Official Title: Pre-Exposure Prophylaxis (PrEP) Provision for Ugandan Fisherfolk (ID: R34MH119924)

NCT05084716

Study Protocol and Statistical Analysis Plan

March 8, 2024

Study Protocol: **RAND HSPC Information Online (RHINO) Application**

Date application created: 2/21/2024 10:19 AM

STUDY BASICS

1. *** 3.1 Title of study**
   Evaluation of the Implementation of PrEP Provision for Ugandan Fisherfolk
2. *** 3.2 Brief summary or abstract.** Note: this was populated from question 1.1c on the pre-screener. Using this information please provide a brief summary or abstract of the study. Describe its purposes, study methods (i.e., participants, procedures, data sources), and expected results.
   Please note that this is a transfer from RHINO 1.0, ID 2019-0571
   Worldwide, fisherfolk are at an exponentially higher risk for HIV than the general population in their regions. In Ugandan fisherfolk communities, HIV prevalence is estimated to be 15-40% - much higher than in the general Ugandan population, for which HIV prevalence is estimated to be 5.9% among those aged 15-49. It is estimated that fisherfolk represent 5% of the population, and about 10% of the labor force is involved in the fisheries sector; fishing regions (lakes, rivers, etc.) cover about 20% of Uganda. Fisherfolk include fishermen and their families, people who support the fish trade business (e.g., fish vendors, boat off loaders), and commercial sex workers (CSWs) who live in fishing communities. A previous RAND study (led by Bogart) with Makerere University School of Public Health, and Mildmay Uganda tested home-based and event-based antiretroviral therapy (ART) distribution models. This study will build on the previous findings and apply them to the development and testing of two PrEP delivery models for high-risk HIV-negative fisherfolk following HIV testing.
   We propose to explore the acceptability and feasibility of PrEP, and to develop and compare the implementation of two interventions to promote PrEP use among fisherfolk: community-based vs. healthcare facility-based PrEP provision. We will partner with the Ministry of Health throughout the project, regularly meeting with its PrEP Technical Working Group to discuss study results and determine next steps for policy and national implementation.
   The Specific Aims are:
   1. To conduct formative qualitative research to examine barriers to and facilitators of PrEP uptake, and to obtain input on acceptable PrEP messaging and provision, for fisherfolk communities on Lake Victoria, Uganda.
   2. To conduct a mixed-methods analysis comparing the implementation of community-based vs. healthcare facility-based PrEP provision for fisherfolk communities on Lake Victoria, Uganda.
   When this study was initially proposed, the intent was to purchase and supply PrEP to study participants as it was not widely used in the country as a whole, or in fishing communities. Since the study was funded, PrEP use has become more widespread in Uganda and is provided by Mildmay Uganda via a Ugandan Ministry of Health program. As a result, the study will no longer purchase and provide PrEP through the grant, and instead will evaluate enhancements (i.e., behavioral interventions) to the standard of care for providing PrEP in Ugandan fishing communities.
3. **3.3 RAND Principal Investigator and Co-Principal Investigator:**

   * **Principal Investigator:** Laura Bogart (lbogart@rand.org) Refresher Course - Expires 2/13/2025

   Co-Principal Investigator (if any):

4.

5. *** 3.4 Does any key staff member have a financial interest related to this research?**
   No

6.

7. *** 3.5 Do you have a protocol, proposal, or project description to upload?** (If yes, you can upload the document below or at the end of this form in Part 7).
   Yes No

   Protocol Documents:

Document	Category	Date Modified	Document History
There are no items to display			

8. *** 3.6 Has this project already had a scientific review-that is, a review of the adequacy of the study design?** Check all that apply.

   Yes - by funder's proposal review committee

9. **3.7 Who is the intended audience for the results of this study? Where and in what form will you disseminate results?**

   *** Who is the intended audience for the results of this study:**
   Our findings will be important in informing researchers and key stakeholders, including healthcare providers and policymakers, about barriers to implementation and potential solutions to address barriers suggested by stakeholders. Throughout the study, we will meet with Ugandan Ministry of Health policymakers to keep them apprised of the study goals and preliminary and final results, and to obtain their input on the PrEP intervention protocols. Importantly, we will engage with policymakers prior to the pilot intervention, to discuss the qualitative results and together determine the pilot intervention protocol, and we will engage with them throughout the pilot intervention implementation, in order to discuss lessons learned, and the brainstorm about how any challenges can be addressed.

   *** Where and in what form will you disseminate results?**
   Following the analysis of the qualitative and quantitative data, we will develop a presentation and summary report that will be shared with the Ugandan Ministry of Health, with the goal of obtaining policymaker input into the interpretation of the results, as well as recommendations for policy based on the results.

10. **STUDY FUNDING SOURCES**

11. *** 3.8 Indicate the primary source of funding whether or not the funding is coming directly to RAND as the prime contractor or grantee. That is, if funding from an agency is being channeled through another organization, check that agency. Check all that apply**

Selection	Name
D.	National Institutes of Health (NIH)

12.

13. * 3.8d Specify the NIH institute:

F. National Institute of Mental Health (NIMH)

14.

15. RESEARCH OVERVIEW - DATES

The dates below should cover the entire project and all population-procedure study components. Please provide the dates below based on your best estimates at this time. These dates should be taken from the contract, grant, or statement of work when possible.

Start Dates

16. * 3.9 Project Start Date. Grant and non-FFRDC research should use the award date as the project start date. FFRDC research should use the date on which the project task number was opened. Pick the best date you can and if necessary use the text field below to explain any uncertainties. Enter dates in the following format: mm/dd/yyyy.
4/1/2020
*** 3.9a Please explain any date uncertainties below, if applicable.**

17. * 3.10 Anticipated Data Acquisition Start Date. (*Note: this should include pilot/pretest activities).* Pick the best date you can and if necessary use the text field below to explain any uncertainties. Enter dates in the following format: mm/dd/yyyy.
6/15/2020
*** 3.10a Please explain any date uncertainties below, if applicable.**

18. End Dates

*** 3.11 Anticipated Data Acquisition End Date.** Pick the best date you can and if necessary use the text field below to explain any uncertainties. Enter dates in the following format: mm/dd/yyyy.
11/30/2023
*** 3.11a Please explain any date uncertainties below, if applicable.**

19. * 3.12 Project End Date. Pick the best date you can and if necessary use the text field below to explain any uncertainties. Enter dates in the following format: mm/dd/yyyy.
3/31/2024

RESEARCH OVERVIEW - EXTERNAL ORGANIZATIONS COLLABORATING IN THE RESEARCH

This section of the study form asks questions about other institutions that are participating in human subjects research for this study. All institutions participating in the research must undergo human subjects review either by the institution's own institutional review board (IRB - the HSPC is RAND's IRB) or by deferring to the IRB of another institution (including RAND).

*** 3.13 Are there other institutions besides RAND involved in this study?**
Yes No

20. *** 3.13a Are you suggesting that RAND should defer to another institution's IRB for this study?**
Yes **No**

*** 3.13a1 Is RAND the only direct recipient of funding for this project?**
Yes

21. *** 3.13a3 Which institution is the prime contractor or grantee?**
RAND
22. **List each institution involved in any aspect of this study. Click the Add button below to add an institution and fill in all of the required information for that institution. Repeat for each institution. Check with each institution listed whether they have a Federalwide Assurance (FWA).**

External Organizations:

Name	Involved Activities	FWA Available?
Makerere University School of Public Health	Obtaining informed consent Collecting data (surveys, interviews, focus groups, record abstraction, observations, biometric measurements, etc) Receiving identifiable person-level data	Yes
Mildmay Uganda	Obtaining informed consent Collecting data (surveys, interviews, focus groups, record abstraction, observations, biometric measurements, etc) Receiving identifiable person-level data	Yes
University of Illinois Urbana Champagne	Sharing responsibility for research design, data analysis, and/or interpreting and reporting results	No

23. *** 3.13i How do you think IRB review should be conducted for this project? RAND HSPC will review your suggested approach and consult with you if needed to make a decision.**
By RAND HSPC as Single IRB/IRB of record
24.
25.
26.

