyers. There will also be information printed for the Community Advisory Board and HPV Cancer Free Tennessee Coalition Meetings. Cost of posters and handouts for conferences.
Total Printing Costs: $725 ($100 Year 1, $125 Year 2; $250 Year 3; $250 Year 4)

Publication Costs – **$2,000 (Year 4)**: This cost will be used to pay the publication fee for an open access journal disseminate my research findings from this proposed research.

Website Costs
In Years 1-2, costs will be needed to develop a website for the intervention of this study. There will also be costs needed for graphic design. In Year 3, costs will be needed to make any modification to the website for implementation for the R01.
Total Website Costs: $25,000 ($9,372 Year 1, $10,500 Year 2; $5,000 Year 3)

Research Participant Incentives

a. Aim 1 Stage 1 (Qualitative Interviews for Intervention Development): To conduct formative research to identify barriers to HPV vaccine uptake among adolescents with HPV vaccine hesitant parents and development message concepts for intervention implementation, we will conduct interviews that will include up to 30 parents ($30 per interview) and 10 providers ($50 per interview). - **Total Costs $1,400 in Year 1.**
b. Aim 1 Stage 2 (Intervention Pre-testing): In order to refine the intervention plan, we will pretest the intervention in a small sample of patients that will include 16 parent ($30 per participant) and 3 physicians ($50 per interview). The parents will participant in the study and do a brief, debriefing interview to ensure feasibility and refine any message concept which is unclear. Debriefing interviews will also be conducted with physicians to ensure the study is feasibility or identify ways to improvement study implementation. Dr. Erves estimates that parent participation will be conducted in Year 2 ($30 each X 16 interviews=$480) and provider interviews ($50 each X 3=$150) in Year 2. - **Total Costs $1260 in Year 2.**
c. Aim 2 Pilot Study: In order to examine feasibility of the intervention to increase HPV vaccination among underserved adolescents with vaccine hesitant parents, we will recruit 70 vaccine hesitant parents participants for the intervention starting in year 2 ($25 per participant; $1750). In addition, we will conduct a maximum of 30 debriefing interviews to determine overall acceptance of intervention content and delivery among 30 parents ($30 per interview; $900) and 10 providers and staff ($50 per interview; $500) – **Total Costs: $3150 in Year 2.**

Total Other Expenses: $81,061 ($ 23,840; Year 1; $ 28,003 Year 2; $18,218 Year 3; $11,000 Year 4)

Existing In-Kind Support:

Go-To-Meeting - Go to Meeting software and toll-free numbers will be required to conduct interviews. According to industry standards, 10,000 minutes will cost $200/month. [redacted] will cover the costs where Dr. Wilkins serves as Executive Director. **Total Costs: $0 Year 1.**

Consultant Services – The Vanderbilt's Clinical and Translational Science Award (CTSA) and the Vanderbilt Institute for Clinical and Translational Research (VICTR) for cover the costs of the transcription and qualitative coding and data analysis necessary to complete this project as described below.

Aim 1 Stage 1 (Qualitative Interviews Transcription Services) –Transcription services through an external vendor, GMR transcription, are included in the proposed budget for up to 40 participants. 30 interviews x 45 mins/interview=1,350 minutes of transcription required @ $1.25 per minute. 10 interviews x 30 mins/interview=300 minutes of transcription required @ 1.25 per minute.
Total Costs: $2,062.50 (Year 1)

Aim 1 Stage 1 (Qualitative Interviews Coding and Analysis) –The Qualitative Research Core at Vanderbilt University Medical Center will code the interview transcripts in preparation for analysis. For the semi-structured interviews, interviews will be initially coded by individuals in the Core who are not directly involved in the study and Dr. Erves will review codes and recommend modifications. Costs are estimated to cover qualitative response for up to 40 participants (30 parents and 10 physicians), although the number of participants included in qualitative analyses will be determined when thematic saturation is reached.
Total Costs: 45 minutes for 30 interviews ($4956.50) and 30 minutes for 10 interviews ($2379.00) – $7,335.50
Total Costs Year 1: $9,398

Aim 1 Stage 2 (Intervention Pretesting Transcription Services) –Transcription services through an external vendor, GMR transcription, are included in the proposed budget for up to 19 participants. 16 interviews x 45 mins/interview=720 minutes of transcription required @ $1.25 per minute. 3 interviews x 30 mins/interview=90 minutes of transcription required @ 1.25 per minute.
Total Costs Year 2: $1,012.50 (Year 2)

Aim 1 Stage 2 (Intervention Pretesting Coding and Analysis) –The Qualitative Research Core at Vanderbilt University Medical Center will code the interview transcripts in preparation for analysis. For the semi-structured interviews, interviews will be initially coded by individuals in the Core who are not directly involved in the study and Dr. Erves will review codes and recommend modifications. Costs are estimated to cover qualitative response for up to 19 participants (16 parents and 3 physicians), although the number of participants included in qualitative analyses will be determined when thematic saturation is reached.
Total Costs Year 3: $ 5,344 (45 minutes for 16 interviews or $3,723.00) and 30 minutes for 3 interviews or $1,621.00)

Year 3
Transcription Services –Transcription services through an external vendor, GMR transcription, are included in the proposed budget for up to 33 participants. 30 interviews x 45 mins/interview=1350 minutes of transcription required @ $1.25 per minute. 3 interviews x 30 mins/interview=90 minutes of transcription required @ 1.25 per minute.
Total Costs: $1,800 (Years 4)

Coding and Analysis– The Qualitative Research Core at Vanderbilt University Medical Center will code the interview transcripts in preparation for analysis. For the semi-structured interviews, interviews will be initially coded by individuals in the Core who are not directly involved in the study and Dr. Erves will review codes and recommend modifications. Costs are estimated to cover qualitative response for up to 33 participants (30 parents and 3 physicians), although the number of participants included in qualitative analyses will be determined when thematic saturation is reached.
Total Costs: 45 minutes for 30 interviews ($4956.50) and 30 minutes for 3 interviews ($1621.00) – ($6,577.00 Year 4)
Total Costs Year 4: $8,377

Total Consultant Services Costs: $24,132 ($9,398 Year 1, $1013 Year 2, $5,344 Year 3, $8,377 Year 4)

H. Indirect Costs:

Per DHHS agreement, tuition costs are excluded from the indirect cost calculation at 8%.

RESEARCH & RELATED BUDGET - Cumulative Budget

	Totals ($)	
Section A, Senior/Key Person		386,112.00
Section B, Other Personnel		35,000.00
Total Number Other Personnel	4	
Total Salary, Wages and Fringe Benefits (A+B)		421,112.00
Section C, Equipment		0.00
Section D, Travel		12,000.00
1. Domestic	12,000.00	
2. Foreign	0.00	
Section E, Participant/Trainee Support Costs		12,654.00
1. Tuition/Fees/Health Insurance	12,654.00	
2. Stipends	0.00	
3. Travel	0.00	
4. Subsistence	0.00	
5. Other	0.00	
6. Number of Participants/Trainees	2	
Section F, Other Direct Costs		36,097.00
1. Materials and Supplies	3,415.00	
2. Publication Costs	2,000.00	
3. Consultant Services	0.00	
4. ADP/Computer Services	0.00	
5. Subawards/Consortium/Contractual Costs	0.00	
6. Equipment or Facility Rental/User Fees	0.00	
7. Alterations and Renovations	0.00	
8. Other 1	10,810.00	
9. Other 2	19,872.00	
10. Other 3	0.00	
Section G, Direct Costs (A thru F)		481,863.00
Section H, Indirect Costs		37,536.00
Section I, Total Direct and Indirect Costs (G + H)		519,399.00
Section J, Fee		0.00
Section K, Total Costs and Fee (I + J)		519,399.00

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OMB Number: 0925-0001

Expiration Date: 03/31/2020

1. Vertebrate Animals Section

Are vertebrate animals euthanized? ○ Yes ● No

If "Yes" to euthanasia

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

○ Yes ○ No

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

2. *Program Income Section

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

○ Yes ● No

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

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

Tracking Number: GRANT12814098 Funding Opportunity Number: PAR-18-365 . Received Date: 2019-03-12T11:51:54.000-04:00

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3. Human Embryonic Stem Cells Section

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

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

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

Cell Line(s) (Example: 0004):

4. 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

5. Change of Investigator/Change of Institution Section

❑ Change of Project Director/Principal Investigator

Name of former Project Director/Principal Investigator

Prefix:

*First Name:

Middle Name:

*Last Name:

Suffix:

❑ Change of Grantee Institution

*Name of former institution:

PHS 398 Career Development Award Supplemental Form

OMB Number: 0925-0001
Expiration Date: 03/31/2020

Introduction	
1. Introduction to Application (for Resubmission and Revision applications)	Erves_Resubmission_StatementF.pdf
Candidate Section	
2. Candidate Information and Goals for Career Development	candidateF.pdf
Research Plan Section	
3. Specific Aims	Specific_AimsF.pdf
4. Research Strategy*	researchstrategyF.pdf
5. Progress Report Publication List (for Renewal applications)	
6. Training in the Responsible Conduct of Research	TRCRF.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)	MentorLettersF_.pdf
9. Letters of Support from Collaborators, Contributors, and Consultants	LOSF_.pdf
Environment and Institutional Commitment to Candidate Section	
10. Description of Institutional Environment	DescriptionOfInstitutionalEnvironmentF.pdf
11. Institutional Commitment to Candidate's Research Career Development	LetterofInstitutionalSupportF.pdf
Other Research Plan Section	
12. Vertebrate Animals	VertebrateAnimalsF.pdf
13. Select Agent Research	SELECTAGENTRESEARCHF.pdf
14. Consortium/Contractual Arrangements	ConsortiumContractualArrangements.pdf
15. Resource Sharing	ResourceSharingPlanF.pdf
16. Authentication of Key Biological and/or Chemical Resources	AuthenticationofKeyBiologicalF_.pdf
Appendix	
17. Appendix	AppendixF.pdf

Tracking Number: GRANT12814098
Funding Opportunity Number: PAR-18-365. Received Date: 2019-03-12T11:51:54.000-04:00

PHS 398 Career Development Award Supplemental Form

Citizenship*:

18. 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.

If you are a non-U.S. citizen with a temporary visa applying for an award that requires permanent residency status, and expect to be granted a permanent resident visa by the start date of the award, check here: Personal Information

Response to Grant Critique

Candidate's Background

My ultimate career goal is to become an independent researcher who makes a significant contribution to the field of public health oncology focused on cancer prevention behaviors and lowering cancer disparities. I have a solid knowledge base and skillset in biology, research methodology, community engagement, and public health. The goal of this K01 is to seek additional knowledge and training to: 1) develop behavioral interventions using innovative, health communication strategies to promote cancer prevention behaviors and reduce cancer disparities for underserved populations; 2) design and conduct a pilot clinical trial to establish feasibility of the behavioral intervention; and 3) gain skills in implementation science to design behavioral interventions for successful implementation in practice settings and my future research agenda. With an initial focus on HPV-related behaviors and vaccination, I will extend my skills to interventions for other cancer prevention behaviors. My background and trajectory leading to my current career and research goals is summarized in Figure 1.

Figure 1. Erves Training Trajectory for Research Independence

Graduate Studies. I completed a bachelors and masters degree in Biology at Tuskegee University, receiving training in biology and quantitative methods. I used biological principles in cervical cancer prevention research to identify risk factors associated with HPV infection in African American (AA) female college students. Exposure to public health in the classroom and my research lead to my focus in public health oncology. I then completed a second masters and doctoral training at UAB in Health Education and Health Promotion. Through coursework and field experiences, I received a strong foundation in behavioral theory, research design, mixed methods, qualitative methods, and survey development. I aided in conducting the American College Health Association-National College Health Assessment, where we identified health insurance as a factor that positively influenced HPV vaccine uptake in college students.[1] For my dissertation, I led a mixed methods study with AA mothers on intentions to vaccinate their daughters for HPV. From this study, I published a survey development paper[2] and a mixed methods paper.[3] This work led to my receipt of the 2014 Outstanding Student for Health Education Doctoral Award, and I obtained certification as a Health Education Specialist. After multiple efforts to engage AAs in my research, my research focus evolved to include community engagement.

Post-Doctoral Fellowship. I completed my fellowship under [redacted] Private Support [redacted]. My training focused on community engagement and grant writing, working with Community Engaged Research Core (CERC) researchers and the CERC capacity building team. I assisted in developing two capacity building activities, a Community Forum and Community Research Day, and conducted qualitative analysis of data collected at these events.[4] I aided in developing a community research training curricula.[3] I became a paid consultant on a [redacted] Private Support [redacted] to train program staff and community members on qualitative data analysis. Under Drs. Pamela Hull, Consuelo Wilkins, and Stephania Miller-Hughes (post-doctorate mentoring team), I did a survey study of parental willingness to allow their child to participate in HPV vaccine clinical trials.[5,6] Under Dr. Miller-Hughes, I did quantitative data analysis to identify intervention targets to improve diabetes self-management among AA obese women.[7] This work peaked my interest in patient-centered outcomes research and clinical trials.

Assistant Professor. In 2015, I became an Assistant Professor in the Department of Internal Medicine at Meharry Medical College (MMC). Drs. Wilkins, Hull, and Dempsey became my research career mentors.

a) **Diversity Supplement Project.** In July 2016, I received a one-year diversity supplement under [redacted] Private Support [redacted] to receive training in clinical and translational science. My research identified key immunization stakeholders' (AA parents and adolescents, healthcare providers, pharmacists, school system staff, and health department staff) views on the role of the medical home and alternative vaccination settings (i.e., pharmacies, health departments, and schools) to increase HPV vaccine rates. Findings from qualitative interviews and quantitative surveys suggested that AA families preferred to be offered and receive the HPV vaccine in the medical home versus alternative settings. Then I decided to focus on the primary care setting for a future intervention to increase HPV vaccination.

b) **K12 Training.** In October 2016, I was awarded a K12 training position as a Vanderbilt Patient-Centered Outcomes Research Career Knowledge, Education and Training (V-POCKET) scholar to gain didactic training and mentoring in patient-centered outcomes research (currently in the third year). My research project seeks to identify health communication needs and preferences of AA parents and adolescent patients in decision-making on HPV vaccination. Based on qualitative interviews and surveys with AA parents and adolescents, I found that families vary in their levels and reasons for HPV vaccine hesitancy, and they have a variety of educational needs (e.g., concerns about vaccine safety) and preferences for channels of information delivery (e.g., websites, videos, brochures) related to HPV vaccination. Families wanted educational information about the HPV vaccine *prior* to a doctor visit to review and discuss the information in their family before making a decision. Together, these findings and the literature, led to my decision to focus on pre-visit patient education targeting HPV vaccine hesitant parents for the intervention proposed in the K01.

c) Additional Training. I applied for and was selected for two programs. 1) Leading Emerging and Diverse Scientists to Success Fellow: I participated in online workshops to gain knowledge/skills related to team science and grant writing. 2) Expanding National Capacity in PCOR through Training Fellow: I gained knowledge on comparative effectiveness research and patient-centered outcomes research.

Despite this training, I **require** additional knowledge and training on how to develop behavioral interventions and optimally design clinical trials assessing efficacy of the interventions. This training will make me uniquely qualified to promote cancer prevention and lower cancer disparities and help me prepare a successful R01.

Career Goals and Objectives

This Mentored Research Scientist Development Award will facilitate my development into a leading, independent public health researcher focused on cancer prevention behaviors and lowering cancer disparities. Despite my robust training experience, I have not yet reached independence to establish my multidisciplinary, research program in cancer prevention. My research plan aims to increase HPV vaccination in adolescents, yet I need to fill specific gaps in my training to evolve into an independent researcher and build upon my preliminary studies (See Figure 1). I require additional training on how to: 1) develop behavioral interventions using innovative, health communication strategies to promote cancer prevention behaviors and reduce cancer disparities for underserved populations; 2) design and conduct a pilot clinical trial to establish feasibility of the behavioral intervention; and 3) use implementation science in cancer prevention for work beyond this K award.

I have four **training objectives** that I will achieve via this K01 award in 4 years:

Training Objective 1: Enhance my skills for conceptualizing and developing theory-based behavioral interventions for cancer prevention, particularly using individual tailoring of health communication.

Training Objective 2: Develop expertise in the optimal design and rigorous implementation of randomized controlled trials (RCTs) to assess the efficacy of behavioral interventions for cancer prevention.

Training Objective 3: Further my empirical and theoretical knowledge about implementation science.

Training Objective 4*:* Advance my professional development and leadership skills to facilitate a successful transition to an independent leader in the field of cancer prevention.

Evaluation Plan: My mentors will monitor my progress through the K01 award period to reach these training objectives. Starting each training year, my individual development plan will be updated with aid of my mentors. Benchmarks of success include a self-assessment, training goals related to data generation on the research project, timing of manuscript submissions, grant writing, skill development, and presentations. The **targets** are: 8-10 peer-reviewed publications, 4-8 national conference or invited presentations, R01 for future RCT by Year 4 (Submit Year 3), and responsible conduct of research (Section 5). Quarterly, my mentors and I will meet together to ensure I progress to my goals, identifying barriers and solutions to success.

Career Development/Training Activities during Award Period

To achieve my training objectives, the first half of the award period involves didactic, experiential, and mentored training, publications, and grant writing. All four years involve educational mentorship. Didactic and mentored training will be less emphasized in later years as research, scientific dissemination, and grant writing are prioritized. I have established an excellent team of mentors and a scientific advisory committee who have expertise needed to guide my achievement of career goals, outlined in Table 1 and further described below.

1. Mentors

Consuelo H. Wilkins, MD, MSCI, Primary Mentor, will oversee my career development and mentoring meetings, facilitate access to resources, and advise on grant applications. She will provide expertise in using community/patient engagement and clinical trial development. We will continue **weekly** meetings in the first two years of this award, then **start meeting twice a month** in Year 3 as I gain more independence.

Pamela Hull, PHD, Co-Primary Mentor, will provide mentoring on intervention development and testing. I will continue to meet with Dr. Hull **twice a month** and attend her weekly research team meetings to learn how she is conducting her quality improvement RCT with pediatric clinics and inform my research.
Amanda Dempsey, MD, PHD, MPH, Co-mentor, will provide her expertise on parental vaccine hesitancy and clinical interventions. We currently engage monthly one-on-one via phone, and I will attend her project meetings **monthly** via conference call or Skype. We will also meet **at least twice a year in person**.

As needed, I will meet with other senior scientists between MMC and Vanderbilt to address specific needs (Table 1). I also attend meetings for HPV ACTIVE program at Vanderbilt (monthly), HPV Cancer Free Tennessee Coalition (monthly), and a Community Advisory Board (CAB, quarterly) to interact with researchers and community stakeholders and learn from other studies and initiatives aimed to increase HPV vaccination.

2. Scientific Advisory Committee. This four-member committee will be composed of experts to provide specific substantive guidance in my research. See Table 1 for committee members, area of expertise and mentoring role. We will convene biannually, and meet individually as needed. (See **Letters of Support**).

Table 1. Summary of Mentors and Scientific Advisory Committee, Their Expertise, and Current Research

Mentors	**Expertise and Current Research**
Consuelo H. Wilkins, MD, MSCI (VUMC & MMC) Associate Professor of Medicine Executive Director: Meharry Vanderbilt Alliance	**Expertise:** Disparities, Clinical trials, Translational & comparative effectiveness research **Current Research:** Development and Implementation of patient/community engagement research methods
Pamela Hull, PhD (VUMC) Assistant Professor of Medicine (Epidemiology)	**Expertise:** Behavioral intervention development and testing for cancer prevention in youth **Current Research:** Quality Improvement for HPV vaccination in pediatric clinics
Amanda Dempsey, MD, PhD, MPH (UC) Assistant Professor for Medicine	**Expertise:** Adolescent vaccines, vaccine hesitancy, clinical trial, implementation science **Current Research:** Motivational Interviewing for MDs with HPV vaccine hesitant parents
Scientific Advisory Committee	**Expertise & Mentoring Role**
Ronald Alvarez, MD, MBA (VUMC) Professor of Obstetrics and Gynecology Leader of HPV ACTIVE Program	**Expertise:** Oncology; Cancer Epidemiology, Prevention and Control **Mentoring Role:** Mentor on HPV-related cancers, cancer prevention continuum, clinical trial study design and implementation.
Susanne Tropez-Sims, MD, MPH (MMC) Professor, Pediatrician MMC Pediatric Group	**Expertise:** Pediatrics, Adolescent Health **Mentoring Role:** Mentor on clinical aspects of HPV vaccination, pediatric care settings, recruitment strategies, intervention development and implementation
Lindsay Mayberry, PhD, MS (VUMC) Assistant Professor of Medicine Center for Effective Health Communication	**Expertise**: Health Communication **Mentoring Role:** Mentor on implementing health communication strategies in the healthcare setting, developing tailored messages for behavioral interventions.
Douglas Landsittel, PhD (UP) Professor of Biomedical Informatics Director of Biostatistics, Starzl Transplant	**Expertise:** Statistics (Advanced Quantitative Analysis) **Mentoring Role:** Mentored on trial design, statistical analysis plan, advanced multivariable longitudinal analysis, conduct quantitative data analysis in Years 3-4.
MMC=Meharry Medical College; VUMC=Vanderbilt University Medical Center; UP=University of Pittsburgh; UC= University of Colorado	

3. Training Plan. To reach my long-term goal, we developed a formal training plan with four training objectives, which include workshops, practical research training, courses, mentoring, and a research project. Because I took several public health courses in my K12 award, this plan has more applied research training.

Training Objective 1: *Enhance my skills for conceptualizing and developing theory-based behavioral interventions for cancer prevention, particularly using individual tailoring of health communication.*
Coursework: I will take the Design of Human Performance Interventions course (LOP 6210/VUMC) (3 credits/Year 1 to learn the process of designing behavioral interventions. This course supports Aim 1.
HPV-ACTIVE (HPV-Associated Cancer Consortium at Vanderbilt): I will learn about ongoing research across the HPV cancer prevention continuum, from primary prevention (vaccination) to treatment; includes an annual symposium. I will get feedback on my project at all stages and gain collaborators for future work (Years 1 - 4).
Practical Research Training Experience: I will gain experience about pediatric clinic operations and intervention implementation by shadowing in the MMC Pediatric Clinic with Dr. Tropez-Sims for 20 hours during the first quarter of Year 1. Also, I will assist Dr. Hull with qualitative analysis of interviews with physician leaders and operational managers in the community-based pediatric clinics in her R01 study, promoting Aim 1 (Year 1). Dr. Dempsey will also provide insight on this experience as a practicing pediatrician and HPV VH researcher.
Research Project: I will learn how to use qualitative research to design and pre-test a tailored health communication intervention with guidance from my mentoring team.
One-on-one mentoring: Dr. Wilkins will provide advice and direction on designing a clinical intervention. Drs. Dempsey and Hull will foster my skills in HPV vaccine intervention development and testing. Dr. Mayberry will teach basics of message tailoring and assist in producing low literacy health education materials (Years 1-4).

Training Objective 2: *Develop expertise in the optimal design and rigorous implementation of randomized controlled trials (RCTs) to assess the efficacy of behavioral interventions for cancer prevention.*

Coursework: I will take Clinical Trials and Experimental Design (BIOS 6321/VUMC) (3 credits/Year 2). This course will provide knowledge and skills on statistical aspects of study design, monitoring, and analysis for clinical trials in biomedical research. This course supports Aims 2 and 3 and the R01 proposal in Year 3.
Clinical Research Center (CRC) Skills Workshop Series: This weekly session covers investigator-driven topics (i.e., recruitment, ethical misconduct, and database management). I will attend relevant sessions (Years 1-4).
Research Project: I will learn how to design an RCT protocol and carry out a pilot study with my mentors.
One-on-one mentoring: In meetings (Years 1-4), I will gain knowledge and skills to conduct clinical research, and observe this process in my mentors' research. We will also discuss potential ethical issues related to my research (e.g., responsible research conduct, conflicts of interest, and responsible authorship and publication).

