Dynamic Prevention Intervention *Phase A* – Informed Consent Form

Project Title:	A Multisectoral Strategy to Address Persistent Drivers of the HIV Epidemic in East Africa (SAPPHIRE)
Sites of Research:	Mbarara District, Uganda; Nyanza Province, Kenya
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INTRODUCTION:

You are being asked to participate in this study because you are receiving medications to prevent HIV, or may be at risk for HIV, the virus that causes AIDS, at a health clinic or in the community. This is a study of ways to improve HIV prevention programs in your community. This study is being done by researchers from Makerere University (MU), the Infectious Diseases Research Collaboration (IDRC), the Kenya Medical Research Institute (KEMRI), the University of California, Berkeley (UCB), and the University of California, San Francisco (UCSF). The U.S. National Institutes of Health (NIH) pays for this study.

Before you decide if you want to take part, we would like to explain the purpose of this study, how the study will be done, and any risks and benefits to you. This is a consent form. It gives information about this study. You are free to ask questions at any time. After this consent form is read to you, and your questions have been answered, we will ask if you want you to be in the study. Medical research includes only people who choose to take part. Take your time to make your decision about participating. You may discuss your decision with your family and friends and with your health care team. If you have any questions, you may ask the researchers. If you agree to participate, we will ask you to sign or provide your fingerprint on this consent form. You will get a copy of this form to keep.

WHY IS THIS STUDY BEING DONE?

Providing successful HIV prevention methods can be difficult for doctors, nurses, hospitals and local governments. Two ways HIV can be prevented is by taking PrEP or PEP. PrEP is a prevention method that involves HIV negative people taking antiviral drugs to try to prevent infection for as long as they are at risk. PEP medications are taken immediately after a suspected exposure to HIV through sexual contact or other ways, and is normally taken for a month. This study will introduce a set of health care measures that seek to improve existing PrEP and PEP services, including convenient access to clinicians for changes to your HIV prevention methods, the offer of other health services to make visits more efficient, options for PrEP and PEP delivery, and discussions with the clinician on ways to overcome any barriers to receiving these services.

If you choose to be in this study, you will be assigned through a randomization process (by chance, like the flip of a coin) to either receive these enhanced methods of providing PrEP and PEP services, or to receive PrEP and PEP services according to standard care guidelines. Regardless of which group you are assigned to, PrEP and PEP medications will available to you according to standard practices in the community.

This part of the study will take place in health centers and communities in Western Uganda and Western Kenya.

WHAT WILL HAPPEN IF I TAKE PART IN THIS STUDY?

Enrollment in the Study

Enrollment will take place at a health facility or in a community location. Study staff will review your clinic record and talk to you about the study to confirm you are eligible to participate. If you are eligible and agree, you will be asked to review and sign this consent form to take part. In addition, if you are between 15 and 17 years old and are not independent from your family, one of your parents or guardians will also need to consent for your participation in the study. Your parent or guardian will not be given your test results or any other information you talk about in the study. The consent discussion and brief questions will take 30 minutes to an hour.

- At the initial study visit, staff will ask you to provide some basic information such as your date of birth, level of education and what you do for work. Staff will also ask for your phone number and home location in case we need to contact you.
- Staff will review what medications you are currently taking and if you are already on PrEP or PEP medications. If you are not on HIV prevention medications and have had a possible exposure to HIV in the last 3 days, staff will refer you to initiation on PEP right away. If you and the clinician feel you are at risk for HIV but are not already taking medications to prevent HIV and have not had a recent exposure, the clinician may recommend to start PrEP today.
- Staff will also review with you any symptoms you may be having and may perform an exam, and refer you to other clinic services as needed.

Randomization

- Staff will perform the randomization procedure to find out if you will continue to receive standard PrEP and PEP services, or the enhanced PrEP and PEP services described below. The procedure will be done using a computer, which will by chance assign you to one of the two groups. The staff involved in this study cannot choose which group you will be assigned to. If you are participating in a study through drop-in centres or households, this randomization will already have been done by the time you consent.

Study Procedures for Participants Assigned to Receive Standard Care

- If you are randomly assigned to <u>not</u> receive enhanced PrEP and PEP services, you will continue to be seen by staff in the HIV clinic or other service location, like a drop-in centre, according to standard care guidelines recommended by the country's Ministry of Health and may choose to seek PrEP and PEP at a local health facility. There will be no change to your care.
- Data from your clinic records will be collected by study staff related to PrEP, PrEP, and other standard prevention methods, including when you were on PrEP/PEP, any HIV or sexually transmitted infections, and other details related to care or HIV prevention.
- You will also be seen for a study visit every 24 weeks for up to 3 years for HIV testing and a survey on what prevention method(s) you have been using. If you are currently using medications such as PrEP or PEP, you may be asked to provide hair, urine, or blood samples in order to measure the level of HIV prevention medications in your body. The results from tests measuring medication levels will not be shared, as this testing is for research only and will be performed in the future. The most blood drawn at a study visit will be about 1 tablespoon.

