MRC/UVRI UGANDA RESEARCH UNIT ON AIDS - MASAKA
PROTOCOL B OPEN COHORT STUDY

INFORMED CONSENT FOR SCREENING/ENROLLMENT INTO THE MAIN STUDY (IAVI OPEN B COHORT)

Title: A Prospective, Open cohort, Observational Study to Determine HIV incidence in Preparation for future Preventive HIV Vaccine Clinical Trials

Reason for this Study

Over 40 million people worldwide are infected with human immunodeficiency virus (HIV), the virus that causes AIDS. New people are being infected every day. Many experts believe that a HIV vaccine may help prevent HIV infection or keep people healthier for longer even if they become infected. Right now there is no vaccine that does this.

This research study aims to find how many people will become infected with HIV while they are receiving regular HIV counseling to reduce their risks for becoming infected and testing for HIV.

Background

The International AIDS Vaccine Initiative (IAVI), the Sponsor of this study, is an international, scientific, non-profit organization, whose mission it is to ensure the development of a safe and effective, preventive vaccine against HIV and to make sure that if such a vaccine is found, those who need it most will get it. The study will also help the MRC/UVRI Uganda Research Unit on AIDS and IAVI to prepare for the testing of HIV vaccines in the future. However, this study does not involve an HIV vaccine.

This document provides information about the study for you. If you wish, it can also be read to you. You may bring a person with you to help you understand the study and to witness that you understand and agree with participating in the study. One copy of this document will be given to you and one will be kept at the MRC/UVRI Uganda Research Unit on AIDS Masaka clinic in a safe and secure place. If you do not wish to keep your copy, it will be kept at this site for you.

Your participation is of your own free will. You may decide to stop being part of the study at any time. You will not lose any rights or benefits you normally have if you do not join the study or if you leave the study.

Study Volunteers

This study will enroll up to 400 male and female volunteers 18 – 49 years old, who qualify for the study and who agree to be in the study.

Duration of the Study

If you join this study, you will have at least 5 scheduled study visits at this research center for up to 12 months. At your last scheduled study visit you may be asked to continue in the study, and the decision to continue with the study at that time will be up to you and the study team.

WHAT WILL HAPPEN IN THE STUDY

If you decide to join this study, after you read, discuss and sign or mark this form, this is what will happen:

Study screening and enrolment:

- At the first visit, study staff will assess your eligibility for the study. You will be asked questions such as your age and how you learned about the study. You will also be asked questions about behaviors that may increase your chance of catching HIV. If you refuse or fail to join the study, reasons for this will be documented.

- About ½ table spoon of blood will be drawn from a vein in your arm.

- Your blood will be tested for HIV. In most cases you will receive the result on the same day in less than one hour. Occasionally the blood will have to be sent for a second test and you should receive the result in 1-2 weeks. If your test results are still not clear, you will be asked to return and be tested again.

- If your test results show that you are not infected with HIV, you may be eligible to enroll into this study.

If your test results show that you are infected with HIV at screening:

- You will be given counseling on HIV, what this means for sexual partner or partners and family members, and how to avoid giving HIV to others in future. If you wish, your partner and/or family members can have counseling with you.

- You will be asked about your health. An examination may be done to find out if you have any medical problems. You may be asked about any illnesses you have had in the past three months.

- Your blood may be tested to find out what your blood counts are, how your liver and kidneys are functioning and your CD4 count. For these tests an additional ½ table spoon of blood will be requested from you. These results will be provided to you so that you can discuss them with your doctor.

- You will be referred for additional care if necessary. If you are a woman infected with HIV and you are pregnant, you will be referred to care for you and your baby and to the "Prevention of Mother to Child Transmission" (PMTCT) program where you may get medicines that can help prevent your baby from getting HIV.

If you enroll in this study:

- Study staff will ask you where you live and how to contact you. If you move, you will be asked to update this information. The staff may use this information to remind you of study visits. If you miss a visit, the study staff will try to contact you by telephone if you have access to one or by visiting your home or place of work if you permit it. They will try to contact you through the people whose names you have provided. If they talk to these people they will not tell them why they are trying to reach you. You will be asked about your health and you will also have a full medical examination.

- You will be asked some questions about behaviors that may increase your chance of catching HIV. Study staff will explain the questions to you so that you can understand them better.

- A hypothetical HIV vaccine trial will be described to you and you will be asked questions about your willingness to participate in such a trial. This will be done at study entry or at the month 3 or 6 visits. At each follow up visit, about ½ tablespoon of blood will be drawn from your arm.

- Your blood will be tested for HIV and the rest will be stored for additional studies. In most cases you will receive the result on the same day in less than one hour. Occasionally the blood will have to be sent for a second test and you should receive the result in 1-2 weeks. If your test results are still not clear, you will be asked to return and be tested again. If your test results show that you are not infected with HIV, you will be told when to return for the first follow up visit.

- There is a small chance that even if your test says you do not have HIV, you may be in the very early period of HIV infection. This period can last up to three months after you have become infected HIV.

- You will be asked about your health. An examination may be done to find out if you have any medical problems. You may be asked about any illnesses you have had in the past three months.

- You are encouraged to come to the clinic anytime you have an STI or have a fever that is not malaria or other common infection as soon as possible so that you can be tested for HIV.

- At the first and one year visits (and if you ever get a sexually transmitted disease (STI), your blood will be tested for syphilis. You will get the test results as soon as they are available. You will receive treatment if you need it, or you will be referred for care.

If your tests results show that you have HIV infection at a follow up visit:

- You will be given counseling on HIV, what this means for your sexual partner or partners and family members, and how to avoid giving HIV to others in future. If you wish, your partner and/or family members can have counseling with you.

- You will be asked questions about how and when you think you may have become infected with HIV.

- About ½ tablespoon of blood will be collected. The blood will be tested to find out what your blood counts are, how your liver and kidneys are functioning and your CD4 cell count. These results will be provided to you so that you can discuss them with your doctor.

- If you are a woman infected with HIV and you are pregnant, you will be referred to care for you and your baby and to the "Prevention of Mother To Child Transmission" (PMTCT) program where you may get medicines that can help prevent your baby from getting HIV.

Storing your Blood (for enrolled volunteers)

Your blood that is stored will only have a number on it and not your name so that no one, other than study staff will know who you are. Your blood may be stored for up to 10 years.

Your stored blood will be used to check that tests in the laboratory are done with very high standards. With the approval of the Ethics Committee, some of your stored blood may be sent to other expert research laboratories, for special research testing related to HIV, or for other diseases or germs common in the area where you live. If you get HIV during the study, some of your stored blood may be tested for HIV using special tests. No other tests will be done without the permission from the Ethics Committee. You will not get the results of these tests as they are research tests

Risks and/or Distress

Taking blood from the arm causes pain. Sometimes bruising can occur where the needle goes into your arm. You may feel dizzy or faint, but this is not common.

You may become embarrassed, worried, or anxious when discussing sex, ways to protect against HIV and your test results. You may become worried or anxious while waiting for your HIV test results. A trained counselor will help you with any feelings or questions you may have.

We will protect your privacy during and after the study. However, it is possible that others may learn of you being in the study and think you have caught HIV. This may lