Consent Form for Male Partners

Alignment of PrEP use with HIV risk in young women and men

The Align Study

Consent Version 1.0
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INFORMED CONSENT

We are asking you to volunteer for a research study. This study is for men who are partners of women in the Kampala Women's Bone study (KWBS), which is another study we are running at this site. In this study, we will provide STI testing and treatment, including testing for HIV. If you are HIV-negative, we will counsel you about HIV prevention and offer you pre-exposure prophylaxis, or PrEP. Before you decide whether to take part in the study, we would like to explain the purpose of the study, the risks and benefits, and what would be expected of you if you join the study. This study is sponsored by the University of Washington and the National Institutes of Child Health and Human Development, which are located in the USA, in partnership with Makerere University in Uganda. The study has been approved by the Mildmay Uganda Research Ethics Committee.

If you decide to continue in the research study, you will be asked to sign this consent form or make your mark in front of a witness. We will give you a copy of this form. This consent form might contain some words that are unfamiliar to you. Please ask us to explain anything you may not understand.

PURPOSE OF THE STUDY

Research has shown that a medication taken every day can be used to prevent men and women from getting new HIV infections – a concept called pre-exposure prophylaxis or PrEP. The term PrEP means to have protection against HIV before exposures occur. The purpose of this study is to understand how women and men decide to take PrEP based on their risk of getting HIV. Your chances of getting HIV can be based on your behavior and test results, and the behavior and test results of your sexual partners. We would like to better understand if men and women decide to use PrEP well when their chance of getting HIV is higher.

In this study we will provide testing and treatment for some sexually transmitted infections (STIs) including HIV. If you test positive for any, we will provide you with treatment or refer you to a clinic of your choice. If you test negative for HIV, we will offer you PrEP. You do not have to initiate PrEP if you do not wish to.

If you choose to enroll in this study, you will be given a unique study ID that will be kept confidential. To help us understand your risk, we will link your study ID to your partners study ID. This anonymous link will be password protected in our study's computer system. Your information will be kept confidential and we will not tell your partner about your STI or HIV test results unless you would like us to do so.

Approximately 200 men will be enrolled in this study at this clinic. Each man will be in the study for up to 6 months.

YOUR PARTICIPATION IS VOLUNTARY

This consent form gives information about the study that we will discuss with you. Once you understand the study, and if you agree to take part, we will ask you to sign your name or make your mark on this form. We will offer you a copy to keep.

Before you learn about the study procedures, it is important that you know the following:

- You do not have to join this study if you do not want to.
- You may decide not to take part in the study, or to withdraw from the study at any time, without losing your regular medical care.
- If you decide not to take part in this study, you can still join another research study later, if one is available and you qualify.
- You may be asked about joining other studies. Due to the time commitment from being in this study, you may not be eligible to join this study if you are in other studies. If you do not agree to join these other studies, you may still take part in this study.

STUDY PROCEDURES

If you decide to take part in the study, your first visit will continue today after you read, discuss, and sign or make your mark on this form. At study visits, several things will happen:

- You will be asked questions about your medical history and sexual behavior.
- You will undergo testing for some STIs, like gonorrhea and chlamydia, and be provided with your results as quickly as possible. If you are positive for any STIs, we will provide you with treatment according to Uganda national guidelines.
- You will be tested for HIV using a rapid kit. If you test positive, we will refer you to treatment and care. If you test negative, we will offer you PrEP. If you would like to take PrEP, we will provide counseling on how to take PrEP every day.
- If you decide to take PrEP, we will ask your permission to obtain a blood sample (up to 35 ml/about 3 tablespoons] so we can check for your kidneys for their health. We will test you again about 6 months after you start using PrEP. If at any time you have an abnormal result, we will contact you so that you will know and schedule you to return for another visit to recheck the result and evaluate you.

- If you decide to take PrEP, the pharmacy staff will provide you with new bottles of pills to last until your next visit. You will be asked to answer questions about the pills you took during the previous month and be counseled about methods for not forgetting to take your pills during the following month. Please bring bottles with you to each clinic visit.
- If we find that you have any STIs, including HIV, study counselors will talk with you about ways that you could tell your sex partners about these results. Counselors will be able to assist you to tell you partners according to your wishes. If you do not wish to tell your partners about your results, you can continue to be in this study and receive care at this clinic.

After today's visit, we will schedule you to have study follow-up visits in one month, two months later, then three months after that. Each visit will take about 60 minutes at this clinic. If you are unable to come to the research clinic for a study visit, we can do the visit procedures away from the research clinic, at your home or a more convenient location, if you agree to that.