Training Objective 3*: Further my empirical and theoretical knowledge about implementation science.*
Coursework: I will take Implementation Science (PUBH 5510/VUMC) (3 credits/Year 2) on basics of Dissemination and Implementation (D&I) Research (i.e. theory and study design). I will apply for NCI 5-Day Training on D & I Research in Cancer (TIDIRC), learning D & I research across the cancer continuum (Year 2).
Center for Clinical Quality and Implementation Research Scholarly Series: Bi-weekly, I will learn about cutting edge methods, research initiatives, and current literature related to Implementation Science (Years 2-3).
Core Elements of Implementation Science Workshop: I will be introduced to the field of Dissemination and Implementation (D&I) and how to design these studies (Years 2-3). This annual workshop is 1-day at VUMC.
One-on-mentoring: Mentors will provide individual mentoring and readings (e.g., *Advancing the Science of Implementation across the Cancer Continuum*) to learn more about D&I and how include it in my R01 proposal.

Training Objective 4*: To advance my professional development and leadership skills to facilitate a successful transition to an independent leader in the field of cancer prevention.*
Vanderbilt University Edge for Scholars: This bi-monthly seminar for early career MD and PhD investigators will give insight on grant writing, mentoring, and a career timeline (Years 1-4).
MMC Rise Office for Professional Development: This office promotes researchers' professional development through workshops, seminars, one-on-one mentoring, and grant writing. I will engage for 4 years **as needed**.
Research Project: This project will produce data to cultivate research dissemination skills (i.e., national meeting presentations, publications), grant writing skills (i.e., R01 submission-Year 3), and research expertise.
National Meetings: To enhance my national reputation in this research area and foster relationships for future collaborations and networking, I will attend and submit abstracts to two national meetings **annually**, American Public Health Association (APHA) and Annual Conference on the Science of D & I in Years 1-4.
Didactic Training: I will attend the Association of American Medical Colleges Early Career Women Faculty Leadership Development Seminar to gain leadership and career building skills and develop leadership goals.
Grant writing: I will learn how to prepare and R01 application and submit it in Year 3. I will attend workshops (Years 3-4), use a VUMC mock study section review, and work with my mentors individually for feedback on proposal drafts, writing a successful grant, common mistakes to avoid, and how to prepare a resubmission.
Manuscripts: Target is 8-10 peer reviewed publications. I will submit at least two yearly, 2nd and 4th quarter.

Table 2. Training Plan Timetable and percent effort (%) to each activity for Dr. Jennifer Erves

Research and Didactic Activities with Specific Mentor	**Year 1**	**Year 2**	**Year 3**	**Year 4**
AIM 1 (CW, PH, AD, LM, ST): To develop a tailored, health communication intervention targeting HPV vaccine-hesitant parents. **AIM 2** (CW, PH, AD, ST, DL, LM): Conduct a pilot study of the intervention and study protocol on a small scale to demonstrate feasibility of the future full-scale RCT **AIM 3** (CW, PH, AD, ST, DL): Examine acceptability of the intervention and protocol among parents and providers.	Percentage of Effort			
Mentoring Meetings: Primary Mentors (weekly) (CW, PH); Co-Mentor (monthly) (AD) Mentoring Meetings: Scientific Advisory Committee (DL, RA, LM, ST) (bi-annual)				
Grant Writing: R01 Writing, Submission, Re-Submission (CW, PH, AD)				
Manuscript Submission (1-2 Submissions each training year in the 2nd and 4th quarter)				
Faculty Development: 1) VUMC Edge for Scholars (bi-monthly); 2) CRC Skills Workshops (monthly); 3) MMC Rise Office for Professional Development (as needed) (MMC faculty)				
Meeting/Presentation: 1)APHA, 2) Annual Conference on the Science of D & I (annually)				
Research Training: Clinic Immersion and Experiential Research Training (ST, CW, PH, AD)				
Workgroups: 1) HPV ACTIVE (PH, RA); HPV-CFC (PH); 2) Community Advisory Board (PH)				
Formal Didactic Training: 1) Design of Human Performance Interventions (LOP 6210/VUMC); 2) Clinical Trials and Experimental Design (BIOS 6321/VUMC); 3) Implementation Science(PUBH 5510/VUMC); 4) NCI 5-Day D & I Training Institute; 5) Core Elements of Implementation Science Workshop (VUMC Faculty); 6) AAMC Early Career Women Faculty Development Seminar				
Other research projects and scholarly activities (non-K01 time)				

Note: CW=Consuelo Wilkins (primary mentor): PH=Pamela Hull (co-primary mentor); AD=Amanda Dempsey (co-mentor); ST=Susanne Tropez-Sims; LM= Lindsay Mayberry; DL= Douglas Landsittel; RA=Ronald Alvarez; MMC=Meharry Medical College; CRC=Clinical Research Center; VUMC=Vanderbilt University Medical Center; AAMC=Association of American Medical Colleges

Specific Aims

Human papillomavirus (HPV) causes 31,500 new cancer cases yearly (i.e., cervical, oropharyngeal, anal, vaginal, vulvar, and penile).[8] Up to 93% of these cancer cases could be prevented with HPV vaccination.[9,10] Improving HPV vaccination among adolescents is an urgent public health priority to prevent and reduce disparities in HPV-associated cancers.[11] Only 49% of adolescents in the US and 39% in Tennessee ages 13–17 have completed the recommended doses of the HPV vaccine.[12] Healthcare providers making an *initial* recommendation using a presumptive approach (i.e., announcement of vaccines due), rather than shared decision-making, appears to be more effective in improving HPV vaccination rates compared with usual care.[13] However, at least one-third of parents are vaccine-hesitant (VH), choosing to delay or refuse the HPV vaccine at initial recommendation.[14,15] Common reasons for parental hesitancy include vaccine concerns (i.e., safety and side effects), misinformation, lack of knowledge, and concerns of transmission through sexual activity.[16-18]

Parents who are VH about HPV vaccine often have different motivations and informational needs than non-VH parents.[14,19] Physicians are their preferred information source.[14,20] Existing interventions have targeted training providers to use motivational interviewing in a clinical encounter to address VH,[21,22] yet to our knowledge, no evidence-based patient education interventions are available for VH parents.[23] Individual tailoring, a highly effective health communication strategy,[24] is a possible solution to address unique educational needs of VH parents after the initial presumptive recommendation fails.[21] Tailoring involves customizing an educational intervention to address each parent's unique attitudes, informational needs, and environment, social norms , and culture related to HPV vaccine uptake.[25] My preliminary data suggest many parents want health education *prior to* a clinic visit to make an informed decision on the HPV vaccine. Tailored, pre-visit education for HPV-VH parents could increase acceptance, prevent parental anxiety, and reduce provider burden in clinic visits.

My **long-term research goal** is to reduce HPV infection among adolescents and prevent morbidity and mortality associated with HPV-associated cancers. The **goal** of this K01 application is to develop and pilot test an individually tailored, pre-visit health communication intervention targeting HPV-VH parents. We will partner with the Meharry Medical College Pediatric Group (MMC Pediatrics), a safety-net clinic serving primarily publicly-insured and uninsured patients. The study has three specific aims.

Aim 1. To develop a tailored, health communication intervention targeting HPV-VH parents prior to clinic visits. The tailored intervention will be delivered to VH parents via mobile phones. We will draft initial content based on the Theory of Reasoned Action[26] and Health Belief Model,[27] previous VH research,[14] and my preliminary data. We will then conduct semi-structured interviews with 25–30 VH parents who previously declined the HPV vaccine and 10 physicians to elicit feedback on draft content. Qualitative data will be collected and analyzed iteratively, informing successive modifications to the intervention to cover a range of potential concerns for VH parents, enhance message relevance, and refine the intervention delivery process. Next, we will work with MMC Pediatrics to develop and refine the study protocol. We will pre-test and get feedback on the protocol from 16 VH parents and 3 physicians to maximize acceptance and feasibility.

Aim 2. Conduct a pilot study of the intervention and study protocol to demonstrate feasibility for the future full-scale randomized control trial (RCT). Based on **Aim 1**, we conduct a small, pilot RCT with 70 VH parents with scheduled clinic visits. Feasibility indicators are recruitment rates, retention rates, and ability to ascertain patients' post-visit HPV vaccine status in the clinical record. VHealth software will be used to extract information from the EHR to identify potentially eligible patients with a previous HPV vaccine refusal and to determine the whether an HPV vaccine dose was received during the scheduled visit.

Aim 3. Examine acceptability of the intervention and protocol among parents and providers. Parents participating in the pilot study will complete a post-visit survey to measure acceptability of the intervention and protocol, provider trust/rapport, and satisfaction with provider–patient communication. In addition, we will conduct semi-structured debriefing interviews with a subset of 20–30 parents and 3 providers to gather qualitative data about their experiences (e.g., unforeseen problems and barriers) and their perceptions of acceptability of the intervention and protocol (e.g., ease of use, content, graphics). The findings will be used identify needs for any additional modifications to the intervention and protocol prior to the RCT.

Impact. This study's **novelty** lies in delivering an individually-tailored, mobile phone-based intervention to promote HPV vaccination among VH parents before clinic visits. Clinical significance is improved clinical care, increase vaccine uptake, and decreased HPV-associated diseases. Results will serve as preliminary data for a subsequent R01 grant proposal for a well-powered, multi-site RCT. This award provides experiential and didactic training in behavioral intervention development, clinic trial design, and implementation science with a stellar mentoring team and advisory committee. This study promotes my **long-term career goal** to become an independent public health researcher focused on cancer prevention through behavioral interventions.

A. SIGNIFICANCE

A1. Human papillomavirus (HPV) cancer burden and HPV vaccination. HPV has been implicated in cervical (91%), oropharyngeal (70%), vaginal (75%), vulvar (69%), anal (91%), and penile (63%) cancers, resulting in 31,500 new cases annually.[8,28] Minority and underserved populations suffer disproportionately from HPV-associated cancer outcomes. For example, incidence rates for cervical, vaginal, penile, and anal cancers are between 13% and 50% higher in African-Americans (AAs) compared with Caucasians, depending on the cancer.[28] The HPV vaccine is exceptionally effective at preventing the most common high-risk HPV types,[29,30] which cause 93% of cancers linked to HPV. Adolescents are the target population for vaccination, as they acquire approximately half of new HPV infections yearly.[31] Yet, HPV vaccination rates are suboptimal in the US. In 2017, only 66% of adolescents ages 13-17 in the US and 56% in Tennessee had received one dose of the vaccine, with even lower rates for completing all recommended doses (49% in US, 39% in Tennessee).[12] *These data highlight the public health burden of HPV-related cancers, emphasizing the need to develop novel interventions to increase to vaccination to lower the HPV disease burden and related cancer disparities.*

A2. Existing interventions to increase HPV vaccination. The Community Guide lists existing evidence-based strategies to improve child and adult immunization coverage in general,[32,33] including provider-focused (e.g., routine recommendations, standing orders, prompts, and provider incentives), patient-focused (e.g., reminders, social marketing, decision support), or multi-component strategies.[13,34-42] Some multi-component interventions have shown modest improvements in HPV vaccination coverage but have design limitations, such as non-random assignment.[43-46] Training healthcare providers to use a presumptive approach for recommending HPV vaccine (i.e., announcement of all adolescent vaccines due today), as opposed to shared decision-making, led to 5% higher clinic-level HPV vaccination rates compared with usual care.[13] The presumptive approach appears to be a promising provider communication strategy during clinic visits for the *initial* recommendation of HPV vaccine. However, *at least one-third of parents are vaccine hesitant (VH), meaning they decline the HPV vaccine* when initially recommended.[14,15] In fact, prior research and my preliminary studies have found that a presumptive recommendation is not effective for VH parents.[47] Thus, providers need to use a second-line approach for VH parents. Studies testing patient education interventions focused on HPV vaccine have had inconsistent results.[48-50 35] Some interventions have trained providers to use motivational interviewing for counseling with VH parents during clinical visits,[21,22] *yet to our knowledge, no evidence-based, patient education interventions are available that directly target HPV-VH parents*.[23]

A3. VH is a critical barrier to HPV vaccination among adolescents. Many factors contribute to low HPV vaccination,[18] but parental vaccine hesitancy toward the HPV vaccine is a growing problem.[51-53] Vaccine hesitancy exists on a continuum (**Fig. 2)** reflecting varying degrees of parental concern about the need for and safety of immunizations in general,[54,55] which also applies to HPV vaccine.[52,56,57] In a national survey, 28% of parents self-reported that they ever *refused* HPV vaccination, while 8% reported that they ever *delayed* the vaccine.[14] Evidence demonstrates increased prevalence of vaccine-preventable diseases when parents refuse to vaccinate their children.[58]

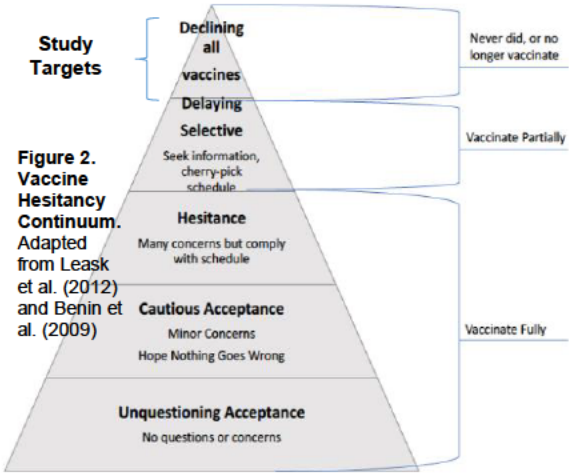

Figure 2. Vaccine Hesitancy Continuum. Adapted from Leask et al. (2012) and Benin et al. (2009)

Many factors influence levels of parental vaccine hesitancy, including contextual influences (e.g., media, influential leaders and anti- or pro-vaccination lobbies), intrapersonal and interpersonal influences (e.g., personal, family, or community experiences with vaccination; attitudes and beliefs about health and prevention; knowledge/awareness), and vaccine-specific issues (e.g., risk/benefit, strength of physician recommendation, knowledge and/or attitude of physician).[59] Interactions between parents and healthcare providers play a major role in shaping parental attitudes toward vaccination.[47,60] VH parents are often dissatisfied with patient–provider communication, undermining parental understanding and confidence in HPV vaccination.[61,62] This further limits many parents' ability to discuss and/or make joint decisions with their adolescents on vaccine uptake.[63] One quarter of parents report secondary acceptance, and a major reason is learning more of the vaccine.[69] *Interventions to reduce VH should aim to improve satisfaction with provider communication among parents by increasing trust and rapport and by addressing individual concerns and barriers.*

A4. Providing tailored education in advance of a clinic visit is a potential strategy for addressing HPV vaccine hesitancy. Tailoring health communication maximizes the "fit" of information to the individual.[24] It

involves customizing an educational intervention to each person's unique attitudes, informational needs, and context of environment, culture, and social norms related to HPV vaccine uptake.[25] Individually tailored, educational interventions have improved many preventive health behaviors, including adult immunizations (e.g., pneumococcal)[64] and some childhood immunizations (e.g., MMR).[65] The President's Cancer Panel identified a need for tailored health communication to promote HPV vaccination among VH parents.[11] Gilkey et al. (2017) found that HPV-VH parents had a range of concerns and barriers to acceptance. For example, those who delayed mainly needed additional information, while those who refused had lower confidence in HPV vaccination, lower perceived effectiveness, and higher perceived harm of the HPV vaccination.[14] Thus, individually tailored vaccine counseling could address the unique concerns and needs of each HPV-VH parent. Yet, providers have limited time during clinic visits, which often prevents their ability to explore individual parental/patient concerns and provide long explanations about HPV vaccine safety or side effects.[66-68] Pediatric clinics are increasingly using text messaging, web sites, and web portals for patient communication.[70-72] Over 90% of adults ages 18-49 own a smartphone, with no racial/ethnic disparity, and low-income families are most likely to use *only* their smartphone to access the Internet.[73] *Providing HPV-VH parents with tailored, pre-visit educational information via mobile phones is a promising strategy to address unique needs, give time to think about the vaccine and prepare questions for the provider during the visit*.[14,55]

The proposed intervention will leverage mobile phone technology to provide VH parents individually tailored, pre-visit education to address specific parental concerns about HPV vaccine, build trust and rapport, and reduce hesitancy while avoiding extra provider burden. To our knowledge, this approach has not been previously tested. VH parents will be provided tailored education based on level of hesitancy (**Fig. 1**), knowledge deficiencies, attitudes and beliefs, and possibly other factors (e.g., cultural values). We *hypothesize* that providing individually tailored, pre-visit education to VH parents will increase HPV vaccine uptake compared with standard care by addressing each parent's unique barriers to vaccination.

B. INNOVATION

B1. Development of patient education materials targeting vaccine hesitancy for HPV vaccine. Most HPV vaccine interventions focus on the *initial* recommendation or completion of follow up doses after the first dose. Providers lack tools to use *after* the initial presumptive recommendation fails with at least one-third of patients. Research has tested provider-focused training to use motivational interviewing for vaccine counseling with VH parents. To our knowledge, this is the *first study* to develop patient education materials specifically targeting HPV-VH parents. These materials could be used as part of multi-component interventions in the future.

B2. Use of individually tailored, pre-visit education for HPV-VH parents. Existing interventions use standard education materials for *all* adolescents, and most deliver the intervention to the community at large[74] or during a clinic visit with the provider.[13,74] We believe this is the *first study* to develop an *individually tailored*, *pre-visit* education intervention for HPV vaccination to be used *after* the initial recommendation has failed. Materials will be given to parents after initial refusal and before their next upcoming clinic appointments.

B3. Delivering the educational intervention using mobile phone technology. Mobile phone technology has been used to deliver reminders and brief educational information to increase HPV vaccination among adolescents.[42,75-77] To our knowledge, this is the first intervention to use mobile phones to deliver tailored, educational information pre-visit to address barriers to HPV vaccine uptake among VH parents.

B4. Incorporating stakeholder engagement throughout formative research, intervention development and feasibility study. Community engagement helps to optimize the likelihood that an intervention will have its intended effect.[78] Community stakeholders and clinical partners were involved in the proposal development and will continue to be involved in all research phases moving forward. Additional stakeholder groups to be included are: (1) parents of adolescents; and (2) providers in local pediatric clinics.

C. APPROACH

C1. Relevant experience of research team. An exceptional multidisciplinary team and partnerships (**Table 3**) have been assembled to support me in completing the Specific Aims of this proposal and my career development, including clinical research and community engagement (Dr. Consuelo Wilkins), HPV vaccine and behavioral interventions (Dr. Hull), and vaccine hesitancy and clinical interventions (Dr. Dempsey). My mentors have significant research experience with over 100 peer-reviewed publications on HPV vaccination, intervention development, and/or community engagement. My Scientific Advisory Committee has additional expertise relevant to my research—health communication (Dr. Mayberry), advanced quantitative analysis (Dr. Landsittel), pediatrics (Dr. Tropez-Sims, MMC Pediatrics), and cancer (Dr. Alvarez) (see **Letters of Support**). I have the foundational research skills to conduct this work and a diverse mentoring team to assure the project's

success (see **Biosketches**). Combining expertise and generating synergy for high-impact research, this team provides a unique opportunity to address HPV vaccination in underserved adolescents with VH parents.

Table 3: Partnerships for Research Proposal	
Community/ Clinical Partner	**Role**
Meharry Medical College Pediatric Clinic	A safety-net clinic serving primarily publicly-insured and uninsured patients
HPV Cancer Free Coalition (HPVCFC)	Statewide coalition that aims to eliminate cervical cancer in Tennessee by increasing HPV vaccination, cervical cancer screening, and early detection
Meharry-Vanderbilt-TSU Cancer Partnership Community Advisory Board	Includes community organizations, parents, teens, cancer survivors, public health and healthcare staff; Facilitates community input into cancer research
HPV-ACTIVE Program	Program brings together Interdisciplinary faculty, physicians, and students at VUMC and Meharry who conduct cross-disciplinary research on HPV-related cancers

C2. Preliminary Studies

C2a. Recruitment pilot. For this proposal, I sought to demonstrate feasibility to recruit VH parents. Using MMC Pediatrics electronic health record (EHR) and the VHealth software, we identified 15 11-12 year old patients who were due for a dose HPV vaccine and did not receive in a recent well visit. In one week, I attempted to contact all 15 parents up to three times with the following outcomes: two bad phone number, five no response, four screened ineligible, 4 screened eligible. All four eligible agreed to do the interview, and none refused, demonstrating feasibility. All four stated interest in receiving information from their child's physician regarding vaccinations via mobile phone technology since they currently use their phone to retrieve health information.

C2b. Parent and adolescent needs for communication about adolescent immunizations from the medical home. In my K12 project, I examined parent–child dyads' (n=30) perceptions toward HPV vaccination and explored satisfaction with patient–provider communication surrounding adolescent vaccines. Among parents who were undecided (n=4) or refused the vaccine (n=6), they had received a doctor's recommendation, an educational brochure, or both. Yet, they still wanted more information on the vaccine (e.g., vaccine safety, ingredients, and need for young age). Preferred communication channels were physicians and/or physician-recommended educational brochures, websites, or videos. Many parents suggested pre-visit information to engage in informed decision-making or prepare questions for the physician during the visit. *These findings led to the proposed intervention, and supports my ability to identify, engage, and recruit parents into this study.*

C2c. Education needs about HPV vaccination for subgroups of parents and adolescents. Dr. Hull et al. (2014) conducted a qualitative study with AA parents and daughters to identify educational needs as it relates to HPV vaccine. Among the unvaccinated, the "Ready if Offered" group simply needed a healthcare provider recommendation and basic information, while the "Skeptical" and "Rejected" groups needed in-depth information to reduce concerns about vaccine safety, perceived newness of vaccine, effectiveness of the vaccine, young recommended age, association with sexual activity, and distrust in drug companies.[79] *Findings suggest HPV-VH parents need tailored education. This supports we can recruit HPV-VH parents.*

C2d. Parent and Provider Perspectives on Communication Tools for HPV-VH parents. Dr. Dempsey and colleagues (2018) conducted a qualitative study to understand the effect of a communication intervention on HPV vaccination rates in a primary care setting. She was able to recruit 20 HPV-VH parents after adolescent well check visits without barriers. *This informs strategies and confirms our ability to recruit HPV-VH parents.*

C3. Research Design and Methods

C3a. Overview of Study Design. The research aims reflect the current state of science, my current level of expertise, and my planned application of knowledge and skills to be gained under this award. My training will increase my knowledge and skills in behavioral interventions, clinical trial design, and implementation science. I will apply these new skills to develop and pilot test a behavioral intervention to improve HPV vaccination in VH parents. Specifically, I will use a qualitative approach to prepare intervention content, delivery methods, and the trial protocol (**Aim 1**). I will use a 2-arm randomized controlled trial (RCT) design to conduct a pilot study to demonstrate feasibility of a future full-scale RCT (**Aim 2**). I will use an observational design with qualitative and survey methods to explore perceived acceptance of the protocol and intervention (**Aim 3**).

C3b. Conceptual Framework. The Theory of Reasoned Action (TRA)[26] may be used to predict behavioral intentions of parents to vaccinate their adolescents based on attitudes and subjective norms. The Health Belief Model (HBM)[27] may be applied to explain and predict parental likelihood of vaccinating their adolescents based on perceived susceptibility to HPV infection and HPV-related cancers; severity of cancer; and benefits of HPV vaccine and whether these benefits outweigh perceived barriers to vaccination. I will apply the HBM components as the attitude component of TRA. These theories have guided many tailored health interventions, including vaccine interventions. They will guide the development of the proposed tailored, pre-visit intervention to increase HPV vaccination among VH parents (**Aims 1 and 2**).

To design the new intervention for future implementation in a clinical setting, constructs from the RE-AIM (reach, effectiveness, adoption, implementation, maintenance) framework will be used to examine the process of implementing the intervention (**Aim 3**).[80] **Table 4** summarizes the application of these models.

