Recipient Information

1. Recipient Name
BRIGHAM & WOMENS HOSPITAL INC
75 FRANCIS ST
BOSTON, MA 02115

2. Congressional District of Recipient
07

3. Payment System Identifier (ID)
1042312909A1

4. Employer Identification Number (EIN)
042312909

5. Data Universal Numbering System (DUNS)
030811269

6. Recipient's Unique Entity Identifier
QN6MS4VN7BD1

7. Project Director or Principal Investigator
Ingrid T. Katz, MD (Contact)
Associate Professor
ikatz2@partners.org
617-525-8194

8. Authorized Official
Robert Singleton

Federal Agency Information

9. Awarding Agency Contact Information
MALLORY ANNE Shramek

NATIONAL CANCER INSTITUTE
mallory.shramek@nih.gov
(240) 276-7851

10. Program Official Contact Information
VERONICA CHOLLETTE
Program Director
NATIONAL CANCER INSTITUTE
vc24a@nih.gov
240 -276-6969

Federal Award Information

11. Award Number
1R34CA283483-01

12. Unique Federal Award Identification Number (FAIN)
R34CA283483

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
Multi-level school-based intervention to improve HPV vaccine uptake and completion in South Africa

15. Assistance Listing Number
93.393

16. Assistance Listing Program Title
Cancer Cause and Prevention Research

17. Award Action Type
New Competing (REVISED)

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information

19. Budget Period Start Date 08/07/2023 **– End Date** 07/31/2024	
20. Total Amount of Federal Funds Obligated by this Action	$0
20 a. Direct Cost Amount	$0
20 b. Indirect Cost Amount	$0
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$339,735
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$339,735
26. Project Period Start Date 08/07/2023 **– End Date** 07/31/2026	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$339,735

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Viviana Knowles

30. Remarks

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

CLINICAL TRIAL PLANNING GRANT
Department of Health and Human Services
National Institutes of Health

NATIONAL CANCER INSTITUTE

SECTION I – AWARD DATA – 1R34CA283483-01 REVISED

Principal Investigator(s):
LISA Michelle BUTLER, PHD
Ingrid T. Katz (contact), MD

Award e-mailed to: bwhgc@partners.org

Dear Authorized Official:

The National Institutes of Health hereby revises this award (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to Brigham and Women's Hospital in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

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

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Cancer Institute of the National Institutes of Health under Award Number R34CA283483. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

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

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

Sincerely yours,

Viviana Knowles
Grants Management Officer
NATIONAL CANCER INSTITUTE

Additional information follows

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

Federal Direct Costs	$212,824
Federal F&A Costs	$126,911
Approved Budget	$339,735
Total Amount of Federal Funds Authorized (Federal Share)	$339,735
TOTAL FEDERAL AWARD AMOUNT	$339,735

AMOUNT OF THIS ACTION (FEDERAL SHARE) $0

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
1	$339,735	$339,735
2	FUTURE COSTS, RECOMMENDED COSTS	
3		

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

Fiscal Information:

Payment System Identifier:	1042312909A1
Document Number:	RCA283483A
PMS Account Type:	P (Subaccount)
Fiscal Year:	2023

IC	CAN	2023	2024	2025
CA	8479565	$339,735	FUTURE COSTS, RECOMMENDED COSTS	

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

NIH Administrative Data:
PCC: 6KSC / **OC**: 41021 / **Released**: Knowles, Viviana 08/09/2023
Award Processed: 08/10/2023 12:08:23 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 1R34CA283483-01 REVISED

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

SECTION III – STANDARD TERMS AND CONDITIONS – 1R34CA283483-01 REVISED

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

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.

e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

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

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

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

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

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

This award has been assigned the Federal Award Identification Number (FAIN) R34CA283483. 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/

Recipients must administer the project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure

meaningful access to programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.

- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment; see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm.
- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:

Additional Costs

SECTION IV – CA SPECIFIC AWARD CONDITIONS – 1R34CA283483-01 REVISED

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.

INFORMATION: This revised award removes the provisional term on the award issued on 08/07/2023 and reflects the National Cancer Institute (NCI) acceptance of the foreign clearance for Queen's University at Kingston.

THE FOLLOWING TERMS FROM THE PREVIOUS NOTICE OF AWARD ALSO APPLY TO THIS AWARD:

INFORMATION: In accordance with the National Cancer Institute's (NCI's) current fiscal year (FY) funding policies, this award has been issued at 91.5% of the adjusted requested level*. Support recommended for future years has been adjusted accordingly.

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

INFORMATION: Although the budget period start date for this award is 08/07/2023, this award includes funds for twelve months of support. Future year budget periods will cycle on 08/01. Allowable pre-award costs may be charged to this award, in accordance with the

conditions in the NIH Grants Policy Statement, and with institutional requirements for prior approval.

REQUIREMENT: The clinical trial(s) supported by this award is subject to the plan dated 10/25/2022 submitted to NIH and the NIH policy on Dissemination of NIH-Funded Clinical Trial Information. The plan states that the clinical trial(s) funded by this award will be registered in ClinicalTrials.gov not later than 21 calendar days after enrollment of the first participant and primary summary results reported in ClinicalTrials.gov, not later than one year after the completion date. The reporting of summary results is required by this term of award even if the primary completion date occurs after the period of performance.

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

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

REQUIREMENT: NCI has determined this award includes foreign components.

All foreign components must be reported in G9 of RPPR, and the dollar amount spent in foreign countries (if applicable) must be reported in E4 in the RPPR.

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

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

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

INFORMATION: This award is contingent upon the following: No individual who receives salary support from this project may receive compensation for more than 12 calendar months (i.e., 100%) total effort from all of their sources of support.

INFORMATION: To help expedite NCI's response to prior approval requests, please submit requests for change of PD/PI, carryover or no cost extensions electronically through the eRA Commons at Prior Approval Module. All other post award requests should be submitted to

NCIGrantsPostAward@nih.gov. All electronically submitted requests will be tracked and forwarded to the appropriate Grants Management personnel.

INFORMATION: This award, including the budget and the budget period, has been discussed between Mallory Shramek of the National Cancer Institute and Robert Singleton on 07/05/2023.

SPREADSHEET SUMMARY
AWARD NUMBER: 1R34CA283483-01 REVISED

INSTITUTION: Brigham and Women's Hospital

Budget	Year 1	Year 2	Year 3
TOTAL FEDERAL DC	$212,824	FUTURE COSTS	
TOTAL FEDERAL F&A	$126,911		
TOTAL COST	$339,735		

Facilities and Administrative Costs	Year 1	Year 2	Year 3
F&A Cost Rate 1	79%	FUTURE COSTS	
F&A Cost Base 1	$160,647		
F&A Costs 1	$126,911		

PI: **Katz, Ingrid T.**	Title: Multi-level school-based intervention to improve HPV vaccine uptake and completion in South Africa	
Received: 10/25/2022	FOA: PAR22-173	Council: 05/2023
Competition ID: FORMS-G	FOA Title: Cancer Prevention and Control Clinical Trials Planning Grant Program (R34 Clinical Trials Optional)	
1 R34 CA283483-01	Dual:	Accession Number: 4766033
IPF: 1080401	Organization: BRIGHAM AND WOMEN'S HOSPITAL	
Former Number:	Department:	
IRG/SRG: ZCA1 TCRB-V (M2)	AIDS: N	Expedited: N
Subtotal Direct Costs (excludes consortium F&A) Year 1: 225,000 Year 2: FUTURE COSTS Year 3:	Animals: N Humans: Y Clinical Trial: Y Current HS Code: 30 HESC: N HFT: N	New Investigator: Early Stage Investigator:
Senior/Key Personnel:	*Organization:*	*Role Category:*
Nicholas Munro	University of KwaZulu-Natal	Co-Investigator
Lisa Butler	University of Connecticut	MPI
Douglas Wassenaar	University of KwaZulu-Natal	Co-Investigator
Catherine Slack	University of KwaZulu-Natal	Co-Investigator
Mkhonzeni Gumede	University of KwaZulu-Natal	Co-Investigator
Purnima Madhivanan	University of Arizona	Co-Investigator
Emily Mudzingwa	University of Connecticut	Co-Investigator
Ingrid Katz	BRIGHAM AND WOMEN'S HOSPITAL	PD/PI

OMB Number 4040-0001
Expiration Date 12/31/2022

APPLICATION FOR FEDERAL ASSISTANCE
SF 424 (R&R)

3. DATE RECEIVED BY STATE	State Application Identifier

1. TYPE OF SUBMISSION*

❍ Pre-application ● Application ❍ Changed/Corrected Application

4.a. Federal Identifier

b. Agency Routing Number

2. DATE SUBMITTED | **Application Identifier**

c. Previous Grants.gov Tracking Number

5. APPLICANT INFORMATION **UEI*:** QN6MS4VN7BD1

Legal Name*: BRIGHAM AND WOMEN'S HOSPITAL
Department:
Division:
Street1*: 75 Francis Street
Street2:
City*: BOSTON
County:
State*: MA: Massachusetts
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: 021156110

Person to be contacted on matters involving this application
Prefix: First Name*: Robert Middle Name: Last Name*: Singleton Suffix:
Position/Title: Senior Grant Administrator
Street1*: 75 Francis St
Street2:
City*: Boston
County:
State*: MA: Massachusetts
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: 02115-6110
Phone Number*: 857-282-1670 Fax Number: Email: rsingleton2@partners.org

6. EMPLOYER IDENTIFICATION NUMBER *(EIN) or (TIN)** 1042312909A1

7. TYPE OF APPLICANT* M: Nonprofit with 501C3 IRS Status (Other than Institution of Higher Education)

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

8. TYPE OF APPLICATION*

● New ❍ Resubmission
❍ Renewal ❍ Continuation ❍ Revision

If Revision, mark appropriate box(es).

❍ A. Increase Award ❍ B. Decrease Award ❍ C. Increase Duration
❍ D. Decrease Duration ❍ E. Other *(specify)* :

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

9. NAME OF FEDERAL AGENCY*
National Institutes of Health

10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER
TITLE:

11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT*
Multi-level school-based intervention to improve HPV vaccine uptake and completion in South Africa

12. PROPOSED PROJECT
Start Date* Ending Date*
07/01/2023 06/30/2026

13. CONGRESSIONAL DISTRICTS OF APPLICANT
MA-007

SF 424 (R&R) APPLICATION FOR FEDERAL ASSISTANCE

14. PROJECT DIRECTOR/PRINCIPAL INVESTIGATOR CONTACT INFORMATION

Prefix: First Name*: Ingrid Middle Name: T. Last Name*: Katz Suffix:

Position/Title: Associate Physician
Organization Name*: BRIGHAM AND WOMEN'S HOSPITAL
Department:
Division: Medicine
Street1*: Women's Health
Street2: 3rd Floor
City*: Boston
County:
State*: MA: Massachusetts
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: 02120-6100
Phone Number*: 617-525-8194 Fax Number: 617-525-7746 Email*: ikatz2@partners.org

15. ESTIMATED PROJECT FUNDING

a. Total Federal Funds Requested*	$912,751.00
b. Total Non-Federal Funds*	$0.00
c. Total Federal & Non-Federal Funds*	$912,751.00
d. Estimated Program Income*	$0.00

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

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

DATE:

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

○ PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW

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

● I agree*

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

18. SFLLL or OTHER EXPLANATORY DOCUMENTATION File Name:

19. AUTHORIZED REPRESENTATIVE

Prefix: First Name*: Robert Middle Name: Last Name*: Singleton Suffix:

Position/Title*: Senior Grants Administrator
Organization Name*: Brigham and Women's Hospital
Department: Research Management
Division:
Street1*: 75 Francis St
Street2:
City*: Boston
County:
State*: MA: Massachusetts
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: 02115-6110
Phone Number*: 857-282-1670 Fax Number: Email*: mghgc@partners.org

Signature of Authorized Representative*
Robert Singleton

Date Signed*
10/25/2022

20. PRE-APPLICATION File Name:

21. COVER LETTER ATTACHMENT File Name:

424 R&R and PHS-398 Specific
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OMB Number: 4040-0010
Expiration Date: 12/31/2022

Project/Performance Site Location(s)

Project/Performance Site Primary Location

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

Organization Name:	BRIGHAM AND WOMEN'S HOSPITAL
UEI:	QN6MS4VN7BD1
Street1*:	75 Francis Street
Street2:	
City*:	BOSTON
County:	
State*:	MA: Massachusetts
Province:	
Country*:	USA: UNITED STATES
Zip / Postal Code*:	021156110
Project/Performance Site Congressional District*:	MA-007

Project/Performance Site Location 1

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

Organization Name:	University of Connecticut
UEI:	WNTPS995QBM7
Street1*:	2006 Hillside Road
Street2:	Unit 1248
City*:	Storrs
County:	
State*:	CT: Connecticut
Province:	
Country*:	USA: UNITED STATES
Zip / Postal Code*:	062690000
Project/Performance Site Congressional District*:	CT-002

Funding Opportunity Number: PAR-22-173. Received Date: 2022-10-25T15:38:13.000-04:00

Project/Performance Site Location 2

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

Organization Name:	University of Arizona
UEI:	ED44Y3W6P7B9
Street1*:	125 North Martin Avenue
Street2:	PO Box 245209
City*:	Tucson
County:	
State*:	AZ: Arizona
Province:	
Country*:	USA: UNITED STATES
Zip / Postal Code*:	857245209
Project/Performance Site Congressional District*:	AZ-002

Project/Performance Site Location 3

❍ 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:	CONFIDENTIAL INFORMATION - REQUESTER IN AGREEMENT
UEI:	
Street1*:	
Street2:	
City*:	Scottsville, Pietermaritzburg
County:	
State*:	
Province:	
Country*:	ZAF: SOUTH AFRICA
Zip / Postal Code*:	3209
Project/Performance Site Congressional District*:	00-000

Additional Location(s) File Name:

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

RESEARCH & RELATED Other Project Information

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

1.a. If YES to Human Subjects

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

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

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

IRB Approval Date:

Human Subject Assurance Number 00000484

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

2.a. If YES to Vertebrate Animals

Is the IACUC review Pending? ❍ Yes ❍ No

IACUC Approval Date:

Animal Welfare Assurance Number

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

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

4.b. If yes, please explain:

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

4.d. If yes, please explain:

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

5.a. If yes, please explain:

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

6.a. If yes, identify countries: South Africa

6.b. Optional Explanation:

	Filename
7. Project Summary/Abstract*	Project_Summary.pdf
8. Project Narrative*	Project_Narrative.pdf
9. Bibliography & References Cited	References.pdf
10.Facilities & Other Resources	Facilities_and_Other_Resources_rev.pdf
11.Equipment	Equipment.pdf
12. Other Attachments	Foreign_Justification.pdf Milestone_Plan.pdf Stakeholder_Engagement_Plan_.pdf Future_Clinical_Trials_Description.pdf Future_Clinical_Trials_References.pdf

Funding Opportunity Number: PAR-22-173. Received Date: 2022-10-25T15:38:13.000-04:00

PROJECT SUMMARY

Human Papillomavirus (HPV) is the most common sexually transmitted infection globally, and is causally linked to cervical, anogenital, and oropharyngeal cancers. HPV-associated cancers have a disproportionate impact in low-resource settings and nowhere is this evident than in South Africa, which has a uniquely vulnerable population due to the convergence of the largest HIV epidemic globally, with HPV rates of up to 85% in young women under the age of 25. ***Cervical cancer is the leading cause of cancer-related mortality among women in South Africa.*** In 2014, the South African National Department of Health implemented a national, school-based HPV immunization program. Despite a promising start, vaccine coverage and dose completion rates dropped precipitously after 2014, with only 37% of girls receiving their first dose in 2021. Recent declines have been attributed to COVID-related program interruptions, increased medical mistrust, and vaccine hesitancy related to misinformation spread on social media. There are additional critical gaps in care – specifically boys who are ineligible for this program, as well as adolescents outside the public school system. There is an urgent need to identify effective, replicable, and scalable strategies to optimize HPV vaccine uptake and completion in school-age children. The **overall objective** of the proposed R34 is to refine and evaluate a school-based multi-level communications strategy that addresses intrapersonal, interpersonal, and institutional factors associated with HPV vaccine uptake and completion amongst fifth graders, as part of a pilot feasibility trial. The proposed study is led by investigators from the United States and South Africa in partnership with the Department of Health and elementary schools in an urban setting with high burden of HPV vaccine preventable cancers in KwaZulu Natal, South African. The project builds upon our team's expertise in HPV prevention, vaccine decision making, health communications, participatory design, and community engagement to pursue the following Specific Aims. **(1) To refine components of a school-based multi-level communication strategy to improve HPV vaccine uptake and completion among girls and boys, and (2) To evaluate preliminary effects of the communications strategy and key criteria to advance to a full-scale hybrid type 2 trial.** Our systems-focused approach leverages established partnerships with area schools serving diverse populations who are not always effectively served by traditional healthcare channels. We will ensure *health equity is at the core of our research* integrating the voices of individuals living in low-resource settings to understand and reduce the barriers to HPV vaccine initiation and completion. This proposal is responsive to NCI's call for cancer prevention and control clinical trials planning grants (PAR-22-173) both in its active stakeholder engagement, and its focus on engaging a diverse, scientifically appropriate study population.

PROJECT NARRATIVE

The proposed study will refine and evaluate components of a school-based multi-level communications strategy that addresses intrapersonal, interpersonal, and institutional factors associated with HPV vaccination uptake and completion. Participatory methods and community engagement are foundational to the approach. Achieving the goals of this project has the potential to inform the South African Integrated School Health Programme regarding effective strategies to promote uptake and completion of HPV vaccine amongst girls and boys and provide an approach that is replicable in other low- and middle-income settings where the burden of HPV-associated cancers is high.

FACILITIES AND RESOURCES

BRIGHAM AND WOMEN'S HOSPITAL

Overview. Brigham and Women's Hospital (BWH) and Massachusetts General Hospital (MGH) are the founding members of Mass General Brigham, a not-for-profit integrated delivery system. BWH and MGH are major teaching affiliates of Harvard Medical School. Both are well-respected leaders in tertiary and quaternary care and have consistently been named among the country's best hospitals by U.S. News and World Report. Over the last ten years, BWH has been either the largest or second largest non-university recipient of research funding from the National Institutes of Health (NIH).

The Department of Medicine at BWH has a rich tradition of fostering a collaborative research environment designed to tackle the world's most challenging diseases. Particular research strengths in the department include clinical research involving disease-oriented research, patient-oriented research and population science. The department's current activity accounts for approximately 67% of total BWH research activity. With over 1000 active projects among the more than 700 active research faculty and fellows, the department currently has over $400 million in committed direct research funding through 2015. The department currently utilizes over 445,000 net assignable square feet of research space both onsite and offsite.

The Division of Women's Health

The Division of Women's Health is based within the Department of Medicine at BWH. The Division works with faculty across divisions and departments to develop initiatives that support scientific discovery pertaining to sex and gender differences in health and disease, and to speed the translation of sex-based research into clinical care. Led by Dr. Rexrode, the Division builds upon its experience developing integrated models of care and multidisciplinary research efforts across specialties to advance the hospital's goals of cutting-edge innovation and discovery; to provide seamless, high-quality and affordable patient-centered care; and to develop the next generation of leaders in medicine.

The Division of Women's Health has a mission to conduct research and programming to eliminate disparities in health and health care delivery globally, particularly as they relate to women's health. Within the Division, Dr. Katz has been part of the Global Women's Health Program, a collaborative initiative with The Harvard Humanitarian Initiative, The Harvard Global Health Institute, and The Harvard School of Public Health, that has a core mission of improving the lives and well-being of women world-wide. She currently serves on the faculty of the Division and provides mentorship and leadership through a Global Women's Health Research retreat, which brings fellows and junior faculty together with senior mentors to encourage support for global health research.

The Mary Horrigan Connors Center for Women's Health and Gender Biology *is a cross-departmental Center at BWH and HMS, started in 1997 as a joint effort between the Departments of Medicine and Obstetrics and Gynecology to ensure that research and clinical expertise extended beyond maternal health to focus on women's health and sex differences more broadly. Endowed in 2002, the Center is the leading entity for women's health and sex-differences activities across BWH and HMS with longstanding broad philanthropic support from community advocates.* Led by Dr. Joffe, the Connors Center serves as a hospital-wide resource to train, advance, and support women's health investigators by using a multidisciplinary approach and providing opportunities for career enhancement for faculty and trainees. The proposed project will be based within the administrative space assigned to the Connors Center and will utilize Connors Center computers, administrative office equipment, and meeting spaces.

Clinical:

Founded in 1832, Brigham and Women's Hospital is a 793-bed teaching affiliate of Harvard Medical School, with approximately 46,000 annual inpatient admissions and 3.5 million outpatient visits. Along with its modern inpatient facilities, BWH boasts extensive outpatient services and clinics, neighborhood primary care health

centers, and state-of-the art diagnostic and treatment technologies. BWH has been ranked on US News and World Report's Honor Roll of America's best hospitals for 23 consecutive years.

Office Resources: With over 42 locations, research at BWH is conducted in over 700,000 square feet of space located throughout the greater Boston area. The Connors Center occupies office space in Boston, Massachusetts within the BWH main hospital campus. The Center provides private office space for all faculty and administrative leadership, a multi-media conference room for meetings and teleconferences, and modular space to accommodate visiting faculty and scholars. Dr. Katz has a private office, a phone, a personal computer, a printer, and access to copier and scanning service.

Computer Resources: All BWH facilities have full computer support, including Excel and Access for clinical work and clinical research, all of which are networked and supported through the BWH hospital-wide computer system. The network is connected to the Partners HealthCare System network, with access to inpatient and outpatient clinical information, World Wide Web, and electronic mail. Security is maintained at the same level as is required for the hospital’s confidential patient data. The SAS statistical package and Microsoft applications are available to researchers. All Harvard faculty, including BWH researchers, have access to Geographic Information.

Library Resources: With a position at Harvard Medical School, Dr. Katz has full access to the Francis A. Countway Medical Library, one of the largest medical libraries in the world, combining the resources of the Harvard Medical School, Harvard T. Chan, Harvard School of Dental Medicine, the Boston Medical Library and the Massachusetts Medical Society. The Countway library holds 630,000 volumes, subscribes to 3,500 current journal titles and retains 10,000 non-current medical journals. Dr. Katz will also have access to Countway research librarians. The library is conveniently located one block away from Dr. Katz’s office.

CONFIDENTIAL INFORMATION - REQUESTER IN AGREEMENT

CONFIDENTIAL INFORMATION - REQUESTER IN AGREEMENT aspires to be the "Premier University of African scholarship" and is located in the CONFIDENTIAL INFORMATION - REQUESTER IN AGREEMENT When compared to all 26 South African universities, UKZN ranked first in terms of research output and is one of only three South African universities consistently listed in the World's top 500 universities, ranking between the 6 h and 9th top university in Africa by different agencies.

CONFIDENTIAL INFORMATION - REQUESTER IN AGREEMENT

antibiotic resistance project. UKZN is probably one of the largest holders of US federal grants in Africa. -

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Drs Munro and Gumede are based in the **School of Applied Human Sciences** which is located in the College of Humanities at UKZN. The School is led by the Dean, Prof Matoane, and houses the Disciplines of Psychology; Culture, Communication, and Media Studies (CCMS); Social Work; and Criminology and Forensic Studies. The School has 57 academic/faculty members of staff based across two campuses (Howard College and Pietermaritzburg) and registers around 9% of all students registered at UKZN. The School has over 600 graduate students registered at honors, masters, and doctoral levels, and graduate students produce dissertations in the range of applied human sciences including health communication, health research ethics, and behavioral change. The school also hosts a new NIH-funded doctoral PhD program in health research ethics leadership. Staff and students in the School engage in interdisciplinary research, teaching, and learning with staff and students in the UKZN College of Health Sciences. The School has, and continues to hold, many competitive grants including the CHVI HIV/AIDS Vaccine Ethics Group (HAVEG) and the NIH-funded South African Research Ethics Training Initiative (SARETI) (two ongoing grants currently held, one continuously since 2002).

Resources. Office resources: UKZN provides its academic and research staff with well-equipped office space. Staff in the School of Applied Human Sciences make use of offices in the Psychology Building on the Pietermaritzburg campus and the Memorial Tower Building on the Howard College campus. Both buildings have multi-media conference room facilities for large group meetings and teleconferences, and Drs Munro and Gumede both have private offices, personal computers, telephones, and access to printers. The Pietermaritzburg building has a dedicated Research Projects wing which houses several externally funded projects and has a well-equipped seminar room for online and virtual meetings and seminars.
Computer resources: All UKZN staff are provided with computers and information and technology support from Information and Communication Services (ICS). The university provides staff and students with institutional access to a full range of computer applications including MS Office suite, Adobe, the World Wide Web, as well as access to and technical support for a range of academic software (e.g., SAS, SPSS, NVIVO, Endnote).
Library resources: There are five physical UKZN libraries which UKZN staff have access to. UKZN also subscribes to a wide range of electronic academic databases electronic journal subscriptions and e-books which students and staff are able to access through their institutional log in.

Research Office. UKZN has a well-established Research Office which is dedicated to supporting external research grants and grantholders with financial and administrative support. The UKZN Research Office has extensive experience managing NIH and other grants, houses three research ethics committees, one of which has Federal-Wide Assurance (assurance number 678, Institution number IORG 0000923 and IRB number 00001293).

Institute for Collaboration in Health, Intervention, and Prevention (InCHIP), University of Connecticut

Overview. InCHIP is a multidisciplinary research center dedicated to the study of the dynamics of health risk behavior and the processes of health behavior change in individuals and targeted at-risk populations. A number of InCHIP researchers design, implement, and evaluate theory-based, but highly practical interventions to change unhealthy behaviors. InCHIP currently has a portfolio of approximately $50.6 million in active external funding, across all years, devoted to health behavior research. More than 250 InCHIP affiliated faculty members, at the UConn and other institutions, perform such research.

Resources. To foster the development and dissemination of new knowledge and theory-based state-of-the-art health behavior change interventions, the Institute provides to its PIs, professional research staff, and graduate students: access to exceptional facilities; cutting-edge information technology resources; assistance identifying funding opportunities and assembling multidisciplinary teams to respond to proposals; consultation in statistics and methodology; expert pre-submission reviews of external grant applications; opportunities to compete for internal funding to support pilot projects, grant writing, and other scholarly activities; consultation in dissemination and implementation of proven interventions; exceptional pre- and post-award grants management services; a bi-weekly lecture series that brings to InCHIP nationally- and internationally-renowned health researchers from a variety of disciplines; and more.

Supporting its multidisciplinary research, InCHIP's 15,000 square foot facility houses more than 55 faculty, post-docs, research associates, and graduate students from a wide variety of disciplines including Allied Health, Anthropology, Communication Science, Geography, Human Development and Family Studies, Kinesiology, Nursing, Nutritional Sciences, Psychology, Sociology, Statistics, and related fields. InCHIP's ability to support so many health researchers and their teams in a single building greatly facilitates interdisciplinary collaboration.

InCHIP's dedicated research space in the Ryan Building in Storrs, CT, includes a focus group room, a lab and observation room, a video control room, 10 small interview rooms, and 3 conference rooms that can be outfitted for small group research. Advancing InCHIP's mission to promote collaboration and dissemination of its research, its facility in Storrs also includes a large, long-distance learning media classroom that seats up to 60 people for the InCHIP Lecture Series; supports real-time webcasting to computers worldwide; and can be reserved for large research projects. In addition, in Storrs InCHIP provides conference spaces for research meetings and presentations that are outfitted with advanced multimedia equipment and, because InCHIP's extramural funding is increasingly international in scope, InCHIP provides international video and phone conferencing capability, using Skype, Microsoft Lync 2013 (video and audio), and site-to-site audio/video conferencing equipment. Both Skype and Lync are accessible to InCHIP's collaborators worldwide, as these technologies require access only to a computer and the Internet and do not require costly, specialized equipment. Videoconferencing is very time- and cost-effective as it minimizes travel and permits rapid and effective communication and decision-making among individuals at multiple sites simultaneously. Equipment that InCHIP makes available for meetings and presentations includes LED projectors, Polycom Soundstation pods, Skype Speakerphones (USB), high-definition digital camcorders, and more. This equipment can also be used to facilitate the dissemination of breaking research findings and the provision of training in interventions developed at InCHIP to individuals at remote international sites, such as InCHIP's clinical partners in Africa.

In addition to our facilities in Storrs, InCHIP has research space at 1 Constitution Plaza in Hartford, CT, located a few miles from Hartford Hospital which will be conveniently located for access by minority, low income, and urban research participants who can attend research appointments using public transportation.

InCHIP has a collaborative arrangement with UConn Digital Media Center which provides design expertise to researchers interested in developing and using interactive technologies to expand their research capabilities. Interactive media applications available include animations, web-based 3D interactive graphics, and Virtual Reality (VR) environments and simulations. The Digital Media Center can develop research stimuli, which can test health behavior change hypotheses in immersive virtual settings, perform health behavior change interventions, and collect intervention outcome data, and the Digital Media Center also does work on phone app development. UITS at UConn also provides services for the development of apps.

InCHIP also has a small onsite library that provides convenient access to InCHIP's health behavior resources and electronic research media. Additionally, InCHIP researchers, students, and staff members have access to the UConn Library and interlibrary loan.

To enable InCHIP researchers to work more efficiently and cost-effectively, InCHIP provides its PIs with dedicated support from 10 onsite professional staff members, who have expertise in Information Technology, pre- and post-award financial management, human resources, communications and information dissemination, and a range of other administrative services.

Information Technology Support. Consistent with its mission, InCHIP offers advanced information technology resources to support the development of theory-based knowledge and cutting-edge, technology-driven health behavior change interventions, including:

1. Virtual machine services, which allow researchers to host server-based interventions, have access to centralized data collection services, and explore new innovations in information technology to supplement their research objectives.
2. Virtual PC Services, which allow researchers and their computers to have easy access to InCHIP network resources from virtually anywhere in the world;
3. Highly-dynamic web-based survey technology;
4. Access to Audio-Computer Assisted Interviewing (ACASI) data collection methodologies and technical support;
5. A variety of statistical software packages.

InCHIP's in-house IT consultants are responsible for maintaining and repairing computer equipment, administering the InCHIP datacenter, and directing all IT-driven research initiatives. InCHIP's IT consultants are available onsite to provide researchers with immediate technical assistance as needed, design information systems, translate health behavior change research objectives into IT system requirements, provide project management support, purchase IT equipment, implement data protection and security, and review IT aspects of grant applications for feasibility and for budgetary purposes.

Significant care is taken to ensure the safety and security of sensitive data within InCHIP's computer network. All servers and workstations are behind a network firewall, which restricts access to the computers from outside of the CHIP network. Server and workstation machines are protected using Microsoft Forefront Endpoint Protection (MFEP) and Windows Server Update Services (WSUS). InCHIP research data is protected using a multi-layered approach. Multiple short- term disk-based storage solutions are in place. One is located in our data center and the other is housed offsite in a separate building on campus. This provides safe, secure, and fast recovery of data. In addition to that storage is our Dell Tape library for longer term storage and archiving. Locally, we have a tertiary storage array for creating images of servers and data. The final layer of protection is the snapshot system that is built into our Equillogic Storage Area Network (SAN). InCHIP's recent expansion of server virtualization technologies has also reduced the costs of IT equipment, co-location, cooling, and energy. At the workstation level, we have implemented network-wide Bitlocker to secure hard drives and prevent data theft.

InCHIP's website effectively links researchers, students, and the community to InCHIP resources and events; provides a venue for affiliates to disseminate their research and intervention materials; and extends InCHIP's international reach. Included on the InCHIP website is a Digital Library that provides access to the InCHIP Lecture Series and scholarship tools developed at InCHIP.

The University of Arizona (UA)

Overview. The UA is the leading public research university in the American Southwest and is an ideal interdisciplinary academic community for the proposed project. UA is a land grant public university and has a 387 acre campus in Tucson, Arizona. The campus includes 159 buildings on the main campus and 25 buildings at the adjacent Health Sciences Center. With close to 40,000 students and 21 Colleges, the UA provides an amazing environment for interacting with students, faculty and researchers from many diverse disciplines. The University's commitment to research was recognized by its ranking from the National Science Foundation as 19th among public universities in the United States for research. The UA is one of 63 members of the prestigious Association of American Universities and has over $625 million in annual research funding.

The university is comprised of 21 colleges, one branch campus in Sierra Vista, and has expanded over the last few years in its colleges of Medicine, Pharmacy and Public Health to downtown Phoenix. The UA also has two supporting colleges—Honors and Outreach—and 76 research centers. More than 345 undergraduate, graduate and professional degree programs are offered on a semester schedule. Educational programs designed to meet the demand for virtual, hybrid, and distance offerings, are added, coordinated, and managed through the Outreach College.

The Arizona Health Sciences Center (AHSC). The AHSC is a 48 acre complex adjacent to the UA. It includes the Colleges of Medicine, Nursing, Pharmacy, Public Health, the University Medical Center and 11 other specialty centers officially recognized by the Arizona Board of Regents. The AHSC enrolls 665 medical students in Tucson and Phoenix; more than 500 undergraduate, graduate and post-graduate nursing students; more than 30 PharmD and graduate level students in the pharmaceutical sciences; and 324 undergraduate and graduate public health students. The AHSC is a major economic engine for the state and during fiscal year 2010, generated almost $154 million in research grants and contracts.

Libraries. The University of Arizona offers several libraries on campus. Two of these libraries, the Main library and the Arizona Health Sciences Library serve the Arizona Health Sciences Center. The Main Library houses extensive collections in the social sciences, humanities, fine arts, education and business as well as media, maps and government documents. The complete holdings of the University Libraries are accessible through the library's online catalog and contain almost 7,000,000 items, displaying 4,000 plus periodicals, books, microforms, maps, government publications, manuscripts and non-book media.

The AZHSC library meets the needs of the colleges of Medicine, Nursing, Pharmacy, and Public Health, and the health-related Internship graduate programs as well as the University of Arizona Medical Center. The AHSC Library, located within the University Medical Center, contains the state's largest collection of health information resources and is open 24 hours a day to UA employees and students. This AZHSC library contains over 212,000 volumes and receives approximately 2,100 periodicals and serial publications. The collection includes books, journals, audiovisuals, electronic resource, and other materials in the health sciences as well as online journals. The University Libraries maintain a membership to BioMed Central which enables all UA faculty and researchers to publish in nearly 200 open access journals at no cost. Major databases available to faculty in the health sciences and social sciences include PubMed, Web of science, MDConsult, UpTo Date and Cochrane.

The Arizona Health Sciences Library of the University of Arizona seeks to improve health by providing quality information to advance education, research, and patient care in Arizona and the Southwest. It is an important partner in the University of Arizona health Sciences Center and provides the following core services:

- Provides electronic access to vast stores of biomedical literature.
- Maintains the Liaison Librarian program, providing on-site librarians in the Nursing, Pharmacy, and Public Health colleges.
- Participates as instructors in the curriculum in the four colleges of AHSC and collaborates with faculty to develop innovative curricula that foster information literacy.
- Shares expertise in information management and works in partnership with faculty, students, researchers & clinicians to advance learning and facilitate research projects.

- Provides document delivery of journal articles and books outside the library's collection that is timely and cost effective.
- Assists Arizona health professionals, public libraries, the Health department and community groups with reference and information seeking.
- Provides comfortable space for small group collaboration and quiet studying in a collegial atmosphere.

The Mel and Enid Zuckerman College of Public Health (MEZCOPH). The Mel and Enid Zuckerman College of Public Health (MEZCOPH) is one of the newest colleges established within the University of Arizona. Located within the 103,000 square-foot Drachman Hall building, MEZCOPH instructional space includes three lecture halls, two distributed learning classrooms, five interactive learning classrooms and a computer instruction classroom. Drachman Hall is also home to all administrative and support offices, academic divisions and research programs for the College. It also offers work areas and offices for faculty, students, academic professionals and staff. The College awards Masters of Public Health (M.P.H.) and/or Master of Science (M.S.) degrees in Biostatistics, Environmental and Occupational Health, Epidemiology, Family and Child Health, Health Behavior and health Promotion and Public Health Policy and Management as well as a Public Health Certificate. Additionally, The College also awards Ph.D. degrees in both Biostatistics and Epidemiology and a DrPH degree.

[redacted]

The College has an established track record of supporting interdisciplinary research. Many faculty are involved with teaching and research activities throughout the University of Arizona, including, but not limited to, the Graduate Interdisciplinary Program in Statistics, the BIO5 institute, the Arizona Respiratory Center, and the Arizona Cancer Center. Such collaborations are evidenced by collaborative research awards. During FY2010-2011, more than $5.5 million was awarded to outside departments for MEZCOPH faculty in a leadership, co-investigator or support role (e.g. Arizona Cancer Center, Arizona Respiratory Center, College of Medicine/Department of Pediatrics, College of Engineering/Mining and Geological Engineering, College of Medicine/Department of Surgery, College of Agriculture and Life Sciences/Department of Nutritional Sciences, College of Nursing, etc.).

The College has several centers, laboratories, and institutes that carry out research and service activities. These include:

- Arizona Center for Rural Health
- Arizona Prevention Research Center
- Arizona Public Health Training Center
- Canyon Ranch Center for Health Promotion and Prevention
- Center of Excellence in Women's Health
- Clinical Research Training Program
- Healthy Aging Laboratory
- Maternal and Child Health Epidemiology Training Program
- Maternal and Child Health Training Program

Computing. MEZCOPH's computing infrastructure is built upon 10 servers running Windows 2003 and Windows 2008. These servers are used for a variety of purposes including web hosting, database management, file sharing, authentication, virtual private networking (VPN), network printing, and other special project specific applications. Servers used for production use are housed in the data center of the Computer Center building. These are monitored and backed up by the staff of the university's central information technology unit, UITS. The campus network is protected by a perimeter firewall and the MEZCOPH network within the campus network is further protected by another firewall. Access to MEZCOPH computing resources from outside the physical spaces allocated to the college requires a virtual private network encrypted connection. Business continuity

support is provided via a replicated data center approximately seven miles from the main campus location. Development and test servers are located in Drachman Hall, home of MEZCOPH.

In Drachman Hall, a computer lab used for training and public health specific instructional needs, is equipped with 21 Windows computer stations and is available solely for use by MEZCOPH faculty, students and staff. Additional student access to computing technology is facilitated through the Arizona Health Sciences Center's library. These facilities provide students with access to special technologies, such as multimedia equipment and special software, along with local and Internet resources. Also, UITS and the Integrated Learning Center, on the main campus, provide similar access to computing labs and resources. A 24/7 help desk is available for technical support.

Classrooms in Drachman Hall are all equipped with projection equipment attached to the speaker's podium that contains a computer, an overhead ELMO projector and other media players. Three of the classrooms are videoconference capable and are able to have real time conferencing with other external locations that are videoconference capable. Portable videoconferencing units are also available for use in conference and meeting rooms.

The IT office is staffed by a Director, a Web Program Manager, a Web Designer/Developer, a Senior IT Support Analyst and an IT Support Analyst. The director has been in the IT industry for over 30 years mainly in higher education and healthcare settings and has been at MEZCOPH for over 10 years. The Web Program Manager is responsible for the web based applications and technologies used in the college along with project management. He has been working in information technology for ten years and has an MBA. The Web Developer/Designer is responsible for the design of the websites and keeping the content of the websites up to date. The IT Support Analysts are responsible for client, desktop, server and network support.

Office. Currently, MEZCOPH conducts business from nine locations in the Tucson and Phoenix metropolitan areas. Allocated and leased space assigned to the College totals at 44,219 net square feet (nsf). The primary location for instruction, administration, meeting and faculty/staff office space is the assigned 18,571 nsf in the Drachman Hall facility (Bldg. 202) located in Tucson.

Arizona Center for Rural Health: For over thirty years, the Center for Rural Health (CRH, formerly the Rural Health Office) has served the state through its mission to improve the health and wellness of Arizona's rural populations. The Center houses the State Office of Rural Health (SORH), the Rural Hospital Flexibility Program (Flex), and the Small Hospital Improvement Program (SHIP). The CRH is funded in part by the state of Arizona, the Office of Rural Health Policy (OHRP), Health Resources & Services Administration (HRSA), and U.S. Department of Health and Human Services (DHHS).

The CRH links community health centers (FQHC's), county and state public health departments, 638 tribal and Indian Health Service hospitals and clinics, Critical Access Hospitals, Emergency Medical Services (EMS) and others. CRH collaborates with individuals, organizations and communities and provides direct technical assistance to increase health insurance coverage, improve access to quality health care, conduct activities to prevent disease and promote health, and build long-term partnerships to decrease health disparities in underserved and rural communities and populations.

The CRH performs research aimed at improving rural health care outcomes, quality, and safety. It analyzes and translates data to inform policymakers, legislation and regulation related to rural health care financing, delivery and sustainability. The CRH serves rural communities through: (1) collecting and disseminating information within the state, regionally, nationally and internationally; (2) providing technical assistance to community partners and providers; (3) coordinating rural health interests statewide; (4) training, recruiting and retaining health professionals for practice in rural and underserved areas; and (5) partnering to improve rural health outcomes, (6) helping FQHC's, Critical Access Hospitals and other providers adapt to the rapidly changing health system to provide quality care to rural populations; (7) identifying and addressing the unmet needs of populations living in rural areas and U.S.-Mexico border communities.