27. Proprietary Data

28. *** 3.17 Could the research involve proprietary information (i.e., trade or business information that belongs to an organization)? Note RAND has policies regarding the handling of proprietary information. Please** review the policies on the intranet page **before acquiring any such information.**

Yes

No
Don't know

30.

31. Non-Disclosure Agreement

32. *** 3.18 Are you required to sign a Non-Disclosure Agreement? Note: All Non-disclosure Agreements need to be signed by RAND Contracts (Director, Financial Operations and not solely by a RAND employee or other Associate). See link to** finance staff page**.**

Yes

No
Don't know

34. Private Health Information (HIPAA)

35. * 3.19 Will private health information (e.g., medical records, health-related administrative data, health insurance claims, pharmaceutical data) be acquired?
Yes

*** 3.19a Who will the private information be acquired from? Check all that apply**

Medical care provider/insurer (e.g., a doctor or other health care provider, hospital, insurance company, managed care company, or other covered entity under HIPAA)

*** 3.19b Does all of the private information to be acquired for this research fall under HIPAA?**

Yes
No
Don't know

36. Agreements for Obtaining Data

37. *** 3.20 Are you required to have one or more written Data Use Agreements to acquire data for this study? Note: All Data Use Agreements need to be signed by RAND Contracts (Director, Financial Operations) and not solely by a RAND employee or other Associate). See link to** finance staff page**.**

Yes

No

39.

40. **Restrictive Conditions to Acquire/Access Data**

41. *** 3.21 Are any of the data to be acquired or accessed available only under certain restrictive conditions (e.g., the data provider requires signing of a data use agreement or requires expedited or full committee review by the HSPC before the data will be released to the study)?**

Yes

No
Don't know

43.

44. **Vulnerable Populations**

45. *** 3.22 Please indicate whether any of the following vulnerable populations will be intentionally and knowingly included in the research. Check all that apply. Click on a category to preview Findings that HSPC might need to make.**

G. Economically or educationally disadvantaged individuals

46.
47.
48. *** 3.23 Could children/minors be included in your sample either inadvertently or by chance?** Yes **No**
49.
50.
51.

52. **Exclusion Criteria**

53. *** 3.24 Are you going to intentionally exclude anyone from the study procedures because of gender, racial/ethnic group, or language fluency? If Yes: please explain by study procedure who you are going to intentionally exclude on the basis of gender, race/ethnic group, or language fluency and why.**

Yes

No

55. *** 3.24a Comments:**
    They must speak English or Luganda (the primary language in the intervention community)
56. *** 3.25 Are there additional criteria for excluding individuals from the study procedures that are not described above (such as minimum time in current job, specific health condition, cognitive impairment, literacy)? If Yes: please explain the additional criteria for excluding individuals from each procedure.**

    Yes

    No

58. **Deception in Research Procedures**
59. *** 3.26 Does the research involve any form of deception or withholding of explicit information about the research project? For example, this might include mystery shopping protocols or withholding of key information about the research purpose or other forms of deception.**

    Yes

    No

61. **Merging Data**
62. *** 3.27 Do you plan to merge person-level secondary data with person-level data from other sources (e.g., other existing records, datasets, or interview data from this study)? *Note: Do not include data that will only be used to contact participants but will not be retained in the study data.***

    Yes

    No

64. *** 3.27a What other information will be merged with the person-level data? Note: This does not include data that would not be retained in the data file, such as name or telephone number.**
    For those who signed a medical release form, medical records data will merged with data collected by Mildmay staff when offering PrEP to people who test HIV-negative, such as: gender, age, occupation, marital status, and residency status (permanent/transient or mobile, and if so, number of times away from the community in the past 3 months).
65. *** 3.27b Will merging the data as described above, increase the likelihood that individuals in the dataset might be identifiable by inference (i.e., comparing details in the data with other information to deduce a subject's identity), whether or not you plan to identify them?**

    Yes

No

67. **Data Identifiers and Links**

68. *** 3.28 Will RAND (including RAND subcontractors) have the capability to link person-level data to the participants using a link file, crosswalk, descrambling algorithm, or other unique identifiers (e.g., any other unique identifying number, characteristic, code, or information that can be used to identify an individual), even if you don't plan to link data identifiers?**

Yes

No

70. *** 3.29 Will any individuals in the dataset be identifiable by inference (i.e., comparing details in the data with other information to deduce a subject's identity), even if you don't plan to do this?**

Yes

No

72. *** 3.28a Please specify the other information that can be used to identify an individual.**
Participant names will only appear (1) on participant consent forms and medical release forms, which will be stored in locked file cabinets and are only accessible to Makerere and Mildmay study staff, and (2) on a master list for participant tracking, which links participants' identification numbers to their names, telephone numbers, and addresses/landing site location. This master list will be password protected and kept in a locked room on a password-protected encrypted computer and in a locked file cabinet that is only accessible to Makerere and Mildmay study staff. Thus, only study staff in Uganda will be able to link participant names with code numbers. The master list will be destroyed following completion of data collection, after all data are cleaned and analyzed. Consequently, it will not be possible to determine the identity of respondents from any of the research material.

73. **Destroying Data Identifiers/Link File**

74. *** 3.30 Will the data identifiers or link file obtained by the project ever be destroyed?**
Yes

*** 3.30a When do you estimate the data identifiers or link files will be destroyed?** Pick the best date you can and if necessary use the text field below to explain any uncertainties. Enter dates in the following format: mm/dd/yyyy.
12/31/2024
3.30b Please explain any date uncertainties below, if applicable.
The study papers are under review or being written in the next few months - we may destroy identifiers earlier

*** 3.31 Where will the data identifiers and link file be stored?**
Participant names will only appear (1) on participant consent forms and medical release forms, which will be stored in locked file cabinets and are only accessible to Makerere and Mildmay study staff, and (2) on a master list for participant tracking, which links participants' identification numbers to their names, telephone numbers, and addresses/landing site location. This master list will be password protected and kept in a locked room on a password-protected

encrypted computer and in a locked file cabinet that is only accessible to Makerere and Mildmay study staff. Thus, only study staff in Uganda will be able to link participant names with code numbers. The master list will be destroyed following completion of data collection, after all data are cleaned and analyzed. Consequently, it will not be possible to determine the identity of respondents from any of the research material.

75.

2024-N0127
View: RAND SF: Part 4A

Part 4A: Research populations & procedures

Tips for completing Populations and Procedures table.

Introduction

If your study has more than one population or procedure, then it has multiple components. To help reviewers understand your study, on the next screen you will be asked to identify the components by associating a population with a procedure in a matrix. Refer to how to structure populations and procedures to see examples of a multiple population-procedure component matrix and a single component matrix.

Populations

4.1 Think about the people involved in your study. Are they discrete groups? Is there one group that has one set of inclusion criteria that doesn't apply to another group? If so, you will need to specify multiple populations, depending on your study. These populations and the procedures defined below will be used to form a matrix on the next page. When identifying populations, think about the topics listed below and try to combine into one population participants that are very similar and separate into different populations participants that are very different. Topics covered in the population detail section include: Pilot or pretest, inclusion/exclusion, recruitment activities, informed consent, and interventions. **Note: If doing an intervention, it is not necessary to split a population into the control and intervention groups.**

1.

*** 4.1a Specify Populations – Click Add to list a population. To edit, click on the Update button. To delete, click the X.**

Population: Please provide a brief descriptive label to the subject population (e.g., physicians, students, parents).

Stakeholders (healthcare providers, community leaders, Ministry of Health policymakers)
Adherence supporters of HIV-negative fisherfolk

HIV-negative fisherfolk

[IF MORE POPULATIONS ARE NEEDED, GO BACK TO 4.1a. OTHERWISE, GO TO 4.2]

2. **4.2 Now that you have named the target population(s), please list each research procedure you will use with each population.**
3. **Earlier you listed the following research procedures for this study. Please review the list below and update it as needed:**
4.