Table 4: Conceptual Framework

Theory: Theory of Reasoned Action (TRA) & Health Belief Model (HBM)		**Model:** RE-AIM Model	
Attitudes: **Perceived Susceptibility**	Perceived susceptibility of adolescent to HPV infection	**Reach**	Total number and rates of adolescents of VH parents getting HPV vaccine
Attitudes: **Perceived Severity**	Perceived severity of HPV-associated cancer	**Effectiveness**	Difference between intervention and control groups in HPV vaccination rates
Attitudes: **Perceived Benefits**	Perceived barriers to HPV vaccination	**Adoption**	Proportion of physicians in setting that adopt the HPV intervention.
Attitudes: **Perceived Barriers**	Perceived Benefits to HPV vaccine	**Implementation**	Extent to which the intervention is used as intended by vaccine providers and parents
Attitudes: **Subjective Norms**	Perceived peers view of HPV vaccine and motivation to comply with peers	**Maintenance**	Extent to which the practice/program becomes or has potential to become routine

HBM constructs as the attitude construct of TRA | Subjective Norms of TRA | RE-AIM Model Constructs

C3c. Importance of community engagement. Community-engaged research (CEnR) is important to develop effective interventions to improve health outcomes and reduce cancer health disparities.[81,82] It involves community participation and collaboration to address issues affecting community's well-being, and has been effective in improving health outcomes across conditions, especially in underserved populations.[78] Use of community-engaged approaches to underserved adolescent populations could improve HPV vaccine rates,[83] and lower HPV-associated cancer rates. In this study, community involvement will occur at all research stages (**Aims 1–3**). We have established partnerships (**Section C1**) to gain input into this proposal and throughout the research process. We will expand our CenR efforts for input from parents and their adolescents. This input will optimize a pilot intervention promoting HPV vaccination at a pediatric site serving underserved adolescents.

C4. Aim 1. Conduct formative research to develop tailored, health communication intervention targeting HPV-VH parents prior to clinic visits.

Stage 1: Intervention Development. We will develop a mobile phone-based intervention aimed at increasing HPV vaccine uptake among VH parents. Research suggests major barriers for HPV-VH parents include lack of knowledge, misinformation, and negative attitudes (e.g., vaccine safety concerns). We plan to address these and other barriers by providing individually tailored, pre-visit education to VH parents. To tailor the education, we will adapt a 10-item vaccine hesitancy scale by Larson and colleagues[56] and a 10-item HPV knowledge scale I developed previously[84] to create a "quiz" to assess specific barriers and needs for each parent **(Appendix)**. Based on their quiz responses, we will give them personalized educational messages framed with a cancer prevention and health promotion focus. We will develop the messages using 3 steps: (1) We will create initial drafts of the educational messages based on the TRA and HBM, our preliminary data, and existing literature; (2) We will show initial drafts of the survey and educational messages to our scientific advisory and community partners to gain input on wording/comprehension, potential impact, and relevance; and (3) we will interview VH parents and providers to iteratively revise and refine the intervention materials.

Proposed Tailoring Variables: We will develop a library of educational messages and map them to specific tailoring variables in the quiz to address specific needs of individual VH parents. Examples of tailoring variables include demographic, knowledge, and attitude variables, which are described below. See **Table 5** of example of how we would tailor a message.

- *Demographic Variables*: The tailored materials will address the parent and child by name to personalize the messages. We will also match materials (e.g., images of people) to parents' ethnicity/race.
- *Knowledge about HPV and vaccines*: We will identify knowledge deficiencies among VH parents using interview and quiz/survey data. Educational messages will be linked to specific knowledge gaps.
- *Attitudes about HPV vaccines*: Based on the quiz/survey and interview data, parental level of hesitancy and specific attitudes and beliefs related to parental HPV-VH (e.g., vaccine safety) will be linked to respective educational messages that could potentially influence their attitudes.

Table 5: Examples of Tailoring Variable and Sample Message

Tailoring Variable	Sample Quiz Item	Tailored Message
Knowledge about HPV and the vaccine	The HPV vaccine is effective.	The HPV vaccine is highly effective in protecting against 93% of cancers caused by HPV. It is most effective when given before age 13.
Attitudes about HPV vaccines	I am concerned about serious adverse effects of the HPV vaccine.	The HPV vaccine is very safe. Vaccines, like any medicine, can have side effects. Many people who get the HPV vaccine have no

		side effects. Some people report mild side effects like a sore arm, fever, nausea, or fever. Serious reactions are very rare.

Intervention Delivery: The intervention will be delivered via mobile phone **(See Figure 3)** by first sending a text message to the parent's phone with a link, then clicking the link will open a website that is optimized for viewing on a mobile phone, which has the look and feel of an app, but without requiring the user to download anything to the phone. On the website, they will be prompted to take the assessment "quiz." Based on the responses, the top barriers/needs (e.g., top three) will each be mapped to a corresponding educational message, which will be displayed to the user with appropriate images/graphics. The parent will be given links to websites with reliable information and suggested questions they can ask the doctor related to each topic. The parent will be prompted to save the tailored messages/questions to their phone as images. Then another text message will be sent to the parent's phone with a link for returning to their tailored page in the future.

Figure 3: Flow Diagram of Intervention Process

Study Design: We will conduct qualitative interviews using a phenomenological approach, which seeks to understand ones' experience in a particular situation (e.g.,, parental decision-making on HPV vaccine).[85] Interviewees will also complete a brief survey, including the quiz. In an iterative process, we will conduct many interviews, analyze the data, and revise materials (e.g., quiz items, draft messages, images/graphics) using feedback. We will repeat the process several times until thematic saturation is reached for revised materials.

Study Population and Sample Size: (A) Twenty-five to 30 VH parents who previously refused the HPV vaccine will be recruited, as the target audience for the intervention materials; and (B) 10 healthcare providers who are future implementers of the intervention. Based on prior work, we anticipate this number will be adequate to achieve thematic saturation during analysis. Additional interviews will be conducted if needed.

Eligibility Criteria: (A) *VH parents*: Parents with unvaccinated children who are patients in MMC Pediatrics aged 11–18, refused HPV vaccine in past two years, speak English, own smartphone; (B) *Providers*: physicians, physician assistants, and nurse practitioners who deliver primary care to patients aged 11–18.

Recruitment: We will recruit a purposeful sample of VH parents and providers. (A) VH parents will be identified using the MMC Pediatrics electronic health record (EHR) and the VHealth software that is currently being used in the clinic under Dr. Hull's R01 study. VHealth is a HIPAA-compliant software that interfaces with the EHR to extract specific patient data using pre-defined filters and analytics, including HPV vaccine refusals. We will contact parents via the contact information (e.g., phone, mail) in the clinic's system to screen for eligibility and invite study participation. (B) Providers from MMC Pediatrics and surrounding clinics will be recruited via email and phone, with suggestions from the Scientific Advisory Committee and partners (see **Letters of Support**).

Study Procedures: Guided by Health Belief Model[27], Theory of Reasoned Action[26], and community partner input, we will draft open-ended interview questions and adapt the survey to elicit: (1) attitudes, facilitators, and barriers to HPV vaccination; and (2) feedback on wording, aesthetics, and format of draft intervention content and delivery to inform revisions. The survey will identify common barriers among HPV-VH parents and the need to modify/add/eliminate barriers in the quiz. Interviews will last 45 minutes for parents, and they will be paid $30. Provider interviews will last 30 minutes, and they will be paid $50.

Analytic Plan: *Interviews* will be recorded, transcribed verbatim, and de-identified. I will develop a codebook with my mentors' input. Trained research analysts from the Vanderbilt Qualitative Research Core will use the codebook initial coding then add to and modify as needed during analysis, based on emerging themes. Two coders will independently review and code each transcript using NVivo 11 qualitative analysis software. Thematic analysis[86] will determine emerging themes. Inter-rater reliability will be assessed, and discrepancies resolved by examining and discussing codes related to themes/subthemes. I will make the final decision when there is not consensus. Strategies to ensure rigor include triangulation, thick descriptions, peer debriefing, and member checks.[87] *Survey* data will be entered in REDCap, a secure web-based data collection application,[88] and analyzed using SPSS version 23 statistical analysis software. I will use descriptive analysis (e.g., means, frequencies) and bivariate analysis (e.g., Chi-square, Fisher's exact tests) to describe patterns in the data. I will consult with my mentoring team and biostatistics core support as needed during the analysis.

Based on the findings of parental perceptions and educational needs along with input from community partners, we will finalize the individually tailored message concepts for VH parents and determine how to best match tailoring variables to specific educational messages.

Stage 2: Pretesting and Optimization.

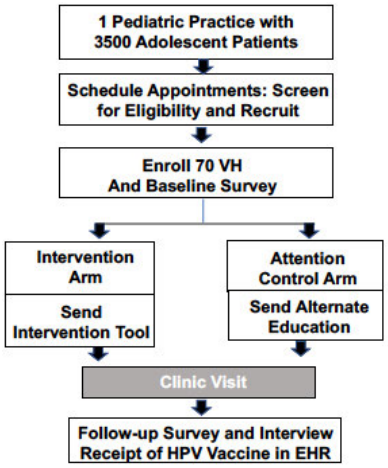

Figure 4: 2-Group Pilot RCT Study Flow Chart

Study Design: A qualitative design will be used to get feedback on how to maximize feasibility and acceptability of the draft intervention and study protocol for **Aim 2**. I will work with MMC Pediatrics to draft the protocol to identify and recruit VH parents, send the educational intervention to them before their scheduled clinic visit, retain participants, and collect data from the participants and the EHR/VHealth. Preliminary pre-testing will be performed to enhance usability of the intervention and feasibility of the trial protocol. First we will conduct cognitive interviews in-person or videoconference (e.g, Video Chat, Skype) with 8 parents to get their feedback on the intervention to monitor time to complete a task, number of errors, and users perceived ease of use and usefulness in real-time using a think-aloud approach. The next 8 parents will be sent the app to use at home, then follow-up phone interviews will explore views and experiences related to acceptability and feasibility of the intervention. We will document tasks performed by all users of the text messages and website (clicked link in text message, read the welcome page on website, complete the assessment, and read the advice).

Study Setting: The study setting will be MMC Pediatrics in Nashville, Tennessee.

Study Population and Sample Size: (A) Sixteen HPV-VH parents; and (B) 3 MMC physicians.

Eligibility Criteria: (A) Parents of patients of MMC Pediatrics aged 11–18, refused HPV vaccination in the past two years, have not received any doses of HPV vaccine, have a clinic appointment scheduled within the coming month, speak English, own smartphone, and did not participate in **Aim 1 Stage 1**.

Recruitment: We will recruit and test the intervention/protocol with 1–2 VH parents at a time, analyze data, and make changes iteratively until reaching thematic saturation. Eligible patients will be identified using the clinic's EHR and VHealth software. We will contact parents by information (e.g. phone, mail) in clinic's system, confirm eligibility by phone, and invite study participation two to three weeks before the child's scheduled clinic visit.

Study Procedures: Clinic and/or study staff will talk to enrolled parents over the phone to explain how the intervention will work (text messages and website) and ask them to use it prior to their clinic appointment. I will conduct post-visit debriefing interviews with parents and physicians after all participants have completed the study procedures. Each parent will receive $30, and physicians will receive $50.

The interview will include open-ended questions to examine the following dimensions of feasibility and acceptability[89,90] from the perspectives of the parent, adolescent, and provider.

- *Feasibility of implementation*: *Providers:* factors affecting implementation ease or difficulty, clinic resources needed to implement, perceived fit with clinic processes.
- *Acceptability of intervention*: *Parent:* satisfaction with intervention and protocol overall and specific components (clarity, ease of use, relevance, helpfulness, attractiveness, new information), actual use (time), satisfaction with provider–patient communication, trust/rapport with provider, influence on intention to get HPV vaccine; *Providers:* benefits of intervention for vaccine counseling during visit; *Both:* suggestions of specific aspects that need improvement.

Analysis Plan: We will use thematic analysis[86] to analyze transcriptions of debriefing interviews, as done in **Aim 1 Stage 1**. We will iteratively analyze data and use results to modify content of prototype materials, intervention delivery methods, recruitment/retention strategies, data collection, and implementation plan. This will optimize feasibility and acceptability from the perspective of the parents, patients, and providers.

C5. Aim 2. Conduct a pilot study of the intervention and study protocol to demonstrate feasibility for the future full-scale RCT.

Purpose of Pilot Study: The future full-scale RCT will assess the efficacy of the intervention compared with attention control. The objective of this pilot study is to demonstrate feasibility of the processes planned for the future RCT.[91-93] Experts recommend that it is not appropriate for a pilot study of a future RCT to compare study arms to assess treatment effects or to estimate effect sizes, due to the small sample size.[91-93]

Study Setting: MMC Pediatrics: 3,500 adolescent patients (ages 11-18), 60% African American, 52% Medicaid

Study Population: VH parents who refused HPV vaccine for adolescent patient

*Note: The details of the pilot trial protocol will be completed after **Aim 1**; tentative plans are described below.*

Study Design: The pilot study will implement the design planned for the future full-scale trial, a two-arm RCT to compare the intervention with attention control (**Figure 4**). The attention control arm will receive pre-visit health

education information on an unrelated topic (e.g., healthy eating and physical activity) via a text message with a website link.

Randomization and Blinding: The unit of randomization is the parent. An independent statistician will randomize the parent to the study arms using a computerized random number generator. It is not possible to blind parents to study assignment given the intervention. To maintain parental trust, providers will be informed of study assignment prior to seeing a patient to confirm to parents they endorse the educational material sent from the clinic and ask them what questions they have after reviewing it. For analysis, statisticians will be provided blinded data labeled A and B for each study arm. Data will be unblinded after analysis is complete.

Eligibility Criteria: (A) Parents/guardians of adolescent patients of MMC Pediatrics aged 11–18, refused HPV vaccination in the past two years, have not received any doses of HPV vaccine, have a clinic appointment scheduled in coming month, speak English, own smartphone, and did not participate in **Aim 1**; and (B) MMC pediatric providers participating in the pilot.

Data Sources: Data will be obtained from the clinic EHR and VHealth databases and parent surveys.

Recruitment: The same recruitment methods in **Stage 2 of Aim 1** will be used, including any changes that were made to the protocol based on debriefing interviews. This will be the recruitment plan for the future RCT.

Sample Size: The primary outcome of the future RCT will be HPV vaccine receipt at the clinic visit (binary/ proportion). (a) Pilot Trial: The necessary sample size for the pilot trial may be calculated using a one-sided 80% confidence interval and expected effect size of the future RCT,[94] based on the expected proportion in the control arm (0.20–0.30) and the clinically meaningful difference to be observed in the intervention arm in the future RCT (at least 0.10 higher).[92,94] A total pilot sample size of 46–60 after attrition will be sufficient (**Table 6**). We will enroll 70 VH parents, expecting 10%–15% attrition (no-show for clinic visit), yielding a final sample of 60–63 parents (28–30 per arm). MMC Pediatrics has 3,500 active adolescent patients ages 11–18, and 60% have not received any HPV vaccine doses. Among the 300 adolescent visits per month, half (150) are scheduled appointments (not walk ins). We estimate 90 (60%) have received no HPV doses and half of them[14] (45) have previously refused HPV vaccine, and will be eligible for the study monthly. We expect to recruit at least 10-15 parents per month, so accrual will take around six months.

Table 6. Pilot Sample Size Calculation (p=Proportion: Receipt of HPV Vaccine at Visit)

Control p	Difference	Future RCT N	Pilot N	80% CI Upper Limit
0.20	0.10	712	60	0.0996 (<0.10)
0.30	0.10	586	46	0.0993 (<0.10)

Study Procedures: Clinic and/or study staff will identify eligible patients using the EHR/VHealth. Study staff will contact and recruit potential participants and collect baseline surveys via phone, email, or mail. After randomization, clinic or study staff will send a corresponding text message for the HPV vaccine intervention or the attention control arm to enrolled parents based on study group assignment. At the end of each patient visit, study staff will ask enrolled patients to complete a brief post-visit survey. Each parent will receive $25 for completing the surveys. I will conduct post-visit debriefing interviews with 20–30 parents per study arm and with 3 physicians after all participants have completed the study procedures. Each parent will receive $25, and physicians will receive $50 for the debriefing interviews.

Feasibility Measures: Feasibility will be assessed based on recruitment rates (# pre-screened, % contacted, % unable to contact, % screened, % enrolled, # enrolled per month), retention rates (% completed baseline survey, % came to clinic visit (primary retention endpoint), % completed post-visit survey), and data collection processes (% ascertained post-visit HPV vaccine status, # minutes to complete surveys). Criteria for success for each of the feasibility measures will be defined based on the results of **Aim 1**.

Analytic Plan: Quantitative data will be summarized using frequencies and descriptive statistics and compared with the criteria for success.

C7. Aim 3. Examine acceptability of the intervention and protocol among parents and providers.
Study Design**:** I will use an observational design combining survey and qualitative methods to explore perceived acceptance of the intervention and protocol, based on analysis of the surveys and debriefing interviews collected in **Aim 2**.

Study Population and Sample Size: (A) Parents/guardians who participated in the intervention in Aim 2, with 60-63 completed baseline/follow-up surveys and 40-60 completed qualitative interviews. (B) 3 pediatric providers who participated in Aim 2.

Parent Survey Measures: The baseline and post-visit surveys will include demographics and measures of *satisfaction with provider–patient communication* and *trust/rapport with provider*.[90] Post-visit surveys will include reasons for accepting the HPV vaccine at the visit and intervention acceptability measures,[90] in which the parents rate how much they agree (scale of 1–5) with a series of statements about the intervention overall,

specific intervention components, the study overall, and specific protocol components (**Appendix**). Acceptability will also be measured with website analytics of intervention engagement (clicking link to view website, number of minutes spent on website, clicking button to save educational information to phone).

Qualitative Interviews: The interview discussion guide will be similar to **Aim 1 Stage 2**, plus questions for providers about RE-AIM implementation components.

Analytic Plan: *Survey Data:* Quantitative data will be summarized using frequencies and descriptive statistics. Exploratory analyses will include bivariate analyses of associations between acceptability, communication satisfaction, trust, HPV vaccination, and reasons for non-vaccination to derive secondary hypotheses for the future RCT. *Interview Data:* Qualitative analysis will be used to analyze transcriptions of interviews, as done in **Aim 1**, to identify unforeseen problems with the protocol that need to be modified and identify ways to improve recruitment and retention rates, intervention delivery, and intervention content in the future RCT.

C7. Timeline for Training and Research Activities. My mentors and I have developed an integrated research and training program that is achievable in the four-year funding period. I will conduct high-impact research, allowing me to submit/resubmit an R01 application in Year 4 of the funding period (**See Table 7**).

Table 7: Timeline for Training and Research Activities

ACTIVITY	Year 1				Year 2				Year 3				Year 4			
IRB Preparation and Submission	■				■				■							
Aim 1: Data Collection & Analysis, Intervention Development, Pretesting	■	■	■	■	■											
Aim 2: Pilot Study of intervention and RCT protocol to assess feasibility					■	■	■	■								
Aim 3: Analysis of surveys and debriefing interviews to explore acceptability of intervention and RCT protocol; Intervention Refinement									■	■	■	■	■	■		
Bi-Annual Scientific Advisory Committee Meetings	■		■		■		■		■		■		■		■	
Monthly CCFTN and HPV-ACTIVE Meetings; Quarterly CAB Meetings	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■
Manuscript submissions based on ongoing data analyses					■		■		■		■		■		■	
Conference Presentations				■				■				■				■
R01 Grant Preparation, Submission (S), and Resubmission (R)									■	■	S	■	■	R	■	■

C8. Limitations and Potential Challenges. **a)** Recruitment problems: To minimize problems in contacting patients, clinic staff will update contact information when parents schedule appointments. If we have trouble reaching our target sample size due to slow recruitment, we can expand to MMC's Family Medicine Clinic located off campus. Community partners and the Scientific Advisory Board will give advice on recruitment and retention strategies (see **Letters of Support**). **b)** Retention problems: When we recruit parents, we will ask for additional forms of contact information (3+ phone numbers, permission to send text messages, email), remind them of their clinic appointments, and contact them to reschedule appointments for no-shows. Dr. Hull (co-primary mentor) previously used the same strategies proposed to recruit parents/teens in this clinic,[38] and Dr. Erves has similar experience in study recruitment. **c)** Health literacy and usability of educational tools: Given the potential challenge of low health literacy in this population, we will design the materials for low literacy audiences. The messages will use plain language (i.e., active voice, simple sentences and infographics), large font, white space, and enhancement with audio files (i.e., voiceover).[95] We will use a 5th grade reading level, test with Flesh-Kincaid Grade Level and Automated Readability Index. We will tailor content, define medical jargon, and organize structure from simple to more complex information,[95] with expert advice from mentors.

During **Aim 1 Stage 2**, I will pre-test and get feedback on materials to optimize usability, comprehension, and engagement. We will also provide a button on the website to hear an audio version of the text on the screen. **d)** Risk of contamination across study arms: To minimize, we will send the intervention link via text message directly to parents at home, reducing chances of interactions in clinic waiting rooms. In debriefing interviews, we will ask about exposure to the other study arm. **e)** Patients accessing other sources of HPV vaccine information: In debriefing interviews, we will ask about exposure to other information sources.

C9. Summary and Future Directions. This proposed research and subsequent studies will support the NIH mission to "improve health through science by leading to cures, treatments, or preventions for human disease". The proposed intervention will address barriers to HPV vaccine uptake among underserved adolescents with VH parents, and potential acceptability will be enhanced through community engagement. The pilot study will demonstrate feasibility and provide preliminary data for an R01 application proposing a larger, well-powered RCT to assess efficacy. If efficacious, we will propose a subsequent implementation study to assess effectiveness and cost-effectiveness under "real-world" conditions (e.g., larger sample of clinics), implementation outcomes, long-term sustainability of effects, and the role of mediators and moderators. In the future, I can also apply for additional funds to have the intervention translated and culturally adapted for Spanish-speaking patients. I will be able to apply skills and experience that I gain from this study and subsequent R01 to develop and test additional cancer prevention behavioral interventions in the future.

Training in the Responsible Conduct of Research

Past Training: At Tuskegee University, I began my Responsible Conduct of Research (RCR) training in a Biosciences research and ethics course under Dr. Leonard Ortmann while pursuing a Master's degree (Fall 2006). Topics included research with human subjects, ethical principles, and ethical problems in this 3-hour, bi-weekly course. I received previous training in data privacy and sharing as an OraQuick counselor doing HIV testing in a clinical setting (February 2009-May 2013). While at UAB (August 2008-December 2013), I took a series of writing courses under Drs. Julia Austin, Susan Olmstead-Wang, and Jennifer Greer on responsible authorship and publication practices (i.e., Writing Successfully-1 hour, Writing and Reviewing Research- 3 hour, Academic and Publishing- 3-hour), and a 3-hour, weekly data collection management course. I also completed the Collaborative Institutional Training Initiative (CITI) course on Human Subjects Protection and RCR in August 2010 prior to conducting my dissertation research to identify factors influencing Black mothers' intention to vaccinate their daughters against the HPV. Module topics were research misconduct, data management, collaborative research, conflicts of interest, and authorship. I completed the CITI refresher training at Meharry Medical College in November 2013. Refresher modules included history and ethical principles, defining research with human subjects, informed consent, privacy and confidentiality, research with children, conflicts of interest in research involving human subjects, RCR, research misconduct, data management, authorship, peer review, mentoring, conflicts of interest, collaborative research, and research involving human subjects. As project manager of my post-doctoral project and collaborator on other projects, my responsibilities included IRB protocol development and working with staff in the Office for Research. I have met the requirement of all PIs required by Meharry, which is consistent with the national standards.

Current and Ongoing Activities: In Spring 2017, I completed and passed the "Public Health Research Ethics Course" offered by Vanderbilt University Master of Public Health Program (3 credits). I have also completed the annually required courses: CITI Online Curriculum which included a HIPAA refresher on February 20, 2018 which was renewed February 19, 2019; and Conflict of Interest Training on February 12, 2018 which was renewed February 11, 2019. I attend monthly one-hour Vanderbilt Elliot Newman Society seminars with face-to-face presentations on mentoring, publications, getting a job, and grant writing led by key, senior Vanderbilt Faculty. I also attend 1-hour RCR events approved by Vanderbilt Institute for Clinical Research (VICTR) as provided, and I provided my first RCR lecture on Friday, January 5, 2018 on how to conduct qualitative research. (See Resources). The proposed research plan for this award can benefit from these experiences by networking with other colleagues similar in career stages, maintaining a positive relationship with my mentors, and learning RCR.

Future Training: During this 5-year award period, I will continue to receive formal and informal training in RCR. I will renew my CITI RCR training offered by the Office of Research yearly. I will attend RCR-related seminars at national meetings twice a year as identified. At Vanderbilt, I will continue attending 1-hour Elliott Newman Society seminar series once week. Topics will include "Keys to Academic Success", "Scholarly Productivity on a Timeline", and "Inside Study Section". This will occur first three years, and then as needed for the fourth year.

