Strategic Antiretroviral Therapy and HIV Testing for Youth in Rural Africa

The SEARCH Youth Study

Intervention Arm Main Informed Consent Form – Uganda sites

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SEARCH Youth Intervention Clinics Informed Consent Form

Project Title:	Strategic Antiretroviral Therapy and HIV Testing for Youth in Rural Africa
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INTRODUCTION:

You are being asked to participate in this study because you are receiving care for HIV, the virus that causes AIDS, at a health center involved with the study. This is a study of ways to improve care and treatment among young people who are infected with the HIV virus. This study is being done by researchers from Makerere University (MU), the Infectious Diseases Research Collaboration (IDRC), the Kenya Medical Research Institute and the University of California, San Francisco (UCSF). The U.S. National Institute of Child Health and Human Development (NICHD) 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 HIV care to adolescents and young adults can be difficult for doctors, nurses, hospitals and local governments. The challenges young people face are different than those of older adults and can make it hard for many with HIV to stay in care and take medications. This study will introduce a set of health care measures, including a review of major life events, more choice in clinic visiting times, and quick HIV viral load test results, to see if they improve care among young people such as yourself. An HIV viral load (VL) measures the amount of virus in the blood.

Your clinic was chosen through a randomization process (by chance, like the flip of a coin) to receive these additional health care measures. The study will take place in 14 health centers in Southwestern Uganda and 14 health centers in Western Kenya. We plan to enroll about 2000 patients into the study, or roughly 50-100 in each health center.

WHAT WILL HAPPEN IF I TAKE PART IN THIS STUDY?

Enrollment in the Study

After signing this consent form, you will be asked to give us a mobile phone number where we can reach you to provide test results, counseling, and check in with you by phone. We will also ask for

your home location in case we need to contact you in person. The consent discussion and brief questions will take up to 1 hour.

Study Visits

a) At the first study visit, the following will occur:

- Study staff will ask you questions about your school or work, your current relationships and living arrangements, lifestyle choices, and any major life events experienced recently. These questions will help us understand more about your daily life and any barriers you may have to continuing HIV care. Staff may provide additional counseling or suggest an appointment with other providers, depending on the discussion.
- Staff will discuss with you your preferences for appointment times. You will be given the choice of future visits during routine clinic hours or after hours, and will have the option of phone call visits in between clinic visits and in some cases may be offered to have visits done outside the clinic.
- Staff will collect about a teaspoon of blood from your arm for VL testing through the study. This sample will be labeled with a unique code number and sent to a study laboratory for immediate testing.
- Once the VL results are available, usually within 1-5 days, staff will call you or visit you in person to discuss your results, provide counseling and, if needed, schedule a follow-up visit for further discussion and repeat testing. If you do not have access to a phone, staff may also schedule a visit for you to return to the clinic to receive the results.

b) At visits every 3 months:

- As at the initial study visit, staff will ask you questions about your school or work, current relationships, major life events and other issues that affect your daily life.
- These discussions may be done in person or over the phone, and could happen more often than every 3 months, depending on your care visit schedule.

c) At visits every 6 months:

- Staff will collect about a teaspoon of blood from your arm for VL testing through the study. Once the VL results are available, in 5 days or less, staff will contact you to discuss your results, provide counseling and, if needed, schedule a follow-up visit for further discussion and repeat testing.

d) At visits at least once a year:

- Study staff will discuss with you your preferences for appointment times. You will be given the choice of future visits during routine clinic hours or after hours, and will have the option of phone call visits in between clinic visits and in some cases may be offered to have visits done outside the clinic. These preferences can be discussed more often than once a year, depending on any changes in your life outside the clinic.

e) In some cases, your study provider may discuss your test results or other information about your care with other research staff or investigators using the WhatsApp messaging service, as a way to help improve your care. No personal information will be used in these discussions that could identify you.

f) You may be asked to return to the health center before your next regular visit, which may include a VL test. Staff will collect about a teaspoon of blood for any additional testing.

g) We will review parts of your medical record to collect information on visit dates, VL results, HIV medications and other topics. If you are a current or past participant in the SEARCH study, we may also review and obtain data that had been collected in the course of SEARCH study activities for use in this study.

h) You may also be asked to complete a brief survey on your satisfaction with the care you receive at this clinic.

These visits will take from 30 minutes to 1 hour. The study will last about 2-3 years.

CAN I STOP BEING IN THE STUDY?

You may decide to stop being in the study at any time and for any reason.

WHAT RISKS CAN I EXPECT FROM BEING IN THE STUDY?

Confidentiality:
Some of the discussion during study visits may make you feel uncomfortable or raise unpleasant memories. You are free to skip any question or topic.

We will do our best to protect the information we collect from you. 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. Study-specific information will be stored in locked files, and only a small number of study staff will have access to it. Your test results and other information that could relate to your engagement in care may be discussed with clinicians via the WhatsApp messaging service, but your name, location or other identifiers will not be used in the text messages. 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.

To advance science, it is helpful for researchers to share information they get from research studies such as this one. This shared information is combined from many studies to learn even more about health and disease. Access to this shared information is limited to researchers who receive approval from an oversight committee. If you agree to take part in this study, some of your health information will be placed into one or more scientific databases, so that it may be used for future research on any topic and shared for research purposes. This information will be anonymous and will not include any details that could identify you, such as name, address or phone number.

Blood Drawing Risks:
Taking blood may cause brief discomfort and bruising. Infection or fainting can happen but are rare.

ARE THERE BENEFITS TO TAKING PART IN THIS STUDY?

There may be no direct benefit to you. Discussions with study staff on issues that affect your health care and faster feedback on VL test results may help you stay in care and take your medications, 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. If you are injured as a result of taking part in this study, you will not have to pay for care for study-related injuries. If you are injured, please contact the study staff.

WILL I BE PAID FOR TAKING PART IN THIS STUDY?

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

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. Any discussions on the WhatsApp messaging system will not contain information that could identify you and the data will be encrypted. 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 (NIH) 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.

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 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