The Arizona Prevention Research Center (AzPRC): The AzPRC is one of 37 Prevention Research Centers funded by the Centers for Disease Control, partners with communities to improve the health and well-being of

people living in US-Mexico Border communities through research, training, advocacy and policy change. Through shared leadership with a Community Action Board of organizational and community members, the center has a set of interrelated projects to: 1) advance health in border communities; 2) reduce ethnic disparities in health; 3) promote the Promotores model for health promotion; 4) study chronic disease interventions with border partners; and, 5) interrelate these activities with community development and advocacy of systems or policy change. The AzPRC has produced a research tested promotora-delivered community-based program, *Pasos Adelante*, shown effective in reducing risk for diabetes and other chronic diseases on the border and disseminated by the CDC. In 2014 the center is also leading the second National Community Health Worker Advocacy Survey to assist in the evaluation of the center's research impact and to contribute to workforce development considering opportunities for sustainability and scalability due to the Affordable Care Act and related state-level policy initiatives.

Arizona Public Health Training Center, AzPHTC: The mission of the Arizona Collaborative Public Health Training Center (AzPHTC) is "to assess, develop and deliver responsive competency-based training to current and future public health professionals, community leaders and community partners through community engagement, education and training activities that strengthen the public health infrastructure." The vision of the AzPHTC is "to have a strong collaborative public health network and public health workforce that collectively works towards the development of healthy communities in Arizona and the Southwest region." In order to accomplish our mission and to reach our vision, the AzPHTC will work with the public health workforce that provides services in rural/frontier areas, to members of Native American Tribes, to communities along the US-Mexico border, and to underserved populations in Arizona's major metropolitan areas, all of which have significant portions of their populations that are underserved and whose workforce has limited access to public health training.

Canyon Ranch Center for Health Promotion and Prevention: The Canyon Ranch Center for Prevention and Health Promotion (CRCPHP) is an integrated center for health scientists engaged in clinical or population-based research to promote improvements in health. As a Level 1 Center of The University of Arizona, the CRCPHP is dedicated to helping people achieve and maintain healthy lives by providing a variety of opportunities that facilitate and support growth in all aspects of health and well-being: physical, social, mental, spiritual, environmental, and emotional. The primary focus of the Center's research efforts is enhancing health through diet/nutrition and physical activity interventions. CRCPHP investigators bring a broad range of expertise to health promotion research including, but not limited to, diet and physical activity interventions for the prevention and treatment of obesity, cancer and cancer survivorship, cardiovascular disease, and diabetes. Additionally, CRCPHP engages in health literacy initiatives, community-based interventions, health as well as diet and physical activity assessments, wellness/health registry, behavioral coaching, study design, study participant recruitment including diverse representation in intervention research and program evaluation. Under the direction of Cyndi Thomson, PhD, Director and Professor, CRCPHP offers faculty researchers opportunities to collaborate and identify support services.

The CRCPHP is also a vital link providing training and research opportunities to students at the undergraduate, graduate, and post-graduate levels. Because of the CRCPHP's multifaceted approach encompassing research, community engagement, and training, students can establish relationships that best meet their academic goals, including advisor, mentor, preceptor, support for proposals and publications, and evaluator.

The center is located at UA Health South Campus – Abrams Building, 3950 S. Country Club. It includes over 12,000 square feet of research space. Services and equipment include: phlebotomy services and biosample processing (centrifuge, - 80 freezer, refrigerator (urine)); integrated computer, web-based, multi-media counseling program; DXA Scans; treadmills; accelerometers; validated questionnaires and related data capture software. The campus also includes training/meeting rooms and a demonstration kitchen.

Center of Excellence in Women's Health: The mission of the Center of Excellence in Women's Health is to improve the health and wellness of women throughout the lifecycle, with an emphasis on underserved girls and women. The Center has as its core values to implement programs and conduct research that is girl/woman-centered, culturally competent, linguistically accessible, evidence-based and cost-effective. Our goal is to deliver

programs that take a life course approach to the health of girls and women and that are responsive to the context of their lives. Activities of the Center include clinical trials and community-based research and service.

Clinical Research Training Program: The Clinical and Translational Research training program is an official UA graduate certificate program. Originally funded by an NIH K30 grant, it is now an integral part of the clinical and translational research training at the College of Public Health and for the Arizona Health Sciences Center. Dr. Duane Sherrill, was the PI on the original grant, and Dr. Zhao Chen is now the program director. The mission of the Clinical and Translational Research graduate certificate is to educate those with advanced graduate degrees (MDs, PharmDs, PhDs, etc.) in the multidisciplinary principles, methods, and techniques of clinical research and to provide them with the tools necessary to become independently funded clinical researchers, who will contribute to the advancement of biomedical science and health care. The 12-unit curriculum consists of four graduate-level courses: one course in epidemiology, two courses in biostatistics, and the final course is an elective appropriate to the scholar's career-development needs. The first group of scholars entered the program in June 2001. Since then, thirty-three scholars have received their certificates of completion. The impact of the Clinical and Translational graduate certificate can best be measured by looking at the funding history of the scholars who have completed the program. Since the program's inception, mechanisms of support for scholars' research projects have come from a variety of sources including: NIH K01, K08, K23, and T32 awards; Health Resources and Services Administration; Arizona Disease Control Research Commission; American Academy of Family Physicians Advanced Research Training Grant; American Thoracic Society; Cancer Research Foundation of America; Pharmaceutical Research and Manufacturers of America; the UA Graduate Medical Education Awards Program; the UA Faculty Small Grant Program; and the College of Medicine Dean's Physician-Scientist Career Development Award. Many of the scholars who have completed the program are also now leaders on the UA campus. For example, select roles include the Department Head and Director of Emergency Medicine; Department Head of Pharmacy Practice and Science; and Director of Infectious Disease Research at BIO5 Institute.

Healthy Aging Laboratory: The Healthy Aging Lab strives to promote healthy aging and to reduce health disparities in older adults from different racial/ethnic backgrounds through innovative biomedical research. Under the direction of Professor Zhao Chen, this epidemiologic research laboratory investigates causes, consequences, and effective interventions for common health conditions in older people. Ongoing studies in the lab focus on similarities and differences in etiologies (including investigating genetic and biomarker associations) and health impact of multiple chronic diseases and conditions, such as osteoporosis (low bone mass and high fracture risk), sarcopenia (low skeletal muscle mass and strength), and anemia (low hemoglobin level) across different racial/ethnic groups of older women. Many of our studies are done in collaboration with national and international study consortiums. The Healthy Aging Lab is situated in a state with a large and racially/ethnically diverse elderly population. The nationwide impact and local relevance of our research has attracted many students, including Native American, Hispanic, African American, and Asian graduate students. With an aim of a comprehensive understanding on the interrelations of osteoporosis, sarcopenia and anemia, our research makes significant contributions to the better overall health of the older adults.

Maternal & Child Health Epidemiology Training Program, HRSA: Populations in isolated Indian Health Service regions and Appalachian counties have disproportionately worse maternal and child health (MCH) outcomes than national averages. Public health professionals serving these populations have identified the need for training in MCH epidemiology. To increase the capacity in MCH epidemiology of health workers serving in rural, isolated, and underserved Indian Health Service regions and Appalachian counties, this project will develop and implement a 154-credit online Graduate Certificate in MCH Epidemiology, using innovative internet technologies and delivery approaches that surpass the face-to-face classroom experience.

Maternal and Child Health Training Grant: MEZCOPH is one of 13 Schools of Public Health awarded funds for five years by the Health Resources and Services Administration's Maternal and Child Health Bureau (MCHB). The goal is to develop the future and current workforce in MCH. Activities include matching six to 10 MCH graduate students with a faculty mentor through graduate assistantships; professional development activities for junior faculty such as monthly development lunches, grants writing course, manuscript review, and mentoring;

and capacity building with community-based agencies by offering accessible trainings in partnership with the Arizona Public Health Training Center.

University of Arizona Cancer Center (UACC). Founded in 1976, the University of Arizona Cancer Center is a Center of Excellence in University of Arizona Health Sciences. Its mission is to prevent and cure cancer. The Cancer Center is one of 49 comprehensive cancer centers in the nation and the only one headquartered in and serving the entire state of Arizona that has been designated by the National Cancer Institute (NCI) as a Comprehensive Cancer Center, the NCI's highest designation. That designation is reserved for centers focusing on patient care as well as basic and clinical research, prevention, education, outreach and training.

The Cancer Center has NCI Specialized Program of Research Excellence (SPORE) grants for both gastrointestinal cancers and lymphatic cancers. The UACC is a leader in research on women's cancers (breast, ovarian), men's cancers (prostate), gastrointestinal cancers (colon, pancreas and liver), lymphoma, and skin cancers and is home to one of the largest Cancer Prevention and Control Programs among the nation's comprehensive cancer centers, with leading prevention research in breast, colon, lung, prostate and skin cancers. With primary locations at the University of Arizona in Tucson and St. Joseph's Hospital and Medical Center in Phoenix, the Cancer Center has more than a dozen research and education offices throughout the state and affiliate sites in Mexico and Colorado. The UACC-North Campus is the Cancer Center's main cancer clinic in Tucson.

The 82,000-square-foot UACC — North Campus has state-of-the-art equipment and highly specialized professionals to diagnose and treat cancer patients. The UACC's 75 research labs and more than 300 nationally and internationally renowned physician and scientist members work to bring the power of research to cancer prevention and treatment through a direct link between the latest research discoveries and patient care. Annually, over 7,200 cancer patients are seen through UACC clinics and over 2,700 of them are new patients. The translational research performed by UACC investigators basic science and translational cancer research has resulted in the development of at least 17 bio-technology and pharmaceutical companies, mostly in Arizona. Biotechnology companies include: Ventana Medical Systems, Cancer Technologies, DeMetrix, and ImaRx. Pharmaceutical companies focused on cancer treatment include: AmpliMed, Arizona Cancer Therapeutics, Cylene, Montigen Pharmaceuticals, ProLx, Sanofi Aventis, and Targeted Cancer Therapeutics, LLC. Pharmaceutical companies focused on cancer prevention include: Cancer Prevention Pharmaceuticals, Clinuvel, Niadyne, Surface Safe, Topical Technologies, Inc., and PHusis Therapeutics. A study performed by the Eller College of Management at the University of Arizona in 2008 suggests that the impact of a sustained $70 million in annual research funding through the UACC includes: 5,180 jobs, $237 million in wages, $795 million in gross sales, $7 million in city and county revenues, and $10.5 million in state revenues.

EQUIPMENT

No equipment needed for this study.

Foreign Justification

[redacted]
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[redacted] HPV-associated cancers take a disproportionate toll in low-resource settings. Cervical cancer is the leading cause of cancer-related mortality among women in South Africa. In 2014, the National Department of Health sought to address this by providing school-based HPV immunization for girls ages 9 to 12 years old enrolled in public schools. While this program showed initial promise, recent evidence shows a decline in the uptake of HPV vaccines due to COVID-related program interruptions, increased medical mistrust, and vaccine hesitancy related to misinformation spread on social media. There are additional critical gaps in HPV vaccine coverage – the current school-based HPV vaccine campaign does not include boys nor students enrolled outside of the public school system. Further, culturally and contextually appropriate strategies for conveying information about the vaccine and for addressing widespread concerns and mistrust are greatly needed in South Africa to achieve the goal of over 80% HPV vaccine coverage.

MILESTONE PLAN (see table below)

	Year 1				Year 2				Year 3			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Study Preparation												
Assemble Stakeholder Working Group (SWG)	x											
First Meeting with SWG		x										
Protocol, Informed Consent Forms, Consent Forms, Manual of Operations	x											
Human Subjects Approval (Brigham and Women's Hospital, U. CONFIDENTIAL INFORMATION U. Connecticut, KZN Department of Health)	x											
Database programming	x											
Staff Preparation and Training	x	x										
Identification of school sites		x										
Development of study organization and governing principles, if appropriate, including a Publications Policy and an Ancillary Studies Policy		x										
Specific Aim 1.1 Elicitation												
Focus Group Discussions		x										
Semi-structured interviews		x										
Data Analysis			x									
Second Meeting with SWG			x									
Specific Aim 1.2 Refinement of health promotions materials												
Refine materials, with iterative feedback from Design Advisory Group			x	x								
Specific Aim 1.3 Pre-post test materials												
Human Subjects Amendment (aim 1.3 activities)				x								
Pre-post test materials				x								
Data Analysis					x							
Third Meeting with SWG					x							
Specific Aim 2: Evaluate acceptability, feasibility, and preliminary effects of communications strategy												
Human Subjects Amendment (aim 2 activities)						x						
Clinical Trial Registration						x						
Obtain donated HPV vaccine (Merck)						x	x					
Randomization (eligible schools will include those with < 70% HPV vaccine uptake in prior year)							x					
Recruitment and Enrollment for Pilot School RCT (8-10 schools; up to 600 children)							x					
Outcomes assessment (HPV vaccine uptake (1st dose)							x					
Interim Data analysis – HPV vaccine uptake								x				
Fourth Meeting with SWG									x			
Outcomes assessment HPV completion (2nd										x		

dose)												
Exit interviews (N=30)										x		
Data Analysis											x	
Fifth Meeting with SWG												x
Publication and Dissemination												x

STAKEHOLDER ENGAGEMENT

Stakeholder engagement is critical to every aspect of this study. All aspects of the proposed study are informed by our team's expertise and extensive experience in areas related to this proposal (e.g., cancer prevention and treatment; vaccine hesitancy; health behavior change; community engagement; curriculum design; adolescent health; ethics), and by considerable input obtained over the past year through engagement with diverse stakeholders who are responsible for or otherwise engaged in the implementation of South Africa's school-based HPV vaccine program. Further, the approach reflects our team's commitment to research that addresses global health equity, capacity strengthening, and generating evidence to inform policy and programs. We have aimed to ensure that the engagement plan meets the recommendations outlined in guidance *(CIOMS, 2016; UNAIDS/AVAC GPP, 2011; UNAIDS, 2021)*. This means ensuring engagement involves a broad and inclusive set of stakeholders (i.e. not focused primarily on the community residing locally). Engagement is implemented early in the research and sustained throughout and engagement is dynamic and responsive to context as well as input from stakeholders.

Dialogue with key stakeholders and community members have already helped the study team members better understand the existing barriers to vaccination and ideas about what might facilitate increased uptake and completion of the HPV vaccine series in this community. Those stakeholders have included representatives from the CONF DENTIAL INFORMATION - REQUESTER N AGREEMENT, school principals and teachers, nurses, as well as parents of boys and girls enrolled in public and private schools in the greater CONFIDENTIAL INFORMATION - REQUESTER IN AGREEMENT

The study presented in this proposal was developed with their feedback in mind, including:

- The strong need for centering community knowledge and support at the heart of the school-based vaccination programs;
- Making the vaccination program inclusive of boys as well as girls;
- Making the vaccination program inclusive of children enrolled in fee-paying (private) schools; and
- Convening community dialogues and a special advisory team to inform the creation of culturally tailored educational materials to raise awareness and to address persistent fears and misunderstandings about vaccination.

Stakeholder engagement is woven throughout the study plan, including a series of community dialogues, focus groups with individuals who are involved in the planning, implementation or support of the school-based HPV program (e.g., representatives from the Department of Health, nurses), and semi-structured interviews with parents and teachers. In addition, we will assemble a Stakeholder Working Group (SWG) in the first quarter of the study; this group will include representation from government, civil society (including representation of parents and youth), as well as others from academia or other settings who are involved in legal, financial ethical or other aspects of the school-based HPV vaccine program. We will meet with this group at key stages of the study (noted in the Timeline) to facilitate a dialogue about the project's progress and other concerns of the group's constituents. Consultation with this group will enable us to stay abreast of issues that may arise over the course of the project, whether directly or indirectly related to the study. If any issues arise during the course of the study – stakeholders may contact the Study Coordinator (Wilkinson) and/or Community Lead (Nzimande) and the issue will be addressed by the working group and study team, depending on its severity and urgency. This will ensure that engagement activities are tailored and responsive to stakeholder feedback and appropriate in the context of the research.

Furthermore, we will convene a special Design Advisory Group to consult on the adaptation and/or creation of the culturally tailored educational materials for parents, children, teachers and health providers. The stakeholders invited to voluntarily participate in the SWG and the Design Advisory Group will be compensated for their time and insight.

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Future Clinical Trials Description

A. Anticipated future trial design.

We anticipate the proposed study will provide critical data for a future Hybrid Type 2 school-randomized controlled trial to determine the effectiveness and potential impact of a school-based implementation strategy to improve HPV immunizations among girls and boys in South Africa.[1] In alignment with this study design, we intend to first determine the effectiveness of our multilevel HPV immunization intervention at a Provincial level using a cluster randomized trial using the 'Standard Protocol Items: Recommendations for Interventional Trials' (SPIRIT) statement as a guide.[2] We will then evaluate potential barriers and facilitators to its implementation, using Proctor et al.'s conceptual model to assess implementation outcomes in both arms.[3] The long-term impact will be to provide an innovative, accessible, community-based strategy that optimize the benefits of an effective cancer prevention strategy.

B. Assessing effectiveness using a pragmatic cluster randomized controlled trial and a factorial design.

B.1 Proposed study design and setting. We propose a future pragmatic cluster randomized controlled trial design,[4] using the unit of randomization (cluster) as the municipality within the Province of [redacted]. The factorial design allows for the evaluation of the multicomponent intervention, considering that each component could be applied alone or in combination with other components. As discussed in our current proposal, we anticipate this package will include three interrelated components that will be developed and refined with active stakeholder collaboration: (1) curriculum-linked learning materials for children, (2) informational materials for parents and teachers, and (3) community dialogue, supported by an adapted Conversation Map™,[18] for use by teachers, nurses, or others who may facilitate community dialogues regarding HPV vaccine.

C. Proposed Implementation Strategy.

C.1 The Proctor et al. framework for assessment of implementation outcomes provides a pragmatic approach to evaluating intervention effectiveness and implementation. Most randomized trials test ***intervention efficacy*** by involving a homogenous, highly motivated population, in a controlled setting, with a focus on internal validity.[5,6] While evidence from randomized trials is critical, it may lack generalizability because of non-representative participants and settings.[7] In contrast, ***effectiveness studies*** measure the impact of an intervention when tested within a population representative of the intended audience and are meant to be generalizable to the target population and setting. The Proctor et al. framework posits that all implementation strategies should specify at minimum: the "actor," the "action," and the "action target" driving behavior. This framework has been used to improve translation of research into practice and to test interventions in "real world" settings,[8-12] but its use to evaluate implementation parameters of a school-based strategy promoting an effective cancer prevention strategy is unique and timely. Each step in this process implies a specific measurement task in our proposed future study:

Actor: Teachers and school nurses, fluent in Zulu, actively engaged with parents, providing information and support on HPV immunization.
Action: Multi-level communication strategy sent to families to inform, influence, and motivate parents to support HPV immunization for their children.
Action Target: Our refined, stakeholder-informed communication strategy has the potential to address barriers to HPV immunization by addressing misinformation and hesitancy, while giving evidence of vaccine benefits through providing knowledge and positive social norms to counteract negative messaging.

D. Study objectives and endpoints.

The primary objective of the proposed future cluster randomized controlled trial phase of our study is to evaluate the effectiveness of a multicomponent intervention on HPV vaccine coverage among boys and girls in fifth grade at the municipality (cluster) level. The corresponding endpoint is HPV vaccine coverage (at least one does) within 2 months after the intervention's implementation. Secondary endpoints would include HPV vaccine coverage (at least one dose) at 6 and 12 months, and HPV vaccine coverage (2 doses) at 2, 6, and 12 months. Secondary objectives include: (1) The impact of the multicomponent intervention in target populations on knowledge, beliefs, behaviors, and practices towards HPV vaccination, intention to initiate HPV vaccination, and the psychological determinants of vaccination intention; (2) the cost-effectiveness and budgetary implications of the components that are

effective; and (3) the implementation of the components of the intervention, and barriers and levels of implementation at both individual and community level. Endpoints corresponding to primary and secondary objectives are described in Table 1.

Table 1: Endpoints for Multicomponent HPV intervention for South African youth

Dimension/measure	Target population	Data sources	Time Frame
Vaccine Coverage (main objective)			
≥1 dose	Fifth graders	School clinical database and surveys	M2, M6, M12
2 doses	Fifth graders	School clinical database and surveys	M2, M6, M12
Knowledge, beliefs, behaviors, practices, intention towards HPV vaccination			
Items of the KABP-6C questionnaire[13,14]	Parents	Self-administered questionnaire	Before intervention, M2
Efficiency			
Incremental cost-effectiveness ratio	Fifth graders	Costs of the intervention, health insurance costs (if applicable)	M2, M6, M12
Annual cost and health gains of generalizing component(s) at a national level*	Fifth graders (whole country)	Costs of the intervention, health insurance costs (if applicable)	N/A
Intervention components implementation			
Intervention components' dose and fidelity: activities performed according to the frame of reference for each component, use of tools developed for each component (assessment of the gap between activities/tools planned and activities/ tools really performed/used)	N/A	Regular activity reports collected on a standardized form during components' implementation	
Reached populations: percentage of target individuals who benefit from (or participate in) activities of each component (assessment of the acceptability of each component)	Fifth graders, parents, school staff	Regular activity reports collected on a standardized form during components' implementation	
Intervention components' adaptation: components modified to adapt them to the local context/environment of each school/municipality	N/A	Regular activity reports collected on a standardized form during components' implementation	
Satisfaction of target populations regarding each activity/component and identification of barriers and levers to components' implementation	Fifth graders, parents, school nurses	Self-administered (paper or online) questionnaires collected at the end of the components' implementation	

*Costs associated with generalizing effective component(s) at 1 and 5 years will be compared with the corresponding health gains in terms of size of the vaccinated population (1 and 2 doses).

E. Description of Measures

E.1 Clinical outcomes. HPV Vaccine completion (at least 1 dose and 2 doses) at 2, 6 and 12 months after components' implementation will be estimated using data from both the school and provincial databases, and direct surveys sent to parents.

E.2. Changes in knowledge, beliefs, behaviors and practices, and intention to initiate HPV vaccination. Items from the Knowledge, attitude, behaviors, practices and six psychological determinants of vaccination intention (Confidence, Complacency, Constraints, Calculation, Collective responsibility, and social Conformism, KABP-6C)[13,14] survey will be assessed using self-administered questionnaires given to parents, linking preassessments and post-assessments by anonymous identifiers. Basic demographic and socioeconomic characteristics will also be collected (e.g., gender, age, educational level) for the target population.

E.3 Efficiency. In the proposed future trial, we would intend to use a micro-costing approach to the analysis as recommended by the US Panel on Cost-Effectiveness in Health and Medicine[15] to carefully track all costs associated with implementing our intervention. Costs in the analysis will be assessed using a school-based perspective, considering all intervention costs, but not costs that accrue to the participant. Also, it would be difficult to accurately value costs incurred given the wide variation in patients' income or transport costs, for example. The cost for each resource will be calculated by multiplying the quantity used by unit cost; total cost will be derived by adding up all the individual costs.[16] Our measure of cost-effectiveness will be the incremental cost-effectiveness ratio (ICER) as laid out in equation (1) below, defined by the difference in the per-capita cost of the interventions divided by the difference in the average effectiveness of the interventions. In general, interventions with low ICERs are considered to be cost-effective relative to the alternative and should be prioritized in terms of resource allocation.[17] We will evaluate the relative cost effectiveness of our multilevel HPV intervention vs. standard of care using standard methodologies described by Gold and colleagues.[18]

(Equation 1) $\frac{\mu_{c2}-\mu_{c1}}{\delta_{e2}-\delta_{e1}}\ \mathrm{CER} = \frac{\mu_{c2}-\mu_{c1}}{\delta_{e2}-\delta_{e1}}$ **,** where μ_{c2} is the per-capita cost of T2, μ_{c1} is the per-capita cost of the T1 vaccine, δ_{e2} is the percentage of participants getting the HPV vaccine in T2, and δ_{e1} is the same measure for participants in the T1 group. As cost effectiveness analyses (CEA) are subject to uncertainty (such as changes in costs or effectiveness), we will provide information on the degree to which our CEA conclusions might change by estimating confidence intervals for our CERs using bootstrap methods.[19] The evolution of the running costs will be tracked carefully to gain information as to whether there are cost efficiencies over time. Cost-effectiveness results will be shared with our partners in the Department of Health and Education and other community stakeholders to inform decisions for future implementation. The CEA analysis will allow us to determine whether the effects of our adaptive intervention are sufficient to justify the cost.

E.4. Dose and Fidelity. During intervention implementation, we would intend to assess activities performed according to the frame of reference for each component, and the use of tools developed for each component (assessment of the gap between activities/tools planned and activities/ tools really performed/used).

E.5 Reached Populations. We would plan to assess the percentage of target individuals who benefit from (or participate in) activities of each component (assessment of the acceptability of each component). This would provide a framework for interpreting the penetration and sustainability of this intervention.

E.6 Intervention components' adaptation: We would plan to assess components that required modification to adapt them to the local context/environment of each school/municipality.

E.7 Satisfaction of target population: We would also assess satisfaction with each component and identification of barriers and levers to components' implementation.

In sum, data on implementation (dose, fidelity, adaptations, reach and satisfaction of target populations) are also critical information for stakeholders to help them decide how the intervention may be replicated and possibly generalized at a national level.[20]

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Credential, e.g., agency login: eRA COMMONS USER NAMES

Project Role*: Co-Investigator Other Project Role Category:

Degree Type: PhD, MSc Degree Year: 2021, 2011

Attach Biographical Sketch*: File Name: Gumede_biosketch_10_21_2022rev.pdf

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Purnima Middle Name Last Name*: Madhivanan Suffix:

Position/Title*: Associate Professor / Graduate Program Dir.
Organization Name*: University of Arizona
Department: Health Promotion Sciences
Division:
Street1*: 1295 N. Martin Ave.
Street2:
City*: Tucson
County:
State*: AZ: Arizona
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 85724-5209

Phone Number*: 5206262914 Fax Number:

E-Mail*: pmadhivanan@arizona.edu

Credential, e.g., agency login: eRA COMMONS USER NAMES

Project Role*: Co-Investigator Other Project Role Category:

Degree Type: PhD, MPH Degree Year: 2007, 2003

Attach Biographical Sketch*: File Name: Madhivanan_biosketch_9_28_2022.pdf

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Emily Middle Name Last Name*: Mudzingwa Suffix:

Position/Title*: Assistant Research Professor
Organization Name*: University of Connecticut
Department: Institute for Collaboration on Health, Intervention, and Policy
Division:
Street1*: 2006 Hillside Road
Street2: Unit 1248
City*: Storrs
County:
State*: CT: Connecticut
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 06269-1248

Phone Number*: 8604865917 Fax Number:

E-Mail*: PERSONAL INFORMATION

Credential, e.g., agency login: eRA COMMONS USER NAMES

Project Role*: Co-Investigator Other Project Role Category:

Degree Type: PhD Degree Year: 2015

Attach Biographical Sketch*: File Name: Mudzingwa_biosketch_10_12_2022.pdf

Attach Current & Pending Support: File Name:

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

BIOGRAPHICAL SKETCH

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

NAME: Katz, Ingrid T.

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

POSITION TITLE: Associate Professor, Harvard Medical School; Associate Director, Harvard Global Health Institute; Associate Physician, Brigham and Women's Hospital; Research Scientist, Center for Global Health, Massachusetts General Hospital

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

INSTITUTION AND LOCATION	DEGREE	COMPLETION DATE	FIELD OF STUDY
Amherst College, Amherst, MA	BA	05/1993	History and French
Johns Hopkins Bloomberg School of Public Health, Baltimore, MD	MHS	06/1997	International Health
University of California at San Francisco, San Francisco, CA	MD	05/2003	Medicine
Brigham and Women's Hospital, Boston, MA	Residency	06/2006	Internal Medicine
Harvard School of Public Health, Boston, MA	Fellowship	08/2008	Clinical Effectiveness
Beth Israel Deaconess Medical Center, Boston, MA	Fellowship	06/2009	Infectious Disease
Brigham and Women's Hospital, Boston, MA	Fellowship	09/2009	Global Women's Health

A. Personal Statement

I am the Associate Faculty Director of the Harvard Global Health Institute, Associate Professor at Harvard Medical School, and Associate Physician in the Department of Medicine at Brigham and Women's Hospital. I am a physician-scientist, clinically trained in Internal Medicine and Infectious Diseases, with additional research expertise in global health (Johns Hopkins, MHS, '97), randomized clinical trials involving behavioral interventions (OBSSR, NIH, 2015), and implementation science (Inter-CFAR Fellowship, 2019-2020). My research over the past decade has been consistently funded through NIH and is focused on addressing the social determinants of health-seeking behavior among populations at risk for preventable diseases due to long term infections from HPV and HIV in South Africa, with the goal of developing sustainable, socio-behavioral interventions aimed at improving care for the most underserved.

The proposed collaborative project reflects overarching goals in my research program: 1) to identify effective, scalable, and sustainable interventions to improve the uptake of life-saving vaccines, and 2) to develop effective strategies for engaging vulnerable populations through community-based participatory research. My role as Multi-Principal Investigator on this project is informed by my training as a physician caring for individuals in underserved communities in Boston and my ongoing leadership role in the Covid-19 response, in which I briefed President Biden on effective strategies to promote vaccines to vulnerable communities. I have a multi-year collaboration with Dr. Butler, whose expertise complements mine. I have a long-term track record of funding for my HPV-related research, starting in 2009. In my role as MPI, I will apply my content expertise in vaccine hesitancy, and my experience with mixed-methods research to engage communities in designing an effective HPV vaccine strategy for young people. Ongoing and recently completed projects that I would like to highlight include:

R21 MH126804
Katz (PI)

09/01/2022 – 08/31/2024
A mixed methods approach to address multi-level barriers to care for migratory men living with HIV in South Africa
The proposal focuses on addressing the unique barriers experienced by men who are living with HIV who migrate within South Africa, using a sequential mixed methods design to explore multi-level barriers to engagement and retention in HIV care; elicit preferred HIV treatment and care attributes and service delivery features; and explore characteristics driving their selection of preferred scenarios using a Discrete Choice Experiment offered to men who migrate within South Africa. We will codesign an intervention package to promote linkage and sustained engagement in HIV care that is responsive to the needs and preferences of recently diagnosed South African migratory men using Design Thinking.

R34 MH114897-01A1
Katz (PI)
06/08/18 – 03/31/23 (NCE)
Standing Tall - A Pilot Randomized Controlled Trial of a Community-Based Intervention to Improve Health Outcomes for Newly Diagnosed HIV-Positive Young Adults in South Africa
This study addresses the need for a theory-driven, empirically informed, sustainable HIV care approach for newly diagnosed HIV-positive adolescents and young adults in South Africa. Specifically, we aim to: 1) identify barriers and facilitators to intervention implementation using qualitative research methodology; 2) develop and pilot test components of our intervention using an iterative phased-approach; and 3) assess feasibility, acceptability, and preliminary efficacy of Standing Tall through a pilot randomized controlled trial.

PRIVATE SUPPORT [redacted]
Katz (PI)
11/01/20 – 10/31/22 (NCE)
Optimizing Peer-Driven Interventions for High-Risk Patients in Low- and Middle-Income Countries
This project will build upon a conceptual framework from a previous project, the Treatment Ambassador Program (R34MH108393), and will provide a nuanced perspective of persistent barriers to care for people living with HIV in South Africa. We will synthesize, prototype, and refine our prior intervention in order to develop a sustainable, peer-based intervention with the goal of improving the health of those living with HIV.
Role: Principal Investigator

B. Positions, Scientific Appointments, and Honors

Positions

2020–Present	Associate Professor of Medicine, Harvard Medical School (HMS), Boston, MA
2018–Present	Associate Faculty Director, Harvard Global Health Institute, Cambridge, MA
2018–Present	Associate Faculty, Ariadne Labs, Boston, MA
2017–2018	National Correspondent, *New England Journal of Medicine*, Boston, MA
2014–2020	Assistant Professor of Medicine, Harvard Medical School (HMS), Boston, MA
2012–Present	Research Scientist, Center for Global Health, Massachusetts General Hospital, Boston, MA
2009–Present	Associate Physician, Division of Women's Health, Department of Medicine, BWH, Boston, MA
2009–2014	Instructor of Medicine, Harvard Medical School (HMS), Boston, MA
2007–2009	Global Women's Health Fellow, Brigham and Women's Hospital, Boston, MA
2006–2009	Fellow in Infectious Diseases, Beth Israel Deaconess Medical Center, Boston, MA
2005–2006	Editorial Fellow, *New England Journal of Medicine*, Boston, MA
2004	Research Fellow, HIV/AIDS Program, World Health Organization, Geneva Switzerland

Other Selected Experience and Memberships

2021–Present	Course Co-Director, for 'Vaccines: History, Science & Policy (Gen Ed 1175)', Harvard University, Cambridge, MA
2020–Present	Steering Committee for Global Environmental Change, Harvard T.H. Chan School of Public Health, Boston, MA

2020–Present	Member, Standing Committee on Global Health and Health Policy, Harvard University, Cambridge, MA
2019–Present	Co-Director, Harvard Women in Global Health 'Learn, Engage, Advance, Disrupt' (LEAD) Fellowship, Harvard University, Cambridge, MA
2019–Present	Steering Committee, Global Mental Health at Harvard Initiative (GMH@Harvard), Harvard Medical School, Boston, MA
2018–Present	Member, Executive Committee of the Harvard University Center for AIDS Research, Boston, MA
2016	Co-Chair, Annual National Center for AIDS Research Meeting, Harvard Medical School, Boston, MA
2015–2016	Faculty Chair, Joint Committee on the Status of Women, Harvard Medical School, Boston, MA
2014–2016	Member, HPV/Cervical Coalition, Department of Health, State of Massachusetts, Boston, MA

Honors

2021	Dean's Award for an Emerging Leader in Women's Careers, Harvard Medical School, Inaugural Recipient
2020	Expert Panel briefing President Joseph R. Biden Jr., on Covid-19
2020	WomenLift Health Leadership Fellow, Stanford University
2019	A. Clifford Barger Excellence in Mentoring Award Recipient, Harvard Medical School
2019	Emerging Leader in Health and Medicine, National Academy of Medicine
2017	Center for AIDS Research Scholar Award
2015	Burke Global Health Fellowship, Harvard Global Health Institute
2011	Center for AIDS Research Scholar Award, Harvard University
2010	Eleanor and Miles Shore Award, Harvard Medical School
2009	Young Investigator Award, 16 h Conference on Retroviruses and Opportunistic Infections
2009	KL2 Merit Award, Harvard Catalyst, Harvard University
2003	Alpha Omega Alpha, UCSF
2000	Award from Medical Students for Choice
1999 & 2000	Dean's Award for Research, UCSF
1996	Highest honors in Qualitative Research Methodology, Johns Hopkins University
1993	Magna Cum Laude, Amherst College

C. Contributions to Science

1. **Biomedical prevention strategies for sexually transmitted infections (STIs):** I have spent the past decade researching effective biomedical prevention strategies for oncogenic STIs. I have primarily focused on prevention of transmission of the Human Papilloma Virus (HPV), specifically by developing a conceptual model of HPV vaccine uptake, that has been widely cited, and has resulted in my receipt of The Harvard Clinical and Translational Science Center and National Institutes of Health Award, Harvard Global Health Institute Travel Award, and The Eleanor and Miles Shore 50th Anniversary Award.

    a. **Katz IT**, Ware NC, Gray G, Haberer J, Mellins CA, Bangsberg DR. Scaling up Human Papillomavirus Vaccination: A Conceptual Framework of Vaccine Adherence. *Sex Health.* 2010 Sep;7(3):279-86. PMCID: PMC3141556.
    b. **Katz IT**, Nkala B, Dietrich J, Wallace M, Bekker LG, Pollenz K, Bogart LM, Wright AA, Tsai AC, Bangsberg DR, Gray GE. A Qualitative Analysis of Factors Influencing HPV Vaccine Uptake in Soweto, South Africa among Adolescents and Their Caregivers. *PLoS ONE*. 2013 Aug 30;8(8):e72094. 8(8): e72094. PMCID: PMC3758285.
    c. Johnson KL, Lin MY, Cabral H, Kazis LE, **Katz IT.** Variation in Human Papillomavirus Vaccine Uptake and Acceptability Between Female and Male Adolescents and Their Caregivers. *J Community Health*. 2017 Jun;42(3):522-532. PMCID: PMC5403619
    d. Ramanadhan S, Fontanet C, Teixeira M, Mahtani S, **Katz I.** Exploring attitudes of adolescents and caregivers towards community-based delivery of the **HPV** vaccine: a qualitative study. *BMC Public Health*. 2020 Oct 9;20(1):1531. PMCID: PMC7547455

2. **Identifying barriers to treatment initiation among people living with HIV in South Africa**: Our group was one of the first to identify high rates of treatment refusal and loss to follow-up among those eligible for treatment in South Africa. Based on this research, our group developed an explanatory model of treatment refusal. We framed our model within the Theory of Triadic Influence, which focuses on three "streams of influence" that impact health behavior at the individual-, social-, and structural-levels. Central to our model is the meaning of treatment initiation – which has broad applicability across multiple chronic diseases that are highly stigmatized. Our research in this area represented a major finding in the field and was recognized at a plenary session of a leading international HIV research conference as being one of the top socio-behavioral studies in HIV in the last 30 years, and has been featured in leading journals, including *AIDS, JAIDS,* and *PLoS Medicine*.

    a. Nardell MF, Yeonsoo SL, Rousseau E, Julies R, Klaas P, Vundhla P, Butler L, Bassett IV, Mellins CA, Bekker LG, **Katz IT**. "You are Not Alone": A Qualitative Study to Explore Barriers to ART Initiation and Implications for a Proposed Community-Based Youth Treatment Club Among Young Adults Newly Diagnosed with HIV in South Africa. AIDS Care. 2020 Dec 21:1-10. PMID: 33345593
    b. **Katz IT**, Musinguzi N, Bell K, Cross, A, Bwana MB, Amayire G, Asiimwe S, Orrell C, Bangsberg DR, Haberer, JE. The Impact of Disease Stage on Early Gaps in ART in the "Treatment for All" Era — A Multisite Cohort Study. JAIDS. 2020 Dec 17; Publish Ahead of Pring. PMID: 3335129
    c. **Katz IT**, Kaplan R, Fitzmaurice G, Leone D, Bangsberg DR, Bekker LG, Orrell C. Treatment guidelines and early loss from care for people living with HIV in Cape Town, South Africa: A retrospective cohort study. PLoS Med. 2017 Nov; 14(11):e1002434. PMCID: PMC29136014.
    d. **Katz IT**, Essien T, Marinda ET, Gray GE, Bangsberg DR, Martinson NA, De Bruyn G. Antiretroviral Refusal among Newly Diagnosed HIV-Infected Adults in Soweto, South Africa. AIDS. 2011 Nov 13;25(17):2177-81. PMCID: PMC3272300.

3. **Developing a care delivery model for migratory men and people who are lost from care:** Our group is leading an initiative to engage with populations who are missing from care in HIV treatment programs in South Africa. Our focus is on developing programs for migratory men who are often transitory due to efforts to seek employment. Our work thus far has been presented to USAID and to the Gates Foundation. My mentee, Dr. Nardell, has presented this research at The International Conference on HIV Treatment and Prevention Adherence and The International AIDS Society Conference.

    a. Nardell MF, Adeoti O, Peters C, Kakuhikire B, Govathson-Mandimika C, Long L, Pascoe S, Tsai AC, **Katz IT**. Men missing from the HIV care continuum in sub-Saharan Africa: a meta-analysis and meta-synthesis. J Int AIDS Soc. 2022 Mar;25(3):e25889. doi: 10.1002/jia2.25889. PMID: 35324089; PMCID: PMC8944222.
    b. **Katz IT**, Bogart LM, Fitzmaurice GM, Staggs VS, Gwadz MV, Bassett IV, Cross A, Courtney I, Tsolekile L, Panda R, Steck S, Bangsberg DR, Orrell C, Goggin, K. The Treatment Ambassador Program: A Highly Acceptable and Feasible Community-Based Peer Intervention for South Africans Living with HIV who Delay or Discontinue Antiretroviral Therapy. AIDS Behav. 2021 Apr;25(4):1129-1143. [Online ahead of print.] PMID: 33125587.
    c. Nardell MF, Govathson C, Mngadi-Ncube S, Ngcobo N, Letswalo D, Long L, **Katz IT***, Pasco S*. (*Equal contribution). Migrant Men and HIV Care Engagement: A Community-Based Study in Johannesburg. International Adherence Conference 2021; Virtual Conference due to Covid-19.
    d. Pascoe S, Govathson C, Ngcobo N, Mngadi-Ncube S, Nardell MF, **Katz IT,** Long L. Fast and Friendly is key to keeping men on HIV treatment! IAS 2021: IAS Conference on HIV Science; Virtual Conference due to Covid-19.

4. **Stigma reduction and HIV care:** Our research on stigma reduction and its impact on HIV care has been nationally recognized, resulting in an oral presentation of our manuscript focused on the impact of HIV-related stigma on treatment adherence at the 8th International Conference on HIV Treatment and Prevention Adherence, and at an NIH-sponsored symposium in Washington, DC. This research has been featured in UNAIDS publications, and throughout the lay press including *Scientific American* and Reuters. Our article in the Journal of the International AIDS Society has been cited over 700 times since its publication. It has received a "Highly Cited Paper" designation by Web of Science: top 1% in Immunology as of Nov/Dec 2018 based on Essential Science Indicators citation data from Thomson Reuters. In addition, it has been cited in clinical practice guidelines, including the British HIV Association Guidelines for

the Treatment of HIV-1-Positive Adults with Antiretroviral Therapy 2015 (HIV Med 2016;17 Suppl 4:S2-S104). Our findings support the need to effectively address the psycho-social burden of living with a highly stigmatized disease to optimize HIV treatment initiation and long-term care.

a. **Katz IT**, Bogart LM, Dietrich JJ, Leslie HH, Iyer HS, Leone D, Magidson JF, Earnshaw VA, Courtney I, Tshabalala G, Fitzmaurice GM, Orrell C, Gray G, Bangsberg DR. Understanding the role of resilience resources, antiretroviral therapy initiation, and HIV-1 RNA suppression among people living with HIV in South Africa: a prospective cohort study. AIDS. 2019 Jun 1;33 Suppl 1:S71-S79. PMID:31397725. PMCID:PMC6712569.
b. Earnshaw VA, Bogart LM, Laurenceau JP, Chan BT, Maughan-Brown BG, Dietrich JJ, Courtney I, Tshabalala G, Orrell C, Gray GE, Bangsberg DR, **Katz IT**. Internalized HIV stigma, ART initiation and HIV-1 RNA suppression in South Africa: exploring avoidant coping as a longitudinal mediator. J Int AIDS Soc. 2018 Oct;21(10):e25198. PMCID:PMC6202800
c. **Katz IT,** Tsai AC. Psychological therapy to improve HIV care and reduce stigma. *Lancet HIV*. 2015;2(5):e172-3. PMCID: PMC4634562.
d. **Katz IT,** Ryu AE, Onuegbu AG, Psaros C, Weiser SD, Bangsberg DR, Tsai AC. Impact of HIV-related stigma and serostatus disclosure on HIV treatment adherence: systematic review, meta-synthesis, and conceptual framework. *Journal of the International AIDS Society*. 2013 Nov 13;16(3 Suppl 2):18640. PMCID: PMC3833107.

5. **Developing Models of Service Delivery for Early Treatment Initiation:** An area of growing interest for our group is focused on understanding how to optimize early treatment initiation for people with HIV. Implementation research on this topic is of particular relevance in communities where resources are limited in order to ensure high-priority programs are effectively and efficiently delivered. This work led to solicited editorials in the *Lancet HIV*, with significant coverage in the lay press, including BBC World News.

a. Rosen S, Grimsrud A, Ehrenkranz P, **Katz I**. Models of service delivery for optimizing a patient's first six months on antiretroviral therapy for HIV: an applied research agenda. Gates Open Res. 2020 Jul 29;4:116. eCollection 2020. PMID:32875281
b. **Katz IT**, Maughan-Brown, B. Improved life expectancy among people living with HIV – who is left behind? Lancet HIV. 2017 Aug;4(8):e324-e326. PMCID: PMC28501496.
c. Bor J, Ahmed S, Fox MP, Rosen SB, **Katz IT,** Meyer-Rath G, Tanser F, Pillay D, Barnighausen T, Effect of eliminating CD4-count thresholds on HIV treatment initiation in South Africa: an empirical modeling study. *Plos One.* 2017 Jun 15;12(6):e0178249. PMCID: PMC5472329.
d. **Katz IT**, Siedner MJ. Does early antiretroviral therapy for HIV Infection in sub-Saharan Africa decrease mortality? *Lancet HIV*. 2015 Sep;2(9):e354-5. PMCID: PMC4634669.

Complete List of Published Work in MyBibliography:
http://www.ncbi.nlm.nih.gov/sites/myncbi/ingrid.katz.1/bibliography/41476114/public/?sort=date&direction=descending

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

BIOGRAPHICAL SKETCH

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

NAME: Butler, Lisa Michelle

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

POSITION TITLE: Associate Research Professor, Institute for Collaboration on Health, Intervention and Policy, University of Connecticut

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

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Start Date MM/YYYY	Completion Date MM/YYYY	FIELD OF STUDY
Smith College, Northampton, MA	B.A.	09/1990	12/1991	Psychology
University of California, Los Angeles, CA	Ph.D.	09/1995	12/2000	Psychological Studies in Human Development
University of California, Berkeley, CA	M.P.H.	09/2000	05/2002	Epidemiology/ Biostatistics & Health and Social Behavior
University of California, San Francisco, CA	Postdoc	09/2002	06/2007	HIV/AIDS Prevention Studies
University of California, Berkeley, CA	Ph.D.	09/2005	05/2009	Epidemiology

A. Personal Statement

I am a behavioral scientist and epidemiologist with methodologic expertise in the design and implementation of RCTs and development of interventions to improve health outcomes for vulnerable and low-literacy populations in eastern and southern Africa. I have 24 years of research and training experience in Africa, including Botswana, South Africa, Kenya, Uganda, and Ghana, with extensive experience with governmental, non-governmental, and community partnerships. Overall, my work focuses on reducing the prevention and treatment gaps for health and mental health amongst vulnerable populations. My research program has included studies focused on Kaposi's sarcoma-associated herpesvirus in sub-Saharan Africa (K01 HD052020), development of training materials regarding Kaposi's sarcoma for traditional health providers and community health workers (D43 CA153717 [NCI]), and research capacity strengthening in primary and secondary prevention strategies for cervical cancer and Kaposi's sarcoma (KS), two of the most common cancers in the general population (U54CA254571 [NCI]). I have experience in the development and implementation of media-based health promotion strategies designed to promote dialogue between community members and/or health providers around selected health topics (e.g., cervical cancer; HIV and HIV-associated malignancies; tuberculosis; child health, nutrition and development; pediatric HIV disclosure; depression), particular amongst lower literacy populations. Through this work, I have collaborated with Jive Media Africa, a multi-media scientific communications firm that will consult on the proposed project, on the development of curricula for a range of users (e.g., community health workers, lay health counselors, biomedical health workers, adolescents) and the production of over 20 educational videos (animated and live action) on various topics. I have also worked closely with MPI Katz on research in South Africa for almost a decade, including studies focused on cervical cancer, preferences for long-acting PrEP amongst adolescent girls and young women and men, and HIV treatment acceptance and adherence following diagnosis. As MPI on this project, I will lead the overall design and implementation of the scientific aims, including development of qualitative guides,

intervention design, and any data analyses. Ongoing and recently completed projects that I would like to highlight include:

NIH R34MH114523
Katz (PI), Role: Co-I
04/01/2018-03/31/2022
Randomized Controlled Trial of Standing Tall - A Community Based Intervention to Improve Linkage, Retention and Health Outcomes for Newly Diagnosed HIV-Positive South African Youth.

NIH 1R01MH109506
PI: Butler
09/30/2016-07/31/2022
Multi-Sectoral Agricultural Intervention to Improve Nutrition, Health, and Developmental Outcomes of HIV- infected and Affected Children in Western Kenya.

NIH 5R01MH107330
PIs: Weiser/Cohen, Role: Co-I
05/07/2015-06/30/2022
Agricultural Intervention for Food Security and HIV Health Outcomes in Kenya.

PRIVATE SUPPORT
PI: Butler
04/01/2021-03/28/2023
The Zivikele Project: Mixed methods study to identify preferences for next-generation PrEP interventions amongst adolescent girls and young women and men in South Africa.

PRIVATE SUPPORT
PI: Butler
04/01/2021-03/28/2023
Mixed methods study to explore perceptions toward potential COVID-19 vaccines among health care providers and key population groups in the United States and Canada.

PRIVATE SUPPORT
PI: Butler
05/01/2018 – 10/31/2021
OPP1190725
Optimizing Mother & Child Health and Development in Botswana.

NIH R01MH109337
PI: King (PI), Role: Co-I
08/24/2016-04/30/2021
A cognitive behavioral and structural HIV prevention intervention for young Ugandan women engaging in high risk sexual behavior.

NIH R34MH114523
PI: King, Role: Co-I
07/01/2017–07/01/2020
Improving Uptake and Adherence to HIV Prevention Services with PrEP and HIV Self-Testing for HIV Negative High Risk Young Women (Aged 15-24) in Kampala, Uganda.

NIH 5U54CA190153
Martin (PI), Role: Co-I/Mentor
09/17/2014-08/31/2019
Uganda-UCSF Consortium on prevention of early detection of HIV-associated cancer, improving early diagnosis of Kaposi's Sarcoma in Uganda.

PRIVATE SUPPORT
PI: Kammerer, Role: Consultant
04/01/2019- 03/31/2020
1.5 million and me. The overall objective of this project is to implement a digital storytelling workshop with HIV-positive adolescents 15-19 years old in Cape Town, South Africa and produce videos about youth's experiences of accessing and staying in HIV care and treatment.

B. Positions, Scientific Appointments and Honors

Employment

2016 -	Associate Research Professor, Institute for Collaboration on Health, Intervention and Policy, University of Connecticut
2016 -2016	Assistant Professor, Department of Pediatrics, Harvard Medical School, Boston, MA
2013 -2016	Lecturer, Department of Pediatrics, Harvard Medical School, Boston, MA
2013 -2016	Associate Scientific Researcher, Division of General Pediatrics, Boston Children's Hospital, Boston, MA
2006 -2013	Assistant Professor, Department of Epidemiology and Biostatistics, UCSF
2005- 2006	Asst Research Epidemiologist, Dept. of Epidemiology and Biostatistics, UCSF
2002 -2005	Postdoctoral Research Fellow, Center for AIDS Prevention Studies, UCSF

Other Positions

2020 -	Research Associate, Botswana Harvard AIDS Institute Partnership
2020 -	Assistant Professor (Status Only), University of Toronto, Dalla Lana School of Public Health

Honors and Awards

2001	Human Rights Summer Fellowship, University of California, Berkeley, CA
2001	Wellness Foundation Fellowship, University of California, Berkeley, CA
2001	Patricia Buffler Epidemiology Fellowship, University of California, Berkeley, CA
1999 -2000	Dissertation Year Fellowship, University of California, Los Angeles, CA
1998 -1999	Fulbright IIE Fellowship (South Africa)
1995 -1998	Pre-Doctoral Research Training Grant, Spencer Foundation
1992	High Honors in Psychology, Smith College
1992	Cum Laude, Phi Beta Kappa, Psi Chi, & Sigma Xi (Smith College)

Other Selected Experience and Memberships

2013 - 2019	NIH ad hoc grant reviewer, including: NIH-PEPFAR Collaboration on Implementation Science for HIV (2015), NIH-Fogarty International Brain Disorders (2016, 2018, 2019, 2020), NICHD Adolescent Trials Network for HIV/AIDS Interventions (2016), and over 20 additional NIH panels since 2013.
2019 --	HIV/AIDS Intra- and Inter-personal Determinants and Behavioral Interventions SRG Standing Review Committee
2005 --	Referee for peer review journals, including: AIDS, AIDS Care, American Journal for Public Health, BMC International Health and Human Rights, BMC Pregnancy and Childbirth, BMC Public Health, Clinical Infectious Diseases, International Journal of Cancer, International Journal of Infectious Diseases, Journal of AIDS, Journal of the International AIDS Society, PLoS ONE

C. Contributions to Science

1. **Research and Capacity Building on HIV-associated malignancies.** Since 2005, I have led or co-led studies focused on HIV-associated malignancies in South Africa and Uganda. With funding from NICHD (K01), I led several large-scale community-based studies in Uganda and South Africa focused on the prevalence of human herpesvirus-8 (HHV-8)/Kaposi's sarcoma-associated herpesvirus (KSHV) in young children and adults as well as practices (sexual and caregiving-related) that may be linked to HHV-8/KSHV transmission. Since 2010, I have been co-investigator on an NCI-funded D43 training program (PI: Martin, UCSF), on HIV-associated malignancies where my primary responsibilities have included development and implementation of training on Kaposi's sarcoma (KS) for biomedical health providers, community

health workers and traditional healers in Uganda. Since early 2015, I have been co-investigator on an NCI-funded U54 consortium project (PI: Martin, UCSF) which aims to build capacity for research on HIV-associated cancers in Uganda and to investigate strategies for increasing community and provider awareness of and timely diagnosis of KS and cervical cancer, the two leading causes of cancer in Uganda. My work on these studies have provided me with invaluable experience in biospecimen collection, processing, storage, shipment and testing, design of large population-based studies, and capacity building with multiple cadres of health providers including traditional healers, community health workers, lab technicians, nurses and physicians.

1. **Butler LM**, Dorsey G, Hladik W, Rosenthal PJ, Brander C, Neilands, TB, Mbisa G, Whitby D, Kiepiela P, Mosam A, Mzolo S, Dollard S, Martin JN. Kaposi's sarcoma-associated herpesvirus seroprevalence in population-based samples of African children: Evidence for at least two patterns of KSHV Transmission. *J Infect Dis*. 2009;200(3):430-438. PMCID: 19534596.
2. **Butler LM**, Osmond D, Graves Jones A, Martin J. Use of saliva as a lubricant in anal sexual practices among homosexual men. *J Acquir Immune Defic Syndr*. 2009;50(2):162-167. PMCID: 19131893.
3. **Butler LM**, Mzolo S, Osmond D, Neilands T, Martin J. A population-based study of how children are exposed to saliva in KwaZulu-Natal, South Africa: implications for the spread of saliva-borne pathogens to children. *Trop Med Int Health*. 2010;15(4):442-453. PMCID: 20149165.
4. **Butler LM**, Were WA, Balindani S, Downing R, Dollard S, Neilands TB, Gupta S, Rutherford G, Mermin J. Human herpesvirus 8 infection in children and adults in a population-based study in rural Uganda. *J Infect Dis*. 2011;203(5):625-634.PMCID: 3071279

2. **Maternal health and mental health in sub-Saharan Africa.** I have led or contributed to studies that have documented important issues facing young mothers in low- and middle-income country settings including limited access to HIV and other health services, poverty, unintended pregnancy, violence and depression. This work has helped me to identify relevant targets for intervention, program and policy change to improve maternal and child health outcomes and reduce health disparities in LMICs.
   1. Horwood C, **Butler LM,** Haskins L, Phakathi S, Rollins N. HIV-infected adolescent mothers and their infants: low coverage of HIV services and high risk of HIV transmission in KwaZulu-Natal, South Africa. *PLoS ONE.* 2013;8(9):e74568. PMCID: PMC3779214
   2. Gibbs A, Carpenter B, Crankshaw T, Hannass-Hancock J, Smit J, Tomlinson M, **Butler L.** Prevalence and factors associated with recent intimate partner violence and relationships between disability and depression in post-partum women in one clinic in eThekwini Municipality, South Africa. *PLoS One.* 2017; 12(7):e0181236
   3. Tuthill EL, Pellowski JA, Young SL, **Butler LM.** Perinatal Depression Among HIV-Infected Women in KwaZulu-Natal South Africa: Prenatal Depression Predicts Lower Rates of Exclusive Breastfeeding. AIDS Behavior, 2017; 21 (8), 1681-1698. PMCID: PMC5393963
   4. Lewinsohn R, Crankshaw T, Tomlinson M, Gibbs A, **Butler L,** Smit J. “This baby came up and then he said , “I give up!”: The interplay between unintended pregnancy, sexual partnership dynamics and social support and the impact on women’s well-being in KwaZulu-Natal, South Africa. *Midwifery.* 2018; 62:29-35.

3. **HIV status disclosure.** I have led and contributed to studies focused on HIV disclosure in several populations including women’s disclosure to their sexual partner(s) during pregnancy, pediatric HIV disclosure, and adolescent disclosure. With colleagues from South Africa, our work on HIV diagnosis disclosure to partners and family members by pregnant women informed development of a conceptual model of HIV-serostatus disclosure in the context of pregnancy. A WHO-commissioned systematic review of studies of interventions for supporting adolescents to disclose their HIV sero-status informed WHO guidelines for adolescent HIV care and treatment which were published in 2013.
   1. Crankshaw TL, Voce A, King RL, Giddy J, Sheon NM, **Butler LM**. Double disclosure bind: Complexities of communicating an HIV diagnosis in the context of unintended pregnancy in Durban, South Africa. *AIDS Behav*. 2014;18(Suppl 1):S53-59.
   2. Etima M, Kurji J, King R, Musoke P, Fowler MG, **Butler L**.Low level of disclosure to HIV-infected children age 7 to 12 years old, Kampala, Uganda/Poster. Presented at the 6th International Workshop on HIV Pediatrics and International AIDS Society Conference on HIV Pathogenesis, Treatment and Prevention, Melbourne, Australia

3. **Butler LM**, Horvath T, Kennedy G, Spaulding A, Rutherford G. Interventions for supporting adolescents to safely and effectively disclose HIV sero-status in resource-constrained settings: A systematic review/Oral Presentation. Presented at the World Health Organization Adolescent HIV Guidelines Expert Meeting, Harare, Zimbabwe.
4. Klingberg S, King R, Seeley J, Lubwama R, Namuganga M, Nabiryo B, Etima M, Musoke P, **Butler LM.** Courage and confidence to stop lying: caregiver perspectives on a video to support paediatric HIV disclosure in Kampala, Uganda. *African Journal of AIDS Research*. 2018; 17(3):273-279. PMID: 30355059

4. **HIV and STI prevention, ART adherence, and PMTCT.** I have led or contributed to intervention studies that have examined structural and behavioral strategies to improving health promotion in low- and middle-income country settings. This work has helped me to identify effective intervention components as well as theoretical constructs which I continue to employ in my ongoing research.
   1. Bress J, Kashemwa G, Amisi C, Armas J, McWhorter C, Ruel T, Ammann A, Mukwege D, **Butler LM**. Delivering integrated care after sexual violence in the Democratic Republic of the Congo. *BMJ Global Health.* 2019; 4(1): e001120
   2. Horwood C, **Butler LM**, Barker P, Phakathi S, Haskins L, Grant M, Mntambo N, Rollins N. A continuous quality improvement intervention to improve the effectiveness of community health workers providing care to mothers and children: a cluster randomised controlled trial in South Africa. *Human Resources for Health,* 2013; 15 (1). PMCID: PMC5470211
   3. Weiser SD, Hatcher AM, Hufstedler LL, Weke E, Dworkin SL, Bukusi EA, Burger RL, Kodish S, Grede N, **Butler LM,** & Cohen CR. Changes in health and antiretroviral adherence among HIV-infected adults in Kenya: Qualitative longitudinal findings from a livelihood intervention. *AIDS and Behavior.* 2018; 21(2): 415-427. PMID 27637497
   4. Tuthill EL, **Butler LM,** Pellowski JA, McGrath JM, Cusson RM, Gable RK, Fisher JD. Exclusive breast-feeding promotion among HIV-infected women in South Africa: an Information-Motivation-Behavioural Skills model-based pilot intervention. Public Health Nutrition. 2017; 20(8):1481-1490

5. **Food security, HIV and infant and child nutrition and neurodevelopment.** I have led and contributed to studies on food security and HIV/AIDS transmission risk, and effectiveness of food security interventions on health and nutrition outcomes of HIV-infected adults and HIV- affected children. My first manuscript in this area showed that food insufficiency contributed to unprotected sex, sex exchange and multiple concurrent sexual partnerships in Botswana and Swaziland. Published in *PLoS Medicine* with Dr. Weiser, this paper won the NIH/Council of Science Editors Award for the Global Theme Issue on Poverty and Human Development, and was one of 7 articles chosen among more than 1000 articles published in 235 journals. I have been PI and co-I on some of the first studies evaluating food security interventions as a way to improve health outcomes for HIV and other chronic conditions in adults and on child nutrition, health and development.
   1. Weiser, S, Leiter, K, Bangsberg D, **Butler LM**, Percy-de Korte F, Hlanze Z, Phaladze N, Iacopino V, Heisler M. Food insufficiency is associated with high-risk sexual behavior among women in Botswana and Swaziland. *PLoS Med*. 2007;4(10):1589-1597. PMCID: 17958460.
   2. Weiser SD, Bukusi EA, Steinfeld R, Frongillo EA, Weke E, Dworkin SL, Pusateri K, Shiboski S, Scow K, **Butler LM**, Cohen CR. Shamba Maisha: Randomized control trial of an agricultural and finance intervention to improve HIV health outcomes in Kenya. *AIDS; 2015; 29(14), 1889-94.* PMCID: PMC4573846
   3. Weiser SD, Hatcher AM, Hufstedler LL, Weke E, Dworkin SL, Bukusi EA, Burger RL, Kodish S, Grede N, **Butler LM**, Cohen CR. Changes in Health and Antiretroviral Adherence Among HIV-Infected Adults in Kenya: Qualitative Longitudinal Findings from a Livelihood Intervention. *AIDS and Behavior,* 2017; 21(2) 415-427. PMID: 276374997
   4. **Butler LM**, Bhandari S, Otieno P, Weiser SD, Cohen CR, Frongillo EA. Agricultural and finance intervention increased dietary intake and weight of children living in HIV-affected households in western Kenya. *Current Developments in Nutrition, 2020,* 4:nzaa003. PMCID: 6981349

Link to NCBI MyBibliography:
http://www.ncbi.nlm.nih.gov/sites/myncbi/1Xusak90q9bQh/bibliography/47974679/public/?sort=date&direction=ascending

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

BIOGRAPHICAL SKETCH

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

NAME: Munro, Nicholas

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

POSITION TITLE: Senior Lecturer in Psychology

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

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
University of Natal, Durban (UND)	B.SocSc	12/1996	Psychology & Legal Studies
University of Natal, Durban (UND)	B.SocSc (Hons)	12/1997	Psychology
University of Natal, Durban (UND)	M.SocSc	06/1999	Counselling Psychology
University of KwaZulu-Natal (UKZN)	PhD	12/2013	Education

A. Personal Statement

I am a Senior Lecturer in Psychology at the University of KwaZulu-Natal and conduct interdisciplinary research in the fields of education, teaching and learning, and health psychology. I have a background in professional counselling psychology with expertise in psychological assessment, a broad range of individual and group-based counselling and psychotherapeutic intervention techniques, and community psychology and engagement. I have been registered as a counselling psychologist with the Health Professions Council of South Africa since 1999. My research expertise falls within the areas of survey research, mixed methodologies, and visual and participatory methodologies. In addition to my teaching duties, clinical and research supervision responsibilities, and community engagement activities, I have served as PI and/or sub-awardee on five research grants over the past 12 years and this has provided me with a solid foundation to serve as site PI on the proposed research titled *Multi-level school-based intervention to improve HPV vaccine uptake and completion in South Africa.* My current work and research involve close collaborations with colleagues from the local Departments of Health and Education. In terms of the former, my work on the Developing Research Innovation, Localization and Leadership (DRILL) project (see details below) involves interviewing nurses, doctors, and other healthcare professionals in South African about various health system strengthening projects. With the Department of Education, I collaborate with several schools in Pietermaritzburg that serve as practicum sites for professional psychology students I am involved in training. In my role as site PI, I will contribute to the development and implementation of study protocols, including facilitating local ethics (IRB) review. I will also take overall responsibility for local study staff communication, coordination, and reporting. My responsibility will also involve overseeing research participant identification and recruitment and ensuring that data are collected and managed appropriately.

Ongoing and completed research projects I would like to highlight include:

1D43TW010131-1
Brysiewicz et al (PI) US$ 3,200,000
2015–2022
Developing Research Innovation, Localization and Leadership (DRILL) in South Africa. International Research Training Award, Fogarty International Center, US National Institutes of Health grant.

Role: Sub-awardee on specific project: Mentoring and supervising early career healthcare researchers: An evaluation of the relational triads embedded within the Developing Research Innovation, Localisation and Leadership in South Africa (DRILL) programme – *"The DRILL mentoring study"*

Munro (PI) PRIVATE SUPPORT
2015–2022
In the line of duty: A participatory inquiry with MSM community health workers about their "workplace" stressors. – The "In the line of duty study." University Capacity Development Programme.
Role: PI

B. Positions, Scientific Appointments, and Honors

Positions and Scientific Appointments

2020 – present	*National Examiner in Counselling Psychology*: Professional Board for Psychology, Health Professions Council of South Africa
2019 – present	*Senior Lecturer:* Discipline of Psychology, School of Applied Human Sciences, University of KwaZulu-Natal
2017 – present	*Ethics Committee Member*: Professional Conduct Committee, Professional Board for Psychology, Health Professions Council of South Africa
2013 – 2021	*Member*: Research and Higher Degrees Teaching and Learning Committee, School of Applied Human Sciences, University of KwaZulu-Natal
2013 – 2021	*Member*: Teaching and Learning Committee, School of Applied Human Sciences, University of KwaZulu-Natal
2013 – 2019	*Lecturer*: Discipline of Psychology, School of Applied Human Sciences, University of KwaZulu-Natal
2012 – 2013	*Lecturer*: School of Education, University of KwaZulu-Natal
2009 – 2011	*Member*: Executive Management Committee, Southern African Association for Counselling and Development in Higher Education (SAACDHE)
2002 – 2011	*Counselling Psychologist / Senior Student Counsellor*: Student Counselling and Careers Centre, University of KwaZulu-Natal
2000 – 2002	*Counselling Psychologist / Student Counsellor*: Student Counselling and Development Centre, Technikon Natal
1999 – 2000	*Counselling Psychologist*: Human Resources, National Department of Foreign Affairs

Honors

2013-2018	Annual Performance Award, University of KwaZulu-Natal
09/2010	SAACDHE annual conference: best research paper award
09/2009	SAACDHE annual conference: best research paper award
09/2008	SAACDHE annual conference: best research paper award
02/2009	Merit award, University of KwaZulu-Natal

C. Contributions to Science

1. **Enhancing learning and educational outcomes**: My most recent contributions to science center around strategies to enhance learning and educational outcomes. These contributions emphasize the importance of strengths-based discourses and practices to education and learning. Specific contributions highlight the reciprocity of teaching and learning, the role of (collective) emotions in behavior change, individual motivations and achievement, and strategies to harness the reciprocity of teaching and learning and collective emotions in educational contexts.
   a. **Munro**, N., & Shuttleworth, T. (2021). Visualizing achievement emotions through photo-elicitation interviews: A methodology for generating data on the dialectical tensions between pride, sadness, and hope among high achieving undergraduate students. In E. Braun, R. Esterhazy, & R. Kordts-Freudinger (Eds.), *Research on teaching and learning in higher education* (pp. 143-162). Waxmann
   b. Senekal, J. & **Munro**, N. (2019). Lessons learnt from two decades of graduate tracer studies: Recommendations for the South African context. *South African Journal of Higher Education*

c. McCullough, K., & **Munro**, N. (2018). Finance students' experiences of lecture-based active learning tasks. *Innovations in Education and Teaching International, 55* (1), 65-73. DOI: 1080/14703297.2016.1189843
d. Mngomezulu, S., Dhunpath, R., & **Munro**, N. (2017). Does financial assistance undermine academic success? Experiences of 'at risk' students in a South African university. *Journal of Education, 68*, 131-148.

2. **Health psychology in educational contexts**: My earlier contribution to science was focused on the field of health psychology in educational contexts, and explored the extent of vulnerability to food insecurity among South African university students. I was involved in a major institutional project which gathered data about (and responded to) levels of vulnerability to food insecurity among university students. The research resulted in a first-of-its-kind publication in South Africa. This research was presented at multiple institutional and national forums, and has informed current higher education funding and student support strategies.
   a. **Munro**, N., Quayle, M., Simpson, H., & Barnsley, S. (2013). Hunger for knowledge. Food insecurity among students at the University of KwaZulu-Natal. *Perspectives in Education, 31*(4), 168-179.

3. **Peer-based interventions to promote healthy sexual behaviors:** Prior to the above contributions, my focus on health psychology in education interrogated the value of peer-based interventions in promoting healthy sexual practices among young adults. The work on peer education also brought to the fore the importance of a strengths-based approach to working with student learning and psychological well-being. Two publications emanated from my work in the field of peer education for health psychology:
   a. **Munro**, N., Chilimanzi, Y., & O'Neill, V. (2012). Covariation of character strengths and dimensions of psychological type in university peer educators. *South African Journal of Psychology, 42*(1), 15-24.
   b. **Munro**, N. (2011). The use of the Myers-Briggs Type Indicator in peer education: A positive psychological approach to peer educator training and peer to peer-based interventions in higher education. *Journal of Counselling and Development in Higher Education Southern Africa 1*(1), 37-47.

Complete List of Published Work in MyBibliography:

https://www.ncbi.nlm.nih.gov/myncbi/nicholas.munro.1/bibliography/public/

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BIOGRAPHICAL SKETCH

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

NAME: Wassenaar, Douglas Richard

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

POSITION TITLE: Professor; PI SARETI

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

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
University of Natal	B.A.	12/1975	Psychology & English
University of Natal	B.A. (Hons)	12/1976	Clinical Psychology
University of Natal	M.A. (*Cum laude*)	12/1978	Clinical Psychology
Health Professions Council of SA	N/A	01/1978	Registered Clinical Psychologist
University of Natal	PhD	02/2003	Psychology (Professional Ethics in Psychology)
Georgetown University	N/A	06/2003	Intensive Bioethics Course

A. Personal Statement

I am a Professor of Psychology at UKZN and a registered Clinical Psychologist. I have been and remain the PI or co-PI on several NIH grants since 2004. I have been PI or co-PI on many other research ethics awards, including from Wellcome, the European Developing Counties Clinical Trials Partnership (EDCTP), UNAIDS, Fogarty/NIH, SA MRC, and the Canadian HIV AIDS Vaccines Initiative (CHVI) exceeding US $20 million. I have been a consultant on research ethics to the World Health Organisation (WHO) and was the ethics advisor on two WHO expert panels to address emergency research in Ebola and Zika in Africa. I am Editor-in-Chief of the *Journal of Empirical Research on Human Research Ethics* (SAGE Publishing) which is a leading journal publishing empirical research on research ethics issues. I have chaired the UKZN IRB for 8 years; excluding 6 years as Deputy Chair. I chaired the Human Sciences Research Council's IRB 2005-2018. I have graduated 89 Masters students, of which 25 were on research ethics topics. I have supervised or co-supervised 7 PhDs of which 4 were on advanced issues in research ethics. I am currently co-supervising one PhD on ethical issues in HIV phylogenetic research, with global COVID-19 expert Dr Tulio de Oliveira. I have examined PhD and masters theses nationally and internationally. I have published 87 peer-reviewed papers, of which about 60 are on research ethics, and 7 chapters on research ethics. A recent joint ethics paper was discussed in an editorial in *Nature*, and earlier collaborative work on data sharing was cited in *Science*. I have reviewed for *American Journal of Bioethics, JERHRE, Bioethics, Developing World Bioethics, Journal of Medical Ethics* and *BMC Medical Ethics*. I am also Co-PI on the NIH/FIC UKZN research training program (DRILL) at UKZN which provides intensive research mentoring and support for talented early-career health researchers. I was also co-PI on the previous MEPI (Glass et al., 2018; Lalloo et al, 2014) iteration of that project, also funded by NIH/FIC which supported several early career academics in health research, one of whom completed a PhD under my supervision. The MEPI work also led to a publication on advanced training of health professionals in *Academic Medicine*. I am on the advisory board of TRREE for Africa, an EDCTP-funded open-access online research ethics training program, contributing to several of the TRREE modules currently available online. The South African TRREE module has enrolled over 42,000 applicants for certificates which are compulsory for all ethics applicants at several South African universities and research centers. I was a longstanding member (2007-2016,

resigned) of the Steering Committee of the Global Forum for Bioethics in Research (GFBR) which is largely funded by Wellcome and FIC/NIH. I served as chair of the NIH Fogarty Bioethics Program Center for Scientific Review Special Emphasis Panel 2016-2017 and have been a protocol and funding reviewer for the European Union and for the Swiss School of Public Health. I thus have a 20-year record of successful awards with a particular focus on ethics and health research. I am well-connected to prestigious health research units at UKZN such as (CAPRISA, HPP, KRISP, HAVEG) and the UKZN IRB. I will advise this team on a wide variety of ethical issues associated with the proposed study. With my deep experience and expertise in capacity strengthening, I will help to develop the competency for in-country staff to lead HPV prevention efforts in their own communities.

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

1D43TW011240-01A1
Wassenaar (PI) US$ 1,224,614
Role: Grantholder, Corresponding PI
2020–2025
Competitive grant from US National Institutes of Health, Fogarty International Center
SARETI (South African Research Ethics Training Initiative) Leadership Program:
An international bioethics research training program, in collaboration with the George Washington University and Johns Hopkins University, Baltimore, USA, this is SARETI's first PhD degree scholarship program specializing in health research ethics on the African continent, based at the University of CONFIDENTIAL INFORMATION - REQUESTER IN AGREEMENT [redacted].

1D43TW010131-1
Brysiewicz et al (PI) US$ 3,200,000
Role: Co-PI
2015–2022
Developing Research Innovation, Localization and Leadership (DRILL) in South Africa. International Research Training Award, Fogarty International Center, US National Institutes of Health grant.

PRIVATE SUPPORT [redacted]
Wassenaar (PI) CONFIDENTIAL INFORMATION - REQUESTER IN AGREEMENT [redacted]
Role: South African Sub-awardee
2013–2019
Competitive grant from PRIVATE SUPPORT [redacted] through the Governing Council of CONFIDENTIAL INFORMATION - REQUESTER IN AGREEMENT [redacted].
CHVI Team in Social and Behavioral Research on HIV Vaccines

B. Positions, Scientific Appointments and Honors

Positions and Employment

2020-present	*Chair*: Biomedical Research Ethics Committee (IRB), Research Office, UKZN (40% time) (previous term: 2008-2015).
2015–2020	*Deputy Chair*: Biomedical Research Ethics Committee (IRB), Research Office, UKZN
2012–2016	*Academic Leader*: Psychology: School of Applied Human Sciences
2010–2019	*Professor*: School of Psychology, University of KwaZulu-Natal, Pietermaritzburg
2005-2018	Chair: Human Sciences Research Council Research Ethics Committee (IRB)
2005–2009	*Associate Professor*: School of Psychology, University of KwaZulu-Natal, Pietermaritzburg
1989–2005	*Senior Lecturer*: Clinical Psychology, University of Natal, Pietermaritzburg
1983–1988	*Lecturer*: Clinical Psychology, University of Natal, Pietermaritzburg
1981–1982	*Senior Clinical Psychologist/Lecturer*: Town Hill and Fort Napier Hospitals, Pietermaritzburg
1979–1981	*Clinical Psychologist/Lecturer*: Town Hill and Fort Napier Hospitals, Pietermaritzburg
1978	*Intern Clinical Psychologist*: Town Hill and Fort Napier Hospitals, Pietermaritzburg

Selected Other Experience and Professional Memberships

2021-present	Member: International Advisory Board, NIH/FIC funded SARETI IV Research Ethics Training Program.

2020-present	*Member: Ministerial Advisory Committee on COVID-19* (National advisory committee to advise the South African Minister of Health on all aspects of the COVID-19 pandemic
2016–present	*Editor-in-Chief*: *Journal of Empirical Research on Human Research Ethics*
2015–2016	*Member*: World Health Organisation: Working group to review and advise on WHO Ebola Vaccine Target Product Profiles
2013–2016	*Associate Editor*: *Journal of Empirical Research on Human Research Ethics*
2011–2016	*Member*: World Health Organisation/UNAIDS Vaccine Advisory Committee
2008–2011	*Member*: International Advisory Board: Health Research Ethics Training for Egypt and the Middle East. (*Universities of Maryland and Cairo*).
2008–2012	*Member*: International Scientific Advisory Board: *World Health Organisation, Geneva*: Mass cholera vaccination programme for Zanzibar
2008–2011	*First Chairperson*: International Public Engagement Awards Funding Committee, *Wellcome Trust*, UK
2008–2009	*Member*: International Scientific Advisory Board: *World Health Organisation, Geneva*: Mass cholera vaccination program for Zanzibar
2008	*South African Medical Association*: Member of invited South African expert panel to submit revisions to World Medical Association: Declaration of Helsinki, February
2008	*World Health Organisation*: Commissioned to conduct training retreat for Ethical Review Committee of the World Health Organisation: *Geneva*, March
2007–2019	*Member*: International Steering Committee: *Global Forum on Bioethics in Research* funded by US NIH Fogarty International Center, UK Medical Research Council, Wellcome Trust.
2006–2016	*Member*: International Advisory Committee: Training and Resources in Research Ethics for Africa (TRREE).
2005–2011	*Member* (2 terms): Biomedical Ethics Funding Committee, *The Wellcome Trust*, UK
2004–2008	*Member*: Advisory Board: West African Bioethics Program, *University of Ibadan, Nigeria*
2004–2008	*Member*: Advisory Board: *University of Malawi & Michigan State University* Fogarty Bioethics Scholarship programme.
2003–2010	*Chair*: *World Health Organisation/UNAIDS African Aids Vaccine Programme*: Ethics Law and Human Rights Working Group
2000–present	*Consultant*: *HIV/AIDS Vaccines Ethics Group, School of Psychology, University of KwaZulu-Natal* (Pmb.), and SA AIDS vaccine Initiative (SAAVI) of the SA Medical Research Council.

Honors

2017	College of Humanities award for grants and excellence
2015	Provincial award for excellent service to health research

C. Contributions to Science

I have devoted my career almost exclusively to research ethics since 2002, spreading my attention to research ethics practice (chairing 2 IRBs), training (through SARETI and MEPI/DRILL), research, and consulting. My research has focused on generating **empirical data on research ethics questions**, and training young researchers to do empirical work on research ethics issues. My research ethics work has been fairly diverse, and has not focused on a single area, as the publications below show. Working in a LMIC I strive to include my students as authors, often as first author. My work was recognized when I was asked to become Editor-in-Chief of the *Journal of Empirical Research on Human Research Ethics* in 2016, a leading international journal showcasing empirical work in research ethics.

A. Ethical issues in infectious disease research in Africa

1. Mathenjwa, T., Nkosi, B., Kim, H-Y., Bain, L., Tanser, F., & **Wassenaar, D**. Ethical considerations in using a smartphone-based GPS app to understand linkages between mobility patterns and health outcomes: The example of HIV risk among mobile youth in rural South Africa. *Developing World Bioethics*
2. Wilkinson, A., Slack, C., Crews, C., Singh, N., Salzwedel, J., & **Wassenaar, D**. (2021). How can research ethics committees help to strengthen stakeholder engagement in health research in South Africa? An evaluation of REC documents. *South African Journal of Bioethics and Law, 14*(1), 6-10.
3. Rossouw, T., **Wassenaar, D.R**., Kruger, M., Blockman, M., Hunter, A., & Burgess, T. (2021). Research ethics support during the COVID-19 epidemic: a collaborative effort by South African Research Ethics Committees. Chapter in K. Govender, G. George, A. Padarath, T. Moeti (Eds.) *South African Health Review 2021*, pp. 163-172. Durban: Health Systems Trust.
4. Mutenherwa, F., **Wassenaar, D.R**., & de Oliveira, T. (2020). Adding a voice to the unique ethical considerations in molecular HIV surveillance. *American Journal of Bioethics*, *20*(10), 34-36.

B. Selected studies of/about Research Ethics Committees/IRBs

1. Silaigwana, B., & **Wassenaar, D.R.** (2019)**.** Research ethics committees' oversight of biomedical research in South Africa: A thematic analysis of ethical issues raised during ethics review of non-expedited protocols. *Journal of Empirical Research on Human Research Ethics 14*(2), 107-116. DOI: 10.1177/1556264618824921
2. Mokgatla, B., IJsselmuiden, C., **Wassenaar, D.R.**, & Kasule, M. (2017). Mapping of Research ethics committees in Africa: Evidence of the growth of ethics review of health research in Africa. *Developing World Bioethics*, *18*(4), 341-348. doi: 10.1111/dewb.12146
3. Kasule, M., **Wassenaar, D.R.,** IJsselmuiden, C.B., & Mokgatla, B. (2016). Silent voices: Current and future roles of African Research Ethics Committee Administrators*. IRB Ethics & Human Research, 38*(1), 13-19.
4. Silaigwana, B., & **Wassenaar, D.R**. (2015). Biomedical research ethics committees in Sub-Saharan Africa: A collective review of their structure, functioning and outcomes. *Journal of Empirical Research on Human Research Ethics, 10*(2)*,* 169-184. doi: 10.1177/1556264615575511

C. Ethical issues in social science research

1. **Wassenaar, D.R.**, & Slack, C.M. (2016). How to learn to love your research ethics committee: Recommendations for psychologists. *South African Journal of Psychology, 46*(3), 306-315. doi: 10.1177/0081246316654348
2. Singh, S., & **Wassenaar, D.R.** (2016). Contextualising the role of gatekeeper in social science research. *South African Journal of Bioethics & Law, 9*(1), 42-46.
3. **Wassenaar, D.R**., & Rattani, A. (2016). What makes health systems research in developing countries ethical? Application of the Emanuel framework for clinical research to health systems research. *Developing World Bioethics, 16*(3), 133-139*.* doi:10.1111/dewb.12101
4. **Wassenaar, D. R**., & Mamotte, N. (2012). Ethical issues and ethics reviews in social science research. In A. Ferrero, Y . Korkut, M . M . Leach, G . Lindsay, & M . J . Stevens (Eds.), *The Oxford handbook of international psychological ethics* (pp. 268-282). New York: Oxford University Press. doi: 10.1093/oxfordhb/9780199739165.013.0019

D. Other work in research ethics

1. Lutge, E., Slack, C, M., & **Wassenaar, D.R**. (2017). Defining and negotiating the social value of research in public health facilities: Perceptions of stakeholders in a research active province of South Africa. *Bioethics*, *31*(2), 128-135*.* doi:10.1111/bioe.12323
2. Denny, S.G., Silaigwana, B., **Wassenaar, D.R.,** Bull, S., & Parker, M. (2015). Developing ethical practices for public health research data sharing in South Africa: Views and experiences from a diverse sample of research stakeholders. *Journal of Empirical Research on Human Research Ethics, 10*(3), 290-301.
3. Bull, S., Cheah, P.Y., Denny, S., Jao, I., Marsh, V., Merson, L., More, N.S., Nhan, L.N., Osrin, D.M., Tangseefa, D., **Wassenaar, D.R**., & Parker, M. (2015). Best practices for ethical sharing of individual-level health research data from low and middle-income settings. *Journal of Empirical Research on Human Research Ethics, 10*(3), 302-313.