I will meet with Dr. Wilkins (primary mentor) weekly for one hour monthly to ensure maintenance of high ethical standards by addressing ethical issues that arise in my work. Discussions may include responsible research conduct and misconduct; sharing and managing data; conflicts of interest related to personal, professional, and financial aspects; and responsible authorship and publication. Dr. Dempsey (co-mentor) and Dr. Hull (co-mentor) will assist me to structure research collaborations and professional networks, understand and implement roles and responsibilities of members of a mentor-mentee relationship, and provide insight on the peer review process. We will meet monthly for one hour individually monthly. At research meetings conducted separately by Drs. Wilkins (1-hour weekly), Dempsey (1-hour monthly), and Hull (1-hour weekly), I will discuss my research topic incorporating RCR principles. This will occur over the first three years of award. I will continue to consult with Meharry IRB staff as-needed when human subjects' issues arise during research.

After gaining substantial experience, I will serve as a mentor in RCR. All research staff will complete CITI training yearly which includes RCR training. I will reiterate these topics (e.g., responsible research conduct and misconduct, responsible authorship and publication) at 1-hour weekly meetings with my staff. I will give presentations on collaborations in public health, data privacy in adolescent health, and authorship and manuscript to students or in works-progress meetings (1-hr meeting, 2-3 times a year). Other presentations will be on good study design, research collaborations with industries, and social impact of my research. These formal and informal training activities will occur over the 4-year career development award period.

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Consuelo H. Wilkins, MD, MSCI
Executive Director and
Associate Professor of Medicine

February 27, 2019

National Institutes of Health (NIH)
9000 Rockville Pike
Bethesda, Maryland 20892

RE: Letter of Support for Jennifer Cunningham Erves, PhD

Dear Members of the K01 Selection Committee:

It is my distinct pleasure to support Dr. Jennifer Cunningham Erves' application for the National Cancer Institute (NCI) Mentored Research Scientist Development Award to Promote Diversity (K0l- Clinical Trial Required) and to serve as her primary mentor. Dr. Erves is an outstanding candidate for testing the feasibility of an individually-tailored health communication to improve human papillomavirus (HPV) vaccine in underserved adolescents with vaccine hesitant (VH) parents. Her combined knowledge and research in biology, health education and health promotion, community engagement, and HPV make her capable of conducting this work. She has a novel approach to improve HPV vaccination among adolescents with VH parents by using tailored messaging prior to a doctor's visit, which has the potential to reach adolescents most at risk of HPV- associated cancers. Dr. Erves training plan involves learning new content areas (i.e., behavioral intervention research, clinical research, health communication theories and practice, and implementation science), which is essential for her career develeopment. This application is highly responsive to the disproportionate impact of HPV related cancers in underserved populations, and worthy of funding.

Dr. Erves is highly intelligent, productive and collaborative. I met Dr. Erves in 2013 when she began as a post-doctoral research fellow in our Community Engaged Research Core (CERC) where I currently serve as the Director. I was immediately impressed by Dr. Erves commitment to excellence and keen insightfulness. Within the first few months of her fellowship, Dr. Erves identified new opportunities to extend her work in HPV-related cancer disparities using community-engaged approaches. During her post-doctoral training, Dr. Erves initiated an independent project to identify factors influencing parental willingness to allow adolescents to participate in HPV vaccine clinical trials. Within six months of receiving IRB approval for her project, Dr. Erves successfully recruited more than 300 parents to her study, 65% of whom were racial/ethnic minorities. Her work generated important new knowledge that fills a gap in understanding barriers to HPV vaccine series completion and barriers to minority adolescents' participation in clinical trials. This work has been extended in her current K12 award, where she seeks to compare effectiveness of patient-centered approaches to increase HPV vaccination in African American adolescents. Also, Dr. Erves has clearly distinguished herself from other trainees as a leader and significant contributor in community engaged research. She has actively participated in the capacity building aim for CERC, helped train colleagues in qualitative and quantitative methods, and helped develop strategies to extend the reach of our core by co-planning Community Research Day and community forum. Dr. Erves led the analysis of data from our core on methods of community engagement, leading to a first-author publication in Clinical and Translational Science. She recently assisted in the development of a research curricula for community members and organizations, with a first-author paper recently accepted. This work has laid the foundation for the need to improve HPV vaccination among adolescents and provided the initial underpinning of skills towards an independent researcher.

My track record as a mentor extends over the past ten years with over 25 pre-doctoral, post-doctoral, and early career investigators with each mentoring term varying in time commitment. Many of these individuals have established themselves with tenure-track faculty positions with extramural funding, clinicians, and instructors. I am equipped with the expertise, leadership, and motivation necessary to mentor Dr. Erves. As Executive Director of

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the Meharry-Vanderbilt Alliance and Director of CERC, I will leverage my resources to support Dr. Erves career development, and I will provide guidance based on my experience as an investigator in clinical, comparative-effectiveness and community-engaged research. I will also assist Dr. Erves to secure Vanderbilt's Clinical and Translational Research (VICTR) services (e.g., Qualitative Research Core for transcription, coding, and data analysis) to complete this research. Funds to support her project within this K application. I will continue to meet with Dr. Erves weekly one-on-one and in my weekly research team meetings. As PI of a NIH/National Institute on Minority Health and Health Disparities grant focused on precision medicine approaches to eradicate health disparities, and Co-PI of the NIH/National Center for Advancing Translational Sciences grant focused on improving clinical trial education, recruitment, and enrollment at CTSA Hubs. I am well-positioned to provide Dr. Erves additional training on clinical trials and community and stakeholder engagement to enhance her research and support the development of novel approaches. I have substantial experience with inter-institutional collaborations and I serve on a multitude of national committees and advisory panels focused on health equity including Lead Team member of the CTSA Consortium Collaboration Engagement Domain Task Force, PCORI advisory panel on Clinical Trials Subcommittee on Recruitment, Accrual, and Retention, and co-chair the PCORnet Patient and Consumer Engagement Task Force. Therefore, she will observe my research projects and be provided one-on-one mentoring in these areas.

Dr. Erves is an Assistant Professor at Meharry Medical College, which will facilitate her ability to develop a program of research to contribute methodological rigor to the emerging field of public health oncology. Her time is fully supported to conduct research as she is supported by Dr. Hull (co-primary mentor) and Dr. Amanda Dempsey (co-mentor), who have complementary expertise in HPV vaccination and clinical and behavioral research in adolescents as well as implementation science. In order to evaluate Dr. Erves progress, we will develop an individual development plan annually and convene quarterly to review her career development progress and research. Dr. Erves will have guidance from her scientific advisory committee including: (1) Dr. Suzanne Tropez-Simms, Professor and Associate Dean of Academic Affiliations in Pediatric Medicine who focuses on improving HPV vaccination uptake in underserved comm.unities; (2) Dr. Lindsay Mayberry, Assistant Professor of Medicine who has experience in implementing health communication strategies in the medical home; (3) Dr. Douglas Landsittel, Professor in Bioinformatics and Director of Biostatistics at the Starzl Transplant Institute with extensive experience in advanced biostatistics, (4) Dr. Ronald Alavarez, Professor of Obstetrics and Gynecology, who has experience in cancer epidemiology and rprevention, and control. .

I am very excited about the broad reach of Dr. Erves' current project, not just in the context of improving HPV vaccination rates in adolescents, but also of its potential to have a positive impact on the disparities in HPV-related cancers. The discovery elements of this project proposes a novel approach of providing tailored messages before their doctors visit to improve HPV vaccine rates. Her project is well-aligned with the overarching theme of NCI to reduce the burden of HPV-associated cancers. The additional training Dr. Erves will acquire as a K01 recipient we believe is necessary and will be critical to her successful transition to an independent researcher focused on cancer prevention and HPV-associated cancer disparities in minorities.

I am fully committed to Dr. Erves' career development and give her application my highest endorsement. Dr. Erves is already an asset to the Meharry-Vanderbilt community and has the full support of these institutions. I highly recommend Dr. Erves for this K01 career development award. I am confident Dr. Erves will achieve her research and career development goals as a leader in public health oncology after receipt of the training provided in this K01 award.

Consuelo H. Wilkins, MD, MSCI
SinceExecutive Director, Meharry-Vanderbilt Alliance
and Meharry Medical College

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VANDERBILT UNIVERSITY MEDICAL CENTER

Institute for Medicine and Public Health
Vanderbilt Epidemiology Center

March 1, 2019

RE: Letter of Support for Jennifer Cunningham Erves, PhD

Dear Selection Committee of the K01 award:

I am pleased to write this letter of support for Dr. Jennifer Cunningham Erves' application for the National Cancer Institute (NCI) Mentored Research Scientist Development Award to Promote Diversity (K01- Clinical Trial Required) and to serve as her co-primary mentor with Dr. Wilkins. I have known Dr. Erves for three years and would like to communicate my enthusiastic support for this award based on her previous performance. I believe Dr. Erves is on the path to becoming a leader in the area of developing behavioral interventions to prevent cancer and reduce racial disparities, with her initial focus being on increasing human papillomavirus (HPV) vaccination.

I met Dr. Erves after she started her position as a post-doctoral fellow for the Meharry-Vanderbilt Community Engaged Research (CERC), and I currently serve as a mentor on her mentoring team. Dr. Erves is intelligent, analytical, curious, well-organized, passionate, and committed – all of which are key characteristics for a budding researcher to be successful. Her independent post-doctoral project sought to identify factors influencing parental willingness to allow their adolescent children to participate in HPV vaccine clinical research trials. This research filled a gap in understanding barriers to adolescent participation, particularly minority adolescent participation, in HPV vaccine clinical research and could inform the development of a theory-based intervention to improve clinical trial participation rates.

After developing her research agenda during her post-doctoral fellowship, she became an Assistant Professor at Meharry Medical College where is a recipient of an internal K12 award from Vanderbilt. She has been conducting important formative research to identify potentially promising strategies to improve HPV vaccination among adolescents using patient-centered approaches. She has been actively involved in my research and building partnerships in the community. She has become involved in the Vanderbilt-Meharry HPV-ACTIVE working group, the Cervical Cancer Free Tennessee Coalition (which I co-chair), the Nashville Health Disparities Coalition, and the MMC-VICC-TSU Cancer Partnership Community Advisory Board. Participating in these groups has allowed Dr. Erves to apply community engagement principles, where she gains community feedback on her projects.

For my current R01 grant, Dr. Erves is observing the implementation and testing of my quality improvement intervention targeting pediatric clinics to improve clinic-level processes to increase HPV vaccination. We have provided the study clinics the "Bug Your Doc – Get 3 Shots!" patient education materials that my team developed to promote HPV vaccine together with the other recommended vaccines for 11- and 12- year olds, Tdap and meningococcal vaccines. While the pediatricians find these materials useful for the initial HPV vaccine recommendation, they expressed that a substantial proportion of parents decline the HPV vaccine and are resistant, and they felt that these parents/teens needed different patient education materials to specifically address their issues of hesitancy. However, despite numerous searches, we could not find any existing evidence-based patient education materials designed to target HPV vaccine hesitant parents. Dr. Erves' ongoing research with parents, adolescents, healthcare providers, and other stakeholders also identified parent/patient education needs for this HPV vaccine hesitant group. Her proposed research will fill these gaps by developing a tailored, family-centered health education intervention that pediatricians can send to HPV vaccine hesitant parents prior to their next scheduled clinic visit, to build trust, improve communication, and increase acceptance.

I am committed to Dr. Erves' success to become an independent researcher in public health oncology by serving as her co-primary mentor. I will foster her skills in forming and maintaining relationships with stakeholders and provide guidance on intervention development and testing. I will continue to meet with Dr. Erves bi-monthly to ensure she is progressing towards her goals outlined in her training plan and to provide her with guidance and support. I will work with Drs. Wilkins and Dempsey to evaluate Dr. Erves' progress, and identify solutions to any problems that may arise.

The K01 career development award will provide the training and mentoring needed for Dr. Erves to continue to advance her research agenda and acquire the knowledge and skills to further complete the transition to an independent researcher in the area of public health oncology. Building upon Dr. Dempsey's work (training physicians in motivational interviewing to address HPV vaccine hesitancy during clinic visits) and my research (patient-education and quality improvement interventions focused on the initial recommendation of HPV vaccine), Dr. Erves' innovative project for the K01 award will fill an important gap for tailored, family-centered patient education materials targeting HPV vaccine hesitant families prior to their next doctor visit. I look forward to working with her on this project if it is funded.

Sincerely,

Pamela C Hull

Pamela C. Hull, Ph.D.
Assistant Professor of Medicine, Division of Epidemiology, VUMC

ACCORDS
ADULT AND CHILD CENTER FOR HEALTH OUTCOMES
RESEARCH AND DELIVERY SCIENCE
UNIVERSITY OF COLORADO | CHILDREN'S HOSPITAL COLORADO

March 1, 2019

National Institutes of Health (NIH)
9000 Rockville Pike
Bethesda, Maryland 20892

Re: National Cancer Institute (NCI) Mentored Research Scientist Development Award to Promote Diversity (K01- Clinical Trial Required) application for Jennifer Erves, Ph.D.

Dear Colleagues:

I am writing this letter to give my strongest support as a co-Mentor for Dr. Jennifer Cunningham Erves in her application for the NCI Mentored Research Scientist Development Award to Promote Diversity (K01- Clinical Trial Required). Dr. Erves is an Assistant Professor for Meharry Medical College. Her research program focuses on cancer prevention behaviors with a specific focus on improving human papillomavirus (HPV) vaccination rates among underserved adolescents. Her proposed project, "A tailored, health communication intervention for HPV vaccine hesitant parents," is innovative in that it explores tailored messaging for vaccination that has the potential to significantly reduce disparities in HPV-associated cancers such as cancers of the cervix and anus. This project has the potential to reduce cancers that disproportionately affect the underserved populations. For this award I will serve as a co-mentor, supporting Dr. Erves in all stages of her research, with an aim for her to transition into an independent researcher in public health oncology by the end of the K-award period.

Dr. Erves and I met during her post-doctoral training in community engagement under Drs. Consuelo Wilkins, Pamela Hull, and Stephania Miller-Hughes. Dr. Erves approached me to be a mentor for her K12 award in March 2015, specifically seeking out my skills in the development of clinical interventions to promote HPV vaccination of adolescents and young adults. From our first meeting I was impressed with Dr. Erves' dedication to public health oncology, particularly prevention of HPV-associated cancers, and her motivation to enhance her skills and collaborations to establish herself as a successful K-award applicant. Shortly after our first meeting we established a plan to have her involved in one of my current projects to increase her knowledge and training of how to conceptualize, develop, implement, and evaluate interventions increase HPV vaccine utilization in adolescents, and to establish a collaboration that can carry her through her K-award activities. As part of this, Dr. Erves came to Denver in May 2015 to observe my project meetings and gain first-hand experience of the "Motivational Interviewing Project" for which she is working directly with me. Her role is to evaluate the efficacy of message tailoring in presenting decision aid information to increase HPV vaccination rates among adolescents and young adults. She has successfully engaged in this project and has learned many new skills in the process. We anticipate a manuscript describing her analysis and findings will be sent for review in the next 2-3 months.

Dr. Erves received her K12 in October 2016 that seeks to compare the effectiveness of patient-centered approaches to improve HPV vaccine uptake among African American adolescents in the medical home. This work has laid the foundation for the research proposed in this award, and I have closely supervised Dr. Erves in her preparation of this K-award application through several in-depth phone meetings, and a series of email messages related to her application. Together we have developed a mentorship plan that I believe will enable me to continue to successfully and intensively support Dr. Erves throughout the K-award period. In this regard, I intend to meet with Dr. Erves by phone or Skype in standing monthly one-on-one meetings related to her K-award activities where I will be providing mentoring directly related to her K-award projects, including assisting her in developing skills in clinical intervention development, assessment for HPV vaccination of adolescents, and implementation science. I will also provide mentorship to Dr. Erves on professional development publication and presentation of results, grant writing, and other aspects of an academic career. Dr. Erves will continue to

attend by phone additional monthly project meetings related to the "Motivational Interviewing Project" that she is currently involved in, which will support the skills she needs to complete the proposed research. In addition to the standing one-on-one and project-related meetings, I am also readily available on a daily basis to provide advice and expertise via email, and also plan to participate in additional K-award project calls with the rest of Dr. Erves' mentorship team quarterly. Dr. Erves will also travel to Denver bi-annually to meet with me in person so that I may facilitate her exposure to other projects that I am working on that relate to her K-award activities, and also help her to develop additional collaborations and national recognition by utilizing contacts in my professional network. Moreover, I will work with Drs. Wilkins and Hull to submit an annual report to NCI on Dr. Erves' performance for the year as it relates to meeting the short-term career objectives in this application.

I have extensive experience mentoring fellows, post-docs and other advanced trainees in academic research settings. Since 2014 I have been the co-director, and since 2017 the Director, of the Surgical/Subspecialist Clinical Outcomes and Research (SCORE) fellowship at the University of Colorado Denver. In this role I oversee the overall direction and running of the program, which currently consists of 8 fellows from a variety of disciplines in pediatric and adult medicine. In addition, I serve as the main academic research mentor of 3 of the fellows, and participate in all fellowship activities including coursework planning, didactic lecture planning, providing didactic lectures, and providing feedback to all fellows during their monthly "work in progress" sections. Over previous years I have mentored 8 additional fellows and trainees, 7 of which have successfully obtained a position in academic research or academic settings (one went into private practice). I believe these past experiences mentoring junior faculty and fellows for careers in academic research, along with my content expertise in HPV vaccine implementation, will serve Dr. Erves well as she moves through her K-award activities and eventually transitions to an independent investigator.

In conclusion, Dr. Erves is a committed, well-qualified candidate for this award. She has demonstrated excellent productivity during her post-doctoral work and as an Assistant Professor, a clear dedication to a career in cancer prevention research. This proposal provides a strong foundation for developing necessary skills to become an individual, academic researcher. I offer my complete support and commitment to Dr. Erves' application as her co-mentor. I feel confident she will achieve her research and career development goals during the time of this award.

Sincerely,

A. Dempsey

Amanda F. Dempsey, MD, PhD, MPH
Associate Professor of Pediatrics

VANDERBILT UNIVERSITY MEDICAL CENTER

Ronald D. Alvarez, M.D., M.B.A.
Betty and Lonnie S. Burnett, Professor,
Chairman and Clinical Service Chief
Department of Obstetrics and Gynecology

March 2, 2019

Jennifer Cunningham-Erves, PhD, MAEd, MS, CHES
Assistant Professor
Department of Internal Medicine
Meharry Medical College
1005 Dr. D.B. Todd Jr. Blvd.
Nashville, TN 37208-3599

Dear. Dr. Erves,

It is with great pleasure to serve on the scientific advisory board for your NCI Mentored Research Scientist Development A ward to Promote Diversity (K0 1) application entitled "A tailored, health communication intervention for HPV vaccine hesitant (VH) parents". This research is timely as vaccine hesitancy in general is a growing problem, and the HPV vaccine is a major contributor. I strongly support this application due to its potential to increase HPV vaccine rates among underserved adolescents and those most at risk to HPV- associated cancer disparities.

In 2016, I became Professor and Chairman of the Department of Obstetrics and Gynecology and I hold the Betty and Lonnie S. Burnett Endowed Chair of Obstetrics and Gynecology at Vanderbilt University Medical Center in Nashville, Tennessee. I have over 25 years experience as a gynecological oncologist and researcher. My long-term research interests include the development of novel therapeutics for ovarian cancer and new screening and prevention strategies for cervical cancer. I have been the recipient of several NCI and other industry funded grants in support of my research, in gene therapeutics for ovarian cancer with over 250 peer-reviewed publications. I have also served on study sections and mentored several K12 early career investigators. I currently lead the HPV-ACTIVE program, which seeks to better understand the burden of HPV-associated cancers in Tennessee and at the Vanderbilt University Medical Center. All of these experiences will supplement your didactic training experience in your award, and contribute to your success in this project and meeting your long-term career goal to be successful in the field of public health oncology.

As a member of your scientific committee, I will:

- Meet twice a year via conference calls to provide expertise in cancer epidemiology and prevention. I will also provide insight in the design, development, and evaluation of the intervention to be developed from this research.
- Mentor you as needed to supplement the courses to advance your understanding of cancer epidemiology and prevention.
- Facilitate your career development through the HPV-ACTIVE program. Specifically, we will provide insight on your current research and networking opportunities. Furthermore, I will direct you to key career development opportunities to support the reach of your long-term career goal. Last, I will collaborate in abstract, manuscript(s), and presentation development resulting from this work.

I strongly support this application, and will provide guidance in the area of cancer epidemiology for this four-year grant period and years to come.

Sincerely,

Ronald D. Alvarez, M.D., M.B.A.
Betty and Lonnie S. Burnett, Professor
Chairman & Clinical Service Chief
Department of Obstetrics & Gynecology
Vanderbilt University Medical Center

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March 4, 2019

Jennifer Cunningham Erves, PhD, MAEd, MS, CHES
Assistant Professor
Department of Internal Medicine
Meharry Medical College
1005 Dr. D. B. Todd Jr. Blvd.
Nashville, TN 37208-3599

RE: PAR-16-401 (NCI K01)

Dear Dr. Jennifer Cunningham-Erves:

It is my pleasure to offer this letter on behalf of Meharry's Department of Pediatrics regarding the project, *A tailored, health communication intervention intended for HPV vaccine hesitant (VH) parents*. Your preliminary study is very compelling and supports the need for this study. Dr. Xylina Bean, our Pediatrics chair, strongly supports efforts to foster improved HPV vaccination rates among adolescents, especially those who are underserved

Over the past four years, we have reviewed our data and while it has improved, the rate is still not at the level of other immunizations. Toward that end, we will provide support to you in several important areas:

- I, and other staff members, will collaborate with the study team to identify the best strategies in recruiting parent-child dyads for participation in the interviews, surveys, and pilot study.
- We will facilitate contact with physicians (i.e., pediatricians) who may be interested in participating in an interview and/or survey.
- We will work with the study team to support the testing of tailored messaging prior to a doctor's visit to encourage age-appropriate vaccination among adolescents. This will be done through providing suggestions and information on the intervention/program to promote success, as well as allowing Dr. Erves to implement her research here in the Pediatric Clinic at Meharry Medical College.
- I personally will meet with Scientific Advisory Committee bi-annually, and with Dr. Erves as needed to discuss the progress of the project and provide input on study design and intervention implementation.

This project is vital in identifying ways to improve HPV vaccination rates among adolescents, particularly those who are underserved, and I endorse this K01 application with high regard.

Sincerely,

Susanne Tropez-Sims, MD

Susanne Tropez-Sims MD, MPH, FAAP
Professor and Associate Dean of Clinical Affiliations
Department of Pediatric
School of Medicine
Office Phone: 615 327 6925

University of Pittsburgh

School of Medicine
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February 28, 2019
Jennifer Cunningham-Erves, PhD, MAEd, MS, CHES
Assistant Professor
Department ofl nternal Medicine
Meharry Medical College
1005 Dr. D. B. Todd Jr. Blvd.
Nashville, TN 37208-3599

Dear Dr. Jennifer Cunningham-Erves:

It is with great pleasure that I look to serve on the scientific advisory board for NCI K0 1 to Promote Diversity application entitled "A tailored, health communication intervention for HPV vaccine hesitant (VH) parents". I strongly support this application as the research is timely to address HPV vaccine hesitancy among parents with adolescents in underserved communities using tailored messaging. This could ultimately increase HPV vaccination among a high-risk group, and lower the HPV-associated cancer disparities. This intervention could also impact other populations who are HPV vaccine hesitant.

I am a Professor of Biomedical Informatics, Biostatistics, and Clinical and Translational Science at the University of Pittsburgh where I have served as the Director of Biostatistics (Research) for the Starzl Transplant Institute over the past 3 years. I also direct a data coordinating center (for imaging studies of polycystic kidney disease) and am finishing a statistical methods contract (which was funded by the Patient-Centered Outcomes Research Institute) as PI, that developed a decision tool for observational comparative effectiveness research. In total, I have over 20 years experience as a biostatistician, collaborator, and independent research, with 124 peer-reviewed publications, and numerous national roles on study sections and expert panels. I have also mentored and/or served as the thesis advisor or research supervisor for over 20 pre-doctoral students.

More notably, as you know, I also direct the Expanding National Capacity in PCOR (patient-centered outcomes research) through Training (ENACT) Program, where I lead two online courses and the experiential training for Fellows such as yourself. In total, over the first 3 years of the ENACT Program, I mentored the 15 Fellows in PCOR methods and provided expertise on the development of their research projects. I will of course have the same role in your training as you continue in the current cohort of ENACT Fellows. This role as the ENACT Program Director further motivates my interest in addressing health disparities since the program is conducted in partnership with Meharry Medical College and five other Minority-Serving Institutions.

As you also know, I have already provided insight into your current proposal. I will provide expertise to the project on PCOR methods, and other study design and analysis issues. More specifically, during the award period, I will supplement the input of your primary mentors to optimize the chances for success of this project and your long-term career goals in the field of public health oncology by:

- Serving as a Scientific Advisory Committee member, which will meet twice a year via conference calls to provide quantitative expertise regarding the design, development, and evaluation of the intervention/program to be developed as a result of the research. I am happy to complement this area of training as you take on courses to develop your understanding of advanced statistical analyses for future work in this area.
- Facilitate your career development as needed through mentoring and/or identifying contacts with expertise specific to your needs. I will also collaborate in the development of abstracts, manuscripts, and presentations resulting from this research. This work will be a natural extension of my role as Director of the Expanding National Capacity in PCOR through Training Program, and will continue throughout the award period and beyond.

To summarize, I strongly support this application, am dedicated to providing the necessary guidance on relevant methodologies, and look forward to collaborating with you over the next four years of this grant and beyond.

Sincerely,
Douglas Landsittel, PhD
Professor of Biomedical Informatics, Biostatistics, and Clinical and Translational Science Director of Biostatistics, Starzl Transplant Institute
Program Director, Expanding National Capacity in PCOR through Training
Core Faculty, Comparative Effectiveness Research Center
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VANDERBILT UNIVERSITY MEDICAL CENTER

Division of General Internal Medicine and Public Health

March 2, 2019

National Institutes of Health (NIH)
9000 Rockville Pike
Bethesda, Maryland 20892

RE: Letter of Support for Jennifer Cunningham Erves, PhD

Dear reviewers:

I am writing to express my strongest possible endorsement of Dr. Jennifer Erves National Cancer Institute Mentored Research Scientist Development Award to Promote Diversity (K01) application. Jennifer is a recipient of training from the Vanderbilt Patient-centered Outcomes Research Career Knowledge, Education and Training program, an institutional K12 award that I also received. Her research is innovative in addressing HPV vaccine-hesitant parents through the provision of tailored messaging intervention prior to a clinic visit. Because this work includes print messaging and a health communication component similar to my own research, I am very happy to collaborate with Jennifer on this important work as member of her Scientific Advisory Committee.

I am a family and community psychologist in the Center for Health Behavior and Health Education in the Department of Medicine at Vanderbilt University Medical Center. I am also a core faculty member of the Center for Effective Health Communication. My research focuses on mechanisms supporting and sustaining health behavior change to improve self-care among adults with chronic illness. More specifically, I have extensive experience developing tailored, theory-based health communication interventions to improve outcomes using the Information-Motivation-Behavioral Skills model as a framework in patients with diabetes. As Jennifer illustrates in her proposal, tailored, theory-based messages have been found effective in engaging and promoting behavior change across patients, and this type of intervention can be effective to address the barriers to health behaviors, such HPV vaccination. Tailoring content to personal barriers can optimize impact. I will meet with the scientific advisory committee bi-annually and with Jennifer individually as needed.

Additionally, I will offer Jennifer guidance and advice regarding her career development in behavioral science. Having graduated from the PhD program in Community Research & Action at Vanderbilt University and completing my postdoctoral fellowship at Vanderbilt University Medical Center, I am familiar with many of the course offerings and other potential collaborators for Jennifer at Vanderbilt. Vanderbilt has very strong institutional expertise in health communication theory and methods, which will be of significant benefit to Jennifer during the course of her research.

In sum, I strongly recommend Jennifer for this award, feel her research will be innovative and address an important problem. If successful, her findings can inform interventions to increase rates of other vaccines. I look forward to a productive collaboration with Jennifer on this and her future work.

Sincerely,

Lindsay S Mayberry

Lindsay Satterwhite Mayberry, MS, PhD
Assistant Professor
Department of Medicine, Division of General Internal Medicine & Public Health Center for Health Behavior and Health Education

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March 5, 2019

Jennifer Cunningham-Erves, PhD, MAEd, MS, CHES
Department of Internal Medicine
Meharry Medical College
1005 Dr. D. B. Todd Jr. Blvd.
Nashville, TN. 37208-3599

Dear Dr. Cunningham-Erves:

I am happy to provide a letter of support for your research grant application aimed at studying the feasibility of an individually-tailored, parent centered health communication intervention for increasing HPV vaccination among underserved adolescents. As you know, I am Director of the Tennessee Immunization Program (TIP) in the Tennessee Department of Health (TDH). It has also been a pleasure to collaborate with you on the Cervical Cancer Free Tennessee coalition (CCFTN), which I co-chair with your co-mentor, Dr. Pamela Hull. As you know, we are in the process of changing our name to HPV Cancer Free Tennessee (HPV-CFTN), reflecting our commitment to prevention of HPV-related cancers in all persons, but that branding transition is not complete. Tennessee is in great need of interventions to help increase HPV vaccine uptake in our state given that in 2016, only 55.3% of Tennessee teens had initiated the HPV vaccine series and we ranked poorly in completion rates.

The goal of CCFTN is to eliminate HPV-related cancers, especially cervical cancer, in Tennessee by increasing HPV vaccination and increasing cervical screening and early detection. To that end, CCFTN has hosted four regional "Teal for 2" conferences targeting health professionals across the state, combining a survivor's perspective on cervical cancer with expert guidance on current screening guidance and the role of immunization, including a heavy emphasis on the current low coverage levels and urgent need for a strong provider recommendation for HPV vaccination and strategies to address HPV vaccine hesitant parents. CCFTN has implemented other community outreach events, and TDH has provided posters to local health departments (LHDs) to encourage patients to ask their providers about cervical cancer screening. Within the past few years, I have been invited to speak about HPV vaccine to statewide meetings of women's healthcare professionals, family physicians, pediatricians, and school nurses. A major focus for the Middle Tennessee Workgroup over the past year has been working with Dr. Hull on her HPV vaccine projects and providing input into the development of your proposal, which the coalition is very excited about.

While CCFTN has made quality improvement efforts to increase HPV vaccination, a major concern remains HPV vaccine hesitancy among parents and teens. More work is needed to explore strategies to address those parents who refuse or delay the vaccine after a doctor's recommendation. The research you propose will help us understand barriers to uptake among this population and whether family-centered, tailored messaging provided in advance of a doctor visit will increase HPV vaccination and reduce HPV-associated cancer disparities. The use of community engagement to identify the best tailored messages to provide in the health communication intervention is also innovative and is likely to improve HPV vaccination among underserved adolescents, as well as other groups. Thus, your innovative proposal clearly advances your long-term career goal in cancer prevention through improving HPV vaccine uptake in adolescents, particularly those who are underserved.

If the study is funded, CCFTN (later name will change to HPV-CFTN) will be able to contribute in the following ways:

- Provide input into the project during monthly CCFTN Middle Tennessee Workgroup meetings throughout the various stages of research
- Facilitate contacts with physicians for key informant interviews and surveys

I enthusiastically support this research grant application and look forward to CCFTN collaborating with you as a partner through our existing CCFTN coalition, if it is funded.

Kelly L. Moore, M.D., MPH
Director, Tennessee Immunization Program Co-Chair, Cervical Cancer Free Tennessee

Meharry-Vanderbilt-TSU Cancer Partnership

March 1, 2019

Jennifer Cunningham-Erves, Ph.D.
Department of Internal Medicine
Meharry Medical College
1005 Dr. D. B. Todd Jr. Blvd.
Nashville, TN 37208-3599

RE: Letter of Support for NCI K01 on HPV Vaccination

Dear Jennifer,

On behalf of the Community Advisory Board (CAB) for the Meharry-Vanderbilt-TSU Cancer Partnership (MVTCP), I am pleased to provide a letter of support for your application for the NCI Mentored Research Scientist Development Award to Promote Diversity (K01) career development award entitled, "A tailored, health communication intervention for HPV vaccine hesitant parents." Due to HPV being implicated in cancers of both men and women, the cause of increasing HPV vaccination in our state is very important to me.

As you know, the MVTCP CAB was created in 2011 to establish a sustainable infrastructure that supports academic-community partnerships for research and outreach initiatives, and it is coordinated and managed by the MVTCP Cancer Outreach Core. The purpose of the CAB is to facilitate the process of community engagement during the development and implementation of cancer-related research. The MVTCP CAB meets quarterly is currently comprised of nearly 20 community members and organizations, including parents from diverse backgrounds, community-based non-profit organizations, and government agencies. Under the CAB, we have a Teen and Parent Committee that has worked with Dr. Hull on developing the "Bug Your Doc – Get 3 Shots!" patient education materials that doctors can use when they make the initial recommendation for HPV vaccine and other adolescent vaccines. We are excited to work with you on this project that will develop new patient education materials that doctors can use with parents/patients who decline the HPV vaccine, so they can continue to educate them about the importance of HPV vaccine at their next appointment.

The MVTCP CAB has already been actively involved in giving input on the development and implementation of your ongoing pilot studies, as well as the development of this proposal. If this proposal is funded, the CAB can contribute to this project during our quarterly meetings by providing input and feedback on plans for the interviews, surveys, and patient education materials to be developed, as well as your subsequent grant proposal. We look forward to continuing to support this project if it is funded.

Sincerely,

Ila McDermott
Co-Chair, MVTCP Community Advisory Board

Description of Institutional Environment

I will conduct this research as an Assistant Professor at **Meharry Medical College (MMC).** I have a private office within the Department of Internal Medicine, which is a short walk or easy access to my primary mentor, with a personal computer and all accessory equipment and software necessary to conduct research. My research will be supported by immense resources and state-of-the-art facilities from Meharry Medical College (MMC) and Vanderbilt University. Resources include MeTRC, Meharry-Clinical and Translational Research Center (CTRC), The Vanderbilt Institute for Clinical and Translational Research (VICTR), and the Meharry Vanderbilt Alliance (MVA). (See Facilities and Resources section for more detail.)

MeTRC (Meharry Clinical and Translational Research Center). U54 MD007593-04, Samuel Adunyah, PI. MeTRC is a long-range endeavor to design and implement transformational clinical and translational research and its related training infrastructure at MMC. This center provides researcher assistance and training via seminars and workshops in study design, biostatistics, survey design, power analysis, sample size estimation, and research ethics. These services were used during my post-doctoral project and will be applied here.
Clinical and Translational Research Center (CTRC). The CTRC in MeTRC assists researchers with clinical study design and execution. This center will assist with study recruitment similar to my post-doctoral research.
Meharry Office of Scientific Editing & Publications. This unit offers support in reviewing grant applications, manuscripts for peer review, and abstracts and posters. These services were used for this application.
The Vanderbilt Institute for Clinical & Translational Research (VICTR). 2UL1TR000445-06, Gordon Bernard (Vanderbilt PI), Duane Smoot (MMC PI). A primary goal of this MMC and Vanderbilt partnership is to provide resources to clinical and translational researchers. In this study, I will use: (1) Community Engagement Studios (CES) in this research to gain valuable patient or community insight on the proposed research; (2) REDCap, a user-friendly Research Electronic Data Capture software, as the primary database for this project to provide a secure program for data entry; (3) REDCap Survey for data entry and information collected directly from research subjects; (4) ResearchMatch (RM) - a national recruitment and engagement platform with over 73,000 volunteers across 50 states to assist in recruitment for this study; and (5) vouchers ($2K max) to obtain preliminary data for translational research grants. These shared resources are available due the formal Alliance, **Meharry-Vanderbilt Alliance (MVA)**, in 1999. I used these resources in my post-doctoral training.
MMC, Vanderbilt-Ingram Cancer Center (VICC), & Tennessee State University (TSU): Partners in Eliminating Cancer Disparities. U54 CA163069-02, Samuel Adunyah (MMC PI), Harold Moses (VICC PI), and Baqar Huslani (TSU PI). The goal of this collaboration is to reduce cancer health disparities in largely, minority communities by conducting: (1) research training and career development of young researchers; (2) basic, translational, and population-based research; and (3) education and outreach. The community advisory board from this partnership assisted past and this research proposals' development.
Meharry-Vanderbilt Alliance (MVA). My primary mentor, Dr. Consuelo Wilkins, is the Executive Director of the MVA. The MVA provides access to experienced grant writers and materials supporting the grant application process. It also provides grant support including proposal editing and writing, budget preparations, biosketch formatting, and letters of intent. The Alliance facilitates grant writing workshops and IRB application assistance. I will continue to use these services as needed. I receive Salary Support from the MVA.
Center for Effective Health Communication (CEHC). This center works in research, education, and community to promote quality health communication. My primary mentor, Dr. Consuelo Wilkins, is faculty within this center at Vanderbilt University Medical Center. This center will provide one-on-one consulting in content development, design, and evaluation of the health communication intervention (print materials) for this study.
Seminars and Workshops. Grand rounds occur weekly or bi-weekly in all Departments in the School of Medicine. Topics include basic, clinical, and behavioral lectures involved with patient care and public health. A grantsmanship workshop conducted by speakers from across the country to educate and improve the grant writing skills of MMC faculty is provided by the Office of Research. In addition, institutional grants such as CTSA and EXPORT offer inter-disciplinary resources and training to junior investigators pursing health services research. The MVA also allows MMC faculty to participate in seminars and workshops being held at Vanderbilt University. I currently and will continue to attend: (1) the Clinical Research-Skills Workshops which are weekly workshops related to clinical research (e.g., basic instruction and strategies to deal with barriers in clinical research); and (2) "Elliot Newman Society"; which discusses topics like grant writing, responsible conduct of research, career timeline, and getting a job in academia. I used the K grant pacing workshop and Edge Review (NIH-like internal review of R or K applications by senior Vanderbilt faculty) to inform this proposal. I will use R grant pacing workshops and Edge Review for future R submissions.

Maria F. Lima, Ph.D.
Dean, School of Graduate Studies and Research
Sr. VP for Research and Innovation

March 1, 2019

National Institutes of Health (NIH)
9000 Rockville Pike
Bethesda, Maryland 20892

Re: Letter of Support for NCI Mentored Research Scientist Development Award to Promote Diversity (K01-Clinical Trial Required) application for Jennifer Cunningham Erves, Ph.D.

Dear Colleagues:

I am writing this letter to express my enthusiastic support on behalf of Dr. Erves application for the *NCI Mentored Research Scientist Development Award to Promote Diversity (K01-Clinical Trial Required).* Dr. Erves was very productive as a post-doctoral fellow for the Meharry-Vanderbilt Community Engaged Research, and currently as an Assistant Professor in the Department of Internal Medicine at Meharry Medical College since May 2016. She is a current Vanderbilt Patient-centered Outcomes Research Career Knowledge, Education, and Training (V-Pocket) K12 scholar.

[redacted] Percentage of Effort

The University is committed to support Dr. Erves' research and career development, will protect time, and will ensure that she has the time and resources to successfully complete work detailed in this application. Dr. Erves' salary and appointment status are not contingent upon receipt of this award. She will have very light teaching, one lecture per semester to the MSPH students and to the medical students in her area of specialty. She is also a member of the Medical School Admissions Committee and is a part of thesis committees for two MSPH students. We are committed to maintaining her assigned office space, and will facilitate mechanisms (e.g., seminars, works-in-progress) to ensure that she receives adequate support in her research and career development.

Dr. Erves has proposed an innovative and comprehensive research and training plan that is well aligned with and will greatly contribute to Meharry's initiatives and programs to support our research education centers of excellence. Along with resources (e.g. ResearchMatch) provided at Vanderbilt University through the Meharry Vanderbilt Alliance, Meharry has a Pediatric Clinic providing a continuum of diagnostic, management, and preventive services, promoting access to the research population.

Aspiring to become an independent researcher in the field of public health oncology focused on cancer prevention behaviors, Dr. Erves' research interest is to design interventions to improve HPV vaccine rates among underserved adolescents. The overall goal of the research proposed in this application is to assess the feasibility and preliminary efficacy of an individually-tailored, health communication intervention to increase HPV vaccination among adolescents with vaccine hesitant parents. This research will contribute to the field by demonstrating that providing tailored education to families prior to an upcoming visit can address parental issues or allow them to develop questions for adolescent visits. This can ultimately change attitudes, increase HPV vaccination, and minimize the HPV-associated cancer disparity in this high-risk group. The mentoring team (Drs. Wilkins, Dempsey, and Hull), scientific advisory board assembled, and the proposed training plan allows Dr. Erves to gain knowledge and skills in HPV vaccinology, clinical/ community engagement, behavioral intervention development, advanced research methods, grant writing, and professional leadership; all key elements that she needs to evolve into an independent investigator. I will meet with her on a regular basis to discuss topics related to research, promotion, and tenure.

I wholeheartedly support Dr. Erves' K01 application and am confident that she will continue to perform at an exceptional level and develop into an outstanding independent investigator in the exceptional research and training environment between Meharry Medical College and Vanderbilt University.

Sincerely,

Maria de Fatima Lima

Maria F. Lima, Ph.D.
Professor and Dean, School of Graduate Studies and Research
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PHS Human Subjects and Clinical Trials Information

OMB Number: 0925-0001 and 0925-0002

Expiration Date: 03/31/2020

Are Human Subjects Involved	● Yes ○ No
Is the Project Exempt from Federal regulations?	○ Yes ● No
Exemption Number	❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑ 6 ❑ 7 ❑ 8
Other Requested Information	

Human Subject Studies

Study#	Study Title	Clinical Trial?
1	To develop a tailored, health communication intervention targeting HPV-VH parents prior to clinic visits.	No
2	Conduct a pilot study of the intervention and study protocol to demonstrate feasibility for the future full-scale randomized control trial (RCT).	Yes
3	Examine acceptability of the intervention and protocol among parents and providers	No

Section 1 - Basic Information (Study 1)

OMB Number: 0925-0001 and 0925-0002

Expiration Date: 03/31/2020

1.1. Study Title *

To develop a tailored, health communication intervention targeting HPV-VH parents prior to clinic visits.

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

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

1.4. Clinical Trial Questionnaire *

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

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

Section 2 - Study Population Characteristics (Study 1)

2.1. Conditions or Focus of Study

- papillomavirus infections
- papillomavirus vaccines
- cancer

2.2. Eligibility Criteria

(A) Vaccine Hesitant Parents: Parents with children not vaccinated for HPV who are patients in MMC Pediatrics aged 11-18; refused HPV vaccine in past two years, speak English, own smartphone
(B) Providers: physicians, physician assistants, and nurse practitioners who deliver primary care to patients aged 11-18.

Exclusion Criteria

(A) Vaccine Hesitant Parents: Parents who child received one or more doses of the HPV vaccine aged 11-18, parents with children who do not receive care at Meharry Medical College Pediatric Practice
(B) Providers: Physicians, nurse practitioners, and physician assistants who do not deliver primary care to pediatric patients aged 11-18 at Meharry and other clinics; providers who do not provide the HPV vaccine.

Stage 2: Eligibility Criteria for Parents and Providers

Inclusion Criteria

(A) Parents of patients of MMC Pediatrics aged 11-18, refused HPV vaccination in the past two years, have not received any doses of HPV vaccine, have a clinic appointment scheduled within the coming month, speak English own smartphone, and did not participate in Aim 1 Stage 1.
(B) Providers: physicians, physician assistants, and nurse practitioners who deliver primary care to patients aged 11-18 and the intervention at Meharry Medical College.

Exclusion Criteria

(A) Parents of patients aged 11-18 not receiving care at MMC pediatrics, have received one or more doses of the HPV vaccine, participated in Stage 1 of Aim 1, no upcoming clinic appointment
(B) Providers: physicians, physician assistants, and nurse practitioners who do not deliver primary care to patients aged 11-18 and did not deliver the intervention at Meharry Medical College.

2.3. Age Limits	Min Age: 18 Years	Max Age: N/A (No limit)
2.4. Inclusion of Women, Minorities, and Children	WomenMinoritiesandChildren1.pdf	
2.5. Recruitment and Retention Plan	RecruitmentAndRetentionPlan1.pdf	
2.6. Recruitment Status	Not yet recruiting	
2.7. Study Timeline	Study_Timeline_1F.pdf	
2.8. Enrollment of First Subject	12/02/2019	Anticipated

INCLUSION OF WOMEN AND MINORITIES

We present the inclusion of women and minorities, and inclusion of children section for both stage 1 and stage 2 of study 1.

Stage 1

Parents: The parent target population (n=30) includes adult men and women who make medical decisions for their adolescent aged 11 to 18 and have delayed or refused the HPV vaccine. We expect to recruit approximately 10% men and 90% because women are the primary decision makers when it comes to child's health. Furthermore, past participation rates of males in research studies were significantly lower than females. In regard to minority inclusion, we will not exclude groups based on race. Therefore, the study enrollment will reflect the general population of Meharry Medical College Pediatric Clinic.

Physicians: For current and potential vaccine providers (n=10), we estimate that 35% will be AA and the other 65% Caucasian. We also expect 60% to be female and 40% to be male. These data are based on the national and state data, as well as the provider data of the clinic.

The proposed study is designed to reduce barriers to recruitment and to be presented in a manner that will be acceptable across cultures and settings with the aim of reaching all participants. A future study with more resources may specifically target recruitment in multiple medical settings that will have a larger portion of underserved, VH parents and providers.

Stage 2

Parents: The parent target population (n=16) includes adult men and women who make medical decisions for their adolescent aged 11 to 18 and have delayed or refused the HPV vaccine. We expect to recruit approximately 10% men and 90% because women are the primary decision makers when it comes to child's health. Furthermore, past participation rates of males in research studies were significantly lower than females. In regard to minority inclusion, we will not exclude groups based on race. Therefore, the study enrollment will reflect the general population of Meharry Medical College Pediatric Clinic.

Physicians: We estimate 86% AA and 14% Caucasian for providers. In terms of gender, we estimate that approximately 71% will be female and 29% will be male. These data are based on Meharry Medical College provider demographics.

The proposed study is designed to reduce barriers to recruitment and to be presented in a manner that will be acceptable across cultures and settings with the aim of reaching all participants. A future study with more resources may specifically target recruitment in multiple medical settings that will have a larger portion of underserved, VH parents and providers.

INCLUSION OF CHILDREN

Stage 1

N/A

Stage 2

N/A

Recruitment and Retention Plan

The recruitment and retention plan was developed based on research experiences of myself, mentors, and members of the scientific advisory committee. We have developed two plans, one for the parents and one for the providers. Plans are provided for Stage 1 and Stage 2 of Study 1.

Stage 1

We will use the VHealth system and EHR at Meharry Medical College to identify unvaccinated patients whose parents recently delayed or refused the HPV vaccine. After these data are collected, we will send an invitation to request their participation in the research study. The method of contact will be determined based on the contact information for the child in the VHealth system and EHR. If the participant agrees to participate, we will consent them for study participation. We have identified strategies to promote retention. We will maintain communication throughout the study with participants as needed. We will listen to participants and address issues if they arise. We will be convenient in scheduling interviews. Participants will be provided positive feedback throughout study participation. We will ensure the staff and research assistant is trained to carry out study protocol correctly, promoting synergy between research staff and study participants. Last, our study protocol will be informed by community stakeholders.

For providers, we will use an existing database of providers from past research participation to recruit providers for interviews. Members of the scientific advisory board and community partners which include providers will also assist in identify providers for study participation. These individuals have assisted in recruitment for past research studies. Other potential recruitment methods include phone, email, or face-to-face via clinical settings. Once the participant agrees to participate, we will obtain consent. For providers participating in study implementation, we will send an email, call, or conduct a face-to-face visit to request their participation in debriefing interviews. To promote retention, we will be convenient in scheduling interviews and communicate with the providers as needed throughout the study. Last, community stakeholders will inform the study protocol.