*** 4.2a. Specify Procedures – Click Add to add a procedure. To edit click on the Update button. To delete, click the X while hovering over the procedure row.**

	Procedure Type	Procedure Name
View	C. Interviews/discussions	Semi-structured interviews (Aim 2)
View	C. Interviews/discussions	Semi-structured interviews (Aim 1)
View	I. Analysis of OTHER previously collected person-level data sets	Medical Records
View	N. Social behavioral or other interventions	Intervention (social behavioral component)

[IF MORE PROCEDURES ARE NEEDED, GO BACK TO 4.2a. OTHERWISE, GO TO 4B]

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View: RAND SF: Part 4B

Part 4B: Component selection

Select the components (combinations of Populations and Procedures) that apply to your study below:

1.

Selection Components:

Component #	Population	Procedure
9	Adherence supporters of HIV-negative fisherfolk	Intervention (social behavioral component)
6	Adherence supporters of HIV-negative fisherfolk	Semi-structured interviews (Aim 2)
15	HIV-negative fisherfolk	Intervention (clinical component)
14	HIV-negative fisherfolk	Intervention (social behavioral component)
13	HIV-negative fisherfolk	Medical Records
12	HIV-negative fisherfolk	Semi-structured interviews (Aim 1)
11	HIV-negative fisherfolk	Semi-structured interviews (Aim 2)
2	Stakeholders (healthcare providers, community leaders, Ministry of Health policymakers)	Semi-structured interviews (Aim 1)
1	Stakeholders (healthcare providers, community leaders, Ministry of Health policymakers)	Semi-structured interviews (Aim 2)

Part 4C: Population & procedure matrix

SHOW Instructions for how to link populations and procedures to identify the various components of your study.

Please add the following information to the population-procedures matrix for each data collection component:

- Expected number of participants
- Expected start and end dates
- Current status [drop down menu] –filled out by project
    - Ready to upload materials for HSPC approval now
    - Not ready to submit materials for approval
    - Other- Explain
    - No longer plan to do this

1.

Component #	Population	Procedure	Expected Number of Participants	Expected Start Date	Expected End Date	Current Component Status	Completion Status	Approva Status
1	Stakeholders (healthcare providers, community leaders, Ministry of Health policymakers)	Semi-structured interviews (Aim 2)	30	6/15/2020	3/31/2024	Ready to upload materials for HSPC approval now	Completed	
2	Stakeholders (healthcare providers, community leaders, Ministry of Health policymakers)	Semi-structured interviews (Aim 1)	30	6/15/2020	3/31/2024	Ready to upload materials for HSPC approval now	Completed	
6	Adherence supporters of HIV-negative fisherfolk	Semi-structured interviews (Aim 2)	10	4/19/2022	3/31/2024	Ready to upload materials for HSPC approval now	Completed	
9	Adherence supporters of HIV-negative fisherfolk	Intervention (social behavioral component)	10	4/19/2022	3/31/2024	Ready to upload materials for HSPC approval now	Completed	
11	HIV-negative fisherfolk	Semi-structured interviews (Aim 2)	245	6/15/2020	3/31/2024	Ready to upload materials for HSPC approval now	Completed	

12	HIV-negative fisherfolk	Semi-structured interviews (Aim 1)	245	6/15/2020	3/31/2024	Ready to upload materials for HSPC approval now	Completed
13	HIV-negative fisherfolk	Medical Records	245	6/15/2020	3/31/2024	Ready to upload materials for HSPC approval now	Completed
14	HIV-negative fisherfolk	Intervention (social behavioral component)	245	6/15/2020	3/31/2024	Ready to upload materials for HSPC approval now	Completed
15	HIV-negative fisherfolk	Intervention (clinical component)	245	6/15/2020	3/31/2024	Ready to upload materials for HSPC approval now	Completed

2.
3.

2024-N0127
View: RAND Population Details Popup

Population & Procedure Details for - # 1 Stakeholders (healthcare providers, community leaders, Ministry of Health policymakers) / Semi-structured interviews (Aim 2)

1. *** 4C.1 Expected Number of Participants:**
   30
2. *** 4C.2 Expected Start Date (enter a date, or text)**
   6/15/2020
3. *** 4C.3 Expected End Date (enter a date, or text)**
   3/31/2024
4. *** 4C.4 Current Component Status**
   Ready to upload materials for HSPC approval now

5.
6.

2024-N0127
View: RAND Population Details Popup

Population & Procedure Details for - # 2 Stakeholders (healthcare providers, community leaders, Ministry of Health policymakers) / Semi-structured interviews (Aim 1)

1. *** 4C.1 Expected Number of Participants:**
   30
2. *** 4C.2 Expected Start Date (enter a date, or text)**
   6/15/2020
3. *** 4C.3 Expected End Date (enter a date, or text)**
   3/31/2024
4. *** 4C.4 Current Component Status**
   Ready to upload materials for HSPC approval now
5.
6.

2024-N0127
View: RAND Population Details Popup

Population & Procedure Details for - # 6 Adherence supporters of HIV-negative fisherfolk / Semi-structured interviews (Aim 2)

1. *** 4C.1 Expected Number of Participants:**
   10
2. *** 4C.2 Expected Start Date (enter a date, or text)**
   4/19/2022
3. *** 4C.3 Expected End Date (enter a date, or text)**
   3/31/2024
4. *** 4C.4 Current Component Status**
   Ready to upload materials for HSPC approval now
5.
6.

2024-N0127
View: RAND Population Details Popup

Population & Procedure Details for - # 9 Adherence supporters of HIV-negative fisherfolk / Intervention (social behavioral component)

1. *** 4C.1 Expected Number of Participants:**
   10
2. *** 4C.2 Expected Start Date (enter a date, or text)**
   4/19/2022
3. *** 4C.3 Expected End Date (enter a date, or text)**
   3/31/2024
4. *** 4C.4 Current Component Status**
   Ready to upload materials for HSPC approval now
5.
6.

2024-N0127
View: RAND Population Details Popup

Population & Procedure Details for - # 11 HIV-negative fisherfolk / Semi-structured interviews (Aim 2)

1. *** 4C.1 Expected Number of Participants:**
   245
2. *** 4C.2 Expected Start Date (enter a date, or text)**
   6/15/2020
3. *** 4C.3 Expected End Date (enter a date, or text)**
   3/31/2024
4. *** 4C.4 Current Component Status**
   Ready to upload materials for HSPC approval now
5.
6.

2024-N0127
View: RAND Population Details Popup

Population & Procedure Details for - # 12 HIV-negative fisherfolk / Semi-structured interviews (Aim 1)

1. *** 4C.1 Expected Number of Participants:**
   245
2. *** 4C.2 Expected Start Date (enter a date, or text)**
   6/15/2020
3. *** 4C.3 Expected End Date (enter a date, or text)**
   3/31/2024
4. *** 4C.4 Current Component Status**
   Ready to upload materials for HSPC approval now
5.
6.

2024-N0127
View: RAND Population Details Popup

Population & Procedure Details for - # 13 HIV-negative fisherfolk / Medical Records

1. *** 4C.1 Expected Number of Participants:**
   245
2. *** 4C.2 Expected Start Date (enter a date, or text)**
   6/15/2020
3. *** 4C.3 Expected End Date (enter a date, or text)**
   3/31/2024
4. *** 4C.4 Current Component Status**
   Ready to upload materials for HSPC approval now
5.
6.

2024-N0127
View: RAND Population Details Popup

Population & Procedure Details for - # 14 HIV-negative fisherfolk / Intervention (social behavioral component)

1. *** 4C.1 Expected Number of Participants:**
   245
2. *** 4C.2 Expected Start Date (enter a date, or text)**
   6/15/2020
3. *** 4C.3 Expected End Date (enter a date, or text)**
   3/31/2024

4. *** 4C.4 Current Component Status**
   Ready to upload materials for HSPC approval now
5.
6.

2024-N0127
View: RAND Population Details Popup

Population & Procedure Details for - # 15 HIV-negative fisherfolk / Intervention (clinical component)

1. *** 4C.1 Expected Number of Participants:**
   245
2. *** 4C.2 Expected Start Date (enter a date, or text)**
   6/15/2020
3. *** 4C.3 Expected End Date (enter a date, or text)**
   3/31/2024
4. *** 4C.4 Current Component Status**
   Ready to upload materials for HSPC approval now
5.
6.