4. Kombe, F., Anunobi, E.N., Tshiffugula, N.P., **Wassenaar, D.R**., Njadingwe, D.N., Mwalukore, S., Chinyama, J., Randrainasolo, B., Akindeh, P., Dlamini, P.S., Ramiandisoa, F.N., & Ranaivo, N. (2014). Promoting research integrity in Africa: An African voice of concern on research misconduct and the way forward. *Developing World Bioethics, 14*, 158-166. doi: 10.1111/dewb.12024.

Complete List of Published Work in ResearchGate:
https://www.researchgate.net/profile/Douglas-Wassenaar

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

BIOGRAPHICAL SKETCH

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

NAME: Slack, Catherine

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

POSITION TITLE: Project Manager HIV AIDS Vaccines Ethics Group (HAVEG), UKZN

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

INSTITUTION AND LOCATION	DEGREE	Completion Date	FIELD OF STUDY
University of Cape Town (UCT), Cape Town, South Africa	BA	12/1991	Psychology, English Literature
University of Natal, Pietermaritzburg, South Africa	BA Honors	04/1993	Psychology
University of Natal, Pietermaritzburg, South Africa	MA	05/1998	Clinical Psychology
Health Professions Council of South Africa (HPCSA)	Clinical Registration	1999	Registered Clinical Psychologist
University of Natal, Pietermaritzburg , South Africa	PhD	04/2015	Psychology

A. Personal Statement

I am a registered clinical psychologist currently employed at the [redacted] as the project director of the HIV AIDS Vaccines Ethics Group (HAVEG). In this position, I manage externally- funded projects exploring ethical-legal complexities in HIV prevention trials. I have experience in conducting conceptual and empirical research into ethical-legal complexities of HIV prevention research, including the complex issue of adolescent enrolment, and I have experience in the development of resource documents for affected stakeholders to help them to strengthen their practices. HAVEG has a long history of interfacing with key stakeholders in HIV prevention research, and in adolescent research, including investigators, Research Ethics Committees (RECs/IRBs) and Community Advisory Boards (CABs), of analyzing barriers to research, and of producing resources to resolve challenges. I was also part of the WHO-UNAIDS Ethics, Law and Human Rights Collaborating Centre of the African AIDS Vaccine Program (AAVP) and as part of this group I was involved in researching the needs of Research Ethics Committees in selected African countries and developing resources for stakeholders committed to the welfare of participants in HIV prevention trials. I was part of the expert panel that assisted to draft the UNAIDS/WHO (2007) guidance document: *Ethical considerations in biomedical prevention trials*. I was a member of the National Health Research Ethics Council (NHREC) in South Africa from 2007 to 2016 - a council established in terms of South Africa's National Health Act (2003) in order to set national norms and standards for research ethics in South Africa. I have also been involved in teaching research ethics at a Master's level – for many years I convened a module on ethical considerations in HIV vaccine trials for the NIH-Fogarty funded South African Research Ethics Training Initiative (SARETI). I will advise the team on ethical-legal challenges in project implementation and develop resources in this regard. I will assist the study team to consider the normative implications of the empirical data.

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

USAID - Project CASPR#
Role: PI (UKZN Sub-Award)
01/01/2017-12/30/2022
Title: Strengthening stakeholder engagement through ethical review: HIV vaccine and biomedical prevention research project Objective 3: Coalition To Accelerate and Support Prevention Research (CASPR)

This project at UKZN involves research and training on how best to strengthen stakeholder engagement through ethical review and how to support key stakeholders with ethics guideline resources to enhance ethics practice. Role: PI on UKZN Sub-Award

B. Positions, Scientific Appointments, and Honors

Employment

2020—present	Project Director: HIV/AIDS Vaccines Ethics Group (HAVEG) [redacted] CONFIDENTIAL INFORMATION - REQUESTER IN AGREEMENT
2000-2020	Project Coordinator: HAVEG UKZN
2001-2003	Interim Project Coordinator: Ethics Law and Human Rights Working Group (UNAIDS/WHO African AIDS Vaccine Program)
1997-1999	Administrator and Coordinator: Postgraduate Diploma in Applied Social Sciences (Psychology); lecturer in Psychology; University of Natal, Pietermaritzburg

Other Positions

2015-present	Member of the DSMB for HVTN 100 and HVTN 702 and HVTN 705.
2015	Scientific Reviewer: NIH Special Emphasis Panel/Scientific Review Group 2015/05 ZRG1 AARR-L (56) R
2013- 2016	Member of the External Advisory Board (EAB) of the HIV Vaccine Trials Network (HVTN)
2009	Track Chair: Social and Economic Sciences, Human Rights and Ethics: 4th South African AIDS Conference, Durban South Africa, 31 March to 3rd April
2008-present	Presenter at the Advanced Vaccinology Course (ADVAC), Fondation Merieux, Annecy, France on ethical complexities in clinical trials of vaccines
2007-2016	Member of the National Health Research Ethics Council (NHREC), South Africa
2007	Member of working party for revision of UNAIDS guidelines: *Ethical considerations in biomedical prevention trials*. UNAIDS/WHO guidance document, UNAIDS: 2007.
2003-2010	Consultant: Ethics, Law and Human Rights (ELH) Working Group: WHO-UNAIDS African AIDS Vaccine Programme (AAVP)
2003	Member of the working party for the development of the South African Medical Research Council (2003) Guidelines on ethics for medical research: HIV preventive vaccine research
1999-present	Registered Clinical Psychologist: Health Professions Council of South Africa (HPCSA)

C. Contributions to Science

1. **Adolescent enrolment:** The South African ethico-legal framework governing adolescent research is a complex one. There are norms affecting adolescent research in various places (national ethical guidelines, human subjects regulations and in the National Health Act [2003]), and these norms are not always well harmonized, and in some instances are restrictive. This can create uncertainty for key stakeholders developing and reviewing adolescent research protocols, and can act as potential barrier to adolescent enrolment in socially valuable and appropriate research. Along with colleagues, I have researched the ethical-legal framework and developed guidance for key research stakeholders to help them implement ethical-legal obligations in adolescent research.
    - Strode, A., & **Slack, C**. (2021). Three Billboards to support ethical-legal adolescent HIV prevention trials in Southern and Eastern Africa. Chapter 5 (pp. 92-109) in Edited Book (Eds Govender K & Poku N). *Preventing HIV Among Adolescents and Young People in Eastern and Southern Africa: Emerging Evidence and Intervention Strategies.* Routledge Studies in Health in Africa.
    - Day, S., Kapogiannis, B., Shah, S., Wilson, C., Ruel, T., Conserve., D., Strode, A., Donenberg, G., Kohler, P., **Slack, C.**, Ezechi, O., Tucker, J on behalf of the PATC3H Consortium (2020). Adolescent Bioethics Working Group Adolescent participation in HIV research: Consortium experience in low and middle-income countries and scoping review. *Lancet HIV, 7:* e844–52.
    - Gill, K., Johnson, L., Dietrich, J., Myer, L., Marcus, R., Wallace, M., Pidwell, T., Mendel, E., Fynn, L., Jones, K., Wiesner, L., **Slack, C.,** Strode, A., Spiegel, H., Hosek, S., Rooney, J., Gray, G., Bekker, L-G. (2020). Acceptability, safety, and patterns of use of oral tenofovir disoproxil fumarate and

emtricitabine for HIV pre-exposure prophylaxis in South African adolescents: an open-label single-arm phase 2 trial. *Lancet Child and Adolescent Health, 4,* 875–83.

- Gill K, Happel A, Pidwell T, Mendelsohn A, Duyver M, Johnson L, Myer L, **Slack C**, Strode A, Hosek S, Mendel E, Fynn L, Wallace M, Spiegel H, Smit D, Jaspan H, Passmore J-A, Rinehart A, Bekker L-G. (2020). An Open-Label, Randomized Crossover Study to Evaluate the Acceptability and Preference for Contraceptive Options in Healthy HIV-Uninfected Female Adolescents, 15-19 Years of Age, as a proxy for HIV prevention methods. *Journal of the International AIDS Society*, 23:e25626

2. **Stakeholder ('community') engagement**: It is well-recognized that the involvement of key role-players in research can strengthen the scientific and ethical rigor of research - for example, engagement of participating community experts can identify risks of which research teams may be unaware. I have been involved in empirical explorations of stakeholder perceptions of engagement for health research and made recommendations for how to strengthen this key ethical component. I have also been involved in identifying cross-setting thematic concerns in stakeholder engagement for HIV prevention trials.
   - Thabethe, S., **Slack, C**., Lindegger, G., Wilkinson, A., Wassenaar, D., Kerr, P., Bekker, LG., Mngadi, K., & Newman P. (2018). "*Why don't you go into suburbs? Why are you targeting us*? Trust and mistrust in HIV vaccine trials in South Africa. *Journal of Empirical Research on Human Research Ethics.* Vol. 13(5) 525– 536 DOI: 10.1177/1556264618804740.
   - **Slack, C**., Thabethe, S., Lindegger, G., Matandika, L., Newman, P., Kerr, P., Wassenaar, D., Roux, S., & Bekker, LG (2016). '*I've gone through this my own self, so I practice what I preach*: Strategies to enhance understanding and other valued outcomes in HIV vaccine trials in South Africa. *Journal of Empirical Research on Human Research Ethics, 11(4), 322-333:* DOI: 10.1177/1556264616675202.
   - Newman, P., **Slack, C**., & Lindegger, G. (2018). Commentary on "A Framework for Community and Stakeholder Engagement: Experiences from a multi-centre study in Southern Africa". *Journal of Empirical Research on Human Research Ethics, 13(4), 333-337.*
   - Lutge, E., **Slack, C.**, & Wassenaar, D. (2017). Defining, negotiating and realizing the social value of research in public health facilities: Perceptions of stakeholders in a research-active province of South Africa. *Bioethics, 31*(2), 128-135.

3. **Role of Research Ethics Committees (RECs)**
   I have been involved in analysis of the international and national ethics guidelines to identify core responsibilities of researchers in prevention trials, and the implications for the ethics review process. I have explored with colleagues the opportunities presented by the ethics review process to elevate ethics practices in the field.
   - **Slack, C**., Ndebele, P., Allen, M, & Salzwedel, J. (2021). Shifts in UNAIDS Ethics Guidance and Implications for Ethics Review of Preventive HIV Vaccine Trials. *Journal of the International AIDS Society* 2021, **24**(S7):e25796
   - Wilkinson, A., **Slack, C**., Crews, C., Singh, N., Salzwedel, J., & Wassenaar, D. (2021). How can Research Ethics Committees help to strengthen stakeholder engagement in health research in South Africa? An evaluation of REC documents. *South African Journal of Bioethics and Law, 14*(1), 6-10. doi:10.7196/SAJBL.2021.v14i1.698
   - Wilkinson, A., **Slack, C.**, Thabethe, S., & Salzwedel, J. (2022). "*It's almost as if stakeholder engagement is the annoying 'have-to-do"* - How could the ethics review process facilitate excellent engagement in clinical trials and beyond? *Journal of Empirical Research on Human Research Ethics.* DOI: 10.1177/15562646221078415
   - **Slack, C**., Wilkinson, A., Salzwedel, J., & Ndebele, P. (2018). Strengthening stakeholder engagement through ethics review in biomedical HIV prevention trials: Opportunities and complexities. *Journal of The International AIDS Society*. 21(S7):e25172

Complete List of Published Work in ResearchGate:

https://www.researchgate.net/profile/Catherine-Slack

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

BIOGRAPHICAL SKETCH

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

NAME: Gumede, Mkhonzeni

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

POSITION TITLE: [redacted]

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

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
University of Zululand	Senior Teacher's Diploma	12/1991	Education
University of Zululand	B. Paed	12/1992	Education
University of Zululand	B A Honors	12/1993	Arts
University of KwaZulu Natal	Masters	12/2011	Social Sciences
University of KwaZulu Natal	PhD	04/2021	Social Sciences

A. Personal Statement

I have over twenty years of experience working in the field of health communication. I am a trained theatre specialist interested in applied arts for health communication. I am passionate about using the arts to facilitate community participation in communication for social change projects. I believe in sustainable development, where development facilitators use their skills and expertise to facilitate bottom-up approaches that empower communities to seek local solutions and implement collective actions to solve community health problems. I believe in evidence-based programming that is informed by research. I have relevant experience for the proposed project, including applying participatory research approaches for health communication, using drama to improve awareness of HIV/AIDS, community engagement, and managing and reporting on donor funding. Previously, I worked in the non-profit sector as a Director of the Outreach Unit of the University of Zululand called DramAidE (Drama in AIDS Education), where we initiated and implemented various health communication projects. One such project is the health-promoting schools project, where we implemented health promotion interventions in the selected schools and assisted them in being declared health-promoting schools. Such projects required the application of Social and Behavior Change theoretical perspectives and health communication approaches, particularly entertainment education. I am currently a Lecturer in the discipline of Communication Media and Society at the University of KwaZulu-Natal. One of the modules that I lecture on is Health Communication for Social Change. Most recently, I worked as a health communication consultant, providing consultancy services to various organizations. Some of this consultancy work included the development of an HIV/AIDS communication strategy for vulnerable populations in KwaZulu Natal, training teachers and the Department of Education Officials on TB/HIV prevention and management, and program development for the South African Young Men's Christian Association. For this proposed work, I will contribute my expertise in health promotion communications to contribute to the design and implementation of an evidence-based intervention strategy for increasing HPV vaccination uptake and completion.

B. Positions, Scientific Appointments, and Honors

Positions

2021 – present	[redacted]
2016 – 2021	Health Communication Consultant
2009 – 2016	Director of DramAidE (University of Zululand)
1996 – 2009	Project Manager – DramAidE (University of Zululand)
1993 – 1996	Project Facilitator – DramAidE (University of Zululand)

Appointments

2022	External reviewer for the *Journal of Communication in Healthcare.*
2021 – present	Member of the Editorial Board of *Critical Arts: A Journal of South-North Cultural and Media Studies.*
2021 – present	Member of the Community Engagement Committee of the School of Applied Human Sciences, UKZN.
2020 – present	Board Chairperson - OneVoice South Africa, Durban.
2012 – 2016	Higher Education AIDS Medical Male Circumcision Coordinating Committee Member.
2006 – 2008	Member of the KZN DoH Health Promoting Schools Committee.
2000	Member of the Management Committee of the National Department of Health Beyond Awareness Campaign.
2000	Appointed as a community representative in the South African Local Organising Committee of the AIDS 2000 Conference secretariat.
1999	Kwa-Zulu Natal Regional Chairperson of the National AIDS Convention of South Africa (NACOSA).

Honors

2016	Selected to participate in the United States of America International Visitors Leadership Program.
2014	Awarded the Musa Njoko Ubuntu Award for leadership and contribution to the HIV/AIDS field in South Africa.

C. Contributions to Science

1. Applied arts for health communication

I have been involved in several projects that use drama to communicate key health messages for applications including HIV, life skills, adolescent health and environmental education. In my academic work, I have also trained and supervised 12 Honours and two Masters students within the school of Applied Human Sciences at the University of KwaZulu-Natal. I am also an Editorial Board member of the *Critical Arts* journal. I have also published two articles on this topic. These are:

- Gumede, M. L., 2012. “Act Alive”: Youth clubs communicating healthy life choices. *Investigating Communication, Health and Development*, 10.
- Gumede, M. L., 2021. Storytelling: The lessons across generations. *Academic and Non-Fiction Authors Association of South Africa*, 6(1), pp. 5-6.

2. Community engagement in health research

Throughout my research, I have been closely involved with community engagement, applying community facilitation approaches such as community dialogues and forum theatre. This has resulted in increased community buy-in and adoption of such projects where communities facilitated their local responses to address their health concerns. I am also currently a member of the Community Engagement Committee at UKZN, where we facilitate the University outreach activities and projects such as providing emergency support and relief to victims of the recent Durban floods and community cohesion projects following the recent looting that resulted in the polarization and tensions amongst racial groups in Durban.

- Developed the Community Engagement Strategy for the School of Applied Human Sciences
- Developed a Work Preparedness Workshop for students
- Developed the first Entertainment Education postgraduate course in conjunction with Johns Hopkins University

- Established partnerships with non-profit organizations to provide research fieldwork opportunities for postgraduate students.

3. Improving HIV / AIDS education in South Africa

I participated in various initiatives to improve HIV/AIDS education in South Africa. Below are some of the key national HIV/AIDS initiatives that I participated in:

- Member of the National Beyond Awareness Campaign, which was one of the first national AIDS awareness communication campaigns in South Africa.
- Appointed by the National Director of Arts and Culture to be a member of the National Life Orientation learning area committee, responsible for drafting the new curriculum.
- Community representative in the local organizing committee of the International AIDS Conference held in Durban in 2000.
- Participant in workshops for conference delegates at the 12th International AIDS Conference held in Switzerland.

4. Engaged scholarship within the field of health communication

As part of my PhD research, I contributed to the Woza Asibonisane Community Responses Programme focused on prevention of HIV and gender-based violence in South Africa. This study explored strategies that can be employed to amplify community voices in the implementation and how power relations amongst different stakeholders can be managed. The study found that power relations embedded within HIV prevention responses that incorporate external interest groups and marginalized local communities can affect “community ownership” and “leadership” in externally funded projects. For this research, I engaged community participation in community-led HIV/AIDS responses projects.

- *Lessons from Woza Asibonisane Community Responses Project in South* Africa – PhD study

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BIOGRAPHICAL SKETCH

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Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: Madhivanan, Purnima

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

POSITION TITLE: Associate Professor, Health Promotion Sciences

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

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
Government Medical College, Mysore, Karnataka, India	M.B.B.S.	06/1993	Medicine & Surgery
University of California, Berkeley, CA, USA	M.P.H	06/2003	Epidemiology
University of California, Berkeley, CA, USA	Ph.D.	03/2007	Epidemiology
San Francisco Department of Public Health, CA, USA	Postdoctoral fellow	05/2010	Public Health & Epidemiology
Institute for Research on Women and Gender, MI, USA	Postdoctoral fellow	07/2011	Gender & Women Health

A. Personal Statement

Over more than two decades, as a physician-scientist, my research has primarily focused on addressing social determinants of health at the population level in resource-limited settings. I have led the design and implementation of more than 30 epidemiological studies and surveys of infectious & chronic diseases, with emphasis on cancer prevention and control among women. I have been involved in primary and secondary prevention of cervical cancer since 2007. I have worked on qualitative and quantitative studies on HPV vaccine initiation and completion. I have worked on examining the policies around HPV vaccination in different states and how that affects vaccination rates and am currently examining the role of microbiome on acquisition and clearance of HPV, which will have implications for HPV vaccinations in the future. In collaboration with my colleagues, we have published over 20 articles on the topic. This proposed study co-led by Drs Katz and Butler is well within my area of inquiry, and I am very pleased to work on this project. I have the necessary expertise and knowhow on conceptualizing, data collection, data analysis and dissemination on this topic. For the proposed study, I will be involved in the conceptualization, data analysis and dissemination of the study findings. I have been a PI or co-investigator on several research and training grants that were successfully completed nationally and internationally. All the projects that I have worked on have resulted in over 200 peer-reviewed publications. (* indicates students or fellows on the publication)

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

R03AG069796
PI: Madhivanan P
09/30/2020-08/31/2023 (NCE)
Project title: Yoga for Healthy Aging (YHA) Study: A Mind-Body Intervention to Reduce Multimorbidity In the Elderly.

[redacted]
Beck-Sague / Madhivanan (MPI)
07/20/2020-08/30/2022
Cervical cancer screening in Mysore District, India with Visual Inspection with Acetic Acid (VIA), Human

Papillomavirus (HPV) DNA Tests, and Cytology: Enhanced Visual Assessment (EVA) and Automated Visual Evaluation (AVE) in Remote Rural Areas

R15 AI128714
PI: Madhivanan P
02/07/2017-01/31/2021
Longitudinal Study of Vaginal Microbiota and Persistent Human Papillomavirus.

D43 TW010540
Lott, B (PI), Role: Co-I
07/01/2017-06/30/2022
Global Health Equity Scholars Program - D43 Fogarty Training

P30 CA118100
Willman (PI), Role: Co-I
11/20/2020-07/01/2021
University of New Mexico
Research title: Understanding Factors Associated with Cervical Cancer Screening among Sexual and Gender Minorities (SGM) in Arizona: A Multi-level Framework

Citations:

1. Srinivas V, Herbst De Cortina S, Nishimura H, Krupp K, Jayakrishna P, Ravi K, Khan A, Madhunapantula SV, **Madhivanan P**. (2021) Community-based Mobile Cervical Cancer Screening Program in Rural India: Successes and Challenges for Implementation. Asian Pac J Cancer Prev. 2021 May 1;22(5):1393-1400. PMCID: PMC8408397
2. Habila* M, Kimaru* L, Mantina* N, Valencia* D, McClelland JD, Musa J, **Madhivanan P**, Sagay A, Jacobs E. (2021) Community engaged approaches to cervical cancer prevention in Sub-Saharan Africa: a scoping review. Frontiers in Women's Health. 2021 Jul 19;2:697607. PMCID: PMC8594022
3. Jeffries* A, Beck-Sagué CM, Marroquin-Garcia AB, Dean M, McCoy V, Cordova-Toma DA, Fenkl E, **Madhivanan P**. (2021) Cervical Visual Inspection with Acetic Acid (VIA) and Oncogenic Human Papillomavirus Screening in Rural Indigenous Guatemalan Women: Time to Rethink VIA. Int J Environ Res Public Health. 2021 Nov 25;18(23):12406. PMCID: PMC8656883
4. Lott* BE, Halkiyo A, Kassa DW, Kebede T, Dedefo A, Ehiri J, **Madhivanan P**, Carvajal S, Soliman A. (2021) Health workers' perspectives on barriers and facilitators to implementing a new national cervical cancer screening program in Ethiopia. BMC Womens Health. 2021 May 3;21(1):185. PMCID: PMC8090515

B. Positions, Scientific Appointments, and Honors

Positions and Scientific Appointments

2020 – 2021	Graduate Program Director, Global Health, Mel and Enid Zuckerman College of Public Health, University of Arizona, Tucson, AZ, USA
2019 – Present	Director, Global Health Equity Scholars Fellowship, University of Arizona, Tucson, AZ, USA
2019 – Present	Associate Professor (tenured), Department of Health Promotion Sciences, Mel and Enid Zuckerman College of Public Health, University of Arizona, Tucson, AZ, USA
2019	Reviewer, Center for Scientific Review Special Emphasis Panel, ZRG1 IDM-Z (55); PAR Panel: Global Infectious Disease Training Program
2017 – 2019	Associate Professor (tenured), Department of Epidemiology, Robert Stempel College of Public Health & Social Work, Miami, FL, USA
2015 – 2017	Executive Committee Member, Global Health Consortium, Herbert Wertheim College of Medicine, Florida International University, Miami, USA
2014 – 2015	Vice-Protocol Chair, Clearance Time of Gonococcal Nucleic Acid By Nucleic Acid Amplification Testing (NAAT), Social & Scientific Systems, Inc., Sexually Transmitted

	Infection Clinical Trials Group Task Order #4, Contract No. HHSN272201300014I, Silver Spring, MD
2013	Reviewer, National Institute of Allergy and Infectious Diseases; Clinical Trials Units for NIAID Network, ZAI1 DR-A
2012 – 2019	Director, Global Health Equity Scholars Fellowship, Florida International University, Miami, FL, USA
2012 – 2016	Graduate Program Director, Department of Epidemiology, Robert Stempel College of Public Health & Social Work, Miami, FL, USA
2011 – 2017	Associate Professor, Florida International University, Robert Stempel College of Public Health & Social Work, Miami, FL, USA
2011 – 2013	Community Initiative Technical Advisory Group Member, Elizabeth Glaser Pediatrics AIDS Foundation
2008 – 2010	Clinical Trials Research Coordinator, Public Health Foundation Enterprise, subcontracted to San Francisco Department of Public Health, San Francisco, CA, USA
2007 – Present	Founding Director, Public Health Research Institute of India, Mysore, India
2005 – Present	Medical Director, Prerana Women's Health Initiative, Mysore, India
2002 – 2004	Scientific Advisory Board Member, Elizabeth Glaser Pediatric AIDS Foundation, India
2002 – 2005	Research Associate, UCSF/Institute for Global Health, San Francisco, CA, USA
2000 – 2001	Scientific Working Committee Member, HIV Prevention and Treatment Network (HPTN) in collaboration with Brown University, RI, USA
1997 – 2001	Medical Officer, YRG Center for AIDS Research & Education, Chennai, India

Honors

2022 – 2023	Fulbright-Nehru Distinguished Scholar Award
2021	Government of Karnataka Vision Group on Science and Technology Award for Research on Women's Health, Karnataka, India
2021	Maria Teresa Velez Outstanding Mentoring Award, University of Arizona, USA
2018	Faculty Award for Excellence in Research & Creative Activities, Florida International University, USA
2011 – 2012	HIV Prevention Research Ethics Training Institute Fellowship, Fordham University Ethics Center, New York, USA
2007	International Leadership Award, Elizabeth Glaser Pediatrics AIDS Foundation, USA
2003 – 2007	Fogarty Fellowship to complete PhD in Epidemiology at University of California, Berkeley, USA
2001 – 2003	Fogarty Fellowship to complete MPH at University of California, Berkeley, USA

C. Contributions to Science

1. Global Health: Much of my work has focused on examining health inequities and increasing access to health care in low- and middle-income countries. This has led me to work in different settings and partners in the field of public health. (* indicates students on the publication)
    a. Cyrus* E, Sanchez J, **Madhivanan P,** Lama JR, Bazo AC, Valencia J, Leon SR, Villaran M, Vagenas P, Sciaudone M, Vu D, Coudray MS, Altice FL. **(**2021) Prevalence of Intimate Partner Violence, Substance Use Disorders and Depression among Incarcerated Women in Lima, Perú. Int J Environ Res Public Health. 2021 Oct 23;18(21):11134. PMCID: PMC8583326
    b. Aceves* B, Denman CA, Ingram M, Torres JF, Nuño T, Garcia DO, **Madhivanan P,** Rosales CB. (2021) Testing Scalability of a Diabetes Self-Management Intervention in Northern Mexico: An Ecological Approach. Front Public Health. 2021 Aug 18;9:617468. PMCID: PMC8416481
    c. Weaver LJ, Krupp K, **Madhivanan P.** (2022) The hair in the garland: hair loss and social stress among women in South India. Cult Med Psychiatry. 2022 Jun;46(2):456-474.
    d. Krupp K, Pope* B, Srinivas A, Ravi* K, Khan* A, Srinivas V, **Madhivanan P**, Bastida E. Parity and later life risk for coronary heart disease among slum-dwelling women in Mysore, India. Indian Heart J. 2021 Sep-Oct;73(5):622-628. PMCID: PMC8514413

2. Cervical Cancer Prevention and Control: Cervical cancer is one of top two causes of death for women in India & US. Our group has been identifying barriers to screening and parental acceptability of HPV vaccine

among minority populations in US and India. I continue to work on understanding factors associated with Primary and Secondary prevention of cervical cancer in UA, as well as in low-and middle-income countries. (* indicates students on the publication)

a. Pierre-Victor* D, Trepka MJ, Page TF, Li T, Stephens DP, **Madhivanan P**. (2017) Impact of Louisiana's HPV Vaccine Awareness Policy on HPV Vaccination among 13- to 17-Year-Old Females. Health Educ Behav. 44(4):548-558.
b. **Madhivanan P,** Nishimura* H, Ravi* K, Pope* B, Coudray* M, Arun A, Krupp K, Jayakrishna P, Srinivas V. (2021) Acceptability and Concordance of Self- Versus Clinician- Sampling for HPV Testing among Rural South Indian Women. Asian Pac J Cancer Prev. 2021 Mar 1;22(3):971-976. PMCID: PMC8286674
c. Gonzalez* M, Montejo KA, Krupp K, Srinivas V, DeHoog E, **Madhivanan P,** Ramella-Roman JC. (2020) Design and implementation of a portable colposcope Mueller matrix polarimeter. J Biomed Opt. 2020 Nov;25(11):116006. PMCID: PMC7666868
d. Degarege* A, Krupp K, Fennie K, Li T, Stephens DP, Marlow LAV, Srinivas V, Arun A, **Madhivanan P**. (2018) Urban-Rural Inequities in the Parental Attitudes and Beliefs Towards Human Papillomavirus Infection, Cervical Cancer, and Human Papillomavirus Vaccine in Mysore, India. J Pediatr Adolesc Gynecol. 31(5):494-502. PMCID: PMC6119521

3. Rural Health: Our group has been identifying risk factors associated with various health issues among rural women and other populations. Understanding factors that protect women from experiencing different health issues continues to be a prime area of research among minority populations in US and rural India. (* indicates students on the publication)
    a. Zahnd WE, Del Vecchio N, Askelson N, Eberth JM, Vanderpool RC, Overholser L, **Madhivanan P,** Hirschey R, Edward J. (2022) Definition and categorization of rural and assessment of realized access to care. Health Serv Res. 2022 Feb 11. PMCID: PMC9108055 (available on 2023-06-01)
    b. Cadet* G, Coudray* G, Stephens D, Adsul* P, Siddhaiah* A, **Madhivanan P**. (2019) Knowledge, Gender and Guidance: Factors influencing Indian Mothers Responses to Attention Deficit Hyperactivity Disorder (ADHD). Ind J Health & Wellbeing. 2019. PMCID: PMC8782239
    c. Krupp* K, Placek* C, Wilcox* M, Ravi K, Srinivas V, Arun A, **Madhivanan P**. (2018) Financial Decision-Making Power is associated with Moderate to Severe anemia: A Prospective Cohort Study among Pregnant Women in Rural South India. Midwifery, 61:15-21. PMCID: PMC5916045
    d. Veeranki* SP, Nishimura* H, Krupp* K, Gowda S, Arun A, **Madhivanan P**. **(2017)** Sub-optimal breastfeeding practices among women in rural and low-resource settings: A study of women in Rural Mysore, India. Annals of Global Health. 83: 3–4; 577-583.

4. HIV Prevention: I started my career working at a HIV care and research center in India, which got me interested in preventing HIV infection in young women. I have worked on this topic for more than a decade identifying and implementing interventions to prevent HIV in women. (* indicates students on the publication)
    a. Taveras* J, Trepka MJ, **Madhivanan P**, Gollub EL, Dévieux JG, Ibrahimou B. (2019) HIV risk and testing behaviors among pregnant women tested for HIV in Florida by site type, 2012. Women Health. 59(7):815-827.
    b. Tamir* H, Krupp* K, Stephens DP, Zohourian* T, Dorcius PM, Arun A, Fisher CB, **Madhivanan P**. (2018) Addressing Prevention Among HIV-Uninfected Women in PMTCT Programs in South India. J Assoc Nurses AIDS Care. 29(1):45-52. PMCID: PMC5742296
    c. Taveras* J, Trepka MJ, **Madhivanan P**, Gollub EL, Dévieux JG, Ibrahimou B. (2017) HIV testing behaviors among Latina women tested for HIV in Florida, 2012. Hiso Health Care Int. 15(1):27-34.
    d. Sheehan* DM, Trepka MJ, Fennie KP, Prado G, **Madhivanan P**, Dillon FR, Maddox LM. (2017) Individual and Neighborhood Determinants of Late HIV Diagnosis among Latinos, Florida, 2007-2011. J Immigr Minor Health. 19(4):825-834. PMCID: PMC5083229

5. Systematic Reviews and Meta-analysis: As an infectious disease epidemiologist and methodologist, I have worked on several teams designing and conducting systematic reviews and meta-analysis. The topic areas range from relationship of parasitic infections to HPV vaccine and sexual disinhibition. The reviews range from global topics to areas that are specific to the US. These publications document different reviews that I have worked on. I have served as a mentor to several graduate and undergraduate students who worked on these reviews with me. (* indicates students on the publication)

a. Ward-Peterson* M, Fennie K, Mauck* D, Shakir* M, Cosner C, Bhoite* P, Trepka MJ, **Madhivanan P**. (2018) Using multilevel models to evaluate the influence of contextual factors on HIV/AIDS, sexually transmitted infections, and risky sexual behavior in sub-Saharan Africa: a systematic review. Ann Epidemiol. 28(2):119-134.
b. **Madhivanan P,** Victor-Pier* D, Mukherjee* S, Bhoite* P, Powell* B, Baptise* N, Clark* R, Avent* T, Krupp* K. (2016) Human Papillomavirus Vaccination and Sexual Disinhibition in Females: A Systematic Review. Am J Prev Med. 51(3):373-83.
c. Adsul* P, Manjunath* N, Srinivas V, Arun A, **Madhivanan P**. (2017) Implementing community-based cervical cancer screening programs using visual inspection with acetic acid in India: A systematic review. Cancer Epidemiol. 49:161-174. PMCID: PMC5571735
d. Osibogun* O, Ogunmoroti O, Michos ED, Spatz ES, Olubajo B, Nasir K, **Madhivanan P**, Maziak W. (2017) HIV/HCV coinfection and the risk of cardiovascular disease: A meta-analysis. J Viral Hepat. 24(11):998-1004.

Complete List of Published Work in My Bibliography:
https://www.ncbi.nlm.nih.gov/myncbi/1ZQusmbCub7Qg/bibliography/public/

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

BIOGRAPHICAL SKETCH

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

NAME: Mudzingwa, Emily Anne

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

POSITION TITLE: Assistant Research Professor, Institute for Collaboration on Health, Intervention and Policy, University of Connecticut

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

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
University of Minnesota, Minneapolis, MN	B.E.	05/2009	Biomedical Engineering
University of Washington, Seattle, WA	Ph.D.	12/2015	Bioengineering
University of Washington, Seattle, WA	Postdoc	06/2016	Bioengineering
RTI International, San Francisco, CA (based in Cape Town, South Africa)	Postdoc	10/2019	Social-behavioral Sciences and User-centered Design
Desmond Tutu HIV Foundation, University of Cape Town, Cape Town, South Africa	Postdoc	05/2021	Social-behavioral Sciences and User-centered Design

A. Personal Statement

I am a bioengineer and social-behavioral scientist with multi-disciplinary research interests spanning user-centered design, participatory research, and global health. My overall research vision is to better include the end-user at earlier stages in product development and implementation of new health technologies. Over the last twelve years, my research experience has been centered in developing new technologies for HIV prevention and contraception from both laboratory and community-based perspectives. My PhD research in bioengineering (University of Washington, 2015) was focused on engineering new nanomaterial platforms for topical vaginal HIV prevention in a laboratory setting. I then completed postdoctoral training based in South Africa with a social-behavioral team at the Desmond Tutu HIV Foundation (University of Cape Town, 2016-2021). During my postdoc, I gathered and integrated end-user preferences into the design of an implant for HIV prevention together with RTI International and other collaborating researchers in South Africa, Kenya, and Zimbabwe. In my current position at the University of Connecticut, I am leading mixed methods research to understand user preferences for long-acting HIV prevention products among young people, MSM, and transgender people in South Africa.

Specific to this project, I bring expertise in all stages of qualitative research, participatory research to guide delivery of new health interventions, and working closely with diverse stakeholders including health providers and adolescents in sub-Saharan Africa. Ongoing and recently completed projects that I would like to highlight include:

**Note: I published as Emily Krogstad up through 2021; published under new last name as Emily Mudzingwa from 2022 – present.*

[redacted]
Butler (PI); Role: Co-I
09/06/2022-09/05/2023
Project OPAL: Mixed methods study to identify preferences for next-generation HIV PrEP interventions amongst men who have sex with men and transgender people in South Africa.

PRIVATE SUPPORT
PIs: Krogstad and Butler
04/01/2021-03/28/2023
The Zivikele Project: Mixed methods study to identify preferences for next-generation PrEP interventions amongst adolescent girls and young women and men in South Africa.

USAID AID-OAA-A-17-00011
PI: Johnson; Role: Post-doc
07/01/2017-07/01/2020
Subcutaneous Contraceptive and HIV Implant Engineered for Long-Acting Delivery (SCHIELD)

NIH R01MH105262
PI: Bekker; Role: Post-doc
09/01/2015-05/31/2019
End-user Research to Optimize Adherence to Injectable HIV Prevention Approaches (iPrevent)

B. Positions, Scientific Appointments, and Honors

Employment

2021 - present	Assistant Research Professor, Institute for Collaboration on Health, Intervention and Policy, University of Connecticut
2021 - present	Consultant, Desmond Tutu HIV Foundation, University of Cape Town, Cape Town, South Africa
2016 - 2019	Postdoctoral Scientist, RTI International, San Francisco, CA (based in Cape Town, South Africa)
2016	Senior Postdoctoral Fellow, Department of Bioengineering, University of Washington, Seattle, WA
2013	Teaching Assistant, Department of Bioengineering, University of Washington, Seattle, WA
2010 - 2015	Graduate Research Assistant, Department of Bioengineering, University of Washington, Seattle, WA
2007 - 2009	Undergraduate Research Assistant, Department of Biomedical Engineering, University of Minnesota, Minneapolis, MN
2006	Teaching Assistant, Department of Chemistry, University of Minnesota, Minneapolis, MN

Other positions

2016 - 2021	Postdoctoral Research Fellow, Desmond Tutu HIV Foundation, University of Cape Town, Cape Town, South Africa

Honors and Awards

2018	Research Scholar for HIVR4P Conference, Madrid, Spain
2016 - 2017	Whitaker Postdoctoral Scholar, Desmond Tutu HIV Foundation, Cape Town, South Africa
2016	Research Scholar for HIVR4P Conference, Chicago, IL, USA
2012 - 2015	National Science Foundation Graduate Research Fellow
2012	Center for AIDS Research Trainee Support Grant for BMES Annual Meeting
2011 - 2013	Science Communications Fellow in Global Health, Pacific Science Center, Seattle, WA
2009	Summa cum laude, University of Minnesota
2007 - 2009	Frank Louk Scholarship for academic excellence and leadership, University of Minnesota
2007 - 2009	Lynn Otten Scholarship for academic achievement, University of Minnesota
2005 - 2009	Presidential Scholarship for academic distinction, University of Minnesota

C. Contributions to Science

1. **Implementation planning for novel HIV prevention / multipurpose prevention product use in sub-Saharan Africa.** Understanding the cultural, behavioral, and societal context of a new technology at an early phase in planning for rollout is critical to its success. Diverse perspectives from health care providers,

product developers, social scientists, and end users themselves are essential in the planning for implementation of technologies that are inextricably linked to behavior, such as HIV prevention products and multipurpose prevention technologies. I am currently an Investigator on two studies evaluating drivers and preferences for five new HIV prevention products among South African adolescent girls and young women, young men, men who have sex with men, and transgender individuals.

a. **Mudzingwa EK**, Parker I (2022) Long-acting injections for HIV prevention among women in sub-Saharan Africa. Lancet. DOI: 10.1016/s0140-6736(22)00613-4.
b. Minnis AM*, **Krogstad E***, Shapley-Quinn MK, Agot K, Ahmed K, Wagner LD, van der Straten A, TRIO Study Team (2021) Giving voice to the end-user: input on multipurpose prevention technologies from the perspectives of young women in Kenya and South Africa. Sexual and Reproductive Health Matters 29(1) (*co-first authors).
c. Hartmann M, Minnis AM, **Krogstad E**, Ndwayana S, Sindelo S, Atujuna M, O'Rourke S, Bekker, L-G, Montgomery ET (2021) iPrevent: Engaging youth as long-acting HIV prevention product co-researchers in Cape Town, South Africa. African Journal of AIDS Research 20(4): 277-286.
d. Montgomery E, Atujuna M, **Krogstad E**, Hartmann M, Ndwayana S, O'Rourke S, Bekker L-G, van der Straten A, Minnis AM (2019) The invisible product: preferences for sustained-release, long-acting pre-exposure prophylaxis to HIV among South African youth. Journal of Acquired Immune Deficiency Syndrome 80(5): 542-50.

2. **End-user input on development of an HIV prevention implant.** People at high risk of HIV living in sub-Saharan Africa are often viewed as technology *recipients* from a perspective of their needs, rather than as technology *ideators and contributors* based on their assets. Collaborating across the Desmond Tutu HIV Foucnation and the nonprofit organization RTI International, I led the first studies to get early-stage feedback from African women and men on implants in development for HIV prevention and as multipurpose prevention technology. I conducted this research as part of multiple clinical studies: TRIO, iPrevent, and SCHIELD, at sites in Kenya, Zimbabwe, and South Africa (Cape Town and Soshanguve), where I implemented and analyzed focus group discussions and interviews with young people and health care providers together with study site staff.

a. **Krogstad E**, Montgomery ET, Atujuna, M, Minnis A, O'Rourke S, Ahmed K, Bekker L-G, van der Straten A (2019) Design of an implant for long-acting HIV pre-exposure prophylaxis: input from South African health care providers. AIDS Patient Care and STDs 33(4): 157-166.
b. **Krogstad E**, Atujuna, M, Montgomery ET, Minnis A, Ndwayana S, Malapane T, Shapley-Quinn MK, Manenzhe K, Bekker L-G, van der Straten A (2018) Perspectives of South African youth in the development of an implant for HIV prevention. Journal of the International AIDS Society 21: e25170 (1-10).
c. **Krogstad E**. What do providers want in a long-acting HIV prevention method? Perspectives of South African nurses and physicians on the design of an HIV prevention implant. Presented at the HIV Research for Prevention (HIVR4P) Conference, Madrid, Spain, 2018, oral presentation (invited).
d. **Krogstad E**, Malapane T, Ndwayana S, Shapley-Quinn M, Manenzhe K, Atujuna M, Luecke E, Malahleha M, Ahmed K, Minnis A, Montgomery E, Bekker L-G, van der Straten A. Listening to at-risk youth: perspectives of young women and men in South Africa on the design of an implant for HIV prevention. Presented at AIDS Impact International Conference, Cape Town, South Africa, 2017, oral presentation.