HIV INFECTION

If you have a positive HIV test during the study:

- The study staff will talk with you about this test result and what this means for you. We will complete confirmatory testing according to national guidelines of Uganda.
- If you were previously taking the PrEP medication you will be asked to stop taking the medication and we will refer you to treatment.

IMPORTANCE OF NOT SHARING PrEP MEDICATION

It is very important that you do not share PrEP medication with partners or with anyone else. The medications contained in PrEP are used to treat HIV infection, but they are only effective as HIV treatment if they are used in combination with other medications. Thus, PrEP by itself is only for HIV-negative people and it should be accompanied by regular HIV testing and adherence counseling.

RISKS AND/OR DISCOMFORTS

You may feel discomfort or pain when your finger is pricked for the HIV rapid test. You may feel dizzy or faint. You may have a bruise where the needle goes into your arm if we need to collect blood from your arm.

You may become embarrassed, worried, or anxious when talking about your sexual practices, ways to protect against HIV and other infections passed during sex, and your HIV test results. You may become worried or anxious while waiting for your test results. If you find out that you have HIV, you could become worried or anxious. Talking about HIV and finding out your test results could cause problems between you and your partners, family, or community. Trained counselors will help you deal with any feelings or questions you may have.

The study staff will make every effort to protect your privacy and confidentiality while you are having the study procedures. However, it is possible that others may learn of your participation here and, because of this, may treat you unfairly or discriminate against you. For example, you could have problems getting or keeping a job, or being accepted by your family or community.

You may have symptoms or adverse effects while participating in the study. These symptoms or adverse effects may be due to participation in the study or due to illnesses that have no relation to the study, like a cold or flu. All persons who participate in this study will be watched carefully to monitor their health. You should tell the doctor of the study clinic about any symptoms that you feel while you are participating in the study. You will be given a telephone number where a study clinician will be available 24 hours a day, 7 days a week. You should call this number if you experience any serious symptoms.

Risks potentially related to the PrEP medication

The adverse effects that can occur in a small proportion of people taking PrEP are well known because the medication has been used by many people. Some mild adverse effects are expected to occur in up to 1 in 10 persons who take PrEP. Other adverse effects are more serious but are expected to occur in less than 1 in 100 persons who take PrEP. Occasional adverse effects include: mild problems of kidney function that are only detected by laboratory tests; lack of energy/fatigue; upset stomach, vomiting, soft or liquid stools; dizziness. Rare adverse effects include: rash; liver function problems; serious kidney damage; allergic reaction. Small changes in the mineral density of bones were observed in studies of people who were given PrEP, but the changes in the mineral density of the bones did not cause any fractures, or other problems that bothered the patients. Lactic acidosis has occurred in HIV-infected persons taking the medicine used as PrEP, in combination with other drugs. Lactic acidosis is a condition that can produce shortness of breath, nausea, and liver failure. This is a serious adverse effect of some medications used for HIV infection. **You should call or come to the study clinic if you have unexplained increased or decreased urination, weight loss, cramps, muscle pain, dizziness, excessive fatigue, nausea, vomiting, or shortness of breath. If you have these symptoms, or any other symptoms that concern you, the study staff will evaluate your symptoms and determine whether you should stop your PrEP pills.**

Other medications

Risk of acquiring HIV infection and drug resistance

You may become infected with HIV during this study from your sexual partner(s). Study counselors will talk with you about all the HIV prevention options that are available to you to prevent HIV, like using condoms and keeping your number of sexual partners low. You could become infected with a strain of the HIV virus that could be resistant to PrEP or other medications used for HIV treatment. Resistance to antiretroviral medications may make effective HIV treatment more difficult and may limit your treatment options. You will be able to discuss treatment and the generation of resistance to medications with the study doctor.

If you have concerns about being part of this study, you can ask the study doctor.

BENEFITS

You may or may not get direct benefit from being in this study. You or others may benefit in the future from information learned in this study. You also may get some personal satisfaction from being part of research on HIV. You will also get counseling services, free condoms, testing and treatment for STIs and PrEP.

NEW FINDINGS

You will be told any new information learned during this study that is important for your health or might cause you to change your mind about staying in the study. You will be told when the results of the study may be available, and how to learn about them.

COSTS TO YOU

There is no cost to you for being in this study. Treatments available to you from the study will be given free of charge.

REASONS WHY YOU MAY BE WITHDRAWN FROM THE STUDY

You may be removed from the study without your consent for the following reasons:

- The study is stopped or canceled.
- The study staff feel that staying in the study would be harmful to you.