2024-N0127
View: RAND SF: Part 5A

Part 5A: Research participation identifiability

Introduction

In determining potential risks to human subjects, it is important for the HSPC to understand whether individuals involved in the research can be identified by the data you acquire and access. Please answer the questions in this section about the types of identifiers you are collecting for each study population.

You indicated in Part 4 that the following populations are involved in this study:

- Stakeholders (healthcare providers, community leaders, Ministry of Health policymakers)
- Adherence supporters of HIV-negative fisherfolk
- HIV-negative fisherfolk

Research Participation Identifiability

Update with identifiers for each population.

1.

Population	Identifiers
Stakeholders (healthcare providers, community leaders, Ministry of Health policymakers)	Audio, video, or biometric indicators Names Location and contact information
Adherence supporters of HIV-negative fisherfolk	Audio, video, or biometric indicators Names Location and contact information
HIV-negative fisherfolk	Audio, video, or biometric indicators Names Location and contact information

2.

2024-N0127
View: RAND SF: Part 5B

Part 5B: Data collection

5.1. **Previously you indicated that you plan to do or may do the following activities involving human subjects.** For each of the activities listed below, click the Update button to answer questions about the data collection for that specific activity. The Completion Status indicates "Complete" if you have answered all of the questions for that activity and "Not Completed" if you have not yet answered all of the questions for the activity. The completion status for all activities must be "Completed" before you can submit the SmartForm.

1.

	Procedure Type	Procedure Name	Completion Status
View	C. Interviews/discussions	Semi-structured interviews (Aim 2)	Completed
View	C. Interviews/discussions	Semi-structured interviews (Aim 1)	Completed
View	I. Analysis of OTHER previously collected person-level data sets	Medical Records	Completed
View	N. Social behavioral or other interventions	Intervention (social behavioral component)	Completed

2.

2024-N0127
View: Detail Create/Edit

5.2 Interviews/Discussions

Previously you indicated that this research involves conducting interviews or discussions with individuals or groups. Please provide these following additional details about these interviews/discussions:

*** 5.2a Who will conduct these interviews/discussions?** Check all that apply.

C. External vendor or collaborator

*** 5.2b List the name(s) of organization(s)**
Makerere University School of Public Health

*** 5.2c What is the mode of data collection?** Check all that apply.

C. In-person (one-on-one)

Guidance for using online video conference platforms.

*** 5.2e How often will you collect these data from the same research participants during the study period?**
Once

*** 5.2f What is the expected length of the interview** (in minutes)**?**
60

2024-N0127
View: Detail Create/Edit

5.2 Interviews/Discussions

Previously you indicated that this research involves conducting interviews or discussions with individuals or groups. Please provide these following additional details about these interviews/discussions:

*** 5.2a Who will conduct these interviews/discussions?** Check all that apply.

C. External vendor or collaborator

*** 5.2b List the name(s) of organization(s)**
Makerere University School of Public Health

*** 5.2c What is the mode of data collection?** Check all that apply.

C. In-person (one-on-one)

Guidance for using online video conference platforms.

*** 5.2e How often will you collect these data from the same research participants during the study period?**
Once

*** 5.2f What is the expected length of the interview** (in minutes)**?**
60

2024-N0127
View: Detail Create/Edit

5.14 Analysis of OTHER previously collected person-level datasets (not DMDC). Includes public and private data. Data may or may not be identifiable (e.g., educational, personnel, criminal, military that is not DMDC, medical records, or other previously collected individual-level data). May include merged datasets.

You previously indicated that your research involves collecting the type of data listed above. Please provide the following additional details about these data collection procedures.

*** 5.14a Are you using individual-level data?**
Yes No

*** 5.14b What information is included in the datasets you will be using** (e.g. medical claims data, arrest records, student test scores, etc)**?**
We will extract from Mildmay clinic testing records the number of clients tested and who screened positive and negative, and negative and PrEP-eligible; and from medical records whether PrEP-eligible clients who were offered PrEP initiated PrEP, reasons for refusal if clients who are offered PrEP decline to start, PrEP start-date, dates and locations of PrEP refills, and any other dates of contacts with the Mildmay team around PrEP (e.g., reminders, intervention sessions). We will also extract all post-PrEP initiation HIV testing results and dates, to assess whether any HIV-negative clients seroconverted. We will extract administrative data, such as attendance at intervention sessions, dates of when clinic staff contact participants to provide reminders, as well as client socio-demographic characteristics. We will also extract a larger overall dataset that contains de-identified patient-level medical records data for the two study communities, which only contains PrEP refill data (dates and refill duration) without any identifiers or any other information such as socio-demographics, so that we can compute the percentage of refills filled in each community 6 months before the intervention start-date, and during and after the 6-month intervention (March 2021-Sept 2022). Update: we will extend the data collection to evaluate implementation of the intervention in the comparison site, which is expected to begin in early 2023. Thus, de-identified data will be extracted from medical records until 6 months after the intervention (likely until December 2023). We will request a no-cost extension from NIH to do so (and thus the project will end March 31, 2024).

*** 5.14c Please name the source(s) of this data and include the url** (e.g. school district, health plan, specific city or state, etc)
Mildmay Uganda Clinic

*** 5.14d Availability of data. If it falls under more than one of the options, please select Other and describe.**
Requires signed Data Use Agreement, Memo of Understanding, or other signed agreement to obtain

*** 5.14f Are you required to pay for this data?**
Yes **No**

*** 5.14h Will you be matching this data with any other data you plan to obtain?**
Yes No

*** 5.14i What data sets will you be matching?**
For those who signed a medical release form, medical records data will merged with data collected by Mildmay staff when offering PrEP to people who test HIV-negative, such as: gender, age, occupation, marital status, and residency status (permanent/transient or mobile, and if so, number of times away from the community in the past 3 months).

*** 5.14j What information will be used to perform matching** (e.g. name, Social Security numbers, GPS, etc.)**?**
Mildmay client ID

5.10 Social-Behavioral and Other Interventions

You previously indicated that your research involves a social behavioral or other intervention. Please provide the following details about the intervention.

*** 5.10a Provide a brief description of the intervention and how it will be carried out.**
The pilot interventions will occur on Nakiwogo and Kigungu landing sites, Wakiso District, Lake Victoria, Uganda. We will offer PrEP to eligible HIV-negative fisherfolk who are tested at Nakiwogo and Kigungu. PrEP will be provided by Mildmay Uganda through the national PrEP program, administered by the Ugandan Ministry of Health.
Mildmay conducts regular (e.g., weekly) community mobilization and healthcare outreach events at the two landing sites, in which HIV testing and PrEP are offered, ART is given to those who test HIV-positive, and other healthcare services are provided. Specifically, to de-stigmatize HIV testing so that healthcare workers are not associated solely with HIV, staff have basic medical supplies on hand in addition to what is needed for HIV testing (e.g., de-worming pills). During community mobilization, Mildmay staff, Village Health Team members (VHTs), and Beach Management Unit (BMU) leaders will conduct outreach with fisherfolk prior to events (e.g., home visits, radio advertisements) and mobilize fisherfolk during events (e.g., using bullhorns), using key messages developed from the Aim 1 formative research to raise awareness around PrEP. During the testing event, BMU leaders will deliver PrEP messages (e.g., via bullhorns), and HIV testing counselors will convey PrEP information in one-on-one conversations. Specifically, Mildmay HIV counseling and testing staff will introduce PrEP to adult fisherfolk (≥18 years-old) who test HIV-negative at post-test counseling using messages developed in Aim 1.
At Nakiwogo, events will be held in a public temporary space (e.g., tent, church) in partnership with Entebbe Hospital, and at Kigungu, Mildmay staff will use space in the nearby public Kigungu Health Center III to test and treat clients during community mobilization events. In Nakiwogo only, we will conduct an enhanced behavioral PrEP intervention to compare to the standard of care in Kigungu. Specifically, in Nakiwogo, we will have a three-pronged intervention: 1) During healthcare outreach events in Nakiwogo, we will conduct PrEP workshops, in which people who want to know more about PrEP can learn basic facts about PrEP and also can be taught skills about how to advocate for PrEP in their community. These PrEP workshops will be conducted by master trainers, who are Mildmay staff who have been trained by the Ugandan Ministry of Health to conduct health workshops and trainings. 2) Check-in Calls: To support PrEP adherence, healthcare workers will call PrEP users regularly (e.g., every 1-2 weeks), to check in about any questions and to remind them of the next date and place to pick up refills. Calls will be more frequent after PrEP initiation, to ask about side effects. 3) To support PrEP adherence, healthcare workers will encourage PrEP users to select an adherence supporter, who is a family member or friend to whom they disclose their PrEP use. The adherence supporter agrees to remind them to adhere to PrEP and get refills. Healthcare workers will ask the PrEP user for the name and contact information, as well as the age and gender, for the adherence supporter, so that the adherence supporter can be contacted to remind them about refills, as well as if the PrEP user does not show up for a refill. All Adherence Supporters will also be invited to the intervention workshop, which is open to all community members. Note that the first intervention component (PrEP workshop) will be adapted from our current work in Uganda on prevention advocacy among people living with HIV (2016-0227; 2021-N0155). The last two intervention components are standard practices for people living with HIV on antiretroviral treatment, and will be adapted for PrEP users; provider guidance for adherence supporters will also be adapted from our current work in Botswana (2019-0253). To train master trainers and healthcare