3. **Contraceptive implant uptake in sub-Saharan Africa.** Uptake of contraceptive implants has not been uniform across different settings in sub-Saharan Africa. While completing my postdoc research gathering end-user perspectives on an implant for HIV prevention, I developed a research interest in exploring the factors influencing the declining uptake of the contraceptive implant in South Africa, as well as understanding lessons learned that can be applied toward the introduction of other new health technologies. I conducted interviews with health care providers and focus group discussions on contraceptive implant acceptability, analyzed qualitative data from multiple research projects on contraceptive implant uptake, and led writing of several manuscripts on this topic.

a. **Krogstad E**, Odhiambo OK, Ayallo M, Bailey VC, Rees H, van der Straten A (2020) Contraceptive implant uptake in Kenya versus South Africa: lessons for new implantable technologies. Contraception 101: 220-225.
b. **Krogstad E**, Atujuna M, Montgomery ET, Minnis A, Morroni C, Bekker L-G (2020) Perceptions matter: narratives of contraceptive implant robbery in Cape Town, South Africa. Culture, Health & Sexuality: 1-14.
c. Howett R, **Krogstad E**, Badubi O, Gertz AM, Bawn C, Mussa A, Kgaswanyane T, Malima S, Maotwe T, Mokganya L, Ramogola-Masire D (2021) Experiences of Accessing and Providing Contraceptive Implant Removal Services in Gaborone, Botswana: A Qualitative Study Among Implant Users and Healthcare Providers. Frontiers in Global Women's Health 2:684694.

4. **Daily oral pre-exposure prophylaxis (PrEP) use among women in South Africa.** While oral PrEP is highly effective at preventing HIV when used consistently, poor adherence to a daily pill-taking regimen has been a challenge, particularly among adolescent girls and young women in sub-Saharan Africa. I have been involved with multiple mixed-methods research projects aimed at understanding barriers and facilitators to PrEP use among young people in South Africa. I am currently leading the qualitative analysis and writing for a study evaluating community-based PrEP delivery in Eastern Cape, South Africa.

a. **Mudzingwa EK**, de Vos L, Atujuna M, Fynn L, Mugore M, Hosek S, Celum C, Bekker LG, Daniels J, Medina-Marino A (2022). Factors influencing adolescent girls and young women's uptake of community-based PrEP services following home-based HIV testing in Eastern Cape, South Africa: a qualitative study. AIDS and Behavior: 1-14.

5. **Developing nanomaterials for vaginal drug delivery**. Many existing vaginal products are limited by poor drug delivery to vaginal tissue, including topical microbicides delivering antiretroviral drugs for HIV prevention. New strategies are needed to improve effectiveness. During my PhD research, I engineered novel vaginal drug delivery platforms for HIV prevention and contraception using nanomaterials (e.g., nanoparticles, nanofibers, and nanoparticle/nanofiber composites). Nanoparticles were developed to load several different antiretroviral drugs and showed enhanced efficacy against HIV-1 *in vitro* compared to free drug alone. Nanofibers were demonstrated to be able to load many agents relevant to vaginal drug delivery at remarkably high levels (up to 60% by mass), provide both quick and sustained drug release, release active drug with action against HIV-1, and act as a physical and chemical barrier to sperm. Finally, nanoparticle/nanofiber composites were found to dramatically enhance nanoparticle and drug retention in the reproductive tract of mice, providing proof-of-concept for a new platform for the vaginal administration of nanoparticles that is both solid-state and practical to administer. This work informs other applications such as STI prevention and treatment, mucosal vaccination, and topical drug delivery to mucosal sites.

a. **Krogstad E**, Ramanathan R, Nhan C, Kraft J, Blakney A, Cao S, Ho R, Woodrow KA (2017) Nanoparticle-releasing nanofiber composites for enhanced *in vivo* vaginal retention. Biomaterials 144: 1-16.
b. **Krogstad E**, Woodrow KA (2014) Manufacturing scale-up of electrospun poly(vinyl alcohol) fibers containing tenofovir for vaginal drug delivery. International Journal of Pharmaceutics 475: 282–291.
c. Chaowanachan T, **Krogstad E**, Ball C, Woodrow KA (2013) Drug Synergy of Tenofovir and Nanoparticle-Based Antiretrovirals for HIV Prophylaxis. PLOS One 8: e61416.
d. Ball C*, **Krogstad E***, Chaowanachan T, Woodrow KA (2012) Drug-Eluting Fibers for HIV-1 Inhibition and Contraception. PLOS One 7: e49792 (*co-first authors).

Full List of Published Work in NCBI My Bibliography:
https://www.ncbi.nlm.nih.gov/myncbi/emily.krogstad.2/bibliography/public/

PHS 398 Cover Page Supplement

OMB Number: 0925-0001

Expiration Date: 09/30/2024

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: GRANT13743483 Funding Opportunity Number: PAR-22-173 . Received Date: 2022-10-25T15:38:13.000-04:00

PHS 398 Cover Page Supplement

3. Human Embryonic Stem Cells Section

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

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

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

Cell Line(s) (Example: 0004):

4. Human Fetal Tissue Section

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

If "yes" then provide the HFT Compliance Assurance

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

5. Inventions and Patents Section (Renewal applications)

*Inventions and Patents: ❍ Yes ● No

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

*Previously Reported: ❍ Yes ❍ No

6. Change of Investigator/Change of Institution Section

❑ Change of Project Director/Principal Investigator

Name of former Project Director/Principal Investigator

Prefix:

*First Name:

Middle Name:

*Last Name:

Suffix:

❑ Change of Grantee Institution

*Name of former institution:

Tracking Number: GRANT13743483 Funding Opportunity Number: PAR-22-173 . Received Date: 2022-10-25T15:38:13.000-04:00

PHS 398 Modular Budget

OMB Number: 0925-0001
Expiration Date: 09/30/2024

Budget Period: 1

Start Date: 07/01/2023 End Date: 06/30/2024

A. Direct Costs

	Funds Requested ($)
Direct Cost less Consortium Indirect (F&A)*	225,000.00
Consortium Indirect (F&A)	29,202.00
Total Direct Costs*	254,202.00

B. Indirect (F&A) Costs

	Indirect (F&A) Type	Indirect (F&A) Rate (%)	Indirect (F&A) Base ($)	Funds Requested ($)
1.	MTDC	79.00	162,900.00	128,691.00
2.				
3.				
4.				

Cognizant Agency (Agency Name, POC Name and Phone Number): Department of Health & Human Services, Michael Stanco, (212) 264-2069

Indirect (F&A) Rate Agreement Date: 09/25/2019

Total Indirect (F&A) Costs: 128,691.00

C. Total Direct and Indirect (F&A) Costs (A + B)

Funds Requested ($): 382,893.00

Funding Opportunity Number: PAR-22-173. Received Date: 2022-10-25T15:38:13.000-04:00

PHS 398 Modular Budget

Budget Period: 2

Start Date: 07/01/2024 End Date: 06/30/2025

A. Direct Costs

	Funds Requested ($)
Direct Cost less Consortium Indirect (F&A)*	200,000.00
Consortium Indirect (F&A)	21,565.00
Total Direct Costs*	221,565.00

B. Indirect (F&A) Costs

	Indirect (F&A) Type	Indirect (F&A) Rate (%)	Indirect (F&A) Base ($)	Funds Requested ($)
1.	MTDC	79.00	83,661.00	66,092.00
2.				
3.				
4.				

Cognizant Agency (Agency Name, POC Name and Phone Number): Department of Health & Human Services, Michael Stanco, (212) 264-2069

Indirect (F&A) Rate Agreement Date: 09/25/2019

Total Indirect (F&A) Costs: 66,092.00

C. Total Direct and Indirect (F&A) Costs (A + B)

Funds Requested ($): 287,657.00

Funding Opportunity Number: PAR-22-173. Received Date: 2022-10-25T15:38:13.000-04:00

PHS 398 Modular Budget

Budget Period: 3

Start Date: 07/01/2025 End Date: 06/30/2026

A. Direct Costs

	Funds Requested ($)
Direct Cost less Consortium Indirect (F&A)*	175,000.00
Consortium Indirect (F&A)	21,912.00
Total Direct Costs*	196,912.00

B. Indirect (F&A) Costs

	Indirect (F&A) Type	Indirect (F&A) Rate (%)	Indirect (F&A) Base ($)	Funds Requested ($)
1.	MTDC	79.00	57,329.00	45,290.00
2.				
3.				
4.				

Cognizant Agency (Agency Name, POC Name and Phone Number): Department of Health & Human Services, Michael Stanco, (212) 264-2069

Indirect (F&A) Rate Agreement Date: 09/25/2019

Total Indirect (F&A) Costs: 45,290.00

C. Total Direct and Indirect (F&A) Costs (A + B)

Funds Requested ($): 242,202.00

Funding Opportunity Number: PAR-22-173. Received Date: 2022-10-25T15:38:13.000-04:00

PHS 398 Modular Budget

Cumulative Budget Information

1. Total Costs, Entire Project Period

Section A, Total Direct Cost less Consortium Indirect (F&A) for Entire Project Period ($)	600,000.00
Section A, Total Consortium Indirect (F&A) for Entire Project Period ($)	72,679.00
Section A, Total Direct Costs for Entire Project Period ($)	672,679.00
Section B, Total Indirect (F&A) Costs for Entire Project Period ($)	240,073.00
Section C, Total Direct and Indirect (F&A) Costs (A+B) for Entire Project Period ($)	912,752.00

2. Budget Justifications

Personnel Justification	NCI_R34_Brigham_Budget_Justification.pdf
Consortium Justification	Consortium_Justification.pdf
Additional Narrative Justification	

Funding Opportunity Number: PAR-22-173. Received Date: 2022-10-25T15:38:13.000-04:00

PERSONNEL JUSTIFICATION

Ingrid Katz, MD, MHS, Principal Investigator (- Person Months) is Associate Faculty Director at the Harvard Global Health Institute, Associate Professor in Medicine at Harvard Medical School and Associate Physician in the Department of Medicine at Brigham and Women's Hospital. She is also a research scientist at the Center for Global Health at Massachusetts General Hospital and Associate Scientist at Ariadne Labs. Dr. Katz is a New Investigator who has worked in South Africa since 2009. Her research over the past decade has focused on addressing the social determinants of health-seeking behavior among populations at risk for preventable diseases due to long term infections from HPV and HIV in South Africa, with the goal of developing sustainable, socio-behavioral interventions aimed at improving care for the most underserved. To date, she has published over 70 original publications and has remained consistently funded through NIH for the last decade. Specifically, she has been the PI on a K23 (K23MH097667, “HIV Treatment Refusal Among Adults Presenting for Testing in Soweto, South Africa”), two R34 grants (R34MH108393, “The Treatment Ambassador Program: Pilot testing a peer-driven intervention to increase treatment initiation among HIV-positive South Africans” and R34MH114897-01A1, “Standing Tall - A Pilot Randomized Controlled Trial of a Community-Based Intervention to Improve Health Outcomes for Newly Diagnosed HIV-Positive Young Adults in South Africa”), and most recently, an R21 (R21MH126804 - 01A1, “A mixed methods approach to address multi-level barriers to care for migratory men living with HIV in South Africa”) - all funded through NIMH, and based in South Africa. Her research has also been featured in UNAIDS publications, and throughout the lay press including Scientific American, Reuters, and the British Broadcasting Corporation (BBC). She has presented at international conferences, including the International AIDS Society Conference and the International Conference on HIV Treatment and Prevention Adherence, as well as national conferences, including The National Center for AIDS Research Conference. Her manuscript focused on ART-refusal among newly diagnosed HIV-positive adults in Soweto was recognized at a plenary session of a leading international HIV research conference as being one of the top socio-behavioral studies in HIV in the last 30 years. She has been a recent leader in the global Covid response, briefing President Biden on the impact of Covid on education, co-leading Gen-Ed courses at Harvard on Covid-19 and vaccines, moderating a Grand Rounds on Global Vaccine Equity with the Center for AIDS Research featuring keynote speakers Dr. Tony Fauci and Dr. John Nkengasong, and publishing a Perspective in the New England Journal on the need for global vaccine equity.

The current proposal builds on her previous work focused on improving HPV prevention for youth in South Africa. As contact MPI on this study, Dr. Katz will co-lead the overall study design and will develop the data collection instruments and intervention. She will assist with providing training and supervision to project staff and serve as a liaison between team members in South Africa and the United States. Throughout the study, she will co-lead data analysis and interpretation and the development of manuscripts for submission to scholarly journals.

Amanda Fata, BA, Research Assistant (- Person Months) is Dr. Katz’s research assistant based in the Division of Women’s Health at Brigham and Women’s Hospital. In this role, she will be responsible for data management and analysis and preparation of manuscripts for scholarly journals.

Alexi Wright, MD, MPH, Consultant. Dr. Wright is the Director of Gynecologic Oncology Outcomes Research at Dana Farber Cancer Institute (DFCI), an Associate Professor of Medicine at Harvard Medical School, a practicing gynecologic oncologist, and a leading expert in health services research. She will contribute up to - hours in each year at a rate of $ /hour. Total requested: $ per year

Anton Immelman, School and Community Engagement Consultant. Mr. Immelman is the Headmaster of Voortrekker High School. He has expertise in school and community engagement. -

CONSULTANT HOURS, CONSULTANT FEES, CONFIDENTIAL INFORMATION - REQUESTER IN AGREEMENT

CONSORTIUM JUSTIFICATION

[redacted] CONFIDENTIAL INFORMATION - REQUESTER IN AGREEMENT

	Year 1	Year 2	Year 3
Total Costs	$70,000	$70,000	$70,000

Personnel

Nicholas Munro, PhD, Site-PI ([redacted] Person Months). Dr. Munro is a senior lecturer in the Department of Psychology and his research focus is on higher education studies involving teaching and learning, emotions in learning, barriers to academic success, and mentoring. He will be responsible for study implementation, including supervision of project staff.

Mkhonzeni Gumede, PhD, Co-Investigator ([redacted] Person Months). Dr. Gumede is a lecturer with a background in implementing HIV/AIDS communications programmes and campaigns at tertiary institutions. His research interests include communication for Development and Social Change. He will provide input to the development of messaging related to HPV vaccination, study tools, interpretation of findings and manuscript preparation.

Douglas Wassenaar, PhD, Co-Investigator ([redacted] Person Months). Dr. Wassenaar is the co-director of the South African Research Ethics Training Initiative where he collaborates with HIV/Aids Vaccines Ethics Group. He also currently chairs the UKZN Biomedical Research Ethics Committee and is Editor-In-Chief of the Journal of Empirical Research on Human Research Ethics (JERHRE). His research interests include issues in health research ethics, and clinical psychology. He will provide input on ethics considerations, study tools, interpretation of findings and manuscript preparation.

Cathy Slack, PhD, Co-Investigator ([redacted] Person Months). Dr. Slack is the project director for the HIV/AIDS Vaccines Ethics Group. She has experience in conducting conceptual and empirical research and developing resource documents for stakeholders. Her research interests include ethical complexities in clinical trials of HIV to ensure protected participation of adolescents, strengthening consent processes, engaging community stakeholders. She will provide input on engaging community stakeholders, ethics issues that may arise, study tools, interpretation of findings and manuscript preparation.

Abigail Wilkinson, Project Coordinator ([redacted] Person Months in Yr 1; [redacted] Person Months in Yrs 2-3). Ms. Wilkinson (MSocSc) is a researcher with the HIV/AIDS Vaccines Ethics Group [redacted] CONFIDENTIAL INFORMATION - REQUESTER IN AGREEMENT Her role at HAVEG is to investigate the ethical and legal complexities of HIV prevention trials with a focus on stakeholder engagement and ethics review. Abigail is also a PhD student at UKZN and a junior PhD fellow at the UKZN Developing Research Innovation, Localisation and Leadership (DRILL) programme. Abigail also has teaching experience as an ad hoc lecturer in the discipline of psychology at UKZN. Ms. Wilkinson will be responsible for the coordination of study activities, assistance in the preparation of study procedures, protocols, and tools, assistance with ethics submissions, and oversight of recruitment and enrollment.

Siyabonga Nzimande, Community Engagement Lead and Research Associate ([redacted] Person Months in Yr 1; [redacted] Person Months in Yr 2; [redacted] Person Months in Yr 3). Mr. Nzimande has extensive experience in community engagement, training, and capacity building. He is the KwaZulu-Natal Civil Society Leader under the South African National AIDS Council (SANAC) leadership, as a Sector leader and Civil Society Exco under the KZN Premiers AIDS response program. He is acting as District AIDS Council Chair for eThekwini, supporting the Mayor's office with technical assistance with coordination of all programs, research, and monitoring and evaluation strategies. He serves regularly as a consultant to UNAIDS Education Plus program and Policy Training and Development for youth

programs in South Africa. Mr. Nzimande will be responsible for facilitating community engagement activities and supporting the Project Coordinator in the coordination of study activities, preparation of study protocols and tools, and conducting focus group discussions and semi-structured interviews.

Fikile Nkwanyana, Statistician ([redacted] Person Months). Ms. Nkwanyana is a statistician who has experience in the analytic techniques required for the proposed study. She works as part of a team at UKZN, and will be supported by senior statisticians, as required.

UNIVERSITY OF CONNECTICUT

	Year 1	Year 2	Year 3
Total Cost	$67,000.00	$51,000.00	$52,000.00

Personnel

Lisa M. Butler, PhD, MPH, PhD, MPI/Site PI ([redacted] Academic Months). Dr. Butler is Associate Research Professor at the University of Connecticut, Institute for Collaboration on Health, Intervention and Policy (InCHIP). She has affiliated faculty appointments at the University of Toronto Dalla Lana School of Public Health as well as Botswana-Harvard AIDS Program. Dr. Butler has doctoral training in Educational Psychology *(PhD, UCLA, 2000)* and Epidemiology *(PhD, UC Berkeley, 2009),* and has over 24 years' research and evaluation experience in diverse settings in sub-Saharan Africa (including South Africa) and North America. She has expertise in the implementation of participatory methods for intervention development, as well as in the design, conduct and analyses of observational and experimental studies (including cluster randomized controlled trials). She has a particular interest in understanding drivers of vaccine uptake and completion amongst pediatric and adult populations. Dr. Butler has previously led and co-led NCI-funded research focused on the development of communications and other strategies for optimizing early identification of Kaposi's sarcoma and cervical cancer in East Africa. Dr. Butler will serve as MPI and will work closely with Drs. Katz and Munro on the development of all study protocols and data collection instruments, design of all intervention components, monitoring of intervention implementation, data analysis and manuscript preparation.

Emily Mudzingwa (*nee* Krogstad), PhD, Co-Investigator ([redacted] Academic Months in Yr 1; [redacted] Academic Months in Yrs 2-3). Dr. Mudzingwa is an Assistant Research Professor at the Institute for Collaboration on Health, Intervention and Policy (InCHIP) at the University of Connecticut. Dr. Mudzingwa has doctoral training in bioengineering HIV prevention products, and recently completed a postdoc at the Desmond Tutu HIV Foundation (DTHF). Drs. Mudzingwa and Butler collaborate on studies focused on biomedical HIV prevention strategies amongst key populations in South Africa (e.g., adolescent girls, young adults, men who have sex with men and transgender populations). Dr. Mudzingwa will lead the design, implementation and analysis of qualitative studies conducted as part of the proposed study.

UNIVERSITY OF ARIZONA

	Year 1	Year 2	Year 3
Total Costs	$29,000	$17,000	$17,000

Personnel

Purnima Madhivanan, PhD, Consortium Principal Investigator ([redacted] Person Months in Yr 1; [redacted] Person Months in Yrs 2-3). Dr. Madhivanan is an Associate Professor in Health Promotion Sciences at the Mel

& Enid College of Public Health. For the past 20 years, her work has focused on disadvantaged populations, elucidating the dynamics of poverty, gender, and the environmental determinants of health, in particular the impact on women and children living in rural communities. Dr. Madhivanan will be involved in the conceptual design, data collection, data interpretation, and dissemination activities related to the grant.

PHS 398 Research Plan

OMB Number: 0925-0001
Expiration Date: 09/30/2024

Introduction	
1. Introduction to Application (for Resubmission and Revision applications)	
Research Plan Section	
2. Specific Aims	Specific_Aims.pdf
3. Research Strategy*	Research_Strategy.pdf
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5. Vertebrate Animals	
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7. Multiple PD/PI Leadership Plan	MPI_Plan_.pdf
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10. Resource Sharing Plan(s)	Resource_Sharing_Plan.pdf
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Tracking Number: GRANT13743483
Funding Opportunity Number: PAR-22-173. Received Date: 2022-10-25T15:38:13.000-04:00

SPECIFIC AIMS

Human papillomavirus (HPV) is the most common sexually transmitted infection (STI),[1] and is causally linked to cervical, anogenital, and oropharyngeal cancers.[2] Cervical cancer remains the leading cause of cancer-related mortality among women in South Africa (SA), yet it is entirely preventable with HPV vaccination prior to sexual debut.[3-9] Since 2014, the SA National Department of Health has implemented a national, school-based HPV immunization program. The program offers the two-dose bivalent vaccine to girls 9-12 enrolled in public schools, free of charge, delivered through bi-annual campaigns.[10,11] Despite a promising start -- 86.6% of age-eligible girls were vaccinated in the program's first year[11] -- vaccine coverage and dose completion rates have dropped precipitously. In 2019, 69% of girls received the first dose of HPV vaccine, and by 2021 only 37% received their first dose.[12] Recent declines have been attributed to COVID-related program interruptions,[5,11,13,14] increased medical mistrust, and vaccine hesitancy related to misinformation spread on social media.[10,11] There are additional critical gaps in HPV vaccine coverage – the current school-based HPV vaccine campaign does not include boys nor students enrolled outside of the public school system. Further, strategies for conveying information about the vaccine and for addressing widespread concerns and mistrust are lacking. A gender-neutral, inclusive, multi-level vaccination strategy is required to achieve the full benefits of HPV vaccination, especially in settings where herd protection is not achieved by a female-only approach. [5,11,15]

In preparation for a Hybrid Type 2 school-randomized controlled trial, we propose a pilot feasibility trial to refine and evaluate a school-based multi-level communications strategy that addresses intrapersonal, interpersonal, and institutional factors associated with HPV vaccination uptake and completion amongst 5th graders. To ensure local relevance and ownership, we will consult with key stakeholders (government, schools, and civil society) throughout the project, and involve a Stakeholder Working Group from project inception to completion. Assessment of intervention feasibility, acceptability and potential effectiveness will be accomplished through testing in schools in KwaZulu-Natal (KZN), a region with a high burden of HPV vaccine-preventable cancers,[16] and where HPV vaccine is offered free of charge to 5th grade girls in public schools. We will ensure health equity is at the core of our research by leveraging established partnerships with area schools serving diverse populations who are not always effectively served by traditional healthcare channels.[15,17] The project builds upon our team's expertise in HPV prevention, vaccine decision-making, health communications, health behaviour, participatory design, and community engagement to pursue the following Specific Aims.

Aim 1. Refine components of a school-based multi-level communication strategy to improve HPV vaccine uptake amongst age-eligible girls and boys. We will take a phased approach to evaluating and improving the design of health promotional materials for parents, teachers, nurses, and children enrolled in Grade 5. *The Elicitation Phase* will include focus group discussions with personnel involved in implementing the existing HPV vaccine program (e.g., government representatives, school administrators, nurses) (N=20), and semi-structured interviews with children enrolled in Grade 5 (N=10), their parents (n=20), and a sample of Grade 5 teachers (N=10), recruited from across five schools in KZN where HPV vaccine uptake has been historically low. The results will inform the refinement of communication materials focused on the effectiveness of the HPV vaccine and the need for immunization prior to sexual debut; *The Design Phase* will serve to tailor health promotional materials for parents, vaccine age-eligible children, as well as individuals who are potentially influential in vaccine decision making (e.g., teachers, nurses), accomplished using established participatory methods, including input from key stakeholders. We anticipate this package will include three interrelated components: (1) curriculum-linked learning materials for children, (2) informational materials for parents and teachers, and (3) community dialogue, supported by an adapted Conversation Map™,[18] for use by teachers, nurses, or others who may facilitate community dialogues regarding HPV vaccine; *The Evaluation Phase* will assess the effect of exposure to the materials on participants' understandings of and considerations about HPV vaccination. We will assess the effectiveness of the materials on increasing understanding about HPV vaccine among parents (N=100), Grade 5 children (N=100), and Grade 5 teachers (N=16). We will assess acceptability and feasibility of the communications materials using the Acceptability of Intervention Measure, Intervention Appropriateness Measure, and Feasibility of Intervention Measure.[19]

Aim 2. Evaluate preliminary effects of the communications strategy and key criteria to advance to a full-scale hybrid type 2 trial. We will conduct a pilot feasibility school-randomized controlled trial including 10 schools (~60 parents/children per school). Schools will be randomized to receive the enhanced vs. standard communication strategy. We will assess preliminary effectiveness on HPV vaccine uptake (dose 1) and completion (dose 2). We will also assess the following criteria: recruitment rate, completion of questionnaires, acceptability of the communications strategy and its implementation among parents, children, teachers, school administrators and Department of Health officials responsible for the school-based program. We will perform exit interviews with parents, teachers, and nurses (N=30) to identify strategies for sustainability.

RESEARCH STRATEGY

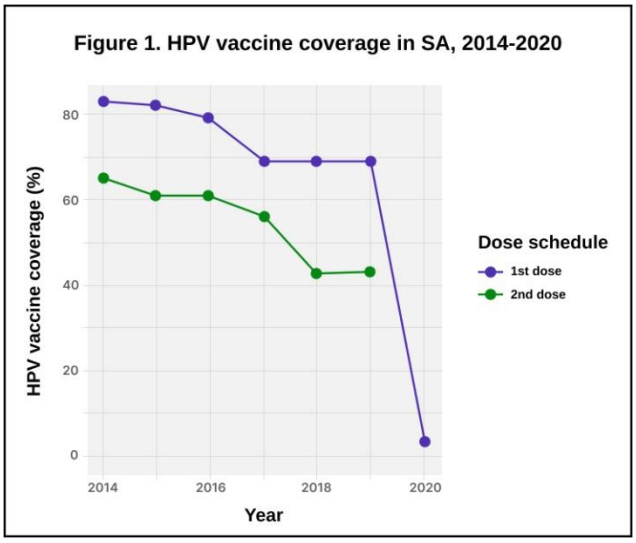
A. SIGNIFICANCE

A.1 Human papillomavirus (HPV) is the most common sexually transmitted infection (STI) globally, and its associated cancers have a disproportionate impact on people living in low-resource settings. Most (~75%) sexually active adults will acquire HPV over their lifespan, making it the most common STI globally.[20] HPV causes nearly all cases of cervical cancer, as well as a sizeable proportion of anogenital and oropharyngeal cancers.[9,20] Based on GLOBOCAN 2020 data,[6] an estimated 4.4% of all cancers worldwide (853,000 new cases) were attributed to HPV, including 7.8% of all cancers in women and 1.4% of all cancers in men. South Africa (SA) has a uniquely vulnerable population due to the convergence of the largest HIV epidemic globally,[21] with HPV rates of up to 85% in young women under the age of 25.[22] Cervical cancer incidence rates in SA are nearly five times higher than the U.S. (35.6 versus 7.8 cases per 100,000, respectively), and associated mortality is nearly nine-times higher (19.5 versus 2.2 deaths, per 100,000 respectively).[23-25] *Cervical cancer is the leading cause of cancer-related mortality among women in SA.*[4]

A.2 The goal of eradicating HPV-associated cancers will only be attained if the most vulnerable populations globally access effective prevention modalities. HPV vaccines provide up to 96% protection against precancerous cervical lesions and subsequently cervical cancer.[26,27] Given the known efficacy of the HPV vaccine,[20,28,29] the World Health Organization (WHO) has set a goal of having 90% of girls age 15 fully vaccinated by the year 2030.[30] Accomplishing this ambitious agenda requires sustainable approaches targeting the highest-risk populations – specifically young people prior to sexual debut – in countries with the highest burden of cervical cancer. Unless effective strategies are employed, SA will not meet the proposed target by 2030, and deaths related to cervical cancers, and other HPV-associated cancers, will continue unabated. *Interventions are needed to address the gap in the uptake of a known effective cancer-prevention strategy that has the potential to be integrated into the SA public health response.*

A.3 Beyond cervical cancer, HPV-associated cancers also impact men. Yet there are limited data available on HPV vaccine acceptability and uptake among boys in SA, as current vaccine research studies and school-based interventions only target girls. In men, HPV has been linked with penile cancer, anal cancer, and oropharyngeal cancer, with an estimated combined crude incidence of 9.1 per 100,000 among men in SA.[23] While the HPV vaccine is routinely offered to boys in North America[31] and some countries in Europe,[32] it is only accessible through private clinics at cost (~$109 per dose) for boys in SA.[5] Most vaccine studies and interventions in SA have focused exclusively on HPV vaccine attitudes and uptake by girls,[11,33-35] despite The Cancer Association of South Africa (CANSA) supporting vaccination for boys as well as girls.[36] To eliminate HPV-associated cancers, HPV vaccine coverage must reach at least 80%.[37] Inclusion of boys in SA's school-based HPV vaccine program would be an important step towards this goal. However, we need a better understanding of the drivers of HPV vaccine uptake and completion amongst boys.

A.4 Misinformation, vaccine hesitancy, and COVID-19 disruptions have fueled a steady decline in HPV vaccine coverage and dose completion rates in SA since 2014.[5] SA rolled out the HPV vaccine in 2014 through a national public-school program to Grade 4 girls following a 2-dose (6 months apart) vaccine schedule.[5] While high vaccine coverage rates were achieved in the first year, vaccine coverage has declined since then (*See Figure 1*).[5,12] Both supply-side and demand-side barriers have disrupted uptake of the HPV vaccine. On the supply-side, factors related to diminished vaccine availability and accessibility during the COVID pandemic have impacted HPV vaccine uptake and completion rates.[5] As supply-side factors have abated, demand-side factors have continued to increase. Vaccine misinformation has fueled safety concerns, as well as fear that the vaccine may encourage risky sexual behavior.[5] Caregivers often lack basic knowledge about the vaccine, as



evidenced by a study in [redacted], which found that 72% of women lacked knowledge and awareness of HPV.[39] The Vaccines And Cervical Cancer Screen (VACCS1 and VACCS2) HPV vaccine trials in South Africa reported similarly low levels of baseline HPV knowledge among mothers and female caregivers in Gauteng and Western Cape provinces and found that low coverage was primarily due to lack of parental consent.[33] These factors have collectively led to caregiver hesitancy, and ultimately diminished uptake of the HPV vaccine.[35,40] *Addressing multifactorial barriers to HPV vaccination is critical to achieving high rates of immunization.*

A.5 Current strategies to effectively communicate HPV vaccine information in SA are inadequate. At the start of the school year, parents of age-eligible girls are currently given standard written HPV vaccine information from the Department of Health along with a consent form to sign if desired. However, the information provided is limited, failing to address common questions and misconceptions about the vaccine. Further, it does not include information about benefits of HPV vaccination for boys, and it is not sent to parents of private school-attending children. In contrast, extensive research has been done to develop locally appropriate strategies to improve HPV uptake in the U.S.,[41-45] Europe,[46,47] Australia,[48] and Asia.[49] Such interventions have targeted health provider communication with parents,[41] parent education,[42,44,45,50] teacher-delivered curriculum,[44] and adolescents and children receiving vaccines.[47,51-53] Testing effectiveness of various types of messages is a critical step in developing locally adapted messaging, such as gain versus loss framing,[54,55] statistical versus narrative messaging,[56] narrative voice (e.g., first person versus third person)[56], and one-sided versus two-sided messaging.[45,57] *Culturally appropriate communications strategies designed to reach parents and others who are influential in vaccine decision making for their children are needed to improve HPV vaccine uptake in SA.*

A.6 Our approach to designing a multi-level communications strategy will engage a diverse group of stakeholders from project inception to completion. Previous studies across diverse cultural contexts have demonstrated the centrality of multi-level stakeholder engagement from an early stage for optimal HPV vaccine uptake.[43,58-63] Not only is stakeholder engagement foundational to an ethical approach to research, but it also maximizes opportunities for an intervention that is locally responsive, and community-supported.[64] An early demonstration project of school-based HPV vaccination in [redacted] highlighted how education and training with multi-level stakeholders were key to high vaccine uptake.[58] Subsequent HPV vaccine studies in SA have reported how delays in stakeholder engagement negatively impacted social mobilization,[11] and noted the challenges of engaging multiple stakeholders as an area for future improvement.[65] In our proposed study, we will consult with representatives from government (e.g., Department of Health), family members of children age 9-12 years old (e.g., children eligible for HPV vaccination), civil society advocates (including youth advocates), school administrators and teachers, and other individuals directly or indirectly involved in the acquisition, distribution or implementation of the HPV vaccine program. Parents, teachers, and children will also be involved in the design of communications materials. In prior work, engaging parents as co-researchers has resulted in enhanced relevance of messaging and empowerment,[66] and improved vaccine uptake.[60] A systematic review of HPV vaccine uptake in 25 low- and middle-income countries found that engaging teachers as partners in social mobilization and consent were critical for high uptake.[67] *Multi-level stakeholder engagement through all stages of intervention refinement and testing is critical towards the development of a culturally and contextually relevant, coherent, and effective gender-neutral HPV vaccination strategy.*

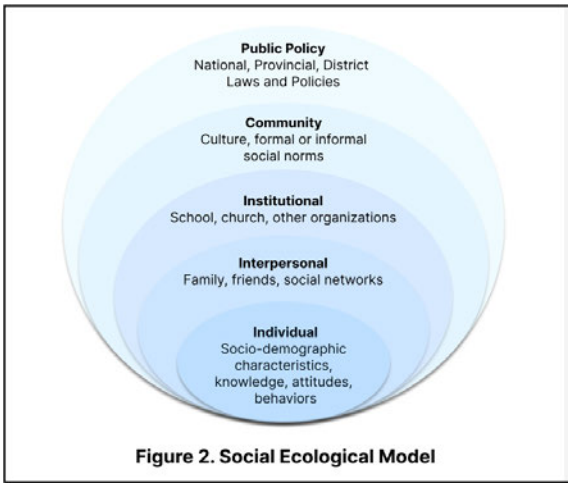
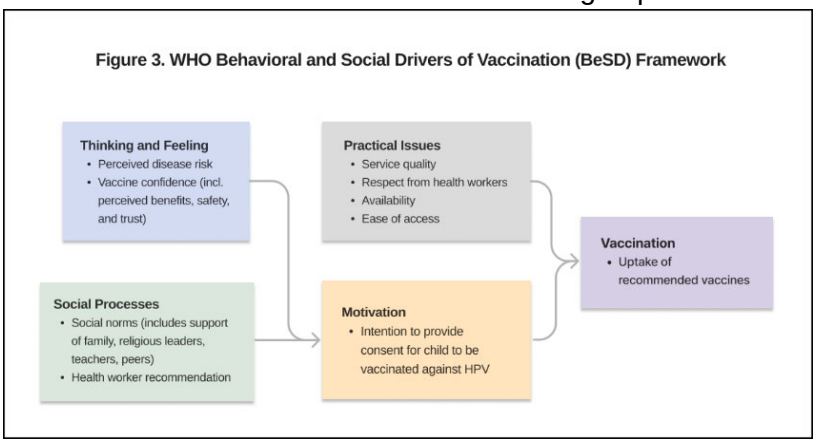


Figure 2. Social Ecological Model

A.7 Our approach is guided conceptually by two frameworks – the Social Ecological Model (SEM)[68] and the WHO Behavioral and Social Drivers of Vaccination (BeSD) framework.[69] The SEM (*See Figure 2*) considers individual, interpersonal, community,



and policy levels as intervention targets. It has previously been used as a framework to design multi-level communications interventions, as it recognizes how multiple factors beyond the individual level influence decision-making around HPV vaccines.[70] We will also draw from constructs in the BeSD framework (*See Figure 3*) to guide the development of focus group discussion, and interview guides and surveys and, ultimately, the construction of message content. The framework includes influences that are specific to vaccination, measurable and potentially modifiable.

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[redacted]

B. INNOVATION

B.1 This will be one of the first studies to utilize a co-creation approach across multiple levels of stakeholders to develop tailored communication strategies responsive to HPV-specific vaccination barriers in SA. Our study uniquely applies a co-creation approach for reviewing and refining culturally appropriate communications strategies responsive to HPV-specific vaccination attitudes, beliefs, and norms. Our co-creation design phase (Aim 1) is a multi-level approach targeting stakeholders across multiple levels of the socioecological framework, including at the individual (children and parents/caregivers), interpersonal (teachers and nurses), and organization level (Department of Health and school administrators). To our knowledge, the co-creation approach has not been widely applied in SA to develop communications strategies for reducing parental hesitancy toward HPV vaccinations for their boys and girls. We expect this approach to lead to more effective, community-supported communications strategies to improve HPV vaccine uptake.

B.2 This study will enable greater understanding of vaccine acceptability and uptake among a culturally and socioeconomically diverse sample of SA parents /caregivers. Most HPV vaccine studies in SA have focused exclusively on public schools,[11,33,40,58,65] with only a few studies focusing on private schools.[35,72] Our study is unique in that we will draw from both public and private schools within the same study, as well as schools which include culturally and socioeconomically diverse student populations. This design will allow for a broader, more inclusive understanding of attitudes and specific barriers across multiple contexts in SA.

B.3 The proposed study will be one of the first to elucidate how attitudes and beliefs about HPV vaccine and vaccine provision logistics in SA have shifted because of the COVID-19 pandemic. A review of nine surveys investigating COVID-19 vaccine acceptability in SA conducted prior to March 2021 suggested that the COVID-19 pandemic may be exacerbating current vaccine hesitancy trends and called for more research on this topic.[73] Understanding how attitudes toward vaccines in general and other vaccine provision logistics have changed during the COVID-19 pandemic is crucial for developing an effective intervention for improving HPV vaccine uptake.

B.4 This will be one of the first studies to provide evidence of barriers and facilitators of HPV vaccine uptake among a group not yet included in school-based implementation in SA: boys and their parents/caregivers. The HPV vaccine has not been made widely available to boys in South Africa, and there is very limited research on this topic. As found in other studies globally, many parents and caregivers lack awareness of the benefits of HPV vaccination in boys, and stakeholders may hold different beliefs about HPV vaccination in boys compared with girls.[74] Such information will help us to develop tailored messaging and demand creation strategies for HPV vaccines among parents/caregivers of boys in the SA context.

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[redacted]

C. APPROACH

C.1 Summary. The primary goal of this pilot feasibility clinical trial is to refine and then evaluate the effectiveness (e.g., of HPV vaccine uptake and completion) and implementation outcomes (e.g., feasibility, acceptability, appropriateness) of a multi-component communications strategy, integrated with the established school-based

HPV vaccine program in [CONFIDENTIAL INFORMATION - REQUESTER IN AGREEMENT] The communications strategy will be aligned with standard messaging about HPV vaccine, while expanding upon the current program to address common questions, concerns and misconceptions held by parents/guardians, children, and others. Our aim is to refine communications materials to raise vaccine confidence amongst parents, vaccine age-eligible children, and others who are important influencers of both parents and children about vaccine decision making (e.g., teachers). A second goal of the study is to generate evidence regarding drivers of HPV vaccine acceptance, consent, and uptake of HPV vaccination amongst age-eligible girls and boys. In **Aim 1**, we will take a phased approach to designing health promotional materials for parents, teachers, nurses, and children ages 9-12. Activities will include **i) Elicitation** activities via focus group discussions with individuals engaged in the planning or implementation of the school-based HPV program (e.g., representatives from the Department of Health, health providers, school administrators) (N=20), and semi-structured interviews with parents/guardians (N=20), teachers (N=10), and children (N=10); **ii) Design** of health promotional materials (curriculum-linked learning materials, informational handout/brochure, community dialogues, using an adapted Community Map), accomplished using established iterative design methods, and **iii) Evaluation** of the effect of exposure to the materials on raising understanding related to HPV vaccination amongst parents, children, and teachers (N=216). In **Aim 2**, we will conduct a pilot feasibility school-randomized controlled trial, where schools (N=10; 600 Grade 5 children) are the unit of randomization, to evaluate the preliminary effectiveness of the multi-level communications strategy on increasing parent/guardian consent for their child to be vaccinated, and subsequently on HPV vaccine uptake (dose 1) and completion (dose 2). We will also assess the following criteria: recruitment rate, completion of questionnaires, acceptability of the communications strategy and its implementation among parents, children, teachers, school administrators and Department of Health officials responsible for the school-based program. We will perform exit interviews with parents, teachers, and nurses (N=30) to identify strategies for sustainability. We will use a mixed methods approach to investigating factors that drive parental consent and HPV vaccine uptake and completion amongst girls and boys. There will be extensive involvement from a Stakeholder Working Group (SWG) from project inception to completion to ensure local relevance and ownership. Assessments of the intervention components' feasibility, acceptability and potential effectiveness will be accomplished through testing in schools in [redacted], where our team is well established. If the intervention components prove to be acceptable, feasible and potentially effective, we will work in close collaboration with the Department of Health to implement this strategy in schools throughout the province, and ultimately throughout SA.