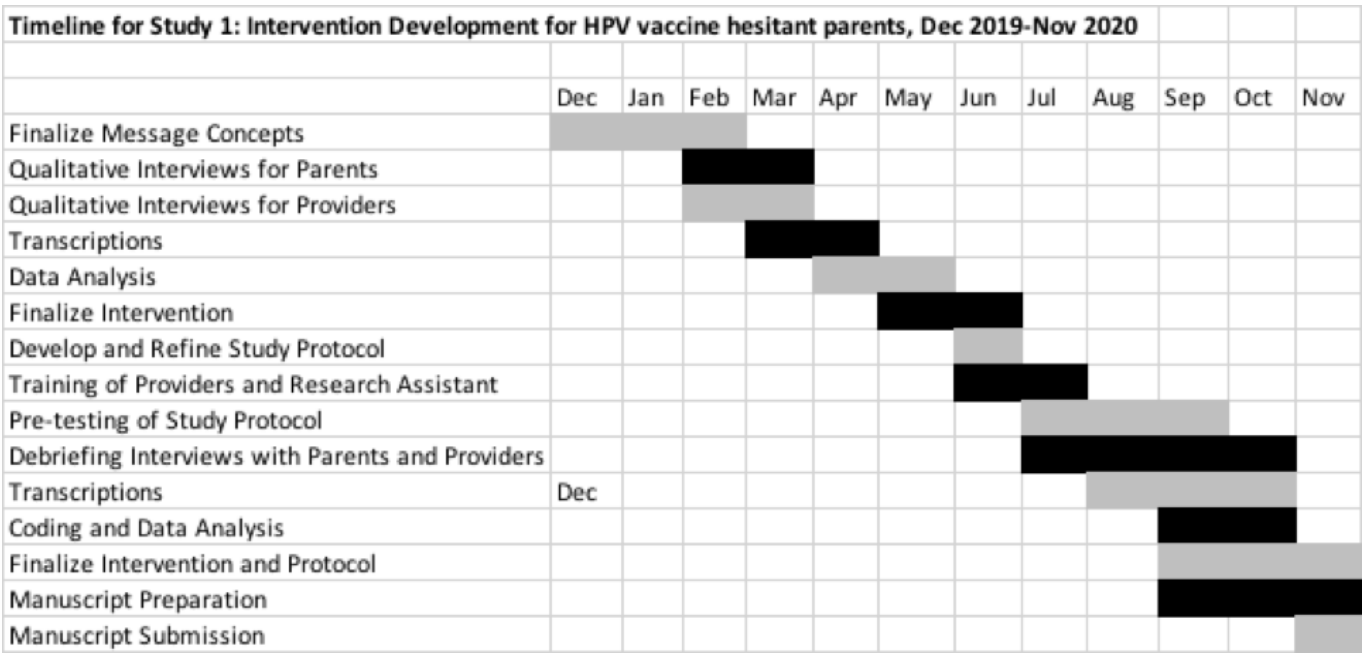
Stage 2

We will use the VHealth system and EHR at Meharry Medical College to identify unvaccinated patients whose parents recently refused the HPV vaccine. After these data are collected, we will send an invitation to request their participation in the research study. The method of contact will be determined based on the contact information for the child in the VHealth system and EHR. If the participant agrees to participate, we will consent them for study participation. We have identified strategies to promote retention. We will maintain communication throughout the study with participants as needed. We will listen to participants and address issues if they arise. We will be convenient in scheduling interviews. Participants will be provided positive feedback throughout study participation. We will ensure the staff and research assistant is trained to carry out study protocol correctly, promoting synergy between research staff and study participants. Last, our study protocol will be informed by community stakeholders.

For providers participating in study implementation, we will send an email, call, or conduct a face-to-face visit to request their participation in debriefing interviews. To promote retention, we will be convenient in scheduling interviews and communicate with the providers as needed throughout the study. Last, providers will inform the study protocol.

Study Timeline

Below is a timeline for study one. We will finalize message concepts with the Scientific Advisory Board as well as Clinic and Community Partners from December 2019 to February 2020. We will conduct qualitative interviews for parents and provider interviews from February 2020 to March 2020. Transcriptions will begin while interviews are conducted, starting March 2020 to April 2020. Data analysis will occur between April and May 2020. The intervention will be finalized between May 2020 to June 2020. We will develop and refine the study protocol with Meharry Medical College Pediatric Clinic in June 2020. We will train providers and the research assistant between June and July 2020. The study protocol will be pretested from July 2020 to September 2020. Debriefing interviews will occur between July 2020 and October 2020. Transcriptions will occur between August 2020 and October 2020, and coding and data analysis will occur between September and October of 2020. We will finalize the intervention between September and November of 2020. Manuscript preparation and submission will occur between September and November of 2020.



Inclusion Enrollment Reports

IER ID#	Enrollment Location Type	Enrollment Location
Study 1, IER 1	Domestic	Pediatric clinics throughout Nashville, TN

Inclusion Enrollment Report 1

Using an Existing Dataset or Resource* : ❍ Yes ● No

Enrollment Location Type* : ● Domestic ❍ Foreign

Enrollment Country(ies): USA: UNITED STATES

Enrollment Location(s): Pediatric clinics throughout Nashville, TN

Comments:

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	30	6	0	0	36
White	6	4	11	2	23
More than One Race	0	0	0	0	0
Total	36	10	11	2	59

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	PROTECTIONOFHUMANSUBJECTS1.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	Data_and_Safety_Monitoring_Plan1F.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	StructureOfStudyTeam1.pdf

PROTECTION OF HUMAN SUBJECTS

We will develop an individually tailored, health communication intervention to increase HPV vaccination among adolescents with VH parents. In stage 1 of Study 1, formative research will occur in Year 1 and include the following research activities: (1) Interview protocol and survey development with an established community advisory board and Scientific Advisory Committee in Year 1; (2) Development of an intervention for HPV vaccine hesitant parents with a purpose to increase HPV vaccination. Participants will be informed at the start of the study that their participation is strictly voluntary. Participants will be consented prior to enrollment and will be compensated for their time. In stage 2 of Study 1 (Year 1), we will conduct pre-feasibility testing of the intervention and refinement using key stakeholders input in debriefing interviews in. Participants will be informed at the start of the study that their participation is strictly voluntary. Participants will be consented prior to enrollment and will be compensated for their time. We will present human subjects information by stages.

Stage 1

A. Risk to Subjects

A.1 Human Subjects' Involvement, Characteristics, and Design. Human subjects will be required for key informant interviews and surveys for intervention development. The table below lists number of participants, recruitment strategies, and data collected for this stage.

	Key Informants
Number of Participants	Three groups 70 (total)
Characteristics of Participants	-Parents (25-30) -Physicians (10)
Recruitment strategies **(Parents)**	- Meharry pediatric clinic EHR and VHealth software -Phone -Email -Mail
(Physicians)	-Email -Phone -Clinical Settings/Clinical Partners -Community Partners
Source of Materials	-Sociodemographic -Audio recording -Interviewer Notes -Researcher notes -Transcripts

The total number of participants for the study is 70. The following criteria will be used for all:

Inclusion Criteria for Parents: (1) female or male; (2) Age 18 years and older; (3) English-speaking; (4) have, care for, or make medical decisions for a male or female adolescent aged 11 to 18 years; (5) Age 18 years and older; (6) Able to give informed consent; and (7) Able to complete surveys/questionnaires and interviews.

Inclusion Criteria for Providers: (1) Able to administer or makes the decision to administer the HPV vaccine to adolescents ages 11 to 18 in a medical home; (2) English-speaking; (3) male or female; (4) Age 18 years and older; (5) Able to give informed consent; and (6) Able to complete surveys/questionnaires and interviews.

Exclusion Criteria: All men and women who do not meet the inclusion criteria for both parents and providers (e.g., cognitively impaired, or unable to provide consent).

A.2 Sources of Materials. Key informant interview and survey data will be obtained from providers who have provided informed, verbal consent after being read or reading IRB approved consent language. Parents will provide their written consent for their participation in the study to obtain key informant interview and survey data. This will be collected for research purposes only and will not be linked with participants.

A.3 Potential Risks. Potential risks associated with participation in this study is unlikely and of mild risks. *A.3.a Physical.* As a result of study participation, there is a minute likelihood of physical risk. Interviewee participants will not engage in any activities that will promote physical risk. Research assistant who will engage in training activities to carry out the survey and interview data collection methods have a small chance of physical risk.

A.3.b Psychological. There may be mild psychological risks posed as a result of participating in interviews and surveys, and the time commitment to complete these activities. Participants (i.e., parents) may increase their thinking of adolescent risk of HPV exposure and associated diseases. Dr. Erves will refer to additional sources such as Centers for Disease and Control (CDC) if participants would like additional information on HPV and the vaccine. Providers may have a small likelihood of psychological risks when trying to provide insight on how to

develop the most effective intervention and methods to implement a new strategy or intervention into their setting to improve HPV vaccination.

A.3.c Social. In identifying barriers of HPV vaccination among HPV vaccine hesitant parents, individuals may gain consciousness of their culture and society and how this reflects their views towards HPV vaccination in general and/or completing the vaccine at the medical home. This may have mild to moderate social risks as it may conflict with ones' culture and/or social order. Through careful training in cultural competency, we believe we can manage and channel these social risks in a positive way. Participants may feel they will not receive adequate services if they do not participate in the study, but will be assured that non-participation in the study will not affect their care. Last, providers may perceive their parents will be dissatisfied in their participation in research which in turn will affect their employment status. These social risks are unlikely to occur.

B. Adequacy of Protection against Risk

B.1 Recruitment and Informed Consent. For the parent interviews for intervention development, participants will be recruited using the VHealth and EHR systems. Providers will be recruited via clinical settings, email, and phone. Parents will provide consent for themselves to take part in the study (i.e., interviews and surveys). Providers will also provide verbal consent to take part in the study. We have sought approval from the Institutional Review Board at MMC to conduct this study. We will ensure that we are meeting all requirements of 45 CFR 46 for informed consent and regulations regarding human subject participation in research.

The investigator and research assistant will have appropriate human subjects training prior to enrolling participants. Participants will be provided information at the time of study participation that clearly explains the procedures, processes, and content of the interviews and/or survey. They will understand that if they feel any of the questions or the study is causing a psychological disturbance, they have the right to withdraw from the study or not answer any question anytime without consequences. Providers who participate in study will recognize their participation in this study will not affect their employment status, and parents will know their current or future services for adolescents at the medical home will not be affected due to this study.

B.2 Protection against Risk to Confidentiality. The following precautions are expected to eliminate participant risk to confidentiality. All data will be safeguarded in accordance with the Health Insurance Portability and Accountability Act (HIPAA) and the principles and practices of strict confidentiality. The interview and survey responses from formative evaluation will not be linked to identifying information except to follow-up with respondents for comprehension on a question response or future studies. Data will be stored in a locked file cabinet and files will be stored on a password protected computer in a password protected database in the office of the PI. Participants will be provided a unique identifier to be used in data analysis. Last, no individuals will be identified in any presentations or publications resulting from this research. In such a way, we are protecting participants from risks from the intervention as well as risks related to privacy and confidentiality.

B.3 Vulnerable Subjects. The target population of this study are vulnerable subjects (e.g., economically and educationally disadvantaged). The opinions of these parents are valuable given the topic of the research is to reduce HPV-associated cancer rates among underserved populations through increased HPV vaccination. The participants will be provided with information at the time of study participation that clearly explains the procedures, processes, and content of the survey and interview. Participants have the right to withdraw from the study at anytime without consequences.

B.4 Potential Benefits of the Proposed Research to the Subjects and Others.

Potential Benefits to Subjects. Parents will be more aware about HPV and the vaccine in order to make informed decision-making on their vaccination status of adolescents. It could increase parental awareness and knowledge of the HPV vaccine and their attitudes to get their adolescent vaccinated against HPV. The engagement of community members in the process and development of this research could build trust in the research process. It could improve their awareness of the HPV and the vaccine. In time the benefit to participants may include improved communication between researchers and communities, as well between physicians. Providers will be key players in developing materials to address HPV vaccine hesitancy among parents. They will become aware of barriers to HPV vaccination among these individuals, and key message concepts to provide to these individuals to address this issue.

Potential Benefits to Society. In time the benefit to participants may include increased awareness to HPV vaccine hesitant parents of the role HPV vaccine has on their child's life, particularly cancer prevention. It will address VH parents perceived barriers (e.g., safety, rationale for recommended age) to HPV vaccination. This knowledge may help them make an informed decision on allowing their child to be vaccinated against HPV. Underserved adolescent populations may benefit from their parents learning about the HPV vaccine, leading to increased HPV vaccination to promote their overall health. This research could also benefit immunization stakeholders, especially pediatricians, providing insight on a new way to address to HPV VH parents, and could potentially extend to other vaccines. In terms of the community, this project can achieve buy-in for communities to engage in health promotion activities and promote policy changes when needed.

B.4 Importance of the Knowledge to be gained. The knowledge gained and intervention developed may assist in the increase of HPV vaccination rates among underserved adolescents with VH parents. Identifying a health communication intervention tailored to the educational needs of these parents could change attitudes towards the HPV vaccine, reduce existing knowledge gaps, and improve communication inequalities. Long-term benefits include the reduction of HPV-related sequelae and its' associated medical costs and lost productivity rates, improving health outcomes for this high-risk population. The proposed benefits of this plan outweigh any potential risks. Incorporation of data management practices and use of encrypted databases will minimize risks related to privacy and confidentiality.

Stage 2

A. Risk to Subjects

A.1 Human Subjects' Involvement and Characteristics. Human subjects will be required for the prefeasibility study and refinement of the intervention. The table below lists number of participants, recruitment strategies, and data collected.

	Pre-Feasibility Study
Number of Participants	Three groups 35 (total)
Characteristics of Participants	-Parents (16) -Physicians (3)
Recruitment strategies **(Parents)**	- Meharry pediatric clinic EHR and VHealth software -Phone -Email -Mail
(Physicians)	-Email -Meharry Clinical Setting -Phone
Source of Materials	-Sociodemographic -Transcripts -Interviewer Notes -Researchers Notes

There are several stages in the study and the total number of participants for the study is 35. The following criteria will be used for all:

Inclusion Criteria for Parents: (1) female or male; (2) Age 18 years and older; (3) English-speaking; (4) have, care for, or make medical decisions for a male or female adolescent aged 11 to 18 years; (5) Age 18 years and older; (6) Able to give informed consent; and (7) Able to complete interviews.

Inclusion Criteria for Providers: (1) Administers or makes the decision to administer the HPV vaccine to adolescents ages 11 to 18 at Meharry Medical College Pediatric Clinic; (2) English-speaking; (3) male or female; (4) Age 18 years and older; (5) Able to give informed consent; and (6) Able to complete interviews.

Exclusion Criteria: All men and women who do not meet the inclusion criteria for both parents and providers (e.g., cognitively impaired, or unable to provide consent).

A.2 Sources of Materials. The intervention will be tested for pre-feasibility and parents and providers will give feedback through debriefing, semi-structured interviews. These individuals will provide informed, written consent after being read or reading IRB approved consent language. This will be collected for research purposes only.

A.3 Potential Risks. Potential risks associated with participation in this study is unlikely and of mild risks. *A.3.a Physical.* As a result of study participation, there is a minute likelihood of physical risk. Prefeasibility study participants will not engage in any activities that will promote physical risk. Staff of Meharry who will engage in training activities to carry out the intervention have a small chance of physical risk.

A.3.b Psychological. There may be mild psychological risks posed as a result of participating in the prefeasibility study and the time commitment to complete these activities. Participants (i.e., parents) may increase their thinking of adolescent risk of HPV exposure and associated diseases. Dr. Erves will refer to additional sources such as Centers for Disease and Control (CDC) if participants would like additional information on HPV and the vaccine. Providers may have a small likelihood of psychological risks when trying to implement a new strategy or intervention into their setting to improve HPV vaccination. We will ensure they have the proper training to pretest the pre-feasibility of this intervention.

A.3.c Social. In pretesting this intervention in the medical home, individuals may gain consciousness of their culture and society and how this reflects their views towards HPV vaccination in general and/or completing the vaccine at the medical home. This may have mild to moderate social risks as it may conflict with ones' culture and/or social order. Through careful training in cultural competency, we believe we can manage and channel these social risks in a positive way. Participants may feel they will not receive adequate services if they do not participate in the study, but we will assure them the services they receive will not be affected if they choose or choose not to participate. Last, providers may perceive their parents will be dissatisfied in their participation in research which in turn will affect their employment status. These social risks are unlikely to occur.

B. Adequacy of Protection against Risk

B.1 Recruitment and Informed Consent. For the intervention pretesting for pre-feasibility, participants will be recruited using the VHealth and EHR systems. Parents will provide consent for themselves to take part in the pretesting of the intervention and the debriefing interviews. For the provider debriefing interviews, they will be recruited via email and phone and provide verbal consent for interview participation. We have sought approval from the Institutional Review Board at MMC to conduct this study. We will ensure that we are meeting all requirements of 45 CFR 46 for informed consent and regulations regarding human subject participation in research.

The investigator and research assistant will have appropriate human subjects training prior to enrolling participants. Participants will be provided information at the time of study participation that clearly explains the procedures and processes for testing the intervention's feasibility and content of the interviews. They will understand that if they feel any of the questions or the study is causing a psychological disturbance, they have the right to withdraw from the study or not answer any question anytime without consequences. Providers who participate in study will recognize their participation in this study will not affect their employment status, and current or future services for adolescents at Medical Medical College Pediatrics Clinic will not be affected due to this study.

B.2 Protection against Risk to Confidentiality. The following precautions are expected to eliminate participant risk to confidentiality. All data will be safeguarded in accordance with the Health Insurance Portability and Accountability Act (HIPAA) and the principles and practices of strict confidentiality. The responses from debriefing interviews and prefeasibility evaluation will not be linked to identifying information except to follow-up with respondents for comprehension on a question response or future studies. Data will be stored in a locked file cabinet and files will be stored on a password protected computer in a password protected database in the office of the PI. Participants will be provided a unique identifier to be used in data analysis. Minutes from the trainings and weekly documentation of activities of the staff at the medical home will not be used in the preparation of analysis of the records. Last, no individuals will be identified in any presentations or publications resulting from this research. In such a way, we are protecting participants from risks from the prefeasibility study as well as risks related to privacy and confidentiality.

B.3 Vulnerable Subjects. The target population of this study are vulnerable subjects (e.g., economically and educationally disadvantaged). The opinions of these parents are valuable given the topic of the research is to reduce HPV-associated cancer rates among underserved populations through increased HPV vaccination. The participants will be provided with information at the time of study participation that clearly explains the procedures and processes of the prefeasibility study and content of the interview. Participants have the right to withdraw from the study at anytime without consequences.

B.4 Potential Benefits of the Proposed Research to the Subjects and Others.

Potential Benefits to Subjects. Parents will be more aware about HPV and the vaccine in order to make informed decision-making on their vaccination status of adolescents. It could improve parental attitudes towards their adolescent getting vaccinated against HPV. The engagement of community members in the process and development of this research could build trust in the research process. It could improve their awareness of the HPV and the vaccine. In time the benefit to participants may include improved communication between researchers and communities, as well between physicians. Providers will be key players in testing this intervention to address HPV vaccine hesitancy among parents, and learning how to engage these parents. They will become aware of different strategies to improve HPV vaccine rates among HPV vaccine hesitant parents.

Potential Benefits to Society. In time, the benefit to participants may include increased awareness of the role HPV vaccine has on their child's life, particularly cancer prevention. It will address VH parents perceived barriers (e.g., safety, rationale for recommended age) to HPV vaccination. This knowledge may help them make an informed decision on allowing their child to be vaccinated against HPV, leading to HPV vaccination to promote their overall health. This research could also benefit immunization stakeholders, especially pediatricians, providing a new way to address to HPV VH parents, and could potentially extend to other vaccines. In terms of the community, this project can achieve buy-in for communities to engage in health promotion activities and promote policy changes when needed.

B.5 Importance of the Knowledge to be gained. The knowledge gained and intervention tested for prefeasibility may assist in identifying new strategies to increase HPV vaccination rates among underserved

adolescents with VH parents. Identifying a health communication intervention tailored to the educational needs of these parents and providing prior to a doctor's visit could change attitudes towards the HPV vaccine, reduce existing knowledge gaps, and improve communication inequalities. Long-term benefits include the reduction of HPV-related sequelae and its' associated medical costs and lost productivity rates, improving health outcomes for this high-risk population. Providing individually-tailored messages to parents prior to a doctor's visits addresses the limited time for providers to educate the parents on HPV, while increasing knowledge and attitudes to ultimately increase HPV vaccine rates and improve health outcomes. The proposed benefits of this plan outweigh any potential risks. Incorporation of data management practices and use of encrypted databases will minimize risks related to privacy and confidentiality.

Data and Safety Monitoring Plan

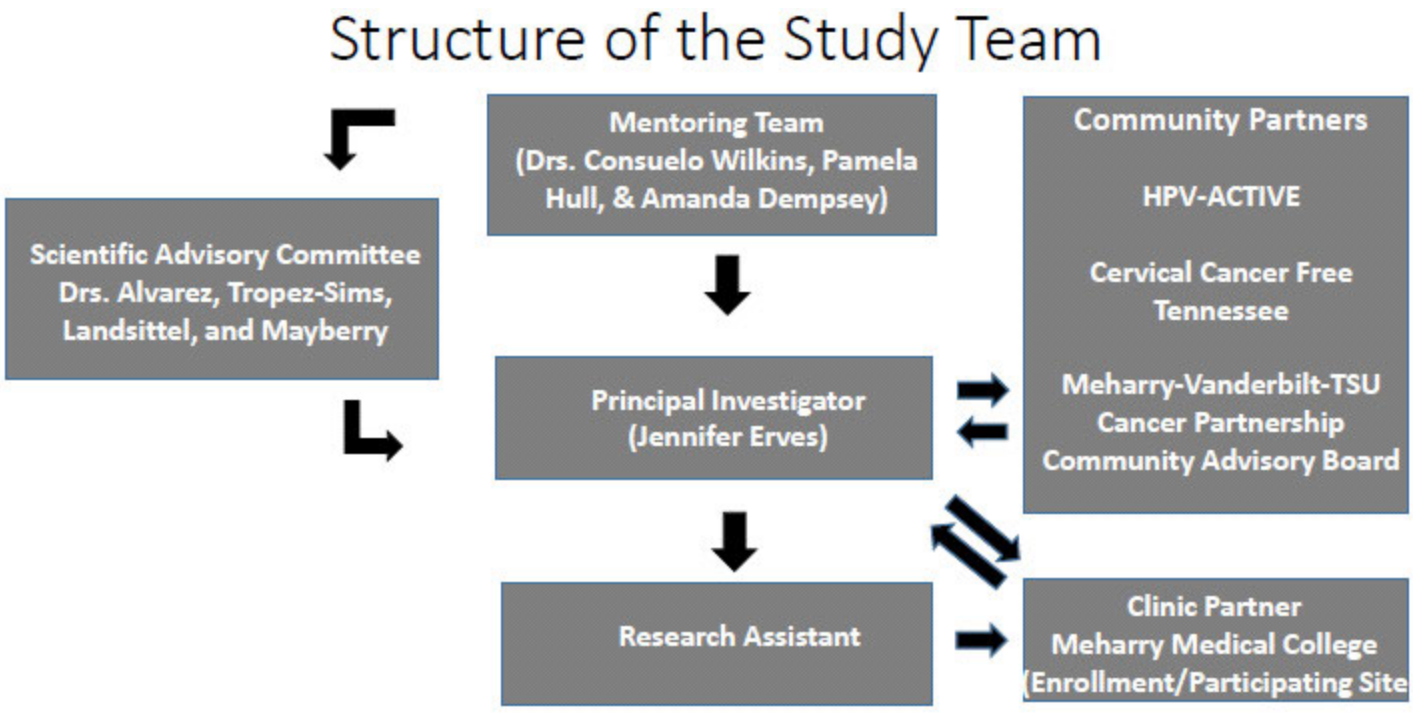
To ensure quality assurance and quality control, the PI will provide close oversight of study staff (i.e., research assistant) during qualitative interviews for protocol adherence. The PI will train the graduate assistant and observe the initial interviews to ensure protocol adherence. Each week the PI will review the study's progress with the graduate assistant, particularly adherence to the study's protocol and any parent and/or provider issues. The PI will review the notebook to ensure the study staff is following the protocol for data management. A refresher training for the research assistant will be provided if needed. For the pretesting of the intervention, the PI will train study staff (research staff and clinic staff) and provide close oversight for protocol adherence during intervention delivery and data collection. The PI will review progress with staff on a weekly basis to review adherence to the study protocol and address any issues related to patient safety. A refresher training for the study staff will be provided if needed.