providers for the intervention, we have modified Ugandan Ministry of Health PrEP training slides for healthcare providers and counselors, tailoring them based on the Phase 1 formative work and adding issues of importance to fisherfolk communities. We have received permission from the Ugandan Ministry of Health to make these modifications, and we are regularly meeting with the Ugandan Ministry of Health to update them about the study, and to help develop the intervention.
Per their usual Ministry of Health compliant procedures for PrEP, Mildmay healthcare providers will use an assumed consent procedure for providing PrEP. That is, individuals who attend an HIV testing event at which PrEP is being provided are assumed to consent to being prescribed PrEP when appropriate per Uganda Ministry of Health guidelines. Mildmay providers will draw blood to screen for PrEP contraindications [HIV-1 infected or evidence of possible acute HIV infection; allergy to Tenofovir Disoproxil Fumarate (TDF) and/or Emtricitabine (FTC); poor renal function; unwilling/unable to return for 3-monthly HIV testing, counseling and safety monitoring visits; weight <35kg]. Those eligible can obtain PrEP during Mildmay's outreach events, either in a temporary community-based venue at Nakiwogo, at Entebbe Hospital near Nakiwogo, or at Kigungu Health Centre III. Per Ministry of Health guidelines, most fisherfolk are eligible for PrEP as members of a high risk key population (with a high prevalence of multiple partners, transactional sex, alcohol use/abuse, serodiscordant relationships, and inconsistent condom use).
Update: After completion of the intervention in the intervention site, Nakiwogo (in Sept 2022), the implementing partner will provide the intervention to the comparison site, Kigungu. We will continue to collect de-identified PrEP user data to evaluate implementation at the comparison site.

*** 5.10b Does this intervention include randomization?**
Yes **No**

*** 5.10c Who will implement the intervention?** Check all that apply.

C. External vendor or collaborator

*** 5.10d List the name(s) of organization(s)**
Mildmay Uganda

*** 5.10e Where will the intervention take place** (e.g., schools, clinics, participants' homes, military bases, etc.)**?**
At Nakiwogo, events will be held in a public temporary space (e.g., tent, church) in partnership with Entebbe Hospital, and at Kigungu, Mildmay staff will use space in the nearby public Kigungu Health Center III to test and treat clients during community mobilization events.

*** 5.10f What will research participants be asked to do as part of the intervention and how much time will it take on average?**
Attend at least one 1-hour PrEP workshop, receive ~1 minute check-in calls, select an adherence supporter

*** 5.10g How often will you administer the intervention to the same research participants during the study?**
Participants can attend as many workshops as they would like

*** 5.10h What is the expected length of the intervention** (in minutes)**?**
60

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View: RAND SF: Part 6

Part 6: Study-level details

Introduction

In this section, please provide additional details about your data collection procedures. Major topics covered are: Benefits, risks, incentives, and costs to study participants; recruitment and consent procedures; study inclusion/exclusion criteria; waivers requested; types of sensitive data acquired or accessed; and other pertinent study level details.

When answering these questions, please include details pertaining to all populations and procedures that you previously listed in the matrix.

I. Population-specific details

The table below lists the populations identified on your study. Click the Update button next to a population to answer the questions for that population. The Status column indicates whether all questions for the given population have been completed. **Note:** these questions are specific to the population. If you have two similar populations (e.g., two populations of students), make sure both populations appear below. If they don't, go back to Part 4 and add the additional populations as necessary.

1.

Population	Completion Status
Stakeholders (healthcare providers, community leaders, Ministry of Health policymakers)	Completed
Adherence supporters of HIV-negative fisherfolk	Completed
HIV-negative fisherfolk	Completed

II. Study-specific details

1. **Plans to Share Data**
2. *** 6.13 Do you have any plans to share the individual-level data from your study in identifiable or de-identifiable form?**
   Yes **No**
3. *** 6.14 Do you have any reason to expect data might be subpoenaed, requested for an administrative procedure or requested by the client?**
   Yes **No**
4. **Data Safeguarding Plan (DSP)**
5. *** 6.15 Do you have the Data Safeguarding Plan (DSP) for this study ready to upload in draft or final form? Please use the HSPC template** here**. Note: If you do not have a DSP**

your HSPC approval of your project may be delayed until a DSP is submitted.
Yes

You can upload the DSP in Part 7 (Project Documents)

Data and Safety Monitoring Plan (DSMP)

6. *** 6.16 Does your funder require a** Data and Safety Monitoring Plan (DSMP) **for your study? The RAND HSPC will make its determination during the review process.**
   Yes – by the funder and/or HSPC
7. **6.16a Do you have the DSMP for this study ready to upload in draft or final form?**
   Yes

   You can upload the DSMP in Part 7 (Project Documents)

8. **Audio/Video Recording**
9. *** 6.17 Will the research team be audio or video recording any interaction procedures for any study participants? If yes, and if the purpose is to supplement notes or is for research purpose only, the informed consent needs to address handling the recordings and ask for permission to record unless recording is a requirement. Note: If you plan to audio or video record any interaction for reasons other than to transcribe or for research purpose (e.g. observing fidelity), you will need to prepare an Audio or Video Release Form for participants to sign. See further instructions and a sample** template**.**
   Yes No

   *** 6.17a Provide a step-by-step description of the audio or video recording procedures. Specify the study population, how long the recordings will be retained and how the recordings will be used (e.g., training, dissemination, etc.)**
   Semi-structured interviews will be audio-recorded, and transcriptions will be transmitted to RAND via Kiteworks.
10. *** 6.18 Do you have the questions you will be asking participants (e.g., the interview protocol, survey instrument, or focus group guide) in draft or final form or a list of domains or topics to be covered?**
    Yes No

    You will be asked to upload the questions in part 7

11.