C.2 Study Team (see Biosketches). In addition to input provided through stakeholder engagement over the past year the proposed study is informed by our team members' multidisciplinary expertise in HPV prevention, vaccine decision-making, health communications, health behavior, participatory design, and community engagement – See Table 1. ***This study will provide an opportunity for our investigative team to actively engage with key stakeholders in South Africa who have the ability and goal to integrate boys into a gender-neutral national HPV immunization program (see Letter of Support).***

Table 1. Multidisciplinary Team
Dr. Katz (Brigham and Women's Hospital, Harvard Medical School, **MPI**) is an infectious diseases-trained physician and global intervention researcher who has focused her research in SA for over a decade. She has expertise in vaccine hesitancy and in designing mixed-methods research studies to engage vulnerable communities, including young people. She will lead all aspects of the study, from design to implementation, as well as data analysis.
Dr. Butler (U of Connecticut, **MPI**) is a behavioral scientist and epidemiologist with methodologic expertise in participatory methods, and design, implementation, and testing of interventions to improve health outcomes for diverse populations. Her research program includes studies to promote early identification of virus-associated cancers (cervical cancer, Kaposi's sarcoma), development of health promotional media, and parent/guardian decision making related to vaccines recommended for children and adolescents. She has over 20 years' research experience in SA and other countries in Africa. She will contribute to the development and implementation of protocols for intervention design and evaluation.
Dr. Munro [CONFIDENTIAL INFORMATION - REQUESTER IN AGREEMENT] **Site-PI/ Co-I**) is a psychologist whose research focuses on the psychosocial and behavioral components of change in educational and health contexts. He has deep experience working with young people and will oversee research participant identification and recruitment. He will be responsible for facilitating local IRB and related research approvals and will ensure data are collected

and managed appropriately. He will also assist with analyses and report on findings in the form of reports and other feedback to stakeholders and scientific journals.
Dr. Madhivanan (U of Arizona, **Co-I**) is a physician and epidemiologist who has been involved in primary and secondary cervical cancer prevention in resource-limited settings since 2007, focusing on identifying barriers to parental acceptability of HPV vaccines among minority populations in the USA, India, and other low- and middle-income countries. Throughout her research, Dr. Madhivanan has worked with engaging stakeholders on multiple levels, including children, adolescents, parents, and health providers. She will be involved in the conceptual design, data collection, data interpretation, and dissemination activities related to the grant.
Dr. Wassenaar (U of KZN, **Co-I**) is an expert in health research ethics and clinical psychology with an established record of research supported by NIH Fogarty. He co-directs the South African Research Ethics Training Initiative, collaborates with the HIV/Aids Vaccines Ethics Group (HAVEG), is Co-PI on the U of KZN DRILL research leadership program. He chairs the U of UKZN Biomedical Research Ethics Committee/IRB. He will guide the team with his expertise in research ethics and capacity strengthening and provide support in navigating the ethical issues associated with conducting a study among local adolescent populations related to the HPV vaccine. He will also provide input on ethics considerations, study tools, interpretation of findings and manuscript preparation.
Dr. Slack (U of KZN, **Co-I**) has expertise in conducting conceptual and empirical research and developing resource documents for stakeholders. She is well-versed in the ethical complexities of clinical trials and methods to ensure protected participation of adolescents, strengthening of consent processes, and engagement of community stakeholders. She will provide input on participatory research, the ethics of engaging minors, study tools, interpretation of findings, and manuscript preparation.
Dr. Gumede (U of KZN, **Co-I**) is a trained theatre specialist with expertise in applied arts for health communication. He has experience in the creation of communications and media for social and behavioral change. He has been involved in the KZN COVID-19 response. He will provide input on the development of messaging related to HPV vaccination, study tools, interpretation of findings, and manuscript preparation.
Dr. Mudzingwa (U of Connecticut, **Co-I**) has training in bioengineering and an established record of multidisciplinary research focused on the design of sexual and reproductive health interventions. She has an established record of research with Dr. Butler on studies involving decision science methods. She will lead the design, implementation, and analysis of qualitative studies conducted as part of the proposed study.

In addition to the study investigators, the project will be supported by **experienced project staff** at the University of KZN who have expertise in stakeholder engagement implementation and monitoring, and a **Stakeholder Advisory Group (SAG).** At U of KZN, project staff members bring experience in the design and implementation of protocols for stakeholder engagement (Wilkinson), and experience in community engagement, training, and capacity building (Nzimande). At project inception, we will invite individuals representing key stakeholder groups to the SAG; these will include up to two representatives from the KZN Department of Health who have responsibility for the HPV vaccine program and health communications, two academic researchers from U of KZN who have a role in SA's vaccine acquisition and distribution, and child rights related to health concerns, two representatives CONFIDENTIAL INFORMATION - REQUESTER IN AGREEMENT High School who has been instrumental in our engagement activities over the past ~ 6 months), and two representatives of civil society representing the interests of children and parents. We will consult with the SAG as a group or individually at regular intervals over the course of the project to discuss progress, raise and discuss questions, and stay abreast of issues that are likely to evolve over the course of the project related to HPV vaccine policy (e.g., potential move to recommendation for 1 instead of 2 doses, inclusion of boys in the national school-based vaccine program, etc.). Finally, we will assemble a **Design Advisory Group** to provide feedback on communications materials designed by Jive Media Africa. This group will consist of parents/guardians, teachers, a representative from the Department of Health who is engaged in communications, and representatives of civil society who represents the interests of parents and children.

C.3 Preliminary research most relevant to proposal.

C.3.1 Understanding factors driving uptake and completion of the HPV vaccine. HPV vaccine uptake is a complex, multi-level challenge, as highlighted by a model developed by Katz (MPI) that emphasizes adolescent, caregiver, provider, and contextual influences.[75] Optimizing HPV immunization rates in low-resourced communities requires a multi-pronged approach to holistically address potential barriers to care at

each level. Prior research by Katz et al. (MPI) in Soweto, SA[76] and in the U.S.,[77] shows the importance of building trust among communities, particularly those with a socio-cultural backdrop of high HIV endemicity, sexual violence, and poverty. In this context, clinic-based immunization programs often present structural barriers to vaccination related to standardization of vaccine administration, time pressures in the clinic, and avoidance of potentially challenging discussions related to negative perceptions of the vaccine from caregivers.[78] Prior research by Madhivanan (Co-I) focusing on identifying barriers to caregiver acceptability of HPV vaccines among minority populations in the USA, India, and other low- and middle-income countries,[79-84] identified specific health messaging that was needed to improve trust and increase HPV vaccine acceptability.[85] *Our approach leverages the resources of a national school-based program with trusted teachers and nurses who have the potential to reach and engage young people who are not always effectively served by traditional healthcare channels.*

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Figure 5: Poster to promote early identification of Kaposi's sarcoma

C.3.3 Experience in the development of engaging health education and promotion materials for school-age children. Jive Media Africa has almost 20 years' experience designing youth-friendly educational material to support and promote science, technology, engineering, and math education for students throughout SA. Their program, "Science Spaza" (See Figure 6), includes the production of interactive, entertaining curriculum-linked learning resources on various topics for use in or outside of the classroom. These science learning resources contain simple, practical activities that help to deepen understanding of science concepts.

Figure 6. Science Spaza materials, from Jive Media Africa

C.4 Study Setting. [redacted] District is one of 5 of the province's 11 districts that experience a high triple burden of cancer,[87] HIV (prevalence 29.7%), tuberculosis, and sexually transmitted infections.[88] Presently, the Department of Health HPV vaccination program offers the bivalent vaccine Cervarix (GlaxoSmithKline) against HPV types 16 and 18 at no cost to girls enrolled in public schools in Grade 5 (and age 9-12 years old). Under this program, KZN Department of Health nurses offer vaccinations on designated days at each of the schools, first at the start of the school year in February/March and then again in September/October. Currently, while HPV vaccine is recommended for all age-eligible girls and boys, girls who are enrolled in independent (or 'private') schools and boys must access HPV vaccine at their own cost privately (current cost R2000/dose [~$110]). There are ongoing discussions between the Independent Schools Association of Southern Africa and the Department of Basic Education regarding strategies to make HPV vaccination more accessible to students in independent schools. *The proposed study will make HPV vaccine available to boys as well as all girls at participating schools to eliminate barriers related to vaccine access or affordability.* While the HPV vaccine may be available for free to boys in SA by the time the planned pilot/feasibility RCT begins (January 2025), we have begun discussions which have been received positively with Merck pharmaceuticals regarding a donation of HPV vaccine (2 doses per person) for approximately 300 male and up to 300 female participants should it be required (Personal Communication with Dr. Ariana Harari, Regional Medical Scientific Director, Merck).

C.5 School selection. [redacted]

C.6 Target Study Population. The primary target population of the proposed intervention are parents/guardians of Grade 5 children, as their consent is required for children to be eligible for vaccination. However, we recognize that parents/guardians' vaccine decisions may be influenced by others including their children, their children's teachers, and health providers to whom the parents may look for advice. Therefore, our communications strategy includes development of materials tailored for the needs of parents/guardians, teachers, nurses, and children.

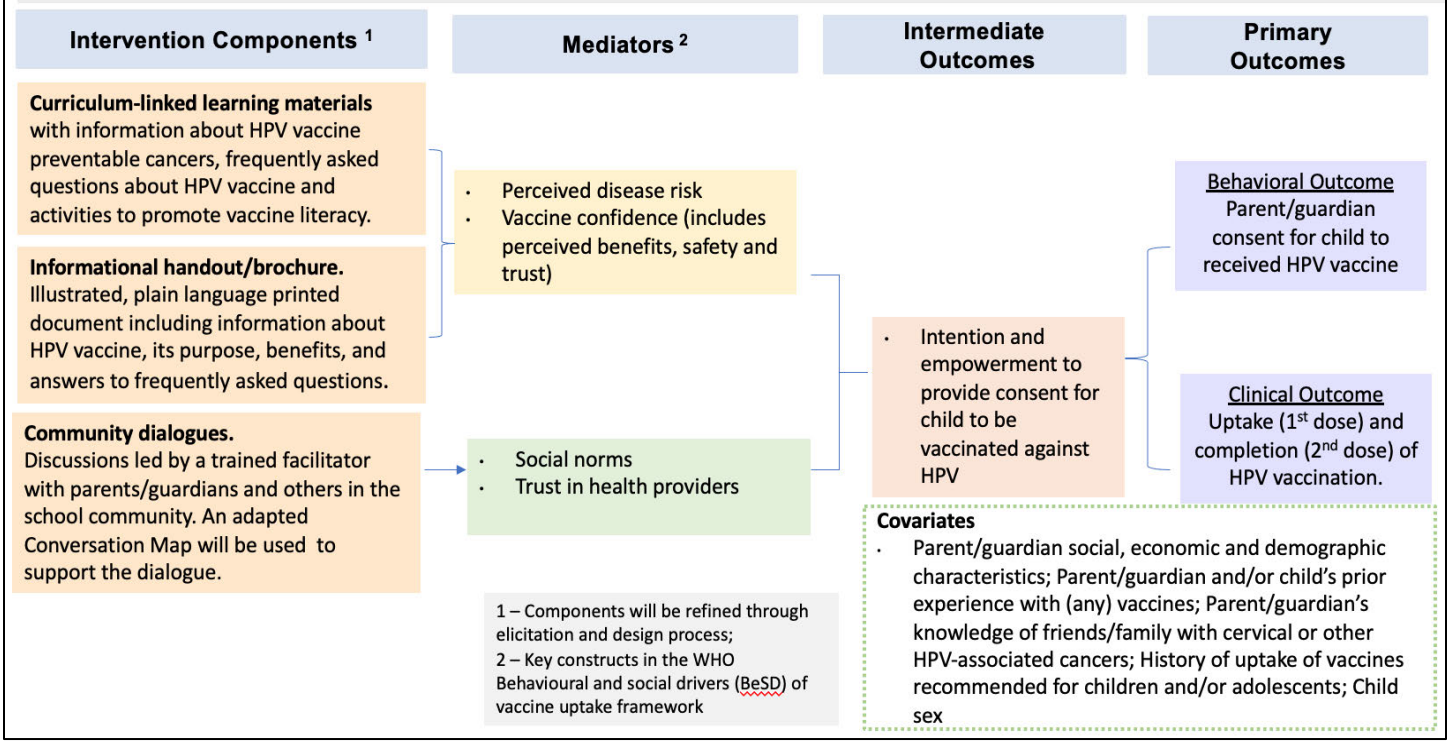
C.7 Description of planned communications strategy. Building upon available materials from the KZN Department of Health and informed by elicitation activities with individuals responsible for planning or implementation of the HPV vaccination strategy, parents, and teachers, as well as input from our Stakeholder Advisory Group and Design Advisory Group, we will adapt and/or create educational materials and tools that will address the key constructs in the BeSD (see A.7 above and Figure 7 below). The following educational materials will be improved (when versions exist) or newly developed, with additional elements likely emerging from inputs obtained through the elicitation and design phases *(see Aim 1 above).*

- **Curriculum-linked learning materials:** We will produce age-appropriate curriculum-linked materials in the style of "Science Spaza" (see C.3.3, and Figure 6, above) focused on vaccine-preventable cancers, with a specific focus on HPV vaccination. These materials will provide information about vaccines in general and HPV vaccines, designed specifically for Grade 5 students. We envision these materials to be introduced by Grade 5 teachers, as a supplement to standard Comprehensive Sexuality Education (CSE) curriculum the students receive within schools, though alternatives may be suggested through the formative phase.
- **Informational handout/brochures:** Illustrated, plain language document including information related to HPV preventable cancers, the benefits of the HPV vaccine, what is understood about vaccine safety, and answers to frequently asked questions. The guides will be purposively designed to be accessible to a diverse audience. We anticipate that these illustrated guides will go home to parents/guardians through students or through other school distribution mechanisms in at the beginning of the school year (project year 2, Q3 –

January 2025). We envision these materials will be similar in style to materials our team has developed previously with Jive Media Africa (see C.3.2 above), though the content, style and channels will be refined based on work in the formative phase of the study. It is possible, for example, that there will be demand for the material to be delivered electronically, provided on the school website, and/or enhanced with short videos to make the messaging more accessible to people with lower levels of literacy.

- **Community dialogues, using an adapted Conversation Map:** We will adapt the Healthy Interactions' *Conversation Map (CM)*^{TM} for use by trained facilitators to guide discussions related to vaccine decision making. A CM is a visual tool used to support dialogue between a health provider or other facilitator and small interactive groups. It is a person-centered, conversation-based approach, originally designed to engage patients living with diabetes in making behavior changes needed for better health, now used in diverse settings globally. It has been shown effective in improved clinical and health behavior outcomes for diabetes,[89] and adapted for other conditions (e.g., HIV).[90] The adapted conversation maps will be used to support dialogue between teachers, nurses and/or other trained facilitators and parents/guardians on topics related to HPV vaccination. Maps will include ideas and agendas for hosting community townhalls and information sessions, tips for creating an atmosphere for dialogue that invites listening and learning, and suggestions for addressing common misconceptions and concerns about HPV vaccines.

Fig. 7. Conceptual Model of Multi-Level Communications Strategy to Optimize Uptake and Completion of HPV Vaccination



C.8 Approach to Aim 1: Refine components of a school-based multi-level communication strategy to improve HPV vaccine uptake amongst age-eligible girls and boys.

C.8.1 Elicitation Phase

We will conduct focus group discussions (FGDs) and semi-structured interviews (SSIs) to inform adaptations to the intervention (three-part communications strategy) as well as survey design (including content, wording of questions, instructions, infographics, etc.). These activities are briefly described below.

Focus Group Discussions (FGDs). We will conduct FGDs with a sample of personnel involved in planning or implementing the existing HPV vaccine program and school administrators (N=20) to elicit information about experiences, strengths, and challenges with the program over past years, current communications strategies and to explore ideas for addressing gaps that are identified and enhancing current communications strategies.

a) **Eligibility.** [redacted] District and school administrators from schools in the district will be eligible for inclusion (N=20).

b) Procedures. We will conduct separate FGDs with each participant group. Groups will last up to 2 hours, led by trained facilitators, and attended by study leadership. FGDs will be conducted in English and Zulu, audio recorded with participant permission, and subsequently transcribed.

Semi-structured interviews. We will conduct semi-structured interviews with a sample of parents/guardians and children to explore knowledge and understandings related to vaccinations in general and HPV vaccine specifically, as well as perceptions of risk, perceived benefits, safety, and trust, as well as perceived social norms, trust in providers social support for vaccination and perceived ability to obtain vaccination for children.

a) Eligibility. We will recruit and enroll a sample of parents of girls and boys enrolled in Grade 5 (N=20) as well as Grade 5 children (N=10) and teachers (N=10) from a random selection of 5 schools (See C.5 above for details).

b) **Procedures.** Semi-structured interviews will be conducted by a bilingual (English and isiZulu) research staff member in a private and secure location that is easily accessible to participants. Interviews with children will last not more than 30 minutes. Interviews with adults will last up to 60 minutes. Examples of interview questions for parent/guardians are as follows:

Eliciting Beliefs:

- What would be some of the *good things*, if any, about having your child vaccinated against HPV? Please list below (tell me) some of the good things, if any, about having your child vaccinated against HPV?
- Are there any other good things you can think of about having your child vaccinated against HPV? Please list below (tell me) any other good things about having your child vaccinated against HPV?
- What would be some of the bad things, if any, about having your child vaccinated against HPV? Please list below (tell me) some of the bad things, if any, about having your child vaccinated against HPV?
- Are there any other bad things you can think of about having your child vaccinated against HPV? Please list below (tell me) any other bad things about having your child vaccinated against HPV?

Eliciting Norms:

- What are the people or groups who *want you* to have your child vaccinated against HPV, if any? We do not want specific names—we just want the type of people (e.g., my mother, my doctor, my minister) who would *approve* of you having your child vaccinated against HPV.
- What are the people or groups who *do not want you* to have your child vaccinated against HPV, if any? We do not want specific names—we just want the type of people (e.g., my mother, my doctor, my minister) who would *not approve* of you having your child vaccinated against HPV.
- Please list these people or groups below/please tell me these people or groups.

Eliciting Perceived Behavioral Control:

- How easy or difficult would it be to have your child vaccinated against HPV?
- In a few words, please tell us why it might be easy to have your child vaccinated against HPV.
- In a few words, please tell us why it might be difficult to have your child vaccinated against HPV.

Qualitative Data Management. Focus groups and interviews will be audio-recorded, and summary notes from interviews will also be completed immediately following an interview. Complete audio recordings, or portions deemed relevant for analysis, will be translated, and transcribed into English. All information that could potentially identify the participant (e.g., names of people or specific locations) will be removed from the transcripts during transcription. Transcripts will be reviewed for accuracy and completeness by site study staff, and subsequently reviewed by other members of the research team.

Qualitative Data Analysis. Transcripts will be coded by the research teams in each country. Three distinct stages will be used for thematic coding as the primary analytic strategy. After reading four transcripts, analysis team members will develop a codebook of themes based on the interview topics, along with those emerging from the data. Two more transcripts will then be reviewed to inform additional topic areas and themes; this process will be repeated until the codebook reaches a stage where no new themes or topic areas emerge. To ensure inter-rater consistency, the analysis team will compare their individual coding of the same transcripts, and a coding concordance will be calculated. All transcripts will then be coded using the final version of the codebook and merged using Dedoose qualitative analysis software. Themes will then be summarized across participants, and analysis will focus on identifying dominant explanations for main issues identified. We will hold discussions with the analysis team to validate interpretations and resolve any interpretation discrepancies. Our analysis will highlight issues described in the study design and issues emerging from participant engagement.

C.8.2 Design Phase.

Information collected via FGDs and interviews will be provided to Jive Media Africa (discussed in C.3). Jive communications and design experts will generate prototypes of each communication type (outlined in C.7.1). The prototypes will be reviewed by members of our **Design Advisory Group (DAG)** (C.2). Design-based research methods rely on progressive refinement of materials through revision. Therefore, we will develop each media type in an iterative fashion, engaging the DAG in several meetings over the course of Y01 to gain feedback on messaging, storylines, and storyboards. Iterative development in consultation with key stakeholders is a critical dimension of any design process but will be particularly vital to the successful development of culturally appropriate health promotion media for promoting awareness about HPV vaccine. A template for evaluating and commenting on each communication type will be provided to the DAG so that all suggestions are documented. Areas for review will include alignment of messaging with the Department of Health, clarity of the message, accuracy and completeness of the information provided, and coherence and relevance of the content for diverse populations. We expect there to be several rounds of edits before advancing to the next phase. Advancement will be made only once the DAG members sign off.

C.8.3 Evaluation Phase.

a. Pre-post test. We will test each communications type to evaluate whether their intended key messages are understood and whether they lead to increased understanding about HPV vaccine.

b. Eligibility. We will enroll a sample of children and parents/guardians of children in Grade 5 in five of the schools eligible for selection participate in the study (N=20 parent/guardians and 20 children from each of five schools, total N=100 parents/guardians, N=100 children), and a sample of Grade 5 teachers (N=16) (See C.5 for description of school selection).

c. Procedures. Participants will be consented verbally in their preferred language (e.g., isiZulu or English) by a research assistant and then interviewed using a structured questionnaire to assess their knowledge about HPV associated cancers and HPV vaccine. Participants would then be given the communications materials to take home and review for 2 weeks. At 2 weeks after enrollment, individuals would be asked to participate in a second interview to assess knowledge about HPV vaccine, as well as *acceptability and feasibility* of the communications materials using the Acceptability of Intervention Measure, Intervention Appropriateness Measure, and Feasibility of Intervention Measure.[19] A semi-structured interview will then be used to solicit reflection on the specific communication type being tested, their interpretation of messages and any other feedback. Results of the evaluation will inform one further round of revisions and improvements, resulting in final versions of communication materials for use a two-arm pilot/feasibility school randomized controlled trial (C.9). To move forward, we have set the following criteria: 1) More than 50% of parents rate health education materials as acceptable, 2) More than 50% of children rate curriculum materials as acceptable, 3) More than 50% of teachers rate curriculum materials as acceptable, 4) More than 50% of teachers and nurses rate Community Mapping tool as acceptable.

C.9 Aim 2. Evaluate preliminary effects of the communications strategy and key criteria to advance to a full-scale hybrid type 2 trial.

C.9.1 Site selection and randomization. We will select 10 schools (~60 parents/children per school) by a stratified random sampling approach (see C.5). We will randomize schools in a 1:1 ratio to the intervention and control arms. Randomization, based on a computer-generated assignment, will occur after the 10 schools have been selected. Control participants will be eligible to receive the intervention materials at the end of the 1-year follow-up period.

C.9.2 Participant eligibility. At both intervention and control schools, we will enroll up to 60 parents/guardians of boys and girls currently enrolled in Grade 5 per school. Individuals will be eligible to participate if they are ≥18 years of age and a parent/guardian of a child enrolled in Grade 5 at the participating school.

C.9.3 Consent and Enrollment Procedures. At the beginning of the school year (i.e., January 2025), parents/guardians of children enrolled in Grade 5 will be invited to participate in the study by way of a letter and consent form sent home via their child. Parents/guardians will be asked to provide written informed consent for their participation in the following activities: a) collection of data through self-completed survey (unless a one-on-one interview is requested), b) if selected, participation in a one-on-one interview after approximately 11 months (after the 2nd annual HPV vaccine campaign). Parents/guardians will be asked to

give consent for the research team to obtain the child's immunization records over the course of the year. The invitation will request parent/guardians to select the method they would like to complete a survey – paper, electronic, or by one-on-one interview. They will be asked to return the form within a week (indicating consent or no consent). Where possible, a notice about the invitation will be sent via email and/or SMS/WhatsApp (most, if not all, schools use an electronic platform for communications to parents/guardians). A reminder will be sent home to those who did not return a consent form within the week. If not returned within 1 more week, a designated school staff member will call parent/guardians to remind them. If still not returned, the parent/caregiver will be documented as "nonresponsive". *This information will be critical for the planning of a future trial.*

C.9.4 Data Collection and measurements. Parent/guardians who return the consent form will be provided a survey via their preferred method (e.g., paper, electronic, or one-on-one). It is important to offer multiple modes to accommodate the needs of as many parent/guardians as possible (e.g., related to literacy, access to computer to complete a survey, etc.). The survey will include questions about their sociodemographic characteristics and questions related to their perceived risk of acquiring HPV, their perceived risk of their child acquiring HPV, perceived benefits of HPV vaccine, safety and trust of the vaccine, social norms and medical mistrust – all key factors outlined in the BeSD model (Figure 3). We will ask that paper surveys be returned to our study team for data input (into Research Electronic Data Capture, RedCAP). Electronic data will be downloaded daily.

C.9.5 Communications intervention.

Prior to the first HPV vaccine campaign (generally held in March), standard information about the HPV vaccine will be sent to all families (see Fig 8). In schools allocated to the intervention arm, the following will occur:

1. Parents/caregivers will be given an enhanced information package (as described above C.8.2). The package will be sent home with their Grade 5 child.
2. Grade 5 students will be provided with engaging learning materials focused on HPV vaccine (as described in C.8.2) to take home to read. They will be encouraged to discuss the information and activities with their parent/guardian and/or family members.
3. Up to 2 community dialogues will be held at each of the intervention schools, led by a trained facilitator, using the adapted Conversation Map. Parents/guardians of Grade 5 students will be invited to attend the discussion. The sessions will be held at a day/time recommended by the Stakeholder Working Group.

C.10 Primary behavioral and clinical outcomes – HPV vaccine uptake (1st dose) and completion (2nd dose). We will extract data from registries completed by nurses who administer the HPV vaccine. A registry is completed for each school including the names of all children enrolled in Grade 5. The registry includes fields for 'consent provided [for vaccine]?' 'Dose 1 given?' 'Dose 2 given?' The primary behavioral outcome is whether consent was given. The primary clinical outcomes are whether the child received the first dose and the second dose.

C.11 Primary process outcomes. We will assess implementation, feasibility, and acceptability of intervention components to inform scale up. Using mixed methods, we will collect qualitative and quantitative data throughout the study. We will document the rate of recruitment (i.e., parent consent to complete the baseline questionnaire), return of completed questionnaires, any issues with the study design or implementation procedures, feedback from school administrators about communications strategy implementation, and feedback from Department of Health about communications strategy content and implementation. We will conduct structured exit interviews with 20 intervention participants (parents and children) to further assess intervention acceptability to inform scale-up. We will ask for detailed feedback on the key intervention components (enhanced information sent to parents; learning materials or children) and elicit suggestions for improvement. We will conduct in-depth interviews with up to 10 additional key informants (e.g., nurses, teachers, school administrators, Dept of Health staff) to assess challenges and facilitators of intervention components from the perspective of those who delivered the intervention. These interviews (Total N=30) will be conducted in either English or isiZulu, last approximately 60 minutes, and will be digitally recorded and transcribed.

C.12 Data quality and management. The vaccine registry includes information related to consent for vaccine and receipt of vaccine for each age-eligible child at each school. Data from the registry and those specifically conducted for this study (survey) will be entered into a computer for data entry operating REDCap, a secure, web-based application for building and managing online surveys and databases. REDCap Software is supported by Partners Healthcare and has been used by MPIs Katz and Butler in their research in SA because of the rigorous standards set to maintain privacy and security. All transactions are fully encrypted, and logins use secure authentication. Procedures to promote data quality will include range and logical checks built into the data entry program and additional error checks after data entry. Code numbers will link data over time. We will investigate the patterns and types of missing data and non-response. Initial analyses also will involve inspection of the distributions of our mediating and outcome variables to identify outlying or unusual values and to assess distributional characteristics. We will also assess validity of scale constructs via exploratory and confirmatory factor analysis and perform internal consistency analyses to assess scales' reliabilities.

C.13 Power/sample size considerations. All analyses will utilize appropriate exploratory methods for the types of data collected. Binary responses and predictors will be assessed via frequency tables to identify sparse categories – combining categories of multinormal variables, if necessary. Continuous predictors will be examined both numerically and graphically to identify important properties such as skewness, heavy tails (i.e., large kurtosis), and outlier presence. All outliers will be examined to make sure data collection was done correctly prior to any consideration of applying nonlinear transformations.

In Aim 1, we will perform a pre- and post-test of our package intervention to assess knowledge about the HPV vaccine, as well as *acceptability and feasibility* of the communications materials using the Acceptability of Intervention Measure, Intervention Appropriateness Measure, and Feasibility of Intervention Measure.[19] Using a semi-structured interview, we solicit reflection on the specific communication type being tested, interpretation of messages, and any other feedback. Results of the evaluation will inform one further round of revisions and improvements, resulting in final versions of communication materials for use a two-arm pilot/feasibility school randomized controlled trial (C.9). As noted in Aim 1, we have set the following threshold to move forward: 1) More than 50% of parents rate health education materials as acceptable, 2) More than 50% of children rate curriculum materials as acceptable, 3) More than 50% of teachers rate curriculum materials as acceptable, 4) More than 50% of teachers and nurses rate Community Mapping tool as acceptable.

The primary responses in Aim 2 are both binary and will each be collected on the same set of subjects at two time points. The cluster-randomized design utilized will have a 1:1 control-to-intervention ratio with an average of 60 students (30 male and 30 female) selected per school. The two most common approaches to modeling binary responses arising from cluster-randomized designs is to use either a generalized linear mixed model (GLMM) approach with a logit link function, or to model using marginal models estimated via generalized estimating equations (GEEs). In our case, with 10 clusters in total, we will plan to utilize marginal models for binary data, with a logit link function, estimated via GEE-based methods after utilizing multiple imputation to replace missing values if our missingness rate exceeds 10% at either time point. Even in the extreme case of 20% attrition, we expect to have moderately large power to detect relatively small differences in vaccine uptake.

C.14 Potential risks and alternative strategies.

C.14.1 Recruitment. Parents of young people can be a challenging population to recruit due to competing demands for their time. However, by partnering with the school systems who have ongoing communication with their students and families, we believe we will easily be able to reach our recruitment goals. Should recruitment or retention rates deviate from anticipated rates, the team will brainstorm novel strategies and/or discuss strategies with our community partners.

C.14.2 Contamination. Recruitment for each arm will take place at different sites, thus minimizing the potential for contamination. We will also inquire about potential contamination during exit interviews and ways to reduce this source of bias.

C.15 Summary and future directions. HPV immunization is a life-saving intervention in a country where HPV-associated cancers take a tremendous toll. By leveraging established partnerships with area schools serving diverse populations, we can ensure that health equity is at the core of our research. Findings from the proposed study will provide critical data to inform a future Hybrid Type 2 school-randomized controlled trial intervention to increase knowledge about the effectiveness of the HPV vaccine and inform the growing literature in cancer prevention strategies, ultimately enabling young people in SA to realize full health and well-being.

PHS Human Subjects and Clinical Trials Information

OMB Number: 0925-0001

Expiration Date: 09/30/2024

Use of Human Specimens and/or Data

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

Human Subject Studies

Study#	Study Title	Clinical Trial?
1	Multi-level school-based intervention to improve HPV vaccine uptake and completion in South Africa	Yes

Section 1 - Basic Information (Study 1)

1.1. Study Title *

Multi-level school-based intervention to improve HPV vaccine uptake and completion in South Africa

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

- HPV vaccine
- Cancer prevention

2.2. Eligibility Criteria

For the clinical trial phase of this study, we will first select 10 schools for inclusion in the study using a stratified random sampling approach (i.e., 2 schools in each of 5 strata that represents socio-economic status of students). At the selected schools, we will recruit all primary caregivers (parent or guardian), age 18 years old older, of children enrolled in Grade 5 in the participating schools. We will obtain consent from parents/guardians for their own participation in a survey and permission to contact for an interview at endline, as well as their permission to obtain data from the Department of Health for immunizations that they may or may not receive. In addition, as part of the process evaluation, we will recruit individuals who are involved in the management or implementation of the school-based HPV vaccine program (e.g., manager(s), nurse(s)).

2.3. Age Limits	Min Age: 9 Years	Max Age: N/A (No limit)
2.3.a. Inclusion of Individuals Across the Lifespan	Inclusion_of_Individuals_Across_the_Lifespan.pdf	
2.4. Inclusion of Women and Minorities	Inclusion_of_Women_and_Minorities.pdf	
2.5. Recruitment and Retention Plan	Recruitment_and_Retention_Plan.pdf	
2.6. Recruitment Status	Not yet recruiting	
2.7. Study Timeline	Study_Timeline.pdf	
2.8. Enrollment of First Participant	10/01/2023	Anticipated

INCLUSION ACROSS THE LIFESPAN

This study will include children enrolled in Grade 5 in participating schools (ages 9-12 years old) in KwaZulu Natal, South Africa, who have no prior history of HPV immunization. We have selected fifth graders for our target population to follow the current Provincial Guidelines. This is in line with National Cervical Guidelines aimed at reaching young people prior to their sexual debut. We have expertise on the team (Drs. Butler and Slack) whose research has incorporated children living in South Africa over two decades, and who will provide training and support for the research team to ensure appropriate sensitivity to working with young people. Drs. Slack and Wassenaar have longstanding expertise in the complex issue of adolescent enrollment, holding leadership roles on their ethics review committees, and have experience in the development of resource documents for affected stakeholders to help them strengthen their practices. They will provide guidance on the ethical framework needed to ensure adequate protection for children. This intervention is school-based and is therefore appropriately suited for enrollment and accommodations for children.

We will also be recruiting parents/caregivers of these children, given their role in decision-making. All parents/caregivers will be at least 18 years old. We will also be including adults who are at least 18 years of age, who are employed at participating schools as teachers or school administrators, and others who are engaged in the planning or implementation of the school-based HPV vaccine program (e.g., representatives from the Department of Health, nurses). We have no upper age limit for this population.

2.4 INCLUSION OF WOMEN AND MINORITIES

In this research study, participants are from South Africa and represent several racial and ethnic groups in [redacted] (e.g., Black, White, Asian, Mixed-Race). There will be no limitations or restrictions on participation by ethnicity. At least half of all participants will be female.

2.5. RECRUITMENT AND RETENTION PLAN

RECRUITMENT

2.5.1 Recruitment site and feasibility of recruiting participants:

Recruitment site: [redacted] CONFIDENTIAL INFORMATION - REQUESTER IN AGREEMENT

Each school is ranked by The Amended National Norms and Standards for School Funding (ANNSSF) – there are five quintiles of which Quintile 1 represents the poorest schools and Quintile 5 the most affluent. To ensure diversity in our sample with respect to socio-economic status, geography, race, and ethnicity, we will sample schools from within each quintile. For schools designated as Quintile 1-4, we will limit selection to schools where HPV vaccine uptake in the prior year is <70% (these data are available from the Department of Health). Historical HPV vaccine uptake data are not available for children in schools in Quintile 5. Prior studies have shown HPV vaccine uptake to be very low in private schools in South Africa. This has been affirmed through stakeholder engagements held to date. We will discuss school selection with key stakeholders from the Department of Health and representatives of area schools in the first quarter of Year 1. Once selection criteria are agreed upon by key stakeholders and study investigators, we will randomly select 5 schools (1 per strata) from amongst those that are eligible for Aim 1. This will be done with transparency, in the presence of stakeholders and investigators. We will convene key stakeholders and investigators again for selection of 10 schools (2 per strata) for Aim 2 activities.

Feasibility of recruiting participants: We will be working in close partnership with the Department of Education and school leaders to optimize the potential for recruitment. All entering students in Grade 5 and their caregivers will be potentially eligible for our study in the designated schools.

2.5.2 Screening and Recruitment:

At the beginning of the school year (i.e., January 2025), parents/guardians of children enrolled in Grade 5 will be invited to participate in the study by way of a letter and consent form sent home via their child. Parents/guardians will be asked to provide written informed consent for their participation in the following activities: a) collection of data through self-completed survey (unless a one-on-one interview is requested), b) if selected, participation in a one-on-one interview after approximately 11 months (after the 2nd annual HPV vaccine campaign). Parents/guardians will be asked to give consent for the research team to obtain the child's immunization records over the course of the year. The invitation will request parent/guardians to select the method they would like to complete a survey – paper, electronic, or by one-on-one interview. They will be asked to return the form within a week (indicating consent or no consent). Where possible, a notice about the invitation will be sent via email and/or SMS/WhatsApp (most, if not all, schools use an electronic platform for communications to parents/guardians). A reminder will be sent home to those who did not return a consent form within the week. If not returned within 1 more week, a designated school staff member will call parent/guardians to remind them. If still not returned, the parent/caregiver will be documented as "nonresponsive". *This information will be critical for the planning of a future trial.*

2.5.3 Informed Consent:

We will obtain written informed consent from individuals who are recruited to and willing to participate in focus group discussions, semi-structured interviews, pre-post surveys, self-completed questionnaires (paper or online where the questionnaire will be available with audio support to ensure access by individuals with lower levels of literacy). For participants who are under age 18, we will obtain parental consent for the child's participation. Relevant study staff will be fluent in the local dialect to obviate the need for translators and, as such, optimize confidentiality. We have designed the informed consent procedure for this study to maximize understanding of potential risks. To ensure correct use of language, all consent forms will be translated into isiZulu and back translated into English. The consent form will also provide contact information for both the Site- Principal Investigator (PI) as well as the Office for the Protection of Research Subjects. All informed consent processes will adhere to the policies set forth by the Institutional Review Board. Signed informed consent forms will be stored in a locked file cabinet to maintain the privacy of all study participants.

RETENTION

While we intend to only retain a small sub-sample of our study population in Aim 2 for our process evaluation, we will utilize our retention strategies that have been refined within our research group over the past decade. We will work closely in partnership with schools to ensure we are able to get an adequate sample for our exit interviews. We will increase retention rates by utilizing the following:

Incentives. We have extensive experience retaining participants in South Africa. While we will not be seeking to retain the vast majority of our participants, we will seek a sub-sample of participants for the process evaluation of our intervention. We will offer participants a stipend equal to US$15 to follow-up with them for exit interviews during Aim 2 of our study. These are standard rates provided by University of KZN, reviewed annually by the Community Advisory Board and Ethics Committee.

Maximize participant control and flexibility. We will elicit participants' preferences for communication and give participants the maximum possible flexibility in choosing the mode (i.e., phone, text, or in person) and timing of contacts. Upon study registration, we will solicit preferred methods of contacting participants for follow-up, to ensure that participants are not lost because of outdated contact information.

Reduce burden on participants. Participants will be personally contacted to schedule an exit interview and assessments through their preferred contact mode.

Emphasize benefits of participation. Benefits of participation will be emphasized at recruitment and throughout the study, including benefits to the participant as well as to larger community.

Trained rapport-building. Building rapport between study staff and participants increases retention. Study staff will be trained by the PI and Site-PI on rapport-building, emphasizing key components such as personalizing visits and communicating empathetically and sensitively. In addition, mock interviews will be conducted to prepare new staff prior to contacting participants on their own. Finally, study staff will be responsive and adapt these retention strategies if participants report that they would prefer not to be contacted.

Participant tracking system. For the study-sub-population we will interview as part of the process evaluation, *w*e will use a locator form to identify multiple points of contact for a participant. A locator form is a crucial component of the retention strategy. Locator information will be reviewed with participants at regular intervals. Locator information is updated during the intervention period, and we check in with participants and update locator information during the follow-up period.

2.7 STUDY TIMELINE (see table below)

We propose a three-year study during which we meet all study aims. The first 4 months of Year 1 will be dedicated to study preparation (e.g., ethics approvals, site preparation, staffing, and training). Elicitation activities and analyses will take place in Year 1 months 5-6. The information gathered will inform materials design, which will take place in Year 1 Q3-Q4. Once finalized, we will test the materials using a pre-post design in Q4-5. The results of the pilot test will indicate whether we move forward or return to design. The RCT would begin in Year 2 Q3, and activities will be done over the course of the year. The final 6 months will be dedicated to data analyses, dissemination of results, and preparation of a NIH R01, should this project be successful.