ALTERNATIVES TO PARTICIPATION

There may be other studies going on here or in the community that you may be eligible for. If you wish, we will tell you about other studies that we know about. There also may be other places where you can go for HIV counseling and testing. We will tell you about those places if you wish. If you do not wish to be involved in the study, we will refer you to another clinic where you may be able to access PrEP without participating in this study.

REIMBURSEMENT

You will receive Shs 30,000 (fifty thousand shillings) at each scheduled visit for time, inconveniences and transport costs.

DATA USE FOR FUTURE STUDIES

The information and/or specimens that we obtain from you for this study might be used for future studies. If we do so, we will remove anything that might identify you from the information and specimens. Then, your information and specimens may be used for future research studies or given to another investigator without getting additional permission from you. It is also possible that in the future we may want to use or share study information that might identify you. If we do, a review board will decide whether or not we need to get additional permission from you.

CONFIDENTIALITY

Efforts will be made to keep your personal information confidential. However, absolute confidentiality cannot be guaranteed. Your personal information may be disclosed if required by law. Any sample from you or information about you will be identified only by code. The link between your name and code will be kept in a secure location at the study clinic only. Using a computer, we will link your information and your partner's information using only the codes that you have been assigned. We will not discuss any information about you with your partner unless you give written permission, and we will encourage you to be present during the discussion. Any publication of this study will not use your name or identify you personally.

Your study records may be reviewed by study staff and representatives of:

- The Mildmay Uganda Research Ethics Committee
- The Uganda National Council for Science and Technology
- The Uganda National Drug Authority
- Uganda Ministry of Health
- The University of Washington
- The United States National Institutes of Health

RESEARCH-RELATED INJURY

The study staff will monitor your health while you are in this study. If you have any health problems between visits, please contact the study staff. If you have a medical emergency that requires immediate care, please contact the study staff immediately on telephone number 0392-265 883/4/5 and quickly go to the nearest regional government hospital.

If you are injured from participating in this study, the study staff will give you immediate necessary treatment for your injuries until complete cure or stabilization. If you require medical care that the study clinic cannot provide, the study doctors will refer you to the appropriate services or organizations that can provide care for the injury, and care for you until the injury resolves. Study participants who experience research related injury are covered by this study. This study based at IDI will cover the costs of the referral and treatment costs up to the time you are stable, or injury is resolved. There is no program for monetary compensation. You do not give up any legal rights by signing this consent form.

PROBLEMS OR QUESTIONS

If you ever have any questions about this study, or if you have a research-related injury, you should contact Dr. Andrew Mujugira, Infectious Diseases Institute, Kampala, Uganda on telephone number +256 392 265 887.

If you have questions about your rights as a research participant, you should contact the chairperson of Mildmay Uganda Research Ethics Committee, Ms. Harriet Chemusto or the office of this committee at Research Office, Kiddukiro House, Mildmay Uganda, Telephone: 0392-174236.

STATEMENT OF CONSENT AND SIGNATURES

I have read this form, or had it read to me. I have discussed the information with study staff. My questions have been answered. I understand that my decision whether or not to take part in the study is voluntary. I understand that if I decide to join the study I may withdraw at any time. By signing this form, I do not give up any rights that I have as a research participant.

Participant Name (print)	Participant Signature/Thumbprint	Date
Study Staff Conducting Consent (print)	Study Staff Signature	Date
Witness name (print)	Witness signature	Date

PERMISSION FOR FUTURE CONTACT REGARDING OTHER STUDIES:

_____ I give permission for the study team to contact me in the future about other studies

_____ I do NOT give permission for the study team to contact me in the future about other studies

PERMISSION FOR OFF-SITE STUDY VISITS

In case you have missed study visits and all efforts to get you via telephone or through other contact you have fail, study staff may visit you at your home. In addition, if you are unable to come to the study clinic to complete scheduled visit activities it may be necessary for study staff to visit you at your home or another location to complete study visit procedures. The study personnel will explain in great detail the requirements to do these visits (like the conditions of the place, the type of visit and the duration of it) and the procedures to maintain your information in a confidential manner. However, it is important that you know that visits to your home could lead to people in your neighborhood knowing about your participation in this study.

For us to be able to visit you, we will need you to give us permission to do so, please read carefully the following statement and initial and date one option. Choosing not to be visited outside of the study clinic will not affect your participant in this study.

Please initial and date one option:

_____ I DO give permission for the study team to conduct off-site study visits if I am unable to come into the research clinic

_____ I do NOT give permission for the study team to conduct off-site study visits if I am unable to come into the research clinic