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View: Part 6 Population Details Popup

Study Level Details for - Stakeholders (healthcare providers, community leaders, Ministry of Health policymakers)

Procedures - Participant Benefits, Incentives, Risks, and Costs

1. **Benefits**
2. *** 6.1 Not counting any participation incentives, are there any specific benefits that might accrue directly to the study participants?**
   Yes **No**
3. **Incentives and Other Forms of Compensation**
4. *** 6.2 Will the study participants receive incentives or some other form of compensation (e.g., cash, gift card, voucher, meals, lottery/prize drawing, other type of reimbursements)? Note: If you plan to use some type of lottery/prize drawing, please review the HSPC guidance at** https://randus.sharepoint.com/research/hspc/Documents/lotteries.pdf **and obtain prior approval from RAND's legal counsel)**
   Yes No
   *** 6.2a Type of incentive(s)**
   20,000 Ugandan Shillings
   *** 6.2b Cash value of incentive (USD)**
   $5.14
   *** 6.2c Incentive distribution procedures**
   Incentives will be distributed upon completion of the interview. The incentive will be provided even if the participant opts not to answer some questions or ends the interview early.
5. **Participant Risks/Harms**
6. *** 6.3 Which of the following types of risk/harm might result from participation in this research? Use drop down menu to check all that apply to this study population. Each risk you indicate here or in 6.3a must appear in the consent form for the relevant population.**

   D Psychological consequences (e.g., distress, embarrassment, or pressure to participate)

7. *** 6.5 Please describe the nature of the harm(s) to this study population, what it might cause, and steps that would be taken to mitigate it.**
   Participants may experience embarrassment, discomfort, or distress when being asked about issues related to HIV. Participants will be given the option not to answer any question that might cause discomfort.
8. **Costs**
9. *** 6.6 Might the study participants incur any financial costs that will not be reimbursed and that they would otherwise not incur?**
   Yes **No**
10. **Coercion or Undue Pressure to Participate**
11. *** 6.7 Are any of the participants in a situation, role, or position where they could be coerced or feel undue pressure to participate (e.g., employer/employee, doctor/patient, supervisor/subordinate, teacher/student)?**
    Yes **No**
12. **Language Translation**

13. *** 6.8 Will informed consent be administered in languages other than English?**
Yes No
*** 6.8a Specify the language(s) to be used and include the following:**
* Procedures to access that each translation is equivalent to the approved English version and written at an appropriate reading level for the target population.
* Qualifications of translators
We will record interviews and use translation-by-committee (into Luganda or other local languages as needed). Two local translators will work independently, taking into account cultural assumptions, and review each other's work for equivalence and accuracy. Transcribed interviews will be transmitted to RAND via Kiteworks.

14. **Informed Consent:**

15. You must provide individuals with the information they need to make an informed decision about participating in your study. The list of elements normally included in an informed consent are shown below. Refer to the following link to find templates to create your informed consent materials: https://randus.sharepoint.com/research/hspc/Pages/consent.aspx

    1. That the project is a research study
    2. Purpose of the research
    3. That participation is voluntary and can be discontinued at any time without penalty
    4. Clear description of procedures and their duration. Note procedures that are experimental (i.e., newly developed or of unknown benefit or risk), if any
    5. Risks from participation, if any (must match 6.3, 6.3a as relevant to population)
    6. Benefits to the individual from participation, if any
    7. A statement describing the extent to which confidentiality of records identifying the subject will be maintained, if at all *
    8. Point of contact for questions or problems regarding the study
    9. Point of contact for HSPC
    10. Signature of participant and/or legally authorized representative
    11. *If you plan to reuse or share deidentified data following the study, state: We may use your deidentified data for future research studies or share your data with other qualified researchers for future research studies.

Waiving Informed Consent

16. In general, IRB may waive or alter the requirement of informed consent under 45 CFR 46.116(f)(3), provided that the IRB finds documents that all of the following four conditions are met:

    1. (i) The research involves no more than minimal risk to subjects;
    2. (ii) The research could not practicably be carried out without the requested waiver or alteration;
    3. (iii) If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;

4. (iv) The waiver or alteration will not adversely affect the rights and welfare of the subjects; and
5. (v) Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

17. *** 6.9 Are you seeking an HSPC approval to waive consent entirely for this population?**
Yes **No**

Waiving Elements of Informed Consent

*** 6.10 Are you seeking an HSPC approval to waive or alter any of the required elements of informed consent for this study population? The list of elements normally included in an informed consent are shown below.**
Yes **No**

- That the project is a research study
- Purpose of the research
- That participation is voluntary and can be discontinued at any time without penalty
- Clear description of procedures and their duration. Note procedures that are experimental (i.e., newly developed or of unknown benefit or risk), if any
- Risks from participation, if any
- Benefits to the individual from participation, if any
- A statement describing the extent to which confidentiality of records identifying the subject will be maintained, if at all
- Point of contact for questions or problems regarding the study
- Point of contact for HSPC
- Signature of participant and/or legally authorized representative

Future Contact After Research Ends

18. *** 6.10e After the project ends, is there a possibility that the participants will be contacted to participate in any future research (including research conducted on other topics by other research teams) because of their participation in this study?** No

19. **<u>Recruitment Procedures</u>**

20. *** 6.11 Will you be recruiting participants for this population on this study?**
Yes No
*** 6.11a Please describe the step-by-step recruitment procedures for this study population. Provide details: who, what, where, when, and how.**
All recruitment activities will be conducted by Makerere University School of Public Health personnel who are part of this study team.
Aim 1: We will recruit approximately 10-15 stakeholders (including Mildmay healthcare providers who work with fisherfolk, Beach Management Unit (BMU) leaders, Village Health Team (VHT) members, and policymakers at the Ugandan Ministry of Health). Stakeholders will be identified by Mildmay and Makerere University School of Public Health Investigators (e.g., based on their professional and workplace connections, such as at Mildmay, at the Ministry of

Health, and in fisherfolk communities) and referred to the study interviewer. Stakeholders will be interviewed at their workplace or a private space convenient for them.
Aim 2: To further assess acceptability of the PrEP interventions, we will conduct semi-structured interviews with 10 healthcare providers (e.g., counselor, lab technician, nurse, doctor, master trainers who conduct intervention sessions; 5 each for Kigungu and Nakiwogo) who deliver PrEP and 10 community stakeholders (e.g., BMU members, VHTs; 5 each for Kigungu and Nakiwogo; sample can overlap if they deliver care in both communities). They will be recruited during a testing/PrEP delivery event or through Ugandan study team contacts (e.g., the team is works with other healthcare providers and community leaders at the outreach events). Interviews will be conducted after 6 months of implementation of the PrEP intervention.

*** 6.11b Do you have recruitment materials (e.g. advertisements, flyers, letters of introduction, email invitations, and reminders) in draft or final form ready to upload?**
No

Sensitive Information

21. *** 6.12 Please indicate which of the following types of sensitive information will be intentionally accessed, acquired or recorded for any study population as part of data collection. These types of information are legally protected, potentially distressing, or otherwise sensitive. The information can also be considered sensitive because of the subject populations or the context of the study.**

    M. None of the above

22.
23.

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View: Part 6 Population Details Popup

Study Level Details for - Adherence supporters of HIV-negative fisherfolk

Procedures - Participant Benefits, Incentives, Risks, and Costs

1. **Benefits**
2. *** 6.1 Not counting any participation incentives, are there any specific benefits that might accrue directly to the study participants?**
   Yes **No**
3. **Incentives and Other Forms of Compensation**
4. *** 6.2 Will the study participants receive incentives or some other form of compensation (e.g., cash, gift card, voucher, meals, lottery/prize drawing, other type of reimbursements)? Note: If you plan to use some type of lottery/prize drawing, please review the HSPC guidance at** https://randus.sharepoint.com/research/hspc/Documents/lotteries.pdf **and obtain prior**

approval from RAND's legal counsel)
Yes No
*** 6.2a Type of incentive(s)**
20,000 Ugandan Shillings
*** 6.2b Cash value of incentive (USD)**
$5.14
*** 6.2c Incentive distribution procedures**
Incentives will be distributed in cash upon completion of the interview. The incentive will be provided even if the participant opts not to answer some questions or ends the interview early.

5. **Participant Risks/Harms**
6. *** 6.3 Which of the following types of risk/harm might result from participation in this research? Use drop down menu to check all that apply to this study population. Each risk you indicate here or in 6.3a must appear in the consent form for the relevant population.**

D Psychological consequences (e.g., distress, embarrassment, or pressure to participate)

7. *** 6.5 Please describe the nature of the harm(s) to this study population, what it might cause, and steps that would be taken to mitigate it.**
A participant could suffer embarrassment or similar social harms if non-participants learned that s/he were involved in a HIV-related study, due to high levels of stigma around HIV. We have strong data protections and training standards in place (see DSP) to avoid a breach of confidentiality occurring.
8. **Costs**
9. *** 6.6 Might the study participants incur any financial costs that will not be reimbursed and that they would otherwise not incur?**
Yes **No**
10. **Coercion or Undue Pressure to Participate**
11. *** 6.7 Are any of the participants in a situation, role, or position where they could be coerced or feel undue pressure to participate (e.g., employer/employee, doctor/patient, supervisor/subordinate, teacher/student)?**
Yes **No**
12. **Language Translation**
13. *** 6.8 Will informed consent be administered in languages other than English?**
Yes No
*** 6.8a Specify the language(s) to be used and include the following:**
* Procedures to access that each translation is equivalent to the approved English version and written at an appropriate reading level for the target population.
* Qualifications of translators
We will record interviews and use translation-by-committee (into Luganda or other local languages as needed). Two local translators will work independently, taking into account cultural assumptions, and review each other's work for equivalence and accuracy. Transcribed interviews will be transmitted to RAND via Kiteworks.