Subject Enrollment Timeline												
	Year 1				**Year 2**				**Year 3**			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Enrollment of 1st subject		X										
10% Enrollment		X										
25% Enrollment							X					
50% Enrollment							X					
75% Enrollment							X					
100% Enrollment							X					
Completion of data collection time period										X		
Completion of primary endpoint and secondary endpoint data analyses										X		
Completion of the final report of the primary outcome												X
Reporting of results in ClinicalTrials.gov												X

2.9. Inclusion Enrollment Reports

IER ID#	Enrollment Location Type	Enrollment Location
Study 1, IER 1	Foreign	CONFIDENTIAL INFORMATION - REQUESTER IN AGREEMENT
Study 1, IER 2	Foreign	
Study 1, IER 3	Foreign	
Study 1, IER 4	Foreign	
Study 1, IER 5	Foreign	

OMB Number: 0925-0770

Expiration Date: 09/30/2024

Inclusion Enrollment Report 1

1. Inclusion Enrollment Report Title* : Aim 1: Elicitation and Design: Focus group discussions (Department of Health, Nurses, School Administration)

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

3. Enrollment Location Type* : ❍ Domestic ● Foreign

4. Enrollment Country(ies): ZAF: SOUTH AFRICA

5. Enrollment Location(s): CONFIDENTIAL NFORMATION - REQUESTER IN AGREEMENT

6. 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	2	2	0	0	4
Native Hawaiian or Other Pacific Islander	0	0	0	0	0
Black or African American	3	3	0	0	6
White	2	2	0	0	4
More than One Race	3	3	0	0	6
Total	10	10	0	0	20

Cumulative (Actual)

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

OMB Number: 0925-0770

Expiration Date: 09/30/2024

Inclusion Enrollment Report 2

1. Inclusion Enrollment Report Title* : Aim 1: Elicitation and Design: Semi-structured interviews (Parents, Teachers, Children)

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

3. Enrollment Location Type* : ❍ Domestic ● Foreign

4. Enrollment Country(ies): ZAF: SOUTH AFRICA

5. Enrollment Location(s): CONFIDENTIAL NFORMATION - REQUESTER IN AGREEMENT

6. 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	5	5	0	0	10
Native Hawaiian or Other Pacific Islander	0	0	0	0	0
Black or African American	5	5	0	0	10
White	5	5	0	0	10
More than One Race	5	5	0	0	10
Total	20	20	0	0	40

Cumulative (Actual)

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

OMB Number: 0925-0770

Expiration Date: 09/30/2024

Inclusion Enrollment Report 3

1. Inclusion Enrollment Report Title* : Aim 1: Elicitation and Design: Pretest materials

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

3. Enrollment Location Type* : ❍ Domestic ● Foreign

4. Enrollment Country(ies): ZAF: SOUTH AFRICA

5. Enrollment Location(s): CONFIDENTIAL NFORMATION - REQUESTER IN AGREEMENT

6. 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	27	27	0	0	54
Native Hawaiian or Other Pacific Islander	0	0	0	0	0
Black or African American	27	27	0	0	54
White	27	27	0	0	54
More than One Race	27	27	0	0	54
Total	108	108	0	0	216

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

OMB Number: 0925-0770

Expiration Date: 09/30/2024

Inclusion Enrollment Report 4

1. Inclusion Enrollment Report Title* : Aim 2: Pilot evaluation

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

3. Enrollment Location Type* : ❍ Domestic ● Foreign

4. Enrollment Country(ies): ZAF: SOUTH AFRICA

5. Enrollment Location(s): CONFIDENTIAL NFORMATION - REQUESTER IN AGREEMENT

6. 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	100	100	0	0	200
Native Hawaiian or Other Pacific Islander	0	0	0	0	0
Black or African American	300	300	0	0	600
White	100	100	0	0	200
More than One Race	100	100	0	0	200
Total	600	600	0	0	1200

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

OMB Number: 0925-0770

Expiration Date: 09/30/2024

Inclusion Enrollment Report 5

1. Inclusion Enrollment Report Title* : Aim 2: Exit Interviews

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

3. Enrollment Location Type* : ❍ Domestic ● Foreign

4. Enrollment Country(ies):

5. Enrollment Location(s): CONFIDENTIAL NFORMATION - REQUESTER IN AGREEMENT

6. 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	3	3	0	0	6
Native Hawaiian or Other Pacific Islander	0	0	0	0	0
Black or African American	5	5	0	0	10
White	2	2	0	0	4
More than One Race	0	0	0	0	0
Total	10	10	0	0	20

Cumulative (Actual)

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

Section 3 - Protection and Monitoring Plans (Study 1)

3.1. Protection of Human Subjects	Protection_of_Human_Subjects.FINAL.pdf
3.2. Is this a multi-site study that will use the same protocol to conduct non-exempt human subjects research at more than one domestic site?	❍ Yes ● No ❍ N/A
Single IRB plan attachment	
3.3. Data and Safety Monitoring Plan	Data_and_Safety_Monitoring_Plan.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	Organization_of_Study_Team.pdf

3.1. PROTECTION OF HUMAN SUBJECTS

All Brigham and Women's Hospital, University of Connecticut [redacted] research meets the requirements for the conduct of research using funds from the U.S. Government. All institutions maintain a Federal Wide Assurance (FWA) and work with an Office for Human Research Protections (OHRP)-approved IRB. The study protocol, the informed consent documents, participant recruitment materials, and any subsequent modifications will be reviewed and approved by all relevant ethics committees responsible for oversight of the study. All staff who have access to data and/or contact with participants will receive training on the protection of human subjects prior to conducting any study activities and every three years thereafter. Key staff also complete routine Good Clinical Practice (GCP) training every three years.

Drs. Katz and Butler (MPIs) be responsible for the overall conduct of the study, including the safety of human subjects. The MPIs, in collaboration with Dr. Munro, will ensure appropriate (1) conduct of the informed consent process (e.g., that informed consent is obtained before proceeding with study procedures); (2) enrollment of study participants; (3) collection and analysis of data; (4) implementation of study procedures to ensure consistent monitoring of participants for possible adverse events; (5) review of adverse events and reporting to the appropriate IRBs; and (6) maintenance of the privacy and confidentiality of study participants.

The PIs will maintain ultimate responsibility for the project and for the safety of study participants. The PIs will be in contact with the research team on a regular basis to review the progress of the study and address any human subject issues that occur. These discussions may involve adverse event prevention measures, recruiting of appropriate study participants, research staff training on protection of human subjects, as well as occurrence of adverse events, unexpected incidents, or protocol problems.

1. RISKS TO HUMAN SUBJECTS

a. Human Subjects Involvement and Characteristics

In preparation for a Hybrid Type 2 school-randomized controlled trial, we propose a pilot feasibility trial to refine and evaluate a school-based multi-level communications strategy that addresses intrapersonal, interpersonal, and institutional factors associated with HPV vaccination uptake and completion amongst 5th graders.

This research will involve human subjects residing in South Africa, and involves primary data collected through qualitative and quantitative methods. There will be extensive involvement from a Stakeholder Working Group (SWG) from project inception to completion to ensure local relevance and ownership. Assessments of the intervention components' feasibility, acceptability and potential effectiveness will be accomplished through testing in schools in the greater [redacted] where our team is well established.

Study participants will include children enrolled in Grade 5 in participating schools (ages 10-12 years old), parents of Grade 5 children, as well as adults 18+ years who are employed at participating schools as teachers or school administrators, and others who are engaged in the planning or implementation of the school-based HPV vaccine program (e.g., representatives from the Department of Health, nurses). We will enroll up to 20 adults to participate in focus group discussions, 40 adults to participate in semi-structured interviews, 100 children (10-12 years old), 100 parent/guardians (18+ years), and 16 teachers (18+ years) to participate in pre-posttest surveys, up to 600 parents and their Grade 5 children to participate in a school randomized controlled trial. We will enrol a sample of 30 parents/caregivers and up to 20 individuals who were involved in the management or implementation of the school-based HPV vaccine program to participate in exit interviews. Total study population: 1496 participants

b. Sources of materials

Description of research data. Individual research data will be obtained through focus group discussions, semi-structured interviews, surveys and registry data captured by the school-based HPV program (indicating receipt of parent consent for child's participating in the vaccine program, receipt of HPV vaccine dose 1 and receipt of dose 2). We will also document issues and concerns raised during community dialogues that will take place over the course of the study; this information will not be linked to individuals, but rather be analyzed in the aggregate. We will collect data pertinent to the planning of a future hybrid type 2 trial, including 1) participants' preferred method(s) for completing surveys (e.g., paper, electronic or one-on-one interview), 2)

response rate across schools, with a particular focus on ensuring a diverse and adequate study population, 3) feasibility of implementing the communications strategy in an efficient and timely manner (e.g., before the start of the HPV vaccine campaign), 4) acceptability of all communications strategy components, and 5) intervention fidelity.

Data management and security. All research materials obtained from human subjects will be used solely for research purposes. Materials collected as part of the study will consist of recruitment logs (electronic), consent forms (paper-based) survey data (paper and electronic), and recordings and transcripts of focus group discussions and semi-structured interviews, which will be translated to English as needed. All data will be de-identified and stored securely. Data will be entered into a password-protected electronic database and all analysis datasets will have the participant ID number as the unique identifier. Forms, audio recordings, and any other source documents that link participant ID numbers to other descriptive identifying information will be stored in a separate, locked file cabinet. Study forms, electronic databases, and printed data will only be supplied to appropriate study staff on an as needed basis. Publication resulting from this study will omit names and any other identifying information.

c. Potential Risks

It is our judgment that this protocol belongs in Category One Research under 45 CFR § 46 Subpart D: research not involving greater than minimal risk, based on the definition of minimal risk in 45 CFR § 46.102 (i): Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. The potential risks are as follows:

The risks to participating in elicitation interviews, focus group discussions, and the self-administered survey will be minimal. The primary risk is that of feeling uncomfortable or embarrassed due to the sensitive nature of some questions. There is also the risk of fatigue.

The risks to receiving HPV vaccine are minimal. HPV vaccines can cause pain, swelling, and redness where the shot was given, as well as headaches, tiredness, and nausea. The most common side effects of HPV vaccination are dizziness and fainting.

Research personnel are trained in strategies designed to minimize these risks and their potential impact on participants. All serious and unexpected adverse events will be reported to the Study PIs and to the relevant IRBs per local regulation. This study is not likely to pose any physical, social, or legal harm to participants.

2. ADEQUACY OF PROTECTION AGAINST RISK

2.a Recruitment and Informed Consent

Research will be conducted according to Good Clinical Practice guidelines, the U.S. Code of Federal Regulations (CFR) Title 21 CFR (Part 50 – Protection of Human Subjects and Part 56 – Institutional Review Boards), and the Declaration of Helsinki. This protocol will be submitted to institutional ethics review boards at Brigham and Women's Hospital, University of Connecticut and the University of KwaZulu Natal for approval. The informed consent of each participant will be obtained before protocol-specified procedures are carried out.

We will obtain written informed consent from individuals who are recruited to and willing to participate in focus group discussions, semi-structured interviews, pre-post surveys, self-completed questionnaires (paper or online where the questionnaire will be available with audio support to ensure access by individuals with lower levels of literacy). For participants who are under age 18, we will obtain parental consent for the child's participation. Relevant study staff will be fluent in the local dialect to obviate the need for translators and, as such, optimize confidentiality. The study site has prior experience in obtaining informed consent for observational and experimental research in South Africa, including studies that involve children.

This study will include vulnerable populations including children and individuals with limited income. Our study staff and personnel are well-trained and experienced in working in a respectful, fair, and non-coercive manner with these populations. All study investigators and staff members with participant contact will have completed CITI training on the protection of human subjects. The study investigators are well-respected research

scientists who are experienced in Human Subjects research and trained in excellent clinical and/or social-behavioral research practices.

2.b Protections against Risk

Planned procedures for protecting against fatigue: Focus group discussions will last up to 2 hours. Semi-structured interviews will last up to 1 hour. Surveys will take up to 30 minutes to complete. Participants will be informed that they can take a break or stop at any time.

Planned procedures for protection of confidentiality or risks to reputation: To ensure confidentiality of participation, all data will be coded by a unique participant identifier number. Data will be kept in locked cabinets and will only be provided to a subject's clinician upon the written request of the subject. Research records will be kept confidential to the level allowed by law. The participant's name or other public identifiers will not be included with study data, which will be identified only by a code number. Interviewers and support staff will be trained on procedures for maintaining privacy and will sign a pledge of confidentiality. All transcripts and computer records will be password-protected to prohibit illicit access. All personal identifiers will be removed from any paper or electronic study forms, which will be coded only by numerical identifiers. When these procedures are followed, it is highly unlikely that any information revealed by participants during the discussions or interviews will be disclosed to anyone outside the research team.

Planned procedure for protection of risks due to vaccination: Nurses are well-trained and experienced in the administration of vaccines. To minimize risks, standard sterile procedures will be used. This may cause momentary discomfort or soreness when blood is drawn as well as minimal bruising.

Planned procedure for reporting of adverse events: All serious adverse events associated with the procedures of this study will be reported within 10 days to the appropriate IRBs. If serious or unexpected adverse events occur, these will be filed with the appropriate IRBs within ten working days. Staff will be trained to complete descriptions of adverse events that will then be sent electronically to the study PIs.

2.c Additional protections for children involved as subjects in research

By definition, children are persons under 18 years old who have not attained the legal age for consent to treatments or procedures involved in the research, under applicable law of the jurisdiction in which the research will be conducted. As such, special care must be taken to ensure that adequate protections are in place. For the proposed study, participants under the age of 18 will be enrolled as part of Aim 1, semi-structured interviews. In addition, their uptake of the HPV vaccine in Aim 2 will be monitored (although the parents will be the enrolled participants for this phase). Research in this capacity falls into the minimal risk category. We will ensure we prevent interviewer fatigue by limiting the time of our interview to 30 minutes with children. In addition, we will de-identify all data, and keep transcripts in a secure and protected electronic storage system that is password encoded, and only available to study staff. We will request both parental consent and child assent for the component of the study that involves direct communication (Aim 1).

3. POTENTIAL BENEFITS OF THE PROPOSED RESEARCH TO HUMAN SUBJECTS AND OTHERS

Participants may benefit from knowing that their participation may help others like them in the future as this work will inform interventions to improve uptake in HPV vaccines among young people in South Africa. We will consult with key stakeholders regarding the implications of the results, how the intervention could be made more widely available, or influence future policy development. Also, we will ensure that study results are appropriately messaged, and disseminated to key stakeholders such as study participants and service-delivery role-players.

4. IMPORTANCE OF THE KNOWLEDGE TO BE GAINED

The proposed study is designed to meet the urgent need for a theory-driven, empirically informed, rigorously evaluated and community-engaged approach for improving HPV vaccine uptake and completion that, if successful, can be adapted to other low- and middle-income countries to improve implementation of school-based HPV vaccination programs more broadly.

3.3. Data and Safety Monitoring Plan

I. Overview

Drs. Ingrid Katz and Lisa Butler (MPIs) will be responsible for the overall conduct of the study, including the safety of human subjects.

Drs. Katz and Butler will ensure appropriate (1) conduct of the informed consent process (e.g., that informed consent is obtained before proceeding with study procedures); (2) enrollment of study participants; (3) collection and analysis of data; (4) implementation of study procedures to ensure consistent monitoring of participants for possible adverse events; (5) review of adverse events and reporting to the appropriate IRBs; and (6) maintenance of the privacy and confidentiality of study participants. The MPIs will maintain ultimate responsibility for the project and for the safety of study participants.

The MPIs will be in contact with the Site-PI, Dr. Munro, on a regular basis to review the progress of the study and address any human subject issues that occur. These discussions may involve adverse event prevention measures, recruiting of appropriate study participants, research staff training on protection of human subjects, as well as occurrence of adverse events, unexpected incidents, or protocol problems. The study team's role in monitoring patient safety will be limited to mandated adverse event/serious adverse event/unanticipated problems reporting (detailed below).

To ensure the integrity of data collection and storage in South Africa, all study forms will be checked for completeness by the study coordinator to ensure that missing or illogical data are corrected. Weekly updates on enrollment numbers, randomization allocation, and data collection will be sent to the MPIs for monitoring progress. Data completeness and quality will also be reviewed on a weekly basis by both the South African site data manager, as well as the statistician. The local team will generate a quarterly data quality report describing the completeness of all data collection. Drs. Katz, Butler, and Munro will also review a 5% sample of all data newly collected every month.

The investigator and the research team have completed mandatory training in the ethical conduct of research, which meets NIH requirements for such training. All research team members are aware of and will comply with these procedures. The research will be conducted in a manner consistent with federal regulations with respect to the protection of human subjects. All members of the Project Team have undergone the CITI human subject protection program training and are well versed with ethnical code of conduct in human subjects' research.

II. Handling of adverse events and safety reporting

Our DSMP includes procedures for adverse events and unanticipated problems to be documented appropriately by the on-site research study coordinator and reported to the site-PI (Munro) and study-MPIs (Katz and Butler) in a timely manner.

Adverse events will include any reported stigma or physical and/or mental harm as a result of participation in the study, including disclosure of HIV status. All adverse events will be recorded on designated forms and rated for both severity and seriousness. Specifically, these events are classified as either Reportable, Adverse, or Not Harmful/Expectable, as described below, and will be reported to the IRB, and Program Officer accordingly, as described below.

In accordance with federal regulations governing Institutional Review Boards (45 CPR 46 and 21 CPR 50 and 56) and Guidance on Reportable Events from the Office of Human Research Protection, the IRB will review only **unanticipated** problems involving risks to participants or others. An unanticipated problem means that the incident, experience, or outcome is not expected (in terms of nature, severity, or frequency) given the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent documents; and the characteristics of the subject population being studied.

While there are many terms used by behavioral/social, clinical, and biomedical scientists to define a given type of reportable event (e.g., serious adverse event [SAE], adverse event [AE], adverse experience, etc.), the IRB uses the following single definition for an immediate, single-incident IRB-reportable event: A

Reportable Event is an unanticipated problem involving risks to participants or others ("Unanticipated Problem") and any event or information that (1) was unforeseen and (2) indicates that the research procedures caused harm to participants or others or indicates that participants or others are at increased risk of harm. Other types of adverse events will be reported in aggregate or summary form to the Sponsor, as described below.

Unanticipated - An event is unanticipated when its specificity or severity is not consistent with, and not included in, the current investigator brochure, protocol, consent form, package insert or label; or unanticipated in its frequency, severity, or specificity.
Related - An event is related to research procedures if, in the opinion of either study-PI and site-PI, it was more likely than not to be caused by the research procedures or if it is more likely that not that the event affects the rights and welfare of current participants.
Harmful - An event is harmful if it has caused harm to participants or others or placed them at increased risk of harm. The harm does not have to be a direct harm to be reportable. The harm, as assessed by the study-PI and site-PI, may have created increased risk (e.g., losing a laptop with participant data). Additionally, the harm does not have to be harm to participants; it could involve risk to others (researchers, technicians, bystanders, the public, etc.).

Note: Non-medical events (e.g., breach of confidentiality, emotional breakdown), if unanticipated, would also be reportable to the IRB.

Some examples of Reportable Events for the present study might be the following:

- Side effects of HPV vaccination (e.g., pain, swelling, and redness where the shot was given, as well as headaches, tiredness, nausea, dizziness, and fainting).
- A deviation or violation from the IRB approved protocol

Summary of Events Classification and Actions Taken		
Level of event	**Examples**	**Action Taken**
Reportable (unanticipated, related to study participation, harmful)	Hospitalizations at least overnight for any medical and/or psychiatric reason associated with study participation; Suicidal or homicidal ideation related to study participation; Incarceration of an enrolled participant; an unresolved participant complaint that indicates a potential increase in risk or unexpected risk; new information that presents a change to the risks or potential benefits; a deviation or violation from the IRB approved protocol; unintentional direct or indirect violation of participant confidentiality by study staff.	(1) Report event to the Mass General Brigham (MGB) IRB and CONFIDENTIAL INFORMATION - REQUESTER IN AGREEMENT Committee (HREC) within **24 hours** (of note, (2) Report event to Sponsor's Program Officer within **24 hours**, (3) Report additional details of event and actions taken to the MGB IRB and UKZN HREC, and NIH Program officer within **72 hours**, (4) Respond to requests for additional information by and/or recommendations from the IRB/HREC and NIH.
Adverse but not "Reportable" (anticipated in the consent form or unanticipated, may or may not be associated with study participation, harmful)	Hospitalizations at least overnight for any medical and/or psychiatric reason not associated with study participation; suicidal or homicidal ideation not related to study participation; drug overdose, namely, an emergency room visit and/or hospitalization due to a reaction to non-prescribed medications not associated with	1) Document event on internal Events Log Form including whether it appears to be related to study participation, (2) Report events in aggregate or summary form to IRB/HREC annually, (3) Report events in aggregate or summary form to Program Officer at NIH at the time of the Progress Report, (4)

	study participation; life threatening or disabling/incapacitating events affecting health and well-being such as serious accidents or physical attacks that result in injury not related to study participation; death not related to study participation; serious distress as a result of study procedures.	provide clinical referral as appropriate at the time of event.
Not Harmful/Expectable (largely anticipated, not harmful)	Mild to moderate distress or anxiety as a result of study procedures	Not reported to IRB/HREC or NIH but provide clinical referral as appropriate at the time of event.

Reporting of Reportable Events to the IRB. In the event that a RELATED, UNANTICIPATED AND HARMFUL event is reported to the study-PI, Dr. Katz will use Brigham and Women's IRB report form to report the event to the IRB within 24 hours of learning of it. Site-PI, Dr. Munro will use the UKZN HREC report form to report the event to the UKZN HREC within 24 hours.

Reporting of Reportable Events to NIH. Drs. Katz and Butler will also report the Reportable Event to the study's Program Officer at the NIH by phone or email within 24 hours and follow-up with a written report (by fax or email) within 72 hours, detailing any additional information and whether or not the event is related to participation in the study or may affect future participation in the study. The PI and IRB are ultimately responsible for the Data and Safety Monitoring Plan.

Suspension of data collection, further IRB review, or modification of the protocol. If the study-MPIs, in consultation with the site-PI, determines that there is sufficient evidence of the need to suspend data collection, further IRB review, modification of the protocol, or other changes, the PI shall make this recommendation to the Chairperson of the IRB. The IRB will reach a determination whether to suspend data collection or to stop the study from proceeding. Resumption shall be based on the concurrence of the study-PI, the site-PI, and the Chairperson of the IRB. The Program Officer at NIH will be informed of this determination and will receive a report by email within 24 hours of any such suspension and/or resumption of data collection.

Clinical care and referrals when Adverse and Reportable Events are uncovered. A plan has been developed for referral to clinical care in the event that Adverse and Reportable Events occur among the research participants. Individualized referrals to medical care, case management or counseling for treatment or support will be made for participants experiencing Adverse and Reportable Events. In rare cases, referrals may be made for Non-harmful/Expectable events.

If no Adverse or Reportable Events are identified. The study-MPIs and site-PI will provide an annual summary report of all Adverse and Reportable Events to the IRB and HREC as part of the annual review. They will also report all Adverse and Reportable Events to the NIH as part of the annual Progress Report. If no Adverse or Reportable Events have occurred, the report will state, "No Adverse or Reportable Events affecting human subjects have occurred during this project year."

Report of changes or amendments to the protocol. Prior to implementation of the study protocol, all study documents including - the protocol, informed consent forms, recruitment materials, intervention manual and other requested documents - will be reviewed and approved by Brigham IRB and UKZN HREC. Both will review the protocol at least annually. The study-PI and site-PI will provide progress reports to their respective IRB's at least annually and within three months of study termination or completion. These reports will include the total number of participants enrolled in the study and the number of participants who completed the study. Substantive changes to the protocol that have the potential to affect study aims will be approved by the study's Program Officer at the NIH prior to submission to the IRB/HREC for approval. The Program Officer at NIH will be informed of any other (that is, any minor) changes to the study's protocol on an annual basis as one component of the Progress Report.

Participant Reporting. All participants are encouraged to contact the study-PI or site-PI, and/or the UKZN's HREC to report complaints or adverse events. Instructions for reporting adverse events and complaints, as well as for contacting the PI and the HREC, are included in the consent documents. When an event is reported, it will be documented on an internal Events Log Form. The Events Log Form will assess the details, seriousness, and outcome of the event. Events are categorized as Not Harmful/Expectable, Adverse, or Reportable. Drs. Katz, Butler, and Munro will determine whether an event is Not Harmful/ Expectable, Adverse, or Reportable.

III. Procedures for data quality assurance and protecting confidentiality of participant data

A. Types of data.
The following data need safeguarding:
1. *Original contact data received during the consent procedure*: We will obtain personal contact information, including first name and phone number. These data will be used to contact participants regarding follow-up surveys.
2. *Survey responses:* Participants will complete self-reported measures via online surveys. The survey data files will only have IDs and will not contain contact or identifying information.
3. *Clinical data:* History of vaccination

B. Data Safeguards.
The study will maintain a study office located at UKZN in South Africa. Access to UKZN offices are restricted to research staff. The building is secure and monitored by security staff. Dr. Katz (MPI) will also have access to data at her office at Brigham and Women's Hospital in Boston and Dr. Butler (MPI) will have access to data at her office at the University of Connecticut. All offices are secured, and all computers are password encrypted.

REDCap. The secure and password protected REDCap database is used for all study activities. Consent forms will be signed, and structured assessments will be conducted in REDCap. Medical record data will also be entered into REDCap. REDCap was designed specifically to protect patient and research participant privacy and confidentiality while assisting investigators in conducting clinical research. System-level and application-level security features include SSL encryption of internet traffic (e.g. https pages), hosting in a secure data center with nightly backup, fine-grained control over user rights, detailed audit trails, record-locking, and de-identification functions for data export. The REDCap database can be shared between authorized staff. Participants will be identified by their PIN in the REDCap database. Only research study staff have access to the REDCap database.

Computers. All computerized data are kept on computers that are double password-protected and are only labeled with PINs.

Confidentiality Safeguards. All participants receive a PIN. This number will be used for all study materials, blood specimens, and assessments. No other information that would disclose the participant's identity will be found on any assessments or specimens. As part of the informed consent process, participants will also be informed that all information they provide in interviews and intervention sessions is confidential with the following exceptions: (1) If they are in imminent danger of committing suicide or homicide, the appropriate agency will be contacted, and (2) if they are found to be physically or sexually abused and are age 17 years or younger, the Child Protection Services in South Africa.

C. Data Quality Management.

The primary goal of quality assurance activities will be to maintain a high standard of data quality. The study statistician's responsibilities will include quantifying the quality of the data, identifying and documenting problems in data quality, and providing feedback to the clinical site and study staff so that corrective procedures may be made promptly.

Data Reporting, Analysis Support & Study Close-Out

Periodic reports on accrual, study progress, adverse events and data quality will be generated and provided to investigators, reviewers, and any quality and safety monitoring boards as may be specified by the protocol and

applicable regulations. The study statistician (Ms. Nkwanyana) will ensure that data analysis needs are addressed during the design phase of the data collection instruments and data management system. Ms. Nkwanyana will have read-only access to the study data to perform interim and final analyses. All databases will be locked once all the data have been collected. Study data will be packaged for data sharing purposes. A snapshot of the database will be taken and stored in a secure folder.

IV. Clinical Trials Registration. In compliance with NIH policy, this clinical trial will be registered with ClinicalTrials.gov. Registration will occur at the time of IRB review and results information will be submitted not later than one year after the trial's primary completion date. Additionally, the relevant informed consent documents will include a specific statement relating to posting of the clinical trial information at ClinicalTrials.gov.

3.5 Overall Structure of the Study Team

Organization of Study Team

MPIs Katz and Butler will share responsibility for overseeing the study. On site, Site PI Munro will oversee day-to-day responsibilities of project administration in partnership with Study Coordinator Abigail Wilkinson and Research Associate/Community Engagement Lead Siyabonga Nzimande, including supervision of staff. They will support Katz and Butler in the intervention refinement and implementation, with consultation from Co-Is Wassenaar, Slack, and Gumede, Consultants Wright and Immelman, and community partners. Munro and Immelman will also be responsible for maintaining relations with our school partners and will be in frequent communication with the administration of participating schools. Stakeholder engagement activities will be coordinated by Ms. Wilkinson and Mr. Nzimande. Site PI Munro and Co-Is Wassenaar, Slack, and Gumede will support Katz and Butler in the development of study protocols, intervention materials, and data collection tools, as well as analysis and preparation of reports and manuscripts. Co-I Mudzingwa will provide technical support on the development, implementation, and evaluation of the qualitative work. Statistician Nkwanyana will provide statistical support through the duration of the project.

MPIs Katz and Butler have an established record of collaboration, and Site-PI Munro and Co-Is Wassenaar, Slack, and Gumede have prior experience working together on research studies and will provide a strong interdisciplinary leadership on site. Site-PI Munro and Study Coordinator Wilkinson will collaborate to oversee daily research activities and lead study staff in the execution of the aims, including preliminary qualitative work, pre-testing, and the final trial. Site-PI Munro and his team have combined decades of experience in the conduct and administration of complex multi-level research and have numerous publications in scientific journals.

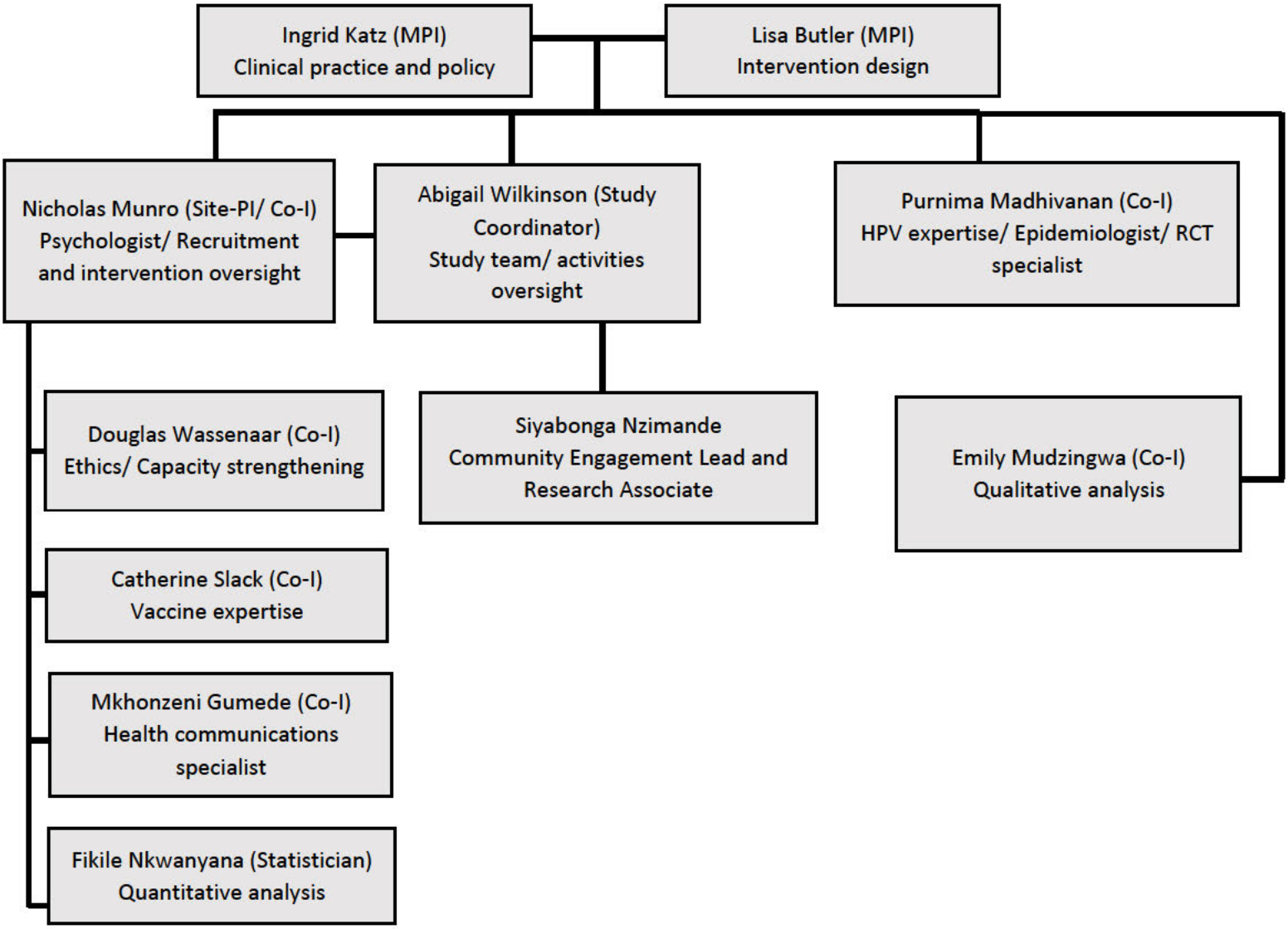
MPIs Katz and Butler, site-PI Munro, Study Coordinator (Wilkinson) and Stakeholder Engagement Lead (Nzimande) will meet weekly to communicate about study progress and implementation, including preparations, stakeholder engagement, recruitment, evaluation and analysis elements of the study.

Communication Plan

The full study team will hold regular meetings to ensure that all data quality and IRB policies and procedures are being followed. This will include ensuring that (1) all participants understand, agree to, and sign a written informed consent form prior to participation; (2) strict adherence is maintained in communicating participants' right to withdraw or refuse to answer questions; (3) staff maintain confidentiality by protecting hard copy and electronic data collection forms and also by avoiding all unauthorized conversations about individual participants; (4) consent forms and identifying information are kept separate from study-related information about participants' socio-demographics, mechanisms of change (i.e., mediators), and outcomes; (5) all identifying information is kept locked at all times and sensitive computer files are maintained on a secured server; (6) our team makes every effort to protect clinical data and ensure confidentiality of participants; and (8) participants are informed in writing about how to contact the study PI, the research director, and the relevant IRB office with any questions or concerns.

Our team meetings will also serve to troubleshoot recruitment challenges if they arise. The MPIs and Site PI and research team will work collaboratively to identify additional recruitment strategies if ours do not yield our recruitment goals.

Organizational Chart



Section 4 - Protocol Synopsis (Study 1)

4.1. Study Design

4.1.a. Detailed Description

Human papillomavirus (HPV) is the most common sexually transmitted infection (STI), and is causally linked to cervical, anogenital, and oropharyngeal cancers. Cervical cancer remains the leading cause of cancer-related mortality among women in South Africa (SA), yet it is entirely preventable with HPV vaccination prior to sexual debut. Since 2014, the SA National Department of Health has implemented a national, school-based HPV immunization program. The program offers the two-dose bivalent vaccine to girls 9-12 enrolled in public schools, free of charge, delivered through bi-annual campaigns. Despite a promising start vaccine coverage and dose completion rates have dropped precipitously. Recent declines have been attributed to COVID-related program interruptions, increased medical mistrust, and vaccine hesitancy related to misinformation spread on social media. There are additional critical gaps in HPV vaccine coverage - the current school-based HPV vaccine campaign does not include boys nor students enrolled outside of the public school system. Further, strategies for conveying information about the vaccine and for addressing widespread concerns and mistrust are lacking. A gender-neutral, inclusive, multi-level vaccination strategy is required to achieve the full benefits of HPV vaccination, especially in settings where herd protection is not achieve by a female-only approach.

In preparation for a Hybrid Type 2 school-randomized controlled trial, we proposed a pilot feasibility trial to refine and evaluate a school-based multi-level communications strategy that addresses intrapersonal, interpersonal, and institutional factors associated with HPV vaccination uptake and completion amongst fifth graders.

In our first Aim, we will refine components of a school-based, multi-level communication strategy to improve HPV vaccine uptake amongst age-eligible girls and boys, using a phased approach to evaluating and improving the design of health promotional materials for parents, teachers, nurses, and children enrolled in Grade 5. For the Evaluation Phase of the first aim, we will assess the effect of exposure to the materials on participants' understand of and considerations about HPV vaccination. We will assess the effectiveness of the materials on increasing understanding about HPV vaccine among parents (N=100), Grade 5 children (N=100), and Grade 5 teachers (N=16). We will assess acceptability and feasibility of the communications materials using the Acceptability of Intervention Measure, Intervention Appropriateness Measure, and Feasibility of the Intervention Measure.

In the second Aim of our study, we will evaluate preliminary effects of the communications strategy and key criteria to advance to a full-scale hybrid type 2 trial. We will conduct a pilot feasibility school-randomized controlled trial including 10 schools (roughly 60 parents/children per school). Schools will be randomized to receive the enhanced vs. standard communication strategy. We will assess preliminary effectiveness on HPV vaccine uptake (dose 1) and completion (dose 2). We will also assess the following criteria: recruitment rate, completion of questionnaires, acceptability of the communications strategy and its implementation among parents, children, teachers, school administrations and Department of Health officials responsible for the school-based program.

We will perform exit interview with parents, teachers, and nurses (N=30) to identify strategies for sustainability. We will use a mixed methods approach to investigating factors that drive parental consent and HPV vaccine uptake and completion amongst girls and boys. There will be extensive involvement from a Stakeholder Working Group from project inception to completion to ensure local relevance and ownership. Assessments of the intervention components' feasibility, acceptability, and potential effectiveness will be accomplished through testing in schools in [redacted], where our team is well established. If the intervention components prove to be acceptable, feasible, and potentially effective, we will work in close collaboration with the Department of Health to implement this strategy in schools throughout the province, and ultimately throughout SA.

4.1.b. Primary Purpose Prevention

4.1.c. Interventions

Type	Name	Description
Behavioral (e.g., Psychotherapy, Lifestyle Counseling)	Multi-level communication intervention	The proposed intervention package will include three interrelated components: (1) curriculum-linked learning materials for children, (2) informational materials for parents and teachers, and (3) community dialogue, supported by an adapted Conversation MapTM, for use by teachers, nurses, or others who may facilitate community dialogues regarding HPV vaccine.

4.1.d. Study Phase: Phase 2

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

4.1.e. Intervention Model: Parallel

4.1.f. Masking ❍ Yes ● No

❑ Participant ❑ Care Provider ❑ Investigator ❑ Outcomes Assessor

4.1.g. Allocation: Randomized

4.2. Outcome Measures

Type	Name	Time Frame	Brief Description
Primary	Acceptability and Feasibility	Six Months	Acceptability and Feasibility will be determined using the Acceptability of Intervention Measure, Intervention Appropriateness Measure, and Feasibility of Intervention Measure. Process evaluation data will be collected using a combination of quantitative, qualitative, and observational methods to assess implementation, feasibility, and acceptability of the different intervention components.
Primary	Preliminary Effectiveness	Six Months	We will assess HPV vaccine uptake at Month one and Vaccine Completion at month six.

4.3. Statistical Design and Power: Statistical_Design_and_Power_.pdf

4.4. Subject Participation Duration: 12 months

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

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

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

4.7. Dissemination Plan: Dissemination_Plan.pdf

Statistical Design and Power.

All analyses will utilize appropriate exploratory methods for the types of data collected. Binary responses and predictors will be assessed via frequency tables to identify sparse categories – combining categories of multinormal variables, if necessary. Continuous predictors will be examined both numerically and graphically to identify important properties such as skewness, heavy tails (i.e., large kurtosis), and outlier presence. All outliers will be examined to make sure data collection was done correctly prior to any consideration of applying nonlinear transformations.

For Aim 1, individuals will be asked to participate in a second interview to assess knowledge about HPV vaccine, as well as *acceptability and feasibility* of the communications materials using the Acceptability of Intervention Measure, Intervention Appropriateness Measure, and Feasibility of Intervention Measure. A semi-structured interview will then be used to solicit reflection on the specific communication type being tested, their interpretation of messages and any other feedback. Results of the evaluation will inform one further round of revisions and improvements, resulting in final versions of communication materials for use a two-arm pilot/feasibility school randomized controlled trial (C.9). To move forward, we have set the following criteria: 1) More than 50% of parents rate health education materials as acceptable, 2) More than 50% of children rate curriculum materials as acceptable, 3) More than 50% of teachers rate curriculum materials as acceptable, 4) More than 50% of teachers and nurses rate Community Mapping tool as acceptable.

The primary responses in Aim 2 are both binary and will each be collected on the same set of subjects at two time points. The cluster-randomized design utilized will have a 1:1 control-to-intervention ratio with an average of 60 students (30 male and 30 female) selected per school. The two most common approaches to modeling binary responses arising from cluster-randomized designs is to use either a generalized linear mixed model (GLMM) approach with a logit link function, or to model using marginal models estimated via generalized estimating equations (GEEs). The choice of which approach should be guided by the number of clusters and the expected amount of missing data. In our case, with 10 clusters in total, GLMMs have been shown to suffer from some power loss *(Bellamy SL, Gibbard R, Hancock L, Howley P, Kennedy B, Klar N, Lipsitz S, Ryan L: Analysis of dichotomous outcome data for community intervention studies. Stat Methods Med Res. 2000, 9: 135-159).* Other studies have supported the use of GEEs after multiple imputation that account for the clustering design has been used to replace data that is not missing completely at random *(Ma, J., Akhtar-Danesh, N., Dolovich, L. et al. Imputation strategies for missing binary outcomes in cluster randomized trials. BMC Med Res Methodol 11, 18 (2011)).* We thus plan to utilize marginal models for binary data, with a logit link function, estimated via GEE-based methods after utilizing multiple imputation to replace missing values if our missingness rate exceeds 10% at either time point. We will include any potential within-cluster and between-cluster covariates that may be important predictors or confounders, which is easily done in the marginal modelling framework. GEE-based methods allow one to either use model-based methods for estimating the standard errors, or to use robust standard errors via the empirical covariance estimator. We will choose the latter given its general small loss in efficiency and robustness to model violations. We also note that the choice of GEE-based marginal models over GLMMs is partly driven by the types of inferences obtained from each. Since we are interest in overall population-level effects of the invention program, marginal models would be preferred. GLMMs provide cluster-specific inferences, which are not of primary interest in this study.

We next examine whether we are adequately powered to detect reasonable effect sizes in aim 2. We begin by assuming a Type I error rate of 0.05, two-sided alternatives, a constant ICC of 0.05 across clusters, and a desired power of 80%. All calculations were done in Stata 17.0 assuming 5 intervention and 5 control clusters, each with 60 subjects.

- Scenario 1: Control uptake = 0.35; intervention uptake = 0.55; difference = 0.20; power = 70.1%
- Scenario 2: Control uptake = 0.50; intervention uptake = 0.70; difference = 0.20; power = 70.5%
- Scenario 3: Control uptake = 0.30; intervention uptake = 0.55; difference = 0.25; power = 88.4%

If we assume a substantial attrition rate of 20% (cluster sizes of 48), the power numbers are similar for each of the scenarios above:

- Scenario 1: Power = 67.6%
- Scenario 2: Power = 68.9%
- Scenario 3: Power = 86.5%

Thus, even in the extreme case of 20% attrition, we expect to have moderately large power to detect relatively small differences in vaccine uptake.

4.7 Dissemination Plan

If funded, Drs. Katz and Butler will ensure that the clinical trial under this award is registered, and information is submitted to ClinicalTrials.gov with the requirements outlined in NOT-OD-16-149 (NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information). Informed consent documents for the clinical trial will include a specific statement relating to posting of clinical trial information at ClinicalTrials.gov. Brigham and Women's Hospital (BWH) has an internal policy in place to ensure that clinical trials registration, project monitoring, and results reporting occur in compliance with policy requirements, good clinical practices, and applicable regulatory requirements; specifically, BWH will initiate a kickoff meeting at the start of each award funded by an NIH Institute and Center to review and confirm registration and reporting requirements and timelines with the PI. For the Clinical Trial phase, we will ensure that 1) registration occurs no later than 21 days after enrollment of the first participant; 2) the submission of registration data elements are tracked; and 3) results are submitted to ClinicalTrials.gov occurs no later than 12 months after the primary completion date. Once results are obtained for the primary outcomes, we will submit the results to ClinicalTrials.gov, as well as update the study description of the page as needed.