As indicated, the PI will collect data which includes audiofiles and transcribed text. Data will be uploaded into NVivo 11, a qualitative data analysis software, to manage the data. This software is located on a password protected computer. This data will also be stored on an external hard drive that will be locked in the file cabinet of the PI, and within an online, secure institutional repository provided for each faculty member. One of the study staff will maintain a notebook on the project details, including the interviews and data management. Once data is collected and analyzed, we have provided a dissemination plan. We have provided a budget which will allow us to carry out this plan. My mentoring team will review progress of the study during one-on-one meetings and collectively at quarterly meetings. The Scientific Advisory Committee will review my progress bi-annually.

Structure of Study Team

For stage 1 of this study, we will develop a tailored, health communication intervention targeting HPV vaccine hesitant parents prior to clinic visits. This will involve conducting qualitative interviews with parents and providers. The mentoring team will advise Dr. Erves on the intervention development process. They will also advise her in the development of the study design, recruitment, qualitative protocol, data collection, and data analysis. The scientific advisory committee will also be sought to advise in this process bi-annually and as needed one-on-one. The Clinic and Community Partners will be involved throughout the process, advising Dr. Erves in the design, recruitment, qualitative protocol, and intervention development process. Dr. Erves will also provide insight to the community/clinic partners on the research process. Dr. Erves will train the research assistant to conduct the study protocol (i.e. qualitative interviews). This training will based on the insight received from the mentoring team, scientific advisory committee, and clinic/community partners.

For stage 2 of this study, we will optimize the feasibility and acceptability of the intervention and study procedures targeting HPV vaccine hesitant parents prior to clinic visits. This will involve pretesting the intervention and study procedures with parents and providers. The mentoring team and Scientific Advisory Board will advise Dr. Erves on the process of pretesting the intervention. The Clinic and Community Partners will be involved throughout the process, advising Dr. Erves on the best ways to pretest the intervention in the clinic and with parents. Dr. Erves will also provide insight to the community/clinic partners on the research process. Dr. Erves will further train the research assistant and providers and staff of Meharry Medical College Pediatric Practice on the study protocol. This training will be based on the insight received from the mentoring team, scientific advisory committee, and clinic/community partners. The graduate research assistant will be trained and will conduct the debriefing interviews with providers and parents.



Section 4 - Protocol Synopsis (Study 1)

4.1. Brief Summary

4.2. Study Design

4.2.a. Narrative Study Description

4.2.b. Primary Purpose

4.2.c. Interventions

Type	Name	Description

4.2.d. Study Phase

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

4.2.e. Intervention Model

4.2.f. Masking ❍ Yes ❍ No

❑ Participant ❑ Care Provider ❑ Investigator ❑ Outcomes Assessor

4.2.g. Allocation

4.3. Outcome Measures

Type	Name	Time Frame	Brief Description

4.4. Statistical Design and Power

4.5. Subject Participation Duration

4.6. Will the study use an FDA-regulated intervention? ❍ Yes ❍ No

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

4.7. Dissemination Plan

Section 1 - Basic Information (Study 2)

OMB Number: 0925-0001 and 0925-0002

Expiration Date: 03/31/2020

1.1. Study Title *

Conduct a pilot study of the intervention and study protocol to demonstrate feasibility for the future full-scale randomized control trial (RCT).

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 2)

2.1. Conditions or Focus of Study

- papillomavirus infections
- papillomavirus vaccines
- cancer

2.2. Eligibility Criteria

Inclusion Criteria for Adolescents and Parent dyads and providers:

(A) Adolescent patients of the Meharry Pediatric Clinic aged 11-18 plus one parent/guardian, refused or delayed HPV vaccination in the past two years, have not received any doses of HPV vaccine, have a clinic appointment scheduled within the coming month, and did not participate in Aim 1.

(B) Meharry pediatric providers participating in the pilot study.

Exclusion Criteria for Adolescent and Parent dyads and Pediatric Providers:

(A) Adolescent patients of the Meharry Pediatric Clinic aged 10 and under plus one parent/guardian, adolescent patients who have received one or more doses of the HPV vaccine, and those who participated in Aims 1 or 2.

(B) Providers who did not participate in the pilot study.

2.3. Age Limits	Min Age: 18 Years	Max Age: N/A (No limit)
2.4. Inclusion of Women, Minorities, and Children	Women_Minorities_and_Children_2F.pdf	
2.5. Recruitment and Retention Plan	RECRUITMENT_AND_RETENTION_PLAN_B-2.pdf	
2.6. Recruitment Status	Not yet recruiting	
2.7. Study Timeline	Study_2_Timeline_F.pdf	
2.8. Enrollment of First Subject	12/01/2020	Anticipated

INCLUSION OF WOMEN AND MINORITIES

Parents: The parent target population (n=70) includes adult men and women who make medical decisions for their adolescent aged 11 to 18 and have delayed or refused the HPV vaccine. We expect to recruit approximately 10% men and 90% because women are the primary decision makers when it comes to child's health. Furthermore, past participation rates of males in research studies were significantly lower than females. In regard to minority inclusion, we will not exclude groups based on race. Therefore, the study enrollment will reflect the general population of Meharry Medical College Pediatric Clinic.

Physicians: For current and potential vaccine providers and staff (n=10), we estimate that 73% will be AA and the other 17% Caucasian. We also expect 71% to be female and 29% to be male. These data are based on the national and state data, as well as the provider data of the clinic.

The proposed study is designed to reduce barriers to recruitment and to be presented in a manner that will be acceptable across cultures and settings with the aim of reaching all participants. A future study with more resources may specifically target recruitment in multiple medical settings that will have a larger portion of underserved, VH hesitant parent and providers.

INCLUSION OF CHILDREN

N/A

RECRUITMENT AND RETENTION PLAN

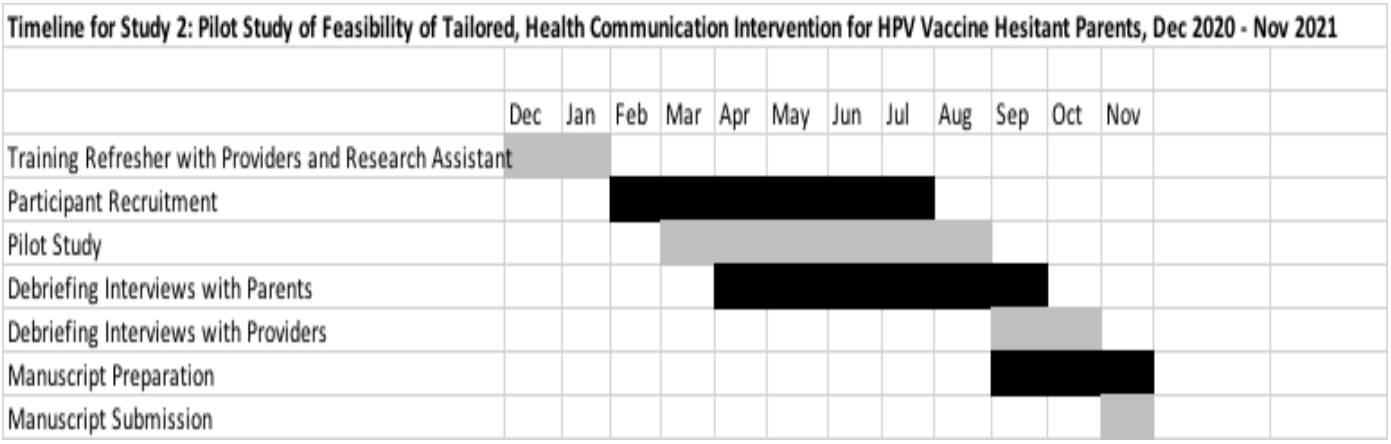
The recruitment and retention plan was developed based on research experiences of myself, mentors, and members of the scientific advisory committee. We have developed two plans, one for the parents and one for the providers.

We will use the VHealth system and EHR at Meharry Medical College to identify unvaccinated patients whose parents recently delayed or refused the HPV vaccine. After these data are collected, we will send an invitation to request their participation in the research study. The method of contact will be determined based on the contact information for the child in the VHealth system and EHR. If the participant agrees to participate, we will confirm eligibility and consent them for study participation. We have identified strategies to promote retention. We will maintain communication throughout the study with participants as needed. We will listen to participants and address issues if they arise. We will be convenient in scheduling interviews. Participants will be provided positive feedback throughout study participation. We will ensure the staff and research assistant is trained to carry out study protocol correctly, promoting synergy between research staff and study participants. Last, our study protocol will be informed by community stakeholders.

For providers participating in study implementation, we will send an email, call, or conduct a face-to-face visit to request their participation in debriefing interviews. To promote retention, we will be convenient in scheduling interviews and communicate with the providers as needed throughout the study. Last, providers will inform the study protocol.

Study Timeline

The timeline for Study 2 is below. Prior to study implementation, there will be a training refresher for the providers and research assistant in December 2020 through January 2021. Study recruitment occurs between February and July of 2021. We then conduct the pilot study at Meharry Medical College Pediatric Clinic between March and August of 2021. We will conduct debriefing interviews with parents and providers between April and August 2021. A manuscript will be prepared and submitted in November 2021.



Inclusion Enrollment Reports

IER ID#	Enrollment Location Type	Enrollment Location
Study 2, IER 1	Domestic	Meharry Medical College Pediatric Clinic, Nashville, TN

Inclusion Enrollment Report 1

Using an Existing Dataset or Resource* : ❍ Yes ● No

Enrollment Location Type* : ● Domestic ❍ Foreign

Enrollment Country(ies): USA: UNITED STATES

Enrollment Location(s): Meharry Medical College Pediatric Clinic, Nashville, TN

Comments: Planned enrollment categories are based on racial composition of providers and adolescents at Meharry Medical College Pediatric Clinic.

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	37	24	0	0	61
White	8	5	2	4	19
More than One Race	0	0	0	0	0
Total	45	29	2	4	80

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 2)

3.1. Protection of Human Subjects	Protection_of_Human_subjects_2A.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	Data_and_Safety_Monitoring_Plan2.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	StructureOfStudyTeam2F.pdf

PROTECTION OF HUMAN SUBJECTS

We will assess the feasibility of using an individually tailored, health communication intervention to increase HPV vaccination among adolescents with VH parents. In Year 2, we will pilot test the intervention for feasibility. Participants will be informed at the start of the study that their participation is strictly voluntary. Participants will be consented prior to enrollment and will be compensated for their time.

A. Risk to Subjects

A.1 Human Subjects' Involvement and Characteristics. Human subjects will be required for pilot testing of the intervention feasibility. The table below lists number of participants, recruitment strategies, and data collection methods.

	Pilot Testing
Number of Participants	Three Groups 80 (total)
Characteristics of Participants	-Parents (70) -Physicians and staff (10)
Recruitment strategies **(Parents)**	-- Meharry pediatric clinic EHR and VHealth software -Phone -Email -Mail
(Physicians)	-Email -Meharry Clinical Setting -Phone
Source of Materials	-Sociodemographic -Survey -Transcripts -Interviewer Notes -Researcher Notes

There are several stages in the study and the total number of participants for the study is 80. The following criteria will be used for all:

Inclusion Criteria for Parents: (1) Parents/guardians of adolescent patients of MMC Pediatrics aged 11–18, (2) refused HPV vaccination in the past two years and identified as vaccine hesitant, (3) have not received any doses of HPV vaccine,(4) have a clinic appointment scheduled in coming month, (5) speak English,(6) own smartphone, and (7) did not participate in **Aim 1**.
Inclusion Criteria for Providers: (1) Administered or made decisions to administer the HPV vaccine to adolescents ages 11 to 18 at Meharry Medical College Pediatric Clinic; (2) English-speaking; (3) male or female; (4) Age 18 years and older; (5) Able to give informed consent; and (6) Able to complete surveys/questionnaires and interviews.

Exclusion Criteria: All men and women who do not meet the inclusion criteria for both parents and providers/staff (e.g., cognitively impaired, or unable to provide consent).

A.2 Sources of Materials. Pilot testing of the intervention will include the recruitment of parents to determine feasibility and semi-structured, debriefing interviews (i.e., providers and members of parents) will be used to evaluate the intervention. Providers and staff will also participant in debriefing interviews. This will be collected for research purposes only.

A.3 Potential Risks. Potential risks associated with participation in this study is unlikely and of mild risks.
A.3.a Physical. As a result of study participation, there is a minute likelihood of physical risk. Pilot study participants and debriefing interviewees will not engage in any activities that will promote physical risk. Staff of Meharry who will engage in training activities to carry out the intervention have a small chance of physical risk.

A.3.b Psychological. There may be mild psychological risks posed as a result of participating in the pilot study and debriefing interviews, and the time commitment to complete these activities. Participants (i.e., parents) may increase their thinking of adolescent risk of HPV exposure and associated diseases. Dr. Erves will refer to additional sources such as Centers for Disease and Control (CDC) if participants would like additional information on HPV and the vaccine. Providers and/or staff may have a small likelihood of psychological risks when trying to implement a new strategy or intervention into their setting to improve HPV vaccination. We will ensure they have the proper training to conduct this intervention.

A.3.c Social. In identifying barriers of HPV vaccination among HPV vaccine hesitant parents in the medical home, individuals may gain consciousness of their culture and society and how this reflects their views towards HPV vaccination in general and/or completing the vaccine at the medical home. This may have mild to moderate social risks as it may conflict with ones' culture and/or social order. Through careful training in cultural competency, we believe we can manage and channel these social risks in a positive way. Participants

may feel they will not receive adequate services if they do not participate in the study, but we will assure them their services in the medical home will not be affected. Last, providers may perceive their parents will be dissatisfied in their participation in research which in turn will affect their employment status. These social risks are unlikely to occur.

B. Adequacy of Protection against Risk

B.1 Recruitment and Informed Consent. Community partners will provide feedback on the intervention prior to implementation. The feasibility study of the intervention will involve recruitment of parents using the VHealth and EHR systems. For the parent participation in interviews to determine acceptance and feasibility of the intervention, participants will be recruited using the VHealth and EHR systems. Parents will provide consent for themselves for participation in the pilot study and debriefing interviews). Providers will be recruited via email and phone. Providers will also provide verbal consent to take part in the debriefing interviews. We have sought approval from the Institutional Review Board at MMC to conduct this study. We will ensure that we are meeting all requirements of 45 CFR 46 for informed consent and regulations regarding human subject participation in research.

The investigator and research assistant will have appropriate human subjects training prior to enrolling participants. Participants will be provided information at the time of study participation that clearly explains the procedures and processes for the pilot study and content of the debriefing interviews. They will understand that if they feel any of the questions or the study is causing a psychological disturbance, they have the right to withdraw from the study or not answer any question anytime without consequences. Providers who participate in study will recognize their participation in this study will not affect their employment status, and current or future services for adolescents in the medical home will not be affected due to this study.

B.2 Protection against Risk to Confidentiality. The following precautions are expected to eliminate participant risk to confidentiality. All data will be safeguarded in accordance with the Health Insurance Portability and Accountability Act (HIPAA) and the principles and practices of strict confidentiality. The interview and survey responses from formative evaluation and post-pilot study evaluation will not be linked to identifying information except to follow-up with respondents for comprehension on a question response or future studies. Data will be stored in a locked file cabinet and files will be stored on a password protected computer in a password protected database in the office of the PI. Participants will be provided a unique identifier to be used in data analysis. Minutes from the trainings and weekly documentation of activities of the staff at the medical home will not be used in the preparation of analysis of the records. Last, no individuals will be identified in any presentations or publications resulting from this research. In such a way, we are protecting participants from risks from the intervention as well as risks related to privacy and confidentiality.

B.3 Vulnerable Subjects. The target population of this study are vulnerable subjects (e.g., economically and educationally disadvantaged). The results of the pilot study are valuable given the topic of the research is to reduce HPV-associated cancer rates among underserved populations through increased HPV vaccination. The participants will be provided with information at the time of study participation that clearly explains the procedures and processes of the prefeasibility study and content of the interview. Participants have the right to withdraw from the study at anytime without consequences.

B.4 Potential Benefits of the Proposed Research to the Subjects and Others.

Potential Benefits to Subjects. There are minimal benefits to participants; however, engagement of community members in the process and development of this research could build trust in the research process. It could improve parental awareness of the HPV vaccine and their attitudes to get their adolescent vaccinated against HPV. In time the benefit to participants may include improved communication between researchers and communities, as well between physicians.

Potential Benefits to Society. In time the benefit to participants may include increased awareness of the role HPV vaccine has on their child's life, particularly cancer prevention. It will address VH families perceived barriers (e.g., safety, rationale for recommended age) to HPV vaccination. This knowledge may help them make an informed decision on allowing their child to be vaccinated against HPV, leading to HPV vaccination to promote their overall health. This research could also benefit immunization stakeholders, especially pediatricians, providing a new way to address to HPV VH families, and could potentially extend to other vaccines. In terms of the community, this project can achieve buy-in for communities to engage in health promotion activities and promote policy changes when needed.

B.5 Importance of the Knowledge to be gained. The knowledge gained and intervention may assist in the increase of HPV vaccination rates among underserved adolescents with vaccine hesitant parents. Identifying a health communication intervention tailored to the educational needs of these families could change attitudes towards the HPV vaccine, reduce existing knowledge gaps, and improve communication inequalities. Long-term benefits include the reduction of HPV-related sequelae and its' associated medical costs and lost productivity rates, improving health outcomes for this high-risk population. Providing individually-tailored messages to families prior to a doctor's visits addresses the limited time for providers to educate the parents on HPV, while increasing knowledge and attitudes to ultimately increase HPV vaccine rates and improve health outcomes. The proposed benefits of this plan outweigh any potential risks. Incorporation of data management practices and use of encrypted databases will minimize risks related to privacy and confidentiality.

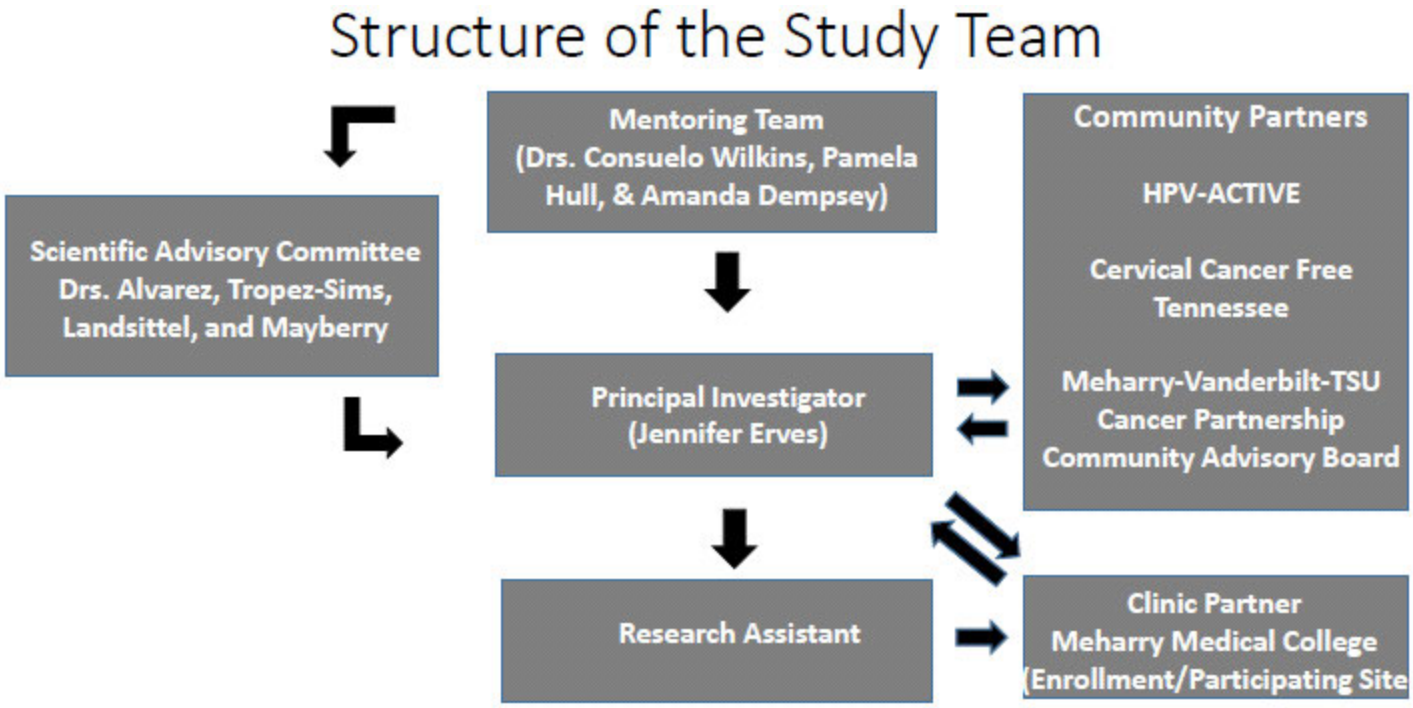
Data and Safety Monitoring Plan

The PI will train study staff (research staff and clinic staff) and provide close oversight for protocol adherence during intervention delivery and data collection. Staff will keep a notebook on the data collection and management process. The PI will review progress with staff on a weekly basis to review adherence to the study protocol and address any issues related to patient safety. A refresher training for the study staff will be provided if needed.

The PI will collect data which includes survey, audiofiles, and transcribed text. Survey data will be uploaded into REDCap, a secure online database. Interview data will be uploaded into NVivo 11, a qualitative data analysis software, to manage the data. The NVivo software is located on a password protected computer. All data will also be stored on an external hard drive that will be locked in the file cabinet of the PI, and within an online, secure institutional repository provided for each faculty member as a backup. One of the study staff will maintain a notebook on the project details, including the surveys and interviews and how they are managed. Once data is collected and analyzed, we have provided a dissemination plan. We have provided a budget which will allow us to carry out this plan. My mentoring team will review progress of the study during one-on-one meetings and collectively at quarterly meetings. The Scientific Advisory Committee will review my progress bi-annually.

Structure of Study Team

For this study, we will conduct a pilot study of the intervention and study protocol on a small scale to demonstrate feasibility of the future full-scale RCT targeting HPV vaccine hesitant parents prior to clinic visits. This will involve working with the pediatric clinic to conduct a small pilot, randomized control trial (RCT) with 70 VH hesitant parents with scheduled clinic visits. The mentoring team and Scientific Advisory Board will advise Dr. Erves on the process of conducting a pilot study. The Clinic and Community Partners will be involved throughout the process, advising Dr. Erves on the best ways to pilot test the intervention in the clinic and with parents. Dr. Erves will also provide insight to the community/clinic partners on the research process. Dr. Erves will further train the research assistant and providers and staff of Meharry Medical College Pediatric Practice on the study protocol. This training will based on the insight received from the mentoring team, scientific advisory committee, and clinic/community partners.



Section 4 - Protocol Synopsis (Study 2)

4.1. Brief Summary

The objectives of this pilot study are to: (1) demonstrate feasibility of the processes planned for the future RCT; and (2) identify unforeseen problems or issues that need to be corrected in the future study protocol. Experts recommend that it is not appropriate for a pilot study of a future RCT to compare study arms to assess treatment effects or to estimate effect sizes, due to the small sample size.

4.2. Study Design

4.2.a. Narrative Study Description

The pilot study will implement the design planned for the future full-scale trial, a two-arm RCT to compare the intervention with attention control. The intervention arm will receive the pre-visit individually tailored information on HPV and the vaccine. The attention control arm will receive pre-visit health education information on an unrelated topic (e.g., healthy eating and physical activity).

4.2.b. Primary Purpose: Prevention

4.2.c. Interventions

Type	Name	Description
Behavioral (e.g., Psychotherapy, Lifestyle Counseling)	Individually Tailored Health Communication Intervention	The intervention will be delivered via mobile phone by first sending a text message to the parent's phone with a link, then clicking the link will open a website that is optimized for viewing on a mobile phone, which has the look and feel of an app, but without requiring the user to download anything to the phone. On the website, they will be prompted to take the assessment quiz. Based on the responses, the top barriers or need will each be mapped to a corresponding educational message, which will be displayed to the user with appropriate images or graphics. The parent will be given links to websites with reliable information and suggested questions they can ask the doctor related to each topic. The parent will be prompted to save the tailored messages or questions to their phone as images. Then another text message will be sent to the parent's phone with a link for returning to their tailored page.

