Date: 07/30/2021

National Clinical Trials #: NCT05084716

Study Title: Evaluation of the Implementation of PrEP for Fisherfolk

Informed consent form to access client / patient information

Version: 1.0
Title of the study: Evaluation of the Implementation of PrEP for Fisherfolk
Names of the Investigators: Dr. Rhoda Wanyenze and Dr. Barbara Mukasa
Sponsor: U.S. National Institutes of Health

Patient Clinic number: _____

Mildmay Uganda, Makerere University School of Public Health, and the RAND Corporation in the United States, with support from the Uganda Ministry of Health, are working on a research program to help prevent HIV in fishing communities using pre-exposure prophylaxis (PrEP), which is a daily medication that prevents HIV in people who are HIV-negative. This study has been approved by an accredited Research Ethics Committee, the Makerere University School of Public Health IRB. As part of this research, we are requesting that people who are prescribed PrEP, authorize Mildmay Uganda to share some medical records information with the study team up to two years after today. This information includes: when and where you get PrEP, your HIV test results and testing dates, dates when the Mildmay Uganda team contacts you about PrEP, and information about why you stopped taking PrEP, if relevant. We will also collect some information about you, including your gender, age, occupation and marital status, and how much you travel away from this area.

The study team will not share your medical records and personal information that directly identifies you, such as your name and contact information, with those not included as the study team. Additionally, we will not include your name with the information from your medical records that is shared with the study team. The information that is shared with the study can be accessed by the Research Ethics committee and Uganda National Council for Science and technology as the regulatory bodies that approved this study. We shall maintain utmost confidentiality and personal identifying information shall not be shared beyond this study team. **There is a small chance of a breach of confidentiality.**

You may refuse Mildmay Uganda sharing this information with the study if you do not want to. If you decide not to share your medical records and personal information, you can still begin PrEP today, and your health care will not be affected; however, you shall not be able to participate in the study today.

You can change your mind later after joining the study and decide not to share your medical records and personal information with the study team; the research shall still use the information before you changed your mind in the study. However, you shall not be able to participate in the study further even though your PrEP and other health care shall not be affected.

We shall keep your medical records for a period of 5 years after the study is complete. Thereafter, the copies shared with the research shall be destroyed. However, all your medical records at the health facility shall continue to be stored in line with the requirements of the Uganda Ministry of Health.

We will provide feedback about the progress and findings of the study to this community, through the healthcare facilities.

Questions about the study: If you have questions about this research project, please contact the principal Investigator: Dr Rhoda Wanyenze, Makerere University School of Public Health (MakSPH); Office: 0414-533957; Mobile: 0772-419-672; Email: rwanyenze@musph.ac.ug

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Questions about participants rights: If you have questions about your rights and welfare, please contact Dr. Suzanne Kiwanuka, Makerere University School of Public Health IRB Chair person; Office: 0393-291397

Mobile: 0708-526-694; Email: skiwanuka@musph.ac.ug

STATEMENT OF CONSENT AND SIGNATURES

I have read this form, or had it read to me. My questions have been answered. I therefore authorize Mildmay Uganda to share my information with the study Team. By signing this form, I do not give up any rights that I have as a research participant.

Name of Participant (please print) Date

Signature of Participant Date

Name and Signature of Witness Date

Name and Signature of Research Staff Date

If participant cannot provide a signature above, have him/her place his/her thumb print in the box below.

Clinic number: _____