14. **Informed Consent:**

15. You must provide individuals with the information they need to make an informed decision about participating in your study. The list of elements normally included in an informed consent are shown below. Refer to the following link to find templates to create your informed consent materials: https://randus.sharepoint.com/research/hspc/Pages/consent.aspx

    1. That the project is a research study
    2. Purpose of the research
    3. That participation is voluntary and can be discontinued at any time without penalty
    4. Clear description of procedures and their duration. Note procedures that are experimental (i.e., newly developed or of unknown benefit or risk), if any
    5. Risks from participation, if any (must match 6.3, 6.3a as relevant to population)
    6. Benefits to the individual from participation, if any
    7. A statement describing the extent to which confidentiality of records identifying the subject will be maintained, if at all *
    8. Point of contact for questions or problems regarding the study
    9. Point of contact for HSPC
    10. Signature of participant and/or legally authorized representative
    11. *If you plan to reuse or share deidentified data following the study, state: We may use your deidentified data for future research studies or share your data with other qualified researchers for future research studies.

Waiving Informed Consent

16. In general, IRB may waive or alter the requirement of informed consent under 45 CFR 46.116(f)(3), provided that the IRB finds documents that all of the following four conditions are met:

    1. (i) The research involves no more than minimal risk to subjects;
    2. (ii) The research could not practicably be carried out without the requested waiver or alteration;
    3. (iii) If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;
    4. (iv) The waiver or alteration will not adversely affect the rights and welfare of the subjects; and
    5. (v) Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

17. *** 6.9 Are you seeking an HSPC approval to waive consent entirely for this population?**
    Yes **No**

Waiving Elements of Informed Consent

*** 6.10 Are you seeking an HSPC approval to waive or alter any of the required elements of informed consent for this study population? The list of elements normally included in an informed consent are shown below.**
Yes **No**

- That the project is a research study
- Purpose of the research
- That participation is voluntary and can be discontinued at any time without penalty
- Clear description of procedures and their duration. Note procedures that are experimental (i.e., newly developed or of unknown benefit or risk), if any
- Risks from participation, if any
- Benefits to the individual from participation, if any
- A statement describing the extent to which confidentiality of records identifying the subject will be maintained, if at all
- Point of contact for questions or problems regarding the study
- Point of contact for HSPC
- Signature of participant and/or legally authorized representative

Future Contact After Research Ends

18. *** 6.10e After the project ends, is there a possibility that the participants will be contacted to participate in any future research (including research conducted on other topics by other research teams) because of their participation in this study?** No
19. **<u>Recruitment Procedures</u>**
20. *** 6.11 Will you be recruiting participants for this population on this study?**
    Yes **No**
    *** 6.11a Please describe the step-by-step recruitment procedures for this study population. Provide details: who, what, where, when, and how.**
    Adherence supporters will be recruited through the PrEP users who are interviewed. PrEP users will be asked whether they agree that we can interview their adherence supporter. If so, we will ask the PrEP user to ask the adherence supporter for permission for the study interviewer to contact them for an interview, or to call the study interviewer for an interview. We will suggest that the PrEP user contacts the adherence supporter in the presence of the interviewer, if possible, so that the interviewer can talk with the adherence supporter about the study and what participation entails. We have successfully used similar procedures in other studies to recruit social network members and adherence supporters of people living with HIV (2021-N0155 and HSPC: 2019-0253).
    Note that all adherence supporters, regardless of whether they are interviewed, may be called to remind them to remind PrEP users about getting refills; during this call we will also ask Adherence Supporters their age and gender and invite them to the intervention workshop (which is open to all community members), if they wish to know more about PrEP for themselves or to support the PrEP user.

*** 6.11b Do you have recruitment materials (e.g. advertisements, flyers, letters of introduction, email invitations, and reminders) in draft or final form ready to upload?**
No

Sensitive Information

21. *** 6.12 Please indicate which of the following types of sensitive information will be intentionally accessed, acquired or recorded for any study population as part of data collection. These types of information are legally protected, potentially distressing, or otherwise sensitive. The information can also be considered sensitive because of the subject populations or the context of the study.**

    M. None of the above

22.
23.

2024-N0127
View: Part 6 Population Details Popup

Study Level Details for - HIV-negative fisherfolk

Procedures - Participant Benefits, Incentives, Risks, and Costs

1. **Benefits**
2. *** 6.1 Not counting any participation incentives, are there any specific benefits that might accrue directly to the study participants?**
   Yes **No**
3. **Incentives and Other Forms of Compensation**
4. *** 6.2 Will the study participants receive incentives or some other form of compensation (e.g., cash, gift card, voucher, meals, lottery/prize drawing, other type of reimbursements)? Note: If you plan to use some type of lottery/prize drawing, please review the HSPC guidance at** https://randus.sharepoint.com/research/hspc/Documents/lotteries.pdf **and obtain prior approval from RAND's legal counsel)**
   Yes No
   *** 6.2a Type of incentive(s)**
   20,000 Ugandan Shillings
   *** 6.2b Cash value of incentive (USD)**
   $5.14
   *** 6.2c Incentive distribution procedures**
   Incentives will be distributed upon completion of the interview. The incentive will be provided even if the participant opts not to answer some questions or ends the interview early.
5. **Participant Risks/Harms**

6. *** 6.3 Which of the following types of risk/harm might result from participation in this research? Use drop down menu to check all that apply to this study population. Each risk you indicate here or in 6.3a must appear in the consent form for the relevant population.**

D Psychological consequences (e.g., distress, embarrassment, or pressure to participate)

E. Social harm (e.g., stigma of participation, damage to reputation)

7. *** 6.5 Please describe the nature of the harm(s) to this study population, what it might cause, and steps that would be taken to mitigate it.**
A participant could suffer embarrassment or similar social harms if non-participants learned that s/he were involved in a HIV-related study and/or taking PrEP, due to high levels of stigma around HIV. We have strong data protections and training standards in place (see DSP) to avoid a breach of confidentiality occurring. Participants may experience embarrassment, discomfort, or distress when being asked about issues related to HIV, due to stigma around HIV. Participants will be given the option not to answer any question that might cause discomfort.

8. **Costs**

9. *** 6.6 Might the study participants incur any financial costs that will not be reimbursed and that they would otherwise not incur?**
Yes **No**

10. **Coercion or Undue Pressure to Participate**

11. *** 6.7 Are any of the participants in a situation, role, or position where they could be coerced or feel undue pressure to participate (e.g., employer/employee, doctor/patient, supervisor/subordinate, teacher/student)?**
Yes **No**

12. **Language Translation**

13. *** 6.8 Will informed consent be administered in languages other than English?**
Yes No
*** 6.8a Specify the language(s) to be used and include the following:**
* Procedures to access that each translation is equivalent to the approved English version and written at an appropriate reading level for the target population.
* Qualifications of translators
We will record interviews and use translation-by-committee (into Luganda or other local languages as needed). Two local translators will work independently, taking into account cultural assumptions, and review each other's work for equivalence and accuracy. Transcribed interviews will be transmitted to RAND via Kiteworks.