Study Procedures for Participants Assigned to Receive Enhanced Services

- If you are randomly assigned to receive the enhanced PrEP and PEP services, you will still receive PrEP and PEP medications according to standard care guidelines, but will also receive the services and procedures described below:
    i. Staff will discuss with you the integrated services offered in this study, described below. All your options will be discussed and questions answered. You will be provided a phone number of a study clinician that you can call any day of the week to start PEP immediately if you have had a recent exposure, or discuss any other urgent issue.
    ii. At each visit, you will take PrEP or PEP medications according to standard care guidelines recommended by the Ministry of Health, or have the option or HIV-testing only if you are not ready to start PrEP.
    iii. You may switch between PrEP, PEP and frequent HIV-testing only at any time, according to your needs and the advice of your provider. At each visit, the HIV prevention method that is best for you will be discussed, with your options and preferences part of this continuing conversation. If new methods, such as the dapivirine vaginal ring, become available, these will also be offered as options. You may also have the option for a longer supply of PrEP medication or to use HIV self-testing.
    iv. Staff will review with you any symptoms you may be having and refer you to other clinic services as needed. If staff think you have signs of recent HIV infection, a test will be ordered to rapidly measure any virus in your blood as an alternative way of testing for HIV.
    v. If there are challenges for you to access your medications, staff may deliver your PrEP or PEP medications and provide follow-up care at home or another location outside of the clinic that works for you. You may opt to change the location of the visit at any time during the study, including having phone visits. For any visits that take place at your home or other offsite location, staff will work with you to find a space that is private and where others cannot overhear the discussion or observe study procedures.
    vi. Staff will also be available at any time to provide support if you have had any traumatic experiences or abuse at home or elsewhere, and will be trained to provide specialized counseling to help you manage these problems and help you find additional resources.
    vii. Most visits will take about the same amount of time as a regular clinic visit for people on PrEP or PEP. If you have discussions about your options or need additional testing, your visit may be an extra 30 or 45 minutes, as needed.
    viii. If you miss a visit, study staff may call you or visit you at your home. If you would not like to be visited at home or have a preference on the best way to be contacted, please tell the study staff.
    ix. Data from your clinic records will be collected by study staff related to PrEP, PrEP, and other standard prevention methods, including when you were on PrEP/PEP, any HIV or sexually transmitted infections, and other details related to care or HIV prevention.
    x. You will also be seen for a study visit every 24 weeks for up to 3 years for HIV testing and a survey on what prevention method(s) you have been using. If you are currently using medications such as PrEP or PEP, you may be asked to provide hair, urine, or blood samples in order to measure the level of HIV

prevention medications in your body. The results from tests measuring medication levels will not be shared, as this testing is for research only and will be performed in the future. The most blood drawn at a study visit will be about 1 tablespoon.

The program described in this consent form may last up to three years.

Testing HIV-Positive

- If you test positive for HIV at any time during the study, you will be referred to the HIV clinic for immediate treatment and care, regardless of which study group you are assigned to. You may also be asked to provide hair, urine, and blood samples (one or two tubes of blood) to confirm HIV infection, test for resistance to HIV medicines, and test for prevention or HIV medication levels at the time you test positive for HIV and 6 and 12 months later.

Storage and Shipment of Samples:
The hair, blood, and/or urine samples we may ask to collect from you to measure medication levels, confirm HIV infection, or test for resistance to HIV medicines will be stored at IDRC study facilities. Samples may be shipped to laboratories in the United States headed by researchers involved in the study: Dr. Monica Gandhi at UCSF in San Francisco or Dr. Urvi Parikh at the University of Pittsburgh. The samples will be stored for no more than 5 years after the conclusion of the study and will only include study ID numbers as identifiers and will not include your name.

If these samples are requested, do you agree to have your samples collected and shipped to the laboratory in the United States for testing? If you decline this collection and shipment, you may still participate in other parts of the study.

Hair samples:

☐ Yes _____ ☐ No _____
Participant's initials or thumbprint and date in space next to answer

Urine samples:

☐ Yes _____ ☐ No _____
Participant's initials or thumbprint and date in space next to answer

Blood samples:

☐ Yes _____ ☐ No _____
Participant's initials or thumbprint and date in space next to answer

CAN I STOP BEING IN THE STUDY?

You may decide to stop being in the study at any time and for any reason. Your access to PrEP and PEP through the clinic will not be affected if you decide to stop participating in the study.

WHAT RISKS CAN I EXPECT FROM BEING IN THE STUDY?

Sensitive Discussions:

Some of the discussion about HIV and recent exposures may make you feel uncomfortable. If you are feel uncomfortable with the topic under discussion, tell the study staff. If the discussion brings up instances of violence against you, including by a partner, family member or stranger, we will refer you to available resources for support or for reporting the event to the police. This is voluntary; it is up to you if you want to utilize such resources.