4.2.d. Study Phase: Other

Health Education Intervention

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

4.2.e. Intervention Model: Parallel

4.2.f. Masking ❍ Yes ● No

❑ Participant ❑ Care Provider ❑ Investigator ❑ Outcomes Assessor

4.2.g. Allocation: Randomized

4.3. Outcome Measures

Type	Name	Time Frame	Brief Description

Primary	Feasibility	1 year	recruitment rates (# prescreened, % contracted, % unable to contact, % confirmed vaccine hesitant, % screened, % enrolled, # enrolled per month), retention rates (% completed baseline survey, % came to clinic visit (primary retention endpoint), % completed post-visit survey), and data collection processes (% ascertained post-visit HPV vaccine status, # minutes to complete surveys)

4.4. Statistical Design and Power — StatisticalDesignAndPower2F.pdf

4.5. Subject Participation Duration — 1 month

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

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

4.7. Dissemination Plan — DISSEMINATIONPLAN2.pdf

Statistical Design and Power

The primary outcome of the future RCT will be receipt of the HPV vaccine at the clinic visit (binary/proportion). (a) Pilot Trial: The necessary sample size for the pilot trial may be calculated using a one-sided 80% confidence interval and the expected effect size of the future RCT,[83] based on the expected proportion in the control arm (0.20–0.30) and the clinically meaningful difference to be observed in the intervention arm in the future RCT (at least 0.10 higher).[81,83] A total pilot sample size of 46–60 after attrition will be sufficient (**Table 1**). We will enroll 70 VH families, expecting 10%–15% attrition (no-show for clinic visit), yielding a final sample of 60–63 families (28–30 per arm). MMC Pediatrics has 2,840 active adolescent patients ages 11–18, of whom 40% have not received any doses of the HPV vaccine. Among the 300 adolescent visits per month, half (150) are scheduled appointments (not walk-ins). We estimate that 60 (40%) have received no HPV doses and half of them[13] (30) have previously delayed or refused HPV and, thus, will be eligible for the study each month. Conservatively, we expect to recruit at least 10-15 parents per month, so accrual will take around seven months.

Table 1. Pilot Sample Size Calculation (p=Proportion: Receipt of HPV Vaccine at Visit)

Control p	Difference	Future RCT N	Pilot N	80% CI Upper Limit
0.20	0.10	712	60	0.0996 (<0.10)
0.30	0.10	586	46	0.0993 (<0.10)

DISSEMINATION PLAN

The purpose of this project is to understand how tailored education prior to a doctor's visit could play a role in improving HPV vaccination among underserved, vaccine-hesitant (VH) parents. Dr. Erves along with her mentoring team and scientific advisory board are committed to the dissemination of research findings to the academic and clinical communities, as well as community members and organizations. This is vital for those within this population because they suffer disproportionately from HPV-associated cancers. Dissemination of study findings will occur throughout and after study completion. The first phase of dissemination will be the sharing of the iterative, tailored intervention process. This involves sharing the process of developing the tailored education and the final product. We will also share findings from the study. Dissemination methods include meetings with community partners and community members. We will also share findings using the community partners' website, community newsletters, community health reports, and community forums. For the academic and clinical community, we will disseminate these findings at national meetings and through publications and invited talks. We will evaluate the dissemination and use of research by number of presentations, number of views on websites, and publication citations. We will explore additional dissemination methods (e.g., toolkits, social media, creating and distributing program materials) throughout the project for consideration. We also respect the rights of our participants in the dissemination process.

Section 1 - Basic Information (Study 3)

OMB Number: 0925-0001 and 0925-0002

Expiration Date: 03/31/2020

1.1. Study Title *

Examine acceptability of the intervention and protocol among parents and providers

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 3)

2.1. Conditions or Focus of Study

- papillomavirus infections
- papillomavirus vaccines
- cancer

2.2. Eligibility Criteria

Inclusion Criteria for Vaccine Hesitant Parents and Pediatric Providers:

(A) Parents/guardians who participated in the intervention in Aim 2, with 60-63 completed baseline/follow-up surveys and 40-60 completed qualitative interviews.

(B) 10 pediatric providers and staff who participated in Aim 2.

Exclusion Criteria for Parents and Pediatric Providers:

(A) Parents who did not participant in Aim 2.

(B) Providers who did not participate in the pilot study.

2.3. Age Limits	Min Age: 18 Years	Max Age: N/A (No limit)
2.4. Inclusion of Women, Minorities, and Children	Women_Minorities_and_Children_3F.pdf	
2.5. Recruitment and Retention Plan	RecruitmentAndRetentionPlan3.pdf	
2.6. Recruitment Status	Not yet recruiting	
2.7. Study Timeline	Study_3_TimelineF.pdf	
2.8. Enrollment of First Subject		

INCLUSION OF WOMEN AND MINORITIES

For study 3, we will use an observational study design, combining survey and qualitative methods, to explore perceived acceptance of the intervention and protocol. This will be based on analysis of the surveys and debriefing interviews collected in **Aim 2**. While we do not include women and minorities officially in this study, the information below reflects individuals who provided the information in Aim 2. There were no children participating in this study.

Parents: The parent target population (n=70) includes adult men and women who make medical decisions for their adolescent aged 11 to 18 and have delayed or refused the HPV vaccine. We expect to recruit approximately 10% men and 90% because women are the primary decision makers when it comes to child's health. Furthermore, past participation rates of males in research studies were significantly lower than females. In regard to minority inclusion, we will not exclude groups based on race. Therefore, the study enrollment will reflect the general population of Meharry Medical College Pediatric Clinic.

Physicians: For current and potential vaccine providers and staff (n=10), we estimate that 73% will be AA and the other 17% Caucasian. We also expect 71% to be female and 29% to be male. These data are based on the national and state data, as well as the provider data of the clinic.

The proposed study is designed to reduce barriers to recruitment and to be presented in a manner that will be acceptable across cultures and settings with the aim of reaching all participants. A future study with more resources may specifically target recruitment in multiple medical settings that will have a larger portion of underserved, VH hesitant parent and providers.

INCLUSION OF CHILDREN

N/A

Recruitment and Retention Plan

For study 3, no participants will be recruited. I will use an observational design combining survey and qualitative methods to explore perceived acceptance of the intervention and protocol, based on analysis of the surveys and debriefing interviews collected in **Aim 2**. The recruitment and retention plan for Aim 2 is provide below.

The recruitment and retention plan was developed based on research experiences of myself, mentors, and members of the scientific advisory committee. We have developed two plans, one for the parent-child dyads and one for the providers.

We will use the VHealth system and EHR at Meharry Medical College to identify unvaccinated patients whose parents recently delayed or refused the HPV vaccine. After these data are collected, we will send an invitation to request their participation in the research study. The method of contact will be determined based on the contact information for the child in the VHealth system and EHR. If the participant agrees to participate, we will consent them for study participation. We have identified strategies to promote retention. We will maintain communication throughout the study with participants as needed. We will listen to participants and address issues if they arise. We will be convenient in scheduling interviews. Participants will be provided positive feedback throughout study participation. We will ensure the staff and research assistant is trained to carry out study protocols correctly, promoting synergy between research staff and study participants. Last, our study protocols will be informed by community stakeholders.

For providers participating in study implementation, we will send an email, call, or conduct a face-to-face visit to request their participation in debriefing interviews. To promote retention, we will be convenient in scheduling interviews and communicate with the providers as needed throughout the study. Last, providers will inform the study protocol.

Study Timeline

The timeline for Study 3 is below. Transcriptions will be conducted in December 2021 through February 2022. We will then conduct qualitative data analysis and survey data management at Meharry Medical College between February 2022 and May 2022. R01 submission will occur in September 2022. A manuscript will be prepared and submitted in November 2022. In year 4, survey data analysis will be conducted in December 2022 through March 2023. The intervention and protocol will be finalized by June 2023, with R01 resubmission coming in the same month. A manuscript will be prepared and submitted by November 2023.

Timeline for Study 3: Examine acceptability of the intervention and protocol among parents and providers, Dec 2021 to November 2023

2021-2022	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov
Transcriptions												
Data Analysis												
Survey Dara Management												
R01Preparation and Submission												
Manuscript Preparation												
Manuscript Submission												

2022-2023	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov
Survey Data Analysis												
Finalize intervention and protocol												
R01 resubmission												
Manuscript Preparation												
Manuscriot Submission												

Inclusion Enrollment Reports

IER ID#	Enrollment Location Type	Enrollment Location
Study 3, IER 1	Domestic	Meharry Pediatric Clinic, Nashville, TN

Inclusion Enrollment Report 1

Using an Existing Dataset or Resource* : ● Yes ❍ No

Enrollment Location Type* : ● Domestic ❍ Foreign

Enrollment Country(ies): USA: UNITED STATES

Enrollment Location(s): Meharry Pediatric Clinic, Nashville, TN

Comments:

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	37	24	0	0	61
White	8	5	2	4	19
More than One Race	0	0	0	0	0
Total	45	29	2	4	80

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	37	24	0	0	0	0	0	0	0	61
White	8	5	0	2	4	0	0	0	0	19
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	45	29	0	2	4	0	0	0	0	80

Section 3 - Protection and Monitoring Plans (Study 3)

3.1. Protection of Human Subjects	PROTECTIONOFHUMANSUBJECTS3.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	Data_and_Safety_Monitoring_Plan3.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	StructureOfStudyTeam3.pdf

PROTECTION OF HUMAN SUBJECTS

In Year 3, we will analyze the de-identified data from the surveys and interviews collected in Study 2. Participants will be consented prior to enrollment and will be compensated for their time in Study 2 for us to analyze the data in Study 3.

A. Risk to Subjects

A.1 Human Subjects' Involvement and Characteristics. We will not recruit participants for Study 3. However, the table below lists number of participants, recruitment strategies, and data collection methods in Study 2 to obtain this data for Study 3.

	Pilot Testing
Number of Participants	Three Groups 80 (total)
Characteristics of Participants	-Parents (70) -Physicians and staff (10)
Recruitment strategies **(Parents)**	-- Meharry pediatric clinic EHR and VHealth software -Phone -Email -Mail
(Physicians)	-Email -Meharry Clinical Setting -Phone
Source of Materials	-Sociodemographic -Survey -Transcripts -Interviewer Notes -Researcher Notes

There are several stages in the study and the total number of participants for the study is 80. The following criteria will be used for all:

Inclusion Criteria for Parents: (1) Parents/guardians of adolescent patients of MMC Pediatrics aged 11–18, (2) refused HPV vaccination in the past two years and identified as vaccine hesitant, (3) have not received any doses of HPV vaccine,(4) have a clinic appointment scheduled in coming month, (5) speak English,(6) own smartphone, and (7) did not participate in **Aim 1**.
Inclusion Criteria for Providers: (1) Administered or made decisions to administer the HPV vaccine to adolescents ages 11 to 18 at Meharry Medical College Pediatric Clinic; (2) English-speaking; (3) male or female; (4) Age 18 years and older; (5) Able to give informed consent; and (6) Able to complete surveys/questionnaires and interviews.

Exclusion Criteria: All men and women who do not meet the inclusion criteria for both parents and providers/staff (e.g., cognitively impaired, or unable to provide consent).

A.2 Sources of Materials. The survey and interview data will be used that was collected in Study 2 or Aim 2 from providers and parents. This will be collected for research purposes only.

A.3 Potential Risks. Potential risks associated with participation in this study is unlikely and of mild risks. *A.3.a Physical.* As a result of study participation, there is a minute likelihood of physical risk. Debriefing interviewees will not engage in any activities that will promote physical risk. Staff of Meharry who will engage in training activities to carry out the intervention have a small chance of physical risk.

A.3.b Psychological. There may be mild psychological risks posed as a result of participating in debriefing interviews, and the time commitment to complete these activities. Participants (i.e., parents) may increase their thinking of adolescent risk of HPV exposure and associated diseases. Dr. Erves will refer to additional sources such as Centers for Disease and Control (CDC) if participants would like additional information on HPV and the vaccine.

A.3.c Social. In identifying barriers of HPV vaccination among HPV vaccine hesitant parents in the medical home, individuals may gain consciousness of their culture and society and how this reflects their views towards HPV vaccination in general and/or completing the vaccine at the medical home. This may have mild to moderate social risks as it may conflict with ones' culture and/or social order. Through careful training in cultural competency, we believe we can manage and channel these social risks in a positive way. Participants may feel they will not receive adequate services if they do not participate in the study, but we will assure them their services in the medical home will not be affected. Last, providers may perceive their parents will be dissatisfied in their participation in research which in turn will affect their employment status. These social risks are unlikely to occur.

B. Adequacy of Protection against Risk

B.1 Recruitment and Informed Consent. There will be no recruitment or informed consent in this process. This would have occurred in study 2. However, data will not be collected from parents unless they have provided consent for themselves for participation in the pilot study and debriefing interviews. They would have been recruited through VHealth and EHR. Interview data from providers also would have been collected in Study 2 with their verbal consent. Providers will have been recruited via email and phone. Providers will also provide verbal consent to take part in the debriefing interviews. We have sought approval from the Institutional Review Board at MMC to conduct this study. We will ensure that we are meeting all requirements of 45 CFR 46 for informed consent and regulations regarding human subject participation in research.

Participants would have been provided information at the time of study participation that clearly explains the procedures and processes for analyzing the interviews. They will understand that if they feel any of the questions or the study is causing a psychological disturbance, they have the right to withdraw from the study or not answer any question anytime without consequences. Providers who participate in study will recognize their participation in this study will not affect their employment status, and current or future services for adolescents in the medical home will not be affected due to this study.

B.2 Protection against Risk to Confidentiality. The following precautions are expected to eliminate participant risk to confidentiality. All data will be safeguarded in accordance with the Health Insurance Portability and Accountability Act (HIPAA) and the principles and practices of strict confidentiality. The interview and survey responses from formative evaluation and post-pilot study evaluation will not be linked to identifying information except to follow-up with respondents for comprehension on a question response or future studies. Data will be stored in a locked file cabinet and files will be stored on a password protected computer in a password protected database in the office of the PI. Participants will be provided a unique identifier to be used in data analysis. Minutes from the trainings and weekly documentation of activities of the staff at the medical home will not be used in the preparation of analysis of the records. Last, no individuals will be identified in any presentations or publications resulting from this research. In such a way, we are protecting participants from risks from the intervention as well as risks related to privacy and confidentiality.

B.3 Vulnerable Subjects. The target population of this study are vulnerable subjects (e.g., economically and educationally disadvantaged). The results of this analysis is valuable given the topic of the research is to reduce HPV-associated cancer rates among underserved populations through increased HPV vaccination. The participants will be provided with information at the time of study participation that clearly explains the procedures and processes of the prefeasibility study and content of the interview. Participants have the right to withdraw from the study at anytime without consequences.

B.4 Potential Benefits of the Proposed Research to the Subjects and Others.

Potential Benefits to Subjects. There are minimal benefits to participants; however, engagement of community members in the process and development of this research could build trust in the research process. It could improve parental awareness of the HPV vaccine and their attitudes to get their adolescent vaccinated against HPV. In time the benefit to participants may include improved communication between researchers and communities, as well between physicians.

Potential Benefits to Society. In time the benefit to participants may include increased awareness of the role HPV vaccine has on their child's life, particularly cancer prevention. It will address VH families perceived barriers (e.g., safety, rationale for recommended age) to HPV vaccination. This knowledge may help them make an informed decision on allowing their child to be vaccinated against HPV, leading to HPV vaccination to promote their overall health. This research could also benefit immunization stakeholders, especially pediatricians, providing a new way to address to HPV VH families, and could potentially extend to other vaccines. In terms of the community, this project can achieve buy-in for communities to engage in health promotion activities and promote policy changes when needed.

B.5 Importance of the Knowledge to be gained. The knowledge gained from this data will help to further modify the intervention which may assist in the increase of HPV vaccination rates among underserved adolescents with vaccine hesitant parents. Identifying a health communication intervention tailored to the educational needs of these families could change attitudes towards the HPV vaccine, reduce existing knowledge gaps, and improve communication inequalities. Long-term benefits include the reduction of HPV-

related sequelae and its' associated medical costs and lost productivity rates, improving health outcomes for this high-risk population. Providing individually-tailored messages to families prior to a doctor's visits addresses the limited time for providers to educate the parents on HPV, while increasing knowledge and attitudes to ultimately increase HPV vaccine rates and improve health outcomes. The proposed benefits of this plan outweigh any potential risks. Incorporation of data management practices and use of encrypted databases will minimize risks related to privacy and confidentiality.

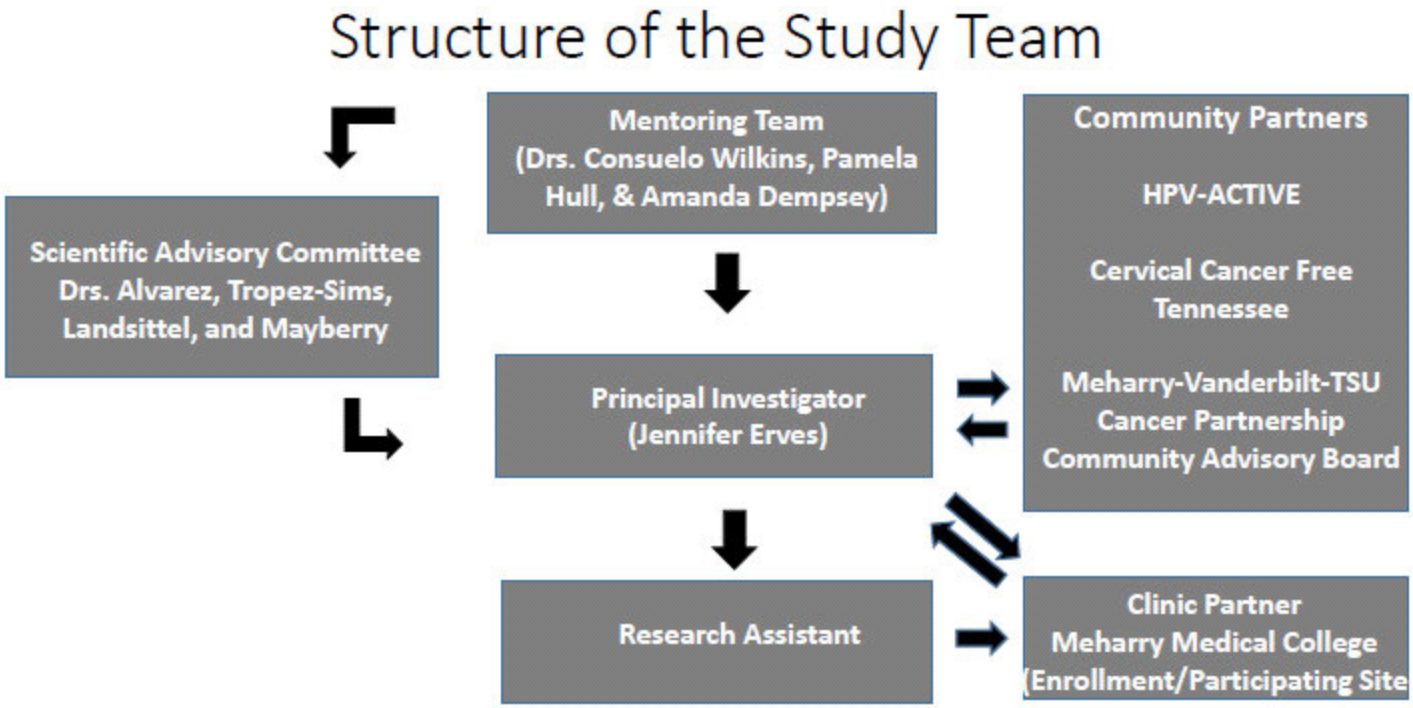
Data and Safety Monitoring Plan

The PI will train study staff (research staff) and provide close oversight to follow the study protocol as it relates to survey data management and quantitative data analysis. She will also ensure study staff are trained in qualitative data analysis to understand the findings. The PI will also ensure the intervention is updated and finalized with accurate representation of the findings. The PI will review progress with the graduate research assistant on a weekly basis to review adherence to the study protocol and address any issues related to patient safety. A refresher training for the graduate research assistant will be provided if needed.

The PI collected data in Aim 2 which includes survey, audiofiles, and transcribed text. Survey data will be retrieved from REDCap, a secure online database. Interview data retrieved from NVivo 11, a qualitative data analysis software, to manage the data. The NVivo software is located on a password protected computer. As in the DSMP Plan in Aim 2, all data will also be stored on an external hard drive that will be locked in the file cabinet of the PI, and within an online, secure institutional repository provided for each faculty member as a backup. One of the study staff will maintain a notebook on the project details, including the surveys and interviews and how they are managed. Once data is collected and analyzed, we will disseminate the findings (e.g., manuscripts, study participants). My mentoring team will review progress of the study during one-on-one meetings and collectively at quarterly meetings. The Scientific Advisory Committee will review my progress bi-annually.

Structure of Study Team

For this study, we will analyze the debriefing interviews and surveys from Study 2. The research assistant will be trained and will assist in analyzing the survey data. Dr. Erves and the research assistant will finalize the results, and will gain oversight from her mentoring committee on the results. She will also present the findings to her scientific advisory committee, community partners, and clinic partners to ensure data, particularly qualitative findings, were interpreted accurately.



Section 4 - Protocol Synopsis (Study 3)

4.1. Brief Summary

4.2. Study Design

4.2.a. Narrative Study Description

4.2.b. Primary Purpose

4.2.c. Interventions

Type	Name	Description

4.2.d. Study Phase

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

4.2.e. Intervention Model

4.2.f. Masking ❍ Yes ❍ No

❑ Participant ❑ Care Provider ❑ Investigator ❑ Outcomes Assessor

4.2.g. Allocation

4.3. Outcome Measures

Type	Name	Time Frame	Brief Description

4.4. Statistical Design and Power

4.5. Subject Participation Duration

4.6. Will the study use an FDA-regulated intervention? ❍ Yes ❍ No

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

4.7. Dissemination Plan

Delayed Onset Studies

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

VERTEBRATE ANIMALS

N/A

SELECT AGENT RESEARCH

N/A

CONSORTIUM/CONTRACTUAL ARRANGEMENTS

N/A

RESOURCE/DATA SHARING PLAN

Dr. Erves along with her mentoring team and collaborators are committed to understanding how tailored education prior to a doctors visit could play a role in improving HPV vaccination among underserved, vaccine-hesitant (VH) parents. This study is important for those within this population because they suffer disproportionately from HPV-associated cancers. We are cognizant of the need for public dissemination of our findings and the intervention and how this supports collaborative efforts. As noted in this proposal, we are committed to disseminating our work broadly. We are also committed to ensuring the protection of intellectual property that is essential to successful development of an innovative intervention. These critical objectives will be achieved by strategically using de-identified data to develop and pilot test an intervention in an alternative setting to improve HPV vaccination in underserved adolescents with VH parents, and subsequently, disclosing these findings and conclusions in oral or poster presentations at national and international meetings and in publications in refereed scientific journals. We also respect the rights of our collaborators in this regard, and will ensure that any agreements with these entities allow for the protection of their intellectual property.

Research data will be shared according to the most recent NIH guidelines.
At this time, our plans are to use data-sharing agreements, which specifically state:

- **What data will be shared:** interview data and pilot survey statistical analysis results, the developed intervention, and results of the pre-feasibilty and feasibility studies.
- **Who will have access to the data:** Final data will be available according to the NIH public access policy.
- **Where will the data be available:** scientific journals, community newsletters, community health reports, poster/oral presentations at national conferences, and community forums.
- **When will the data be shared:** We anticipate final data to be ready for sharing during year 4 of the proposal.
- **How will researchers locate and access the data:** Researchers will be able to access the data through standard methods (digital journals, direct contact with authors and investigators etc.).

We are committed to the sharing of final research data, being mindful that the rights and privacy of people who participate in research must be protected at all times, that there is the need to protect patentable and other proprietary data, and that restrictions on data sharing may be imposed by agreements with third parties. Meharry Medical College is and will remain HIPAA compliant, and therefore any datasets resulting from human participant research will be free of any identifiers that would permit linkages to individual research participants and variables that could lead to deductive disclosure of individual subjects.

Timelines for distribution of data will vary depending on any required restrictions as mentioned above. In addition to speaking engagements and publications, these data also may be distributed in other communication channels such as a number of electronic methods, including web-based databases, datasets, and spreadsheets, or via electronic media such as CDs, DVDs, and tape.

Authentication of Key Biological and/or Chemical Resources

N/A