14. **Informed Consent:**

15. You must provide individuals with the information they need to make an informed decision about participating in your study. The list of elements normally included in an informed consent are shown below. Refer to the following link to find templates to create your informed consent materials: https://randus.sharepoint.com/research/hspc/Pages/consent.aspx

    1. That the project is a research study

2. Purpose of the research
3. That participation is voluntary and can be discontinued at any time without penalty
4. Clear description of procedures and their duration. Note procedures that are experimental (i.e., newly developed or of unknown benefit or risk), if any
5. Risks from participation, if any (must match 6.3, 6.3a as relevant to population)
6. Benefits to the individual from participation, if any
7. A statement describing the extent to which confidentiality of records identifying the subject will be maintained, if at all *
8. Point of contact for questions or problems regarding the study
9. Point of contact for HSPC
10. Signature of participant and/or legally authorized representative
11. *If you plan to reuse or share deidentified data following the study, state: We may use your deidentified data for future research studies or share your data with other qualified researchers for future research studies.

Waiving Informed Consent

16. In general, IRB may waive or alter the requirement of informed consent under 45 CFR 46.116(f)(3), provided that the IRB finds documents that all of the following four conditions are met:
    1. (i) The research involves no more than minimal risk to subjects;
    2. (ii) The research could not practicably be carried out without the requested waiver or alteration;
    3. (iii) If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;
    4. (iv) The waiver or alteration will not adversely affect the rights and welfare of the subjects; and
    5. (v) Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.
17. *** 6.9 Are you seeking an HSPC approval to waive consent entirely for this population?**
    Yes **No**

Waiving Elements of Informed Consent

*** 6.10 Are you seeking an HSPC approval to waive or alter any of the required elements of informed consent for this study population? The list of elements normally included in an informed consent are shown below.**
Yes **No**

- That the project is a research study
- Purpose of the research

- That participation is voluntary and can be discontinued at any time without penalty
- Clear description of procedures and their duration. Note procedures that are experimental (i.e., newly developed or of unknown benefit or risk), if any
- Risks from participation, if any
- Benefits to the individual from participation, if any
- A statement describing the extent to which confidentiality of records identifying the subject will be maintained, if at all
- Point of contact for questions or problems regarding the study
- Point of contact for HSPC
- Signature of participant and/or legally authorized representative

Future Contact After Research Ends

18. *** 6.10e After the project ends, is there a possibility that the participants will be contacted to participate in any future research (including research conducted on other topics by other research teams) because of their participation in this study?** No

19. **Recruitment Procedures**

20. *** 6.11 Will you be recruiting participants for this population on this study?**
Yes No
*** 6.11a Please describe the step-by-step recruitment procedures for this study population. Provide details: who, what, where, when, and how.**
All recruitment activities will be conducted by staff at Makerere University School of Public Health and Mildmay who are part of the study team.
Aim 1: We will recruit 40 fisherfolk aged 18 and older who are HIV-negative to participate in the Aim 1 qualitative interviews. Participants will be purposively recruited by gender and occupation [fishermen, other fishing industry workers (e.g., fish cleaners, fish sellers, boat off loaders), CSWs, unemployed]. Participants will be recruited through healthcare providers (e.g., at testing events or healthcare facilities), who will refer to study staff (an interviewer from Makerere University School of Public Health) clients who are HIV-negative. The interviewer who will be present at the healthcare facility or testing event, and will explain the study further. Individuals can participate immediately after post-test counseling, or can schedule a later time for the interview.
Aim 2: Mildmay currently conducts monthly healthcare outreach events (with HIV testing and ART provision, as well as provision of other medical services) at the Nakiwogo and Kigungu landing sites (lakeside locations used by fisherfolk to launch boats), Wakiso District, Lake Victoria. Outreach events are provided in healthcare facilities or in temporary and other structures in the community. During these events, Mildmay staff, Village Health Teams (VHTs), and Beach Management (BMU) leaders conduct community mobilization with fisherfolk prior to these events (e.g., home visits, radio ads) as well as during events (e.g., using bullhorns). As part of this study, Mildmay staff will offer PrEP to 100 eligible HIV-negative fisherfolk who are tested at Nakiwogo and Kigungu landing sites (the first 50 per site). To assess acceptability of PrEP among fisherfolk, after PrEP is offered to HIV-negative testing clients, HIV testing staff will record whether the client agrees or refuses PrEP, and why, and then refer the client to a study interviewer, who will be present at the facility or the event, or who will follow up by phone with interested potential participants for interviews. The interviewer will accompany the client to a nearby private space for study activities (e.g., in a school or church, or outside away from others)

for informed consent and interviewing.
We will interview 20 PrEP-eligible HIV testing clients who refused PrEP and 20 PrEP-eligible HIV testing clients who accepted PrEP at baseline, within a month after HIV testing, to explore barriers to and facilitators of PrEP uptake, with half of clients recruited from each community (Kigungu, Nakiwogo).
We will also interview 40 clients (approximately 20 men, 20 women, approximately half currently taking PrEP and half who discontinued PrEP; approximately half from each community within each category) about 6 months after their PrEP initiation, to explore barriers to adherence, any reasons for discontinuation, and general acceptability of PrEP and the PrEP behavioral interventions, as well as any gender differences. For these 6-month interviews, fisherfolk participants who have initiated PrEP in the last 6 months (during the study intervention period) in one of the study communities will be recruited by the healthcare provider team during check-in calls or other contacts (e.g., during healthcare outreach events, when they receive a PrEP refill) and referred to the study interviewer, who will be present at the facility or the event, or who will follow up by phone with interested potential participants. Interviews will be conducted in-person if possible, or by phone if the participant has traveled far from the landing site or for precautionary measures due to COVID-19.

*** 6.11b Do you have recruitment materials (e.g. advertisements, flyers, letters of introduction, email invitations, and reminders) in draft or final form ready to upload?**
No

Sensitive Information

21. *** 6.12 Please indicate which of the following types of sensitive information will be intentionally accessed, acquired or recorded for any study population as part of data collection. These types of information are legally protected, potentially distressing, or otherwise sensitive. The information can also be considered sensitive because of the subject populations or the context of the study.**

B. Physical health	including diagnosis, treatment, or other private physical health information

22.
23.

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View: RAND SF: Part 7

Part 7: Study documents

Introduction

In this section, please upload the study documents (in draft or final form) that are ready for HSPC review

and approval at this time. Please clearly label each document so the materials can be linked to the population-procedures matrix. Include the name of the study population-procedure, and any other pertinent details (such as study phase, wave, etc.) in the header of each consent document and/or file name so reviewers can link the materials to the research procedures-population matrix you completed in Part 4.

Component #	Population	Procedure
9	Adherence supporters of HIV-negative fisherfolk	Intervention (social behavioral component)
6	Adherence supporters of HIV-negative fisherfolk	Semi-structured interviews (Aim 2)
15	HIV-negative fisherfolk	Intervention (clinical component)
14	HIV-negative fisherfolk	Intervention (social behavioral component)
13	HIV-negative fisherfolk	Medical Records
12	HIV-negative fisherfolk	Semi-structured interviews (Aim 1)
11	HIV-negative fisherfolk	Semi-structured interviews (Aim 2)
2	Stakeholders (healthcare providers, community leaders, Ministry of Health policymakers)	Semi-structured interviews (Aim 1)
1	Stakeholders (healthcare providers, community leaders, Ministry of Health policymakers)	Semi-structured interviews (Aim 2)

Part 8: Conclusion

1. *** 8.1 Does the proposed study involve any ethical issues not already discussed in the study application?**
   Yes **No**
2. **8.2 Please enter any other comments or information that you would like to share with the HSPC reviewer that would be relevant to the review.**
   It should be clarified that the intervention test is of the different implementation modes of PrEP provision (a behavioral intervention), rather than testing the effectiveness of PrEP (a biomedical intervention). This application notes the risks of PrEP (e.g., side effects) as part of the

intervention, although such risks are not expected to be related to the behavioral intervention.

Statistical Analysis Plan

Analyses will compare data from before the intervention to during the intervention period. Separate logistic regression models will be used to predict the likelihood of PrEP persistence (i.e., PrEP possession at 6-months and PrEP possession ratio of >80% in 6-months) with a time indicator (before vs. during the intervention). PrEP user age and gender will be included as covariates. If PrEP persistence is 0% at follow-up, logistic regression, which allows cannot be used as the odds ratio would be undefined. Thus, in this case, Fisher's Exact test will be used to evaluate change in the persistence outcome.