Confidentiality:
We will do our best to protect the information we collect from you, but confidentiality cannot be guaranteed and there is a small chance your information may be revealed. We will replace your name and all other identifying information with a unique code number on all study documents except those kept for contact information. There is a chance visits conducted at your home or other offsite location could be noticed by others, but we will work with you to find a private space in which to conduct the visit. Study-specific information will be stored in locked files, and only a small number of study staff will have access to it. You will not be identified in any report from this study. All information will be handled in compliance with Uganda and United States law for private information.

Hair Collection and Blood Drawing Risks:
If you are taking HIV prevention medicines like PrEP or PEP, a small hair samples may be collected (about 50-100 strands – the amount naturally lost each day). The hair sample will be collected from the back of the scalp using a clean pair of scissors in a process that takes 90 seconds. There is a potential but low risk of cutting the skin with the scissors. If you are suspected to have recently been exposed to HIV, a blood sample may be drawn by study staff to detect any HIV virus that may be in the blood. Taking blood may cause brief discomfort and bruising. Infection or fainting can happen but are rare.

Randomization Risks:
You will be assigned by chance to either receive the enhanced services for PrEP and PEP programs or to continue standard care, and the group to which you are assigned may prove to be less effective or have fewer benefits than the other group. No matter which group you are assigned to, PrEP and PEP medications will be provided through the Ministry of Health program.

ARE THERE BENEFITS TO TAKING PART IN THIS STUDY?

There may be no direct benefit to you. The enhanced measures to improve PrEP and PEP delivery, if you are assigned to the group that receives it, may help you stay on medications or receive care, but this cannot be guaranteed. Your participation in the study may benefit the community, scientists and doctors who work on providing HIV care in health centers such as yours.

WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?

There will be no cost for you to take part in this study.

WILL I BE PAID FOR TAKING PART IN THIS STUDY?

You will not be paid for taking part in this study.

HOW WILL MY INFORMATION BE USED?

Researchers will use information to conduct this study. Once the study is done using your information, we may share them with other researchers so they can use them for other studies in the future. We will not share your name or any other personal information that would let the researchers know who you are. We will not ask you for additional permission to share this de-identified information.

WILL INFORMATION ABOUT ME BE KEPT PRIVATE?

Care will be taken to protect your privacy. Study participants will be identified only by their unique code number on all study documents except those kept for contact information. All information will be handled in compliance with Uganda and U.S. law for confidential information. The Makerere School of Medicine Research Ethics Committee (SOMREC) and Uganda National Council for Science and Technology (UNCST), which are institutions that oversee human research, may have access to study information that may have your name. In addition, authorized representatives from the National Institutes of Health and University of California may review your research data for the purpose of monitoring or managing the conduct of the study. Besides these institutions, the universities and research organizations running this study are not allowed to let others know the identity of the people in the study.

WHAT ARE MY RIGHTS IF I TAKE PART IN THIS STUDY?

Participating in this study is voluntary. You do not have to take part if you do not want to. If you choose not to take part, there will be no penalty or loss of health care that you usually receive.

We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

WHO CAN ANSWER MY QUESTIONS ABOUT THE STUDY?

If you have any questions about this study, including those about research-related harm, please contact the lead investigator in Uganda, Dr. Moses Kamya, at 031-2-281479/0752900012. You may also contact Assoc. Prof Ponsiano Ocama, the chair of the Makerere University School of Medicine - Research and Ethics Committee in Uganda at 077-2-421190, which approved this study, for questions about participants' rights and research-related harm.

In addition, a description of this study will be available on http://www.ClinicalTrials.gov. This website will not include information that can identify you. After the study is over, this website will include a summary of its results.

CONSENT: WHAT YOUR SIGNATURE OR THUMBPRINT MEANS

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to participate or to withdraw from participation at any point in this study without penalty or loss of benefits to which you are otherwise entitled. A copy of this consent form will be given to you. Your signature or thumbprint below means that you have had this study explained to you. Your signature or thumbprint below means you have had the opportunity to ask questions and get answers. If you wish to participate in this study, you should sign or place your thumbprint below.

Name of Participant (printed)

Signature or Fingerprint* of Participant Date

Name of Parent/Guardian (for Participants 15-17 years old)

Parent/Guardian Signature or Fingerprint* Date

Name of Study Staff Administering Consent (printed) Position/Title

Signature of Study Staff Administering Consent Date

Name of Translator (if necessary)

Signature of Translator Date

*If the participant is unable to read and/or write, an impartial witness must be present during the consent discussion. After the written informed consent form is read and explained to the participant, and after he or she has orally consented participate in this study, and has either signed the consent form or provided his or her fingerprint, the witness must sign and personally date the consent form. By signing the consent form, the witness attests that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the participant, and that consent was freely given.

Name of Person Witnessing Consent (printed)

Signature of Person Witnessing Consent Date