We anticipate drafting at least three manuscripts for this study, based on main findings from each phase of our study (elicitation, refinement, pilot testing). Authorship for peer-reviewed manuscripts, book chapters, scientific conference presentations, policy and clinical briefs, and dissemination briefs resulting from project activities will be determined prior to creating drafts for these outputs. Authorship will be negotiated based on the relative scientific contributions of the PIs, site-PI, and other key personnel, and issues discussed openly and honestly. In addition to dissemination to academic audiences, we will also present results in an ongoing manner to our community partners in South Africa, including the Departments of Education and Health, along with our stakeholders, to solicit ongoing feedback and optimize planning for future implementation. We plan to do this through holding multiple dissemination meetings with community stakeholders, including: 1) government representatives, 2) study advisory group; 3) school meetings with parents; 4) existing community advocacy groups meetings. We will communicate key findings from the study and provide opportunities for stakeholder reflection on results.

Delayed Onset Studies

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

Multi-PI/PD Leadership Plan

Rationale and justification for choosing the multiple PI approach.

Dr. Katz and Dr. Butler each bring unique strengths to the proposed study. Dr. Katz is a clinical researcher with expertise in HPV vaccination decision making. She has led research on HPV vaccine acceptability in both the U.S. and South Africa, focused on understanding barriers to immunization. She developed a model of HPV vaccine uptake and completion that has been widely cited. She has worked in South Africa since 2009.

Dr. Butler is an epidemiologist and behavioral scientist with extensive experience in developing and evaluating behavioral interventions. She brings content area and methodological expertise to the study, as well as experience leading randomized controlled trials, including cluster randomized controlled trials.

CONFIDENTIAL INFORMATION - REQUESTER IN AGREEMENT

Drs. Katz and Butler work and have worked together on a number of research projects in South Africa (including studies funded by the National Institutes for Health, Merck Investigator Studies Program, Aerosmith Foundation and other internally funded projects) and have proven their ability to lead multi-disciplinary, multi-national study teams collaboratively.

Governance and organizational structure.

Drs. Katz and Butler will oversee all aspects of the study for its duration including creation of any policies, procedures, and process including but not limited to intervention development, pilot testing, and analysis. As MPIs, Drs. Katz and Butler will both be responsible for overseeing implementation of the scientific aims and ensuring compliance with U.S. and South African law, as well as NIH and South African Departments of Health and Education policies. Specifically, Dr. Katz will be responsible for all U.S. research approvals and will work closely with the local team in South Africa on their ethical approvals. Dr. Katz will also serve as contact-PI and assume fiscal and administrative management including the coordination of weekly and monthly meetings with the local study team.

Dr. Butler will oversee stakeholder engagement activities, as well as elicitation, design, and materials testing phases of Aim 1. Dr. Butler will also be the point person for communication with local study staff in South Africa. Both Drs. Katz and Butler will oversee the pilot feasibility matched-pair school-randomized controlled trial and related data collection for Aim 2 and will work collaboratively on subsequent analyses. A publication policy will be established based on the relative scientific contributions of the PIs and key personnel. Authorship for publication will be decided based on participation of the PIs, co-Is and relevant students. Both PIs will ensure that junior South African investigators lead papers and are significantly involved in the development and writing of main papers.

Dr. Katz and Dr. Butler will communicate at least bi-weekly throughout the three-year study period with the South African site-PI, management team and other investigators. Video calls (Zoom or MS Teams) will be used to facilitate communication between members of the research team. Twice per year, key members of the research team will meet at the study site in South Africa. These meetings will provide opportunities for the research team to develop study protocol details, plan for study launch, respond to problems that may have arisen, share preliminary data, and make decisions about the scientific directions of the study.

Process for making decisions on scientific direction

Scientific results will be shared in bi-weekly meetings and next steps discussed. The leadership team who makes decisions will consist of Dr. Katz, Dr. Butler and Dr. Munro. All investigators and, where appropriate, other team members will be invited to provide input on issues that arise. Decisions will be made on bi-weekly conference calls and at the in-person investigator meetings.

Procedures for resolving conflicts

Should a conflict develop, that cannot be resolved to the satisfaction of the management team through discussion, an arbitration committee will be formed. Membership of this committee will consist of three senior executives, one each chosen by Dr. Katz (from Brigham and Women's Hospital), Dr. Butler (U Connecticut) and Dr. Munro (UKZN). The members of the arbitration committee will have no direct relationship with the research project or the source of conflict. Both PIs agree to abiding by the decision making of this impartial body.

Contingency plans for relocation

If a PI moves to a new institution, attempts will be made to transfer the relevant portion of the grant to the new institution. In the event that a PI cannot carry out his/her duties a new PI will be recruited as a replacement at one of the participating institutions.

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STATEMENT OF INTENT

PASS THRU ENTITY (PTE) – Prime Institution	
Prime PI	Ingrid Katz, MD, MHS
Prime Institution	Brigham and Women's Hospital
Project Title	Multi-level school-based intervention to improve HPV vaccine uptake and completion in South Africa

SUBRECIPIENT					
Cooperating Inst.	University of KwaZulu-Natal				
PI Name	Nicholas Munro, PhD		ERA Commons ID	eRA COMMONS USER NAME	
PI Phone	+27332605371	PI Fax	PI E-Mail	munron@ukzn.ac.za	
Project Period	2024-2026		Direct Costs	$195,297.99	Total Costs $210,921.83
Performance Site	Pietermaritzburg, South Africa		F&A Costs	$15,623.84	
BUSINESS CONTACT INFORMATION					
Name	Karen Reinertsen				
Address	University Road, Westville, Private Bag X 54001, Durban, 4000, South Africa				
Bus. Phone	+27312602384	Bus. Fax	Bus. E-Mail	reinertsenk@ukzn.ac.za	
DUNS #	637360244		Congressional District #		

PROJECT INFORMATION	YES/NO	ASSURANCE #	APPROVAL DATE OR PENDING
Human Subjects	YES	00000678	Pending
Vertebrate Animals	NO		
Human Embryonic Stem Cells	NO		
Inventions And Patents *(For Renewal Applications)*	NO		
Program Income	NO		

CERTIFICATIONS

The appropriate programmatic and administrative personnel of each institution involved in this grant application are aware of the PHS-NIH consortium grant policies and are prepared to establish the necessary inter-institutional agreements consistent with those policies. In signing below, the Cooperating Institution certifies it has implemented and is enforcing a written policy of conflicts of interest consistent with the provisions of 42 CFR Part 50, Subpart F & 45 CFR Subtitle A, Part 94.

In signing below and offering to participate in this research program, the Cooperating Institution certifies that neither they nor their principals are presently debarred, suspended, proposed for debarment, declared ineligible or voluntarily excluded from receiving funds from any federal department or agency and are not delinquent on any federal debt; they are in compliance with the Drug Free Workplace Act of 1988; they are in compliance with U.S. Code, Section 1352, restrictions on the use of federal funds for the purpose of lobbying; they have filed annually with the Office of Scientific Integrity a PHS form 6349 governing Misconduct in Science; they have filed with DHHS compliance offices certification forms governing Civil Rights (441), Handicapped Individuals (641), Sex Discrimination (639-A), and Age Discrimination (680); they are in compliance with PHS policy governing Program Income; they have established policies in compliance with 45 CFR Part 46, Subpart A (protection of human subjects); the Animal Welfare Act (PL-89-544 as amended) and the Health Research Exchange Act of 1985 (Public Law 99-158); and that they are in compliance with NIH guidelines regarding human pluripotent stem cell research, transplantation of fetal tissue, recombinant DNA and human gene transfer research, and inclusion of women, children & minorities in research. The appropriate programmatic and administrative personnel of each institution involved in this grant application are aware of the PHS-NIH consortium grant policies and are prepared to establish the necessary inter-institutional agreements consistent with those policies. In signing below, the Cooperating Institution certifies it has implemented and is enforcing a written policy of conflicts of interest consistent with the provisions of 42 CFR Part 50, Subpart F & 45 CFR Subtitle A, Part 94. If a conflict is identified by the Cooperating Institution during the period of the award contemplated under this agreement, the Cooperating Institution will report to the Prime Awardee the existence of the conflict, including the grant title, PI (if different from the investigator with the financial interest) and the specific method the Cooperating Institution adopts for addressing the conflict (managing, reducing, or eliminating it). The Cooperating Institution will rely on the Prime Awardee to report the existence of the conflict to NIH.

COOPERATING INSTITUTION BUSINESS OFFICIAL:

Prof Mosa Moshabela

Name and Title

Signature

20 Oct 2022

Date

Statement of Work

CONFIDENTIAL INFORMATION - REQUESTER IN AGREEMENT

Project:
Multi-level school-based intervention to improve HPV vaccine uptake and completion in South Africa

Study Period: 7/1/23-6/30/26

As part of the above research study, the University of KwaZulu Natal will undertake the following activities in line with all final approved research protocols:

1) Support research design and methodology

- Provide guidance during development of the research protocol to ensure methodology remains in line with local best practice and is feasible within the South African context.
- Inform participant identification and recruitment strategy.
- Contribute to questionnaire and interview development to ensure data collection remains culturally appropriate and specific to target research population.

2) Facilitate local IRB and research approvals

- Support the finalization of local IRB and research advisory committee applications.
- Manage IRB and/or research advisory committee applications to facilitate final approval in line with study timelines.
- Contribute to the completion of application comments or edits as required by IRBs and/or research advisory committees.
- Monitor ongoing local ethical approval during and after study implementation.

3) Manage and monitor community engagement activities

- Identify participants for community engagement activities, including individuals representing municipal and provincial offices (e.g., Department of Health, Department of Education), school administrators and teachers, parent and youth advocates.
- Organise, facilitate and document input provided by community engagement discussion groups.

4) Facilitate research participant identification and recruitment methodology and selection

- Design participant selection strategy to identify participants for semi-structured interviews.
- Design school selection strategy to identify schools eligible for consideration for school-randomized controlled trial.
- Design functional strategies to
    - recruit and enroll parent/guardians of Grade 5 children at selected schools to participate in a self-completed survey (on paper or on-line, depending on participant preference) and the beginning of the school year (prior to the 1st

annual HPV vaccine campaign) and at the end (after the 2nd HPV vaccine campaign).
- obtain consent for linkage of child's immunization records to unique study ID, and
- recruit and enroll a sub-set of parent/guardians to an exit interview

5) Data collection, Management, Analysis, and Dissemination

- Ensure the safe collection, storage, and transmission of surveys.
- Support the cleaning, analysis, and interpretation of data collected.
- Support development of reports and journal articles.
- Disseminate results and findings to key stakeholders.
- Maintain regular communications with the study team.

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PROPOSAL COVER PAGE

PRINCIPAL INVESTIGATOR	Lisa Butler
SPONSOR	Brigham & Women's Hospital
ORIGINATING SPONSOR *(if applicable)*	NIH
PROJECT TITLE	Multi-level school-based intervention to improve HPV vaccine uptake and completion in South Africa
PROPOSED PROJECT PERIOD	7/1/23-6/30/26
TOTAL AMOUNT REQUESTED	$169,552
DIRECT COSTS	$134,565
F&A COSTS	$34,987

The appropriate programmatic and administrative personnel involved in this application are aware of the sponsoring agency policies and are prepared to establish the necessary agreements consistent with those policies. The University of Connecticut makes all applicable assurances/certifications and has implemented an active and enforced conflict of interest policy compliant with Federal requirements.

Please direct questions to the Office of the Vice President for Research, Sponsored Program Services at 860-486-3622 or preaward@uconn.edu

Thank you for your consideration. The University of Connecticut looks forward to working with you.

Authorized Representative Signature:

Tracy Bourassa, Director - Pre Award Services

Digitally signed by Tracy Bourassa, Director - Pre Award Services
Date: 2022.09.27 14:06:24 -04'00'

Name: Tracy Bourassa
Title: Director of Pre-Award Services

Date

Office of the Vice President for Research
Sponsored Programs
438 WHITNEY ROAD EXTENSION, UNIT 1133
STORRS, CT 06269-1133
PHONE 860.486.3622
FAX 860.486.3726
www.osp.uconn.edu

SCOPE OF WORK
University of Connecticut

Title: Multi-level school-based intervention to improve HPV vaccine uptake and completion in South Africa

PI: Ingrid Katz, MD

The University of Connecticut agrees to serve as a subcontractor to Brigham and Women's Hospital in carrying out the responsibilities and tasks resulting from the project referenced above. The objective of the project is to develop and pilot test a multi-level communications intervention to increase uptake of HPV vaccine amongst youth age 9-11 years old in the greater [redacted].

As a subcontractor, the University of Connecticut will provide the necessary staff and resources for the conduct of all tasks associated with this subcontract to Brigham and Women's Hospital. The faculty members detailed in our bid, Drs. Lisa Butler and Emily Krogstad, are presently employed at the University of Connecticut, and will be available to work on this project if awarded. In collaboration with Dr. Katz and other team members, Drs. Butler and Krogstad will provide technical expertise intervention development, qualitative data collection and analyses, and trial design and implementation.

THE UNIVERSITY OF ARIZONA.

Arizona Health Sciences
Medical Research Building

P.O. Box 245218
Tucson, AZ 85724
Phone: (520) 626-4317
Fax: (520) 626-3644

LETTER OF INTENT TO ESTABLISH A CONSORTIUM AGREEMENT

Institution:	**Arizona Board of Regents, University of Arizona**
Date:	**09/21/2022**
Application Title:	**Multi-level school-based intervention to improve HPV vaccine uptake and completion in South Africa.**
Proposed Project Period:	**07/01/2023-06/30/2026**
Principal Investigator:	**Purnima Madhivanan**
Sponsor:	**Brigham and Women's Hospital/ NIH** **Ingrid Katz, PhD, Principal Investigator**

[redacted] CONFIDENTIAL INFORMATION - REQUESTER IN AGREEMENT

On behalf of the Arizona Board of Regents, University of Arizona, we are pleased to endorse the above referenced proposal and our intention to collaborate as a consortium.

This letter certifies that the University of Arizona is not delinquent on any federal debt, nor is it presently debarred, proposed for debarment, declared ineligible or voluntarily excluded from covered transactions by a Federal department or agency.

The appropriate programmatic and administrative personnel at the University of Arizona involved in this grant application are aware of the pertinent Federal regulations and policies and are prepared to establish written inter-organizational agreements that will ensure compliance with all such policies.

Arizona Board of Regents, University of Arizona

Kristen Edmonds Digitally signed by Kristen Edmonds
Date: 2022.10.19 13:14:17 -07'00'

FOR:Sangita Pawar, PhD, MBA
Vice President, Operations
Research, Innovation and Impact
University of Arizona

Scope of Work

Project Title: Multi-level school-based intervention to improve HPV vaccine uptake and completion in South Africa

The University of Arizona will provide insights and assistance on study design and implementation for this project.

We agree to perform the following:

- Advice on the conceptual design, development of data collection processes.
- Participate on regular conference calls to develop and implement study protocols, review recruitment and review collected data.
- Advise on the development of all analysis plans and review results of all statistical analyses.
- Participate and [redacted]

CONFIDENTIAL INFORMATION - REQUESTER IN AGREEMENT

[redacted]

17th October 2022

Ingrid T. Katz, MD, MHSc
Department of Medicine, Division of Women's Health, Brigham and Women's Hospital
1620 Tremont Street
Boston, MA 02120

Lisa M. Butler, PhD, MPH, PhD
University of Connecticut – Institute for Collaboration on Health, Intervention and Policy
2006 Hillside Road, Unit 1248
Storrs, Connecticut 06269-1248

Dear Drs Katz and Butler

Re: Support for study "Multi-level school-based intervention to improve HPV vaccine uptake and completion in South Africa"

Cervical cancer is one of the most important causes of death amongst women in South Africa. Despite the efficacy and availability of the HPV vaccine, it remains under-utilised in this country and thus its potential to reduce mortality related to cervical cancer remains unrealized. Your study will address the slow uptake of this vaccine, and thus provide important evidence to increase its impact on women's health in South Africa. The proposed inclusion of boys in the schools-based HPV vaccination programme, which is an innovation in South Africa, would through this study provide useful information about factors that drive uptake of the vaccine amongst boys.

I am very happy to support this study and hope that your application for funding will be successful.

Yours faithfully

Elizabeth Lutge (PhD)
Director: Health Research and Knowledge Management
[redacted] Department of Health

Fighting Disease, Fighting Poverty, Giving Hope

UCONN
UNIVERSITY OF CONNECTICUT

Institute for Collaboration on Health, Intervention, and Policy
Lisa M. Butler, PhD, MPH, PhD
Associate Research Professor

September 20, 2022

Ingrid T. Katz, MD, MHSc
Department of Medicine, Division of Women's Health, Brigham and Women's Hospital
1620 Tremont Street
Boston, MA 02120

Dear Ingrid:

I am writing to confirm my participation as MPI in your 3-year NIH R34 entitled ***Multi-level school-based intervention to improve HPV vaccine uptake and completion in South Africa.*** As you know, I am deeply committed to improving HPV vaccine access and uptake for all populations, especially in settings like South Africa where HPV-associated cancers are a leading cause of cancer-related mortality.

As you know, over the past year, I have personally met with individuals from the [redacted] who are involved in the management and implementation of the school-based HPV program in [redacted] as well as school principals, parents of children (boys and girls) who are enrolled in Pietermaritzburg area schools, members of the general public, as well as academic researchers and others who have or continue to be involved in decision making at the national and provincial level regarding HPV vaccine rollout. These many discussions have reinforced several key points that are addressed in this proposal – 1) communication about HPV vaccination needs to be clearer and needs to address people's misconceptions and concerns, 2) mistrust of vaccines and medical providers has increased greatly during the 'Covid Era', and 3) the HPV vaccine program needs to be more inclusive – i.e. to include boys as well as children enrolled in Quintile 5 (most affluent) schools. There is a general sense that the current approach of providing the vaccine for free only to girls in less affluent schools is stigmatizing and is contributing to the belief that HPV is a feminine problem and a problem of the poor. It is essential that these misconceptions are addressed and that the highly effective vaccine is made available to all.

As MPI, I will support you and the team in the assembly of a Stakeholder Working Group with whom we will meet at least 5 times over the study period. I will also support you in the development of study protocols, synthesizing inputs (provided through engagement with key stakeholders and data collection with key informants) to guide Jive Media Africa in their development / refinement of communications materials for different populations (parents/guardians, teachers, nurses, children), oversight of data collection and collaboration throughout data analysis, interpretation of results, manuscript, and presentation preparation.

I have so enjoyed our longstanding collaborations together on NIH and other funded projects in South Africa spanning almost a decade, including studies focused on cervical cancer, preferences for long-acting PrEP amongst adolescent girls and young women and men, and HIV treatment acceptance and adherence following diagnosis. As MPI, I look forward to collaborating with you on another pertinent and timely project in South Africa.

Sincerely,

Lisa M. Butler, PhD, MPH, PhD

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UNIVERSITY OF KWAZULU-NATAL
INYUVESI YAKWAZULU-NATALI

October 13, 2022

Ingrid T. Katz, MD, MHSc
Department of Medicine, Division of Women's Health, Brigham and Women's Hospital
1620 Tremont Street
Boston, MA 02120

Lisa M. Butler, PhD, MPH, PhD
University of Connecticut - Institute for Collaboration on Health, Intervention and Policy
2006 Hillside Road, Unit 1248
Storrs, Connecticut 06269-1248

Dear Ingrid and Lisa,

Thank you for leading this R34 titled *Multi-level school-based intervention to improve HPV vaccine uptake and completion in South Africa.* Your project addresses a critical need in HPV-related cancer control in South Africa. Your focus on human-centered design principles, stakeholder engagement, and health equity at every stage of this project is critical to building a well-informed, feasible intervention strategy.

As a researcher focused on the psychosocial and behavioral components of change in educational and health contexts, I will contribute to this project by serving as the subrecipient PI on the site where the proposed study will take place. I am a permanent academic [CONFIDENTIAL INFORMATION - REQUESTER IN AGREEMENT] More specifically, I envision working collaboratively with the research team on the research design and methodology to ensure alignment with best and ethical practices in the local context. I will also take responsibility for facilitating local IRB and related research approvals, will oversee research participant identification and recruitment, and ensure that data is collected and managed in credible and reliable ways. I will also assist with data analysis, and reporting on the findings in the form of reports/feedback to stakeholders and scientific journal articles.

Your project proposes a deep exploration of the social norms, behaviors, and attitudes related to HPV vaccination that are prevalent in youth and their influencers and contribute to suboptimal uptake, with the goal of responding directly to stakeholder concerns. As a Co-Investigator located in South Africa, I will support all on-site research and ensure that the project is successful. I [CONFIDENTIAL INFORMATION - REQUESTER IN AGREEMENT]

[CONFIDENTIAL INFORMATION - REQUESTER IN AGREEMENT]

School of Applied Human Sciences

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THE UNIVERSITY OF ARIZONA
Mel and Enid Zuckerman College of Public Health

Division of Health Promotion Sciences

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Purnima Madhivanan, MBBS, MPH, PhD
Associate Professor & Graduate Program Director

Email: pmadhivanan@email.arizona.edu
Phone: (520) 621-5730

September 22, 2022

Ingrid T. Katz, MD, MHSc
Department of Medicine, Division of Women's Health, Brigham and Women's Hospital
1620 Tremont Street
Boston, MA 02120

Lisa M. Butler, PhD, MPH, PhD
University of Connecticut - Institute for Collaboration on Health, Intervention and Policy
2006 Hillside Road, Unit 1248
Storrs, Connecticut 06269-1248

Dear Drs. Katz and Butler,

I am delighted to offer my support as a Co-Investigator for your upcoming R34 titled, "*Multi-level school-based intervention to improve HPV vaccine uptake and completion in South Africa*", which addresses the urgent need for interventions that enhance HPV vaccination uptake and completion in South Africa.

As a researcher focused on intersection of infectious and chronic diseases, I have been working in the field of primary prevention of cervical cancer and HPV vaccine intentions since 2007. I have been involved in over six mixed-methods epidemiologic studies related to HPV vaccine initiation and completion. I have over 15 publications on the topic. It is with this expertise that I am enthusiastic to contribute to this project. I will work with the team on conceptualization, planning and community engagement processes, data analysis and dissemination.

In this research, I hope to offer my expertise in understanding the barriers and challenges to engaging young people in HPV prevention and look forward to collaborating with you and the rest of your team

Sincerely,

Purnima Madhivanan
Associate Professor & Graduate Program Director, Health Promotion Sciences, Mel & Enid Zuckerman College of Public Health
Associate Professor, Medicine & Family Community Medicine, College of Medicine
Director, Global Health Equity Scholars Fellowship, University of Arizona
Director, Public Health Research Institute of India

THE UNIVERSITY OF ARIZONA
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September 22, 2022

Ingrid T. Katz, MD, MHSc
Department of Medicine, Division of Women's Health, Brigham and Women's Hospital
1620 Tremont Street
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Lisa M. Butler, PhD, MPH, PhD
University of Connecticut - Institute for Collaboration on Health, Intervention and Policy
2006 Hillside Road, Unit 1248
Storrs, Connecticut 06269-1248

Dear Drs. Katz and Butler,

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Sincerely,

Purnima Madhivanan
Associate Professor & Graduate Program Director, Health Promotion Sciences, Mel & Enid Zuckerman College of Public Health
Associate Professor, Medicine & Family Community Medicine, College of Medicine
Director, Global Health Equity Scholars Fellowship, University of Arizona
Director, Public Health Research Institute of India

UCONN
UNIVERSITY OF CONNECTICUT

Institute for Collaboration on Health, Intervention, and Policy
Emily A. Mudzingwa, PhD
Assistant Research Professor

October 12, 2022

Ingrid T. Katz, MD, MHSc
Department of Medicine, Division of Women's Health, Brigham and Women's Hospital
1620 Tremont Street
Boston, MA 02120

Lisa M. Butler, PhD, MPH, PhD
University of Connecticut – Institute for Collaboration on Health, Intervention and Policy
2006 Hillside Road, Unit 1248
Storrs, Connecticut 06269-1248

Dear Drs. Katz and Butler,

I am delighted to support your proposed R34, ***Multi-level school-based intervention to improve HPV vaccine uptake and completion in South Africa***, as a Co-Investigator. This study offers an innovative and much-needed approach to improve HPV vaccination among girls and boys in South Africa, drawing on close collaboration with stakeholders throughout the study and on expertise from a multi-disciplinary team.

My research uniquely spans the disciplines of end-user research, bioengineering, and social-behavioral sciences with a focus on sub-Saharan Africa. I bring to the team my experience incorporating diverse stakeholder perspectives into product development and implementation planning for new health technologies, including five years of postdoc research based in South Africa. I also bring expertise in study design and implementation, qualitative data collection and analysis, and participatory research. I am eager to contribute to the qualitative portion of this study and help in any other way that I can as Co-Investigator.

I am looking forward to working with your exceptional team and engaging with stakeholders to develop a communication strategy to improve HPV vaccine uptake in Kwa-Zulu Natal, South Africa. Thank you for inviting me to be part of this important work.

Sincerely,

Emily Mudzingwa

Emily Mudzingwa, PhD
Assistant Research Professor, Institute for Collaboration on Health, Intervention, and Policy
University of Connecticut
Storrs, CT, USA

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UNIVERSITY OF KWAZULU-NATAL
INYUVESI YAKWAZULU-NATALI

September 22, 2022

Ingrid T. Katz, MD, MHSc
Department of Medicine, Division of Women's Health, Brigham and Women's Hospital
1620 Tremont Street
Boston, MA 02120

Lisa M. Butler, PhD, MPH, PhD
University of Connecticut - Institute for Collaboration on Health, Intervention and Policy
2006 Hillside Road, Unit 1248
Storrs, Connecticut 06269-1248

Dear Drs. Katz and Butler,

It is my pleasure to offer you my enthusiastic support of your proposed R34 study, Multi-level school-based intervention to improve HPV vaccine uptake and completion in South Africa. I am excited about your project's focus on public health communications as a tool to increase HPV vaccine uptake and am thrilled to be a part of the multidisciplinary team you have put together in designing this intervention.

As a researcher with in-depth knowledge, expertise and experience in heath communication programme development and research, I hope to contribute my knowledge and expertise to inform the various project processes of this study.

I look forward to collaborating with you on this timely project as a Co-Investigator in South Africa. I believe this project addresses a critical gap in achieving optimal HPV vaccination uptake and am looking forward to this work.

Sincerely,

Mkhonzeni Lancelotte Gumede, PhD
Lecturer - Centre for Culture Media and Society

College of Humanities
School of Applied Human Sciences
Postal Address: University of KwaZulu Natal, Howard College Campus Durban 4041

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ACTIVATE AFRICAN KNOWLEDGE
Jive Media Africa

Ingrid T. Katz, MD, MHSc
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Lisa M. Butler, PhD, MPH, PhD
University of Connecticut - Institute for Collaboration on Health, Intervention and Policy
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September 19, 2022

Dear Drs. Katz and Butler

Re: Letter of Support – Communications Intervention for Improved HPV Vaccine Uptake

Thank you for the opportunity to collaborate and support your proposed R34 grant titled Development of a multi-level intervention to improve uptake and completion of HPV vaccine doses among South African youth 9-11 years old. In South Africa, although there is a national HPV vaccination strategy for girls in public schools, gaps still exist in vaccine uptake and dose completion, and some populations (including girls at fee-paying schools as well as all boys) are missed.

Jive Media Africa are experts in public engagement capacity enhancement and media production around co-creation or participatory design processes for public health intervention. Jive Media Africa has partnered with leading science and research organizations over the past 16 years on numerous public health communications projects. Jive Media Africa is confident that the multi-level project that has been proposed, focusing on behavior change, has real potential to increase vaccine coverage for young people by working directly with stakeholders, listening to their concerns, and building health communication materials that respond directly to these perceptions and are designed in a way that is contextually appropriate for different groups.

Recent examples of this work within a public healthcare context include a Uganda based Early Detection of Karposi Sarcoma (EDKS) campaign, a Uganda based Cervical Cancer campaign, Community Health Worker Assistive Technologies (CHAT), an RCCE COVID-19 campaign for UNICEF, among others. https://www.unicef.org/southafrica/reports/covid-19-covered-•-clean-•-caring

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ACTIVATE AFRICAN KNOWLEDGE
Jive Media Africa

We have also so enjoyed working with Dr. Katz on a research study focused on adapting an evidence-based HPV prevention program for community and faith-based organizations serving low socioeconomic status and racial/ ethnic minority populations. This study was funded through the Dana-Farber/ Harvard Cancer Center. We are excited to be involved in the planning and execution of the proposed activities and look forward to lending our support.

Your faithfully

Robert Inglis (MPhil in Science Engagement – Stellenbosch University)
Director – Jive Media Africa – Research Communications Specialists

UNIVERSITY OF KWAZULU-NATAL
INYUVESI YAKWAZULU-NATALI

October 13, 2022

Ingrid T. Katz, MD, MHSc
Department of Medicine, Division of Women's Health, Brigham and Women's Hospital
1620 Tremont Street
Boston, MA 02120

Lisa M. Butler, PhD, MPH, PhD
University of Connecticut - Institute for Collaboration on Health, Intervention and Policy
2006 Hillside Road, Unit 1248
Storrs, Connecticut 06269-1248

Dear Ingrid and Lisa,

I am writing to express my full support of your proposed R34 study, *Multi-level school-based intervention to improve HPV vaccine uptake and completion in South Africa.*

This project responds directly to the urgent need for interventions that will enhance HPV vaccination uptake in South Africa, where HPV is the leading cause of cancer-related mortality among women.

I have experience in conducting conceptual and empirical research into ethical-legal complexities of vaccine and prevention research, including the complex issue of adolescent enrolment, and I have experience in the development of resource documents for affected stakeholders to help them to strengthen their practices.

The HIV AIDS Vaccines Ethics Group (of which I am the project director) has a long history of interfacing with key stakeholders in prevention research, and in adolescent research, including investigators, Research Ethics Committees (RECs/IRBs) and Community Advisory Boards (CABs), of analysing barriers to research, and uptake, and of producing resources to resolve challenges.

As a co-investigator, I will bring to this team 20 years of experience in vaccine trials to guide the team in the implementation of this multi-level communication intervention. I will advise the team on ethical-legal challenges in project implementation and develop resources in this regard. I will assist the study team to consider the normative implications of the empirical data.

Sincerely,

CONFIDENTIAL INFORMATION - REQUESTER IN AGREEMENT

SIYABONGA MZIMANDE
1 Nyoni Drive Hillcrest, 3610| hope2Educate@icloud.com | +27(0)733330272

23 October 2022

Ingrid T. Katz, MD, MHSc
Department of Medicine, Division of Women's Health, Brigham and Women's Hospital
1620 Tremont Street
Boston, MA 02120

Lisa M. Butler, PhD, MPH, PhD
University of Connecticut - Institute for Collaboration on Health, Intervention and Policy
2006 Hillside Road, Unit 1248
Storrs, Connecticut 06269-1248

RE: Stakeholder Engagement

Dear Drs. Katz and Butler,

I am so pleased to write a letter to confirm my enthusiastic support for your proposal to the US National Cancer Institute " *Multi-level school-based intervention to improve HPV vaccine uptake and completion in South Africa".*

Meaningful stakeholder engagement is vital for closing the gap between research and practice, ensuring full participation of stakeholder and communities. Stakeholder engagement recognizes that stakeholder contribution to decision-making is fundamental to achieving sustainable, equitable and lasting solutions. The quality of decisions can be improved and made more transparent and accountable by the inclusion of a broad range of stakeholders who can bring important knowledge and perspectives to the process.

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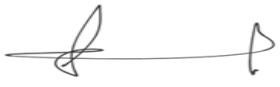
In my role on this project, I will be responsible for facilitating stakeholder engagement activities, and supporting the Project Coordinator in the coordination of these engagements as well as other study activities. I will also assist the team in the development of study protocols and tools, facilitate focus group discussions and conduct semi-structured interviews. Throughout all activities, I will ensure that the project keeps the needs of children and their families at the center of all considerations.

They key objectives will be to share information in a timely and regular manner to broader stakeholders for better understanding of the subject, to engage in discussions with broader stakeholders in different stages of research and to provide feedbacks and recommendations from broader stakeholders for the consideration of study teams and/or others (in terms of planning and decision making).

My passion and values towards stakeholder engagement will ensure that the study becomes successful in it aims and objectives, providing solution that will lead to inclusion for all parties involved in the research and advocacy for future implantation should the study result become positive to improve people's lives.

Sincerely,

Siyabonga Nzimande – KZN Civil Society Leader



UNIVERSITY OF KWAZULU-NATAL
INYUVESI YAKWAZULU-NATALI

CONFIDENTIAL INFORMATION - REQUESTER IN AGREEMENT

October 11, 2022

Ingrid T. Katz, MD, MHSc
Department of Medicine, Division of Women's Health, Brigham and Women's Hospital
1620 Tremont Street
Boston, MA 02120

Lisa M. Butler, PhD, MPH, PhD
University of Connecticut – Institute for Collaboration on Health, Intervention and Policy
2006 Hillside Road, Unit 1248
Storrs, Connecticut 06269-1248

Dear Ingrid and Lisa,

I am looking forward to collaborating with you and the rest of your team on this R34 study, *Multi-level school-based intervention to improve HPV vaccine uptake and completion in South Africa.* Your project addresses a critical gap in achieving optimal HPV vaccination uptake and completion by youth in South Africa. As a co-Investigator, I will guide the team with my expertise in research ethics and capacity building.

As a researcher focused on ethical issues in HIV prevention research and research ethics in general, I hope to be able to assist the team in negotiating some of the ethical issues in conducting this health-related multidisciplinary study on an important local health issue among local adolescent populations.

Your exceptional team brings together a broad range of different expertise which will be critical in building a communication strategy together with stakeholders that ultimately has the

potential to increase vaccine uptake among youth in the greater Pietermaritzburg area. I greatly look forward to supporting this work in my role as a Co-Investigator in South Africa.

Sincerely,

CONFIDENTIAL INFORMATION - REQUESTER IN AGREEMENT

UNIVERSITY OF KWAZULU-NATAL
INYUVESI YAKWAZULU-NATALI

23 October 2022

Ingrid T. Katz, MD, MHSc
Department of Medicine, Division of Women's Health, Brigham and Women's Hospital
1620 Tremont Street
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Lisa M. Butler, PhD, MPH, PhD
University of Connecticut - Institute for Collaboration on Health, Intervention and Policy
2006 Hillside Road, Unit 1248
Storrs, Connecticut 06269-1248

RE: Stakeholder Engagement for project "Multi-level school-based intervention to improve HPV vaccine uptake and completion in South Africa".

Dear Drs. Katz and Butler,

I am writing in enthusiastic support of your proposed R34 study, *Multi-level school-based intervention to improve HPV vaccine uptake and completion in South Africa.*

I have worked primarily in the field of HIV prevention as a researcher for the HIV/AIDS Vaccines Ethics Group (HAVEG), where my focus has been on exploring how stakeholder engagement can be improved through the ethics review process. As part of the coalition to support prevention research, funded by USAID, I worked with AVAC to develop an online course aimed at strengthening the ethics review of stakeholder engagement. I have also contributed to several publications in the area. I understand stakeholder engagement to be an important research ethics goal and is recommended by international as well as local research ethics guidance. Stakeholder engagement offers many beneficial outcomes to the research process. These include empowerment of stakeholders through capacity building and offsetting power inequalities improved stakeholder relationships and collaborative partnerships subsequently enhancing trust and support and improved protections for participants, communities and the research itself.

In my role as Project Coordinator, I will be responsible for the oversight and monitoring of stakeholder engagement throughout the study. In partnership with the study's Community Engagement Lead, Mr. Siyabonga Nzimande, I will support the team by ensuring that the plan meets the recommendations outlined in current guidance. Firstly, by ensuring that engagement involves a broad and inclusive set of stakeholders. Stakeholders will include representatives from government, healthcare, civil society, advocacy groups representing parents and children, educators and schools, as well as individuals concerned with legal and ethical protections of children and their families. Secondly, by encouraging engagement that is early and sustained throughout the research. As outlined in the proposal, we will engage with key stakeholders from the start of the study and continue to the end. Lastly, supporting engagement that is dynamic and responsive to the context. For this reason, stakeholder inputs will be solicited in various forms from different stakeholders, whether part of the advisory group or as individuals representing key partners and/or participants. Feedback regarding research outcomes will also be continuously disseminated ensuring responsiveness and enhanced social value.

UNIVERSITY OF KWAZULU-NATAL
INYUVESI YAKWAZULU-NATALI

I very much look forward to collaborating with you and the rest of your multidisciplinary team as we work towards greater HPV vaccine equity for all youth in South Africa.

Sincerely,

CONFIDENTIAL INFORMATION - REQUESTER IN AGREEMENT

Dana-Farber Cancer Institute

HARVARD MEDICAL SCHOOL

CONFIDENTIAL INFORMATION - REQUESTER IN AGREEMENT

[redacted]

October 13, 2022

Dear Ingrid and Lisa,

I am writing to express my enthusiastic support of your R34 application entitled, *"Multi-level school-based intervention to improve HPV vaccine uptake and completion in South Africa."* I look forward to serving as a consultant on this project and tackling this essential public health problem together.

As a practicing gynecologic oncologist at the Dana-Farber Cancer Institute, I regularly take care of women with advanced cervical cancers who experience severe complications, including fistulas between the tumor, bowel, and bladder, recurrent infections, and intractable pain. We have unparalleled resources to treat this disease in the United States and, despite this, women still experience tremendous suffering from a disease that could be prevented with early HPV vaccination. This is a public health failure. Yet, as we learned during the COVID pandemic, vaccine uptake and completion is no simple matter.

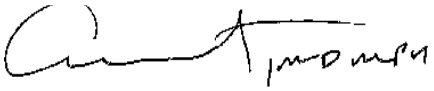
Your project is both important and innovative. You are studying HPV vaccine uptake and completion in South Africa, where cervical cancer is the leading cause of cancer-related deaths among women. You have partnered with the South African Department of Health and school districts in KwaZulu Natal to co-design a scalable intervention to increase HPV vaccine initiation and completion rates that builds upon South Africa's prior investments in HPV vaccination, while extending it to school-aged boys. Because you are co-designing this intervention with the key stakeholders, your intervention has a rea potential for future scalability and sustainability.

Importantly, the project will also generate important insights into how adolescents, parents/caregivers, teachers and school administrators, nurses, and representatives from the South African Department of Health think about the HPV vaccine; identify barriers and facilitators to vaccine initiation and uptake; and co-design materials for a

multi-level intervention tailored to overcome these barriers to increase HPV vaccination. Finally, your interdisciplinary team has deep expertise in HPV prevention, vaccine decision making, health communications, participatory design, and community engagement. In short, this project has all of the necessary ingredients for success.

As a consultant on this project, I will contribute my expertise in cervical cancer, as well as my research experience in intervention design and dissemination. I look forward to offering my expertise and supporting this project in any way possible.

Sincerely,



Alexi A. Wright, MD MPH

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23 October 2022

Ingrid T. Katz, MD, MHSc
Department of Medicine, Division of Women's Health, Brigham and Women's Hospital
1620 Tremont Street
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Lisa M. Butler, PhD, MPH, PhD
University of Connecticut - Institute for Collaboration on Health, Intervention and Policy
2006 Hillside Road, Unit 1248
Storrs, Connecticut 06269-1248

RE: Stakeholder Engagement

Dear Drs. Katz and Butler,

I am so pleased to write a letter to confirm my enthusiastic support for your proposal to the US National Cancer Institute "*Multi-level school-based intervention to improve HPV vaccine uptake and completion in South Africa".*

Meaningful stakeholder engagement is vital for closing the gap between research and practice, ensuring full participation of stakeholder and communities. Stakeholder engagement recognizes that stakeholder contribution to decision-making is fundamental to achieving sustainable, equitable and lasting solutions. The quality of decisions can be improved and made more transparent and accountable by the inclusion of a broad range of stakeholders who can bring important knowledge and perspectives to the process.

CONFIDENTIAL INFORMATION - REQUESTER IN AGREEMENT

In my role on this project, I will be responsible for facilitating stakeholder engagement activities, and supporting the Project Coordinator in the coordination of these engagements as well as other study activities. I will also assist the team in the development of study protocols and tools, facilitate focus group discussions and conduct semi-structured interviews. Throughout all activities, I will ensure that the project keeps the needs of children and their families at the center of all considerations.

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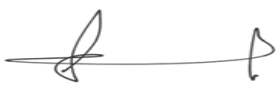
Sincerely,

Siyabonga Nzimande – KZN Civil Society Leader



Resource Sharing Plan

Data collected in the execution of the aims described in the application will be shared in the form of peer-reviewed journal publications and conference presentations. Following publication of the main paper(s) for this study, we will make the data publicly available in the form of an electronic database for researchers who successfully complete a registration process. Data will be de-identified and will not contain any direct identifiers or indirect identifiers that could identify participants by inference. We will provide documentation in the form of a codebook in which each variable name and values are defined. As part of the registration process, users must agree to the conditions of use governing access to the public release data, including restrictions against attempting to identify study participants, destruction of the data after analyses are completed, reporting responsibilities, restrictions on redistribution of the data to third parties, and proper acknowledgement of the data resource. Users must submit brief proposals regarding intended use of the data; the study team will determine the scientific soundness of the proposal as part of the decision for the researcher to be able to access the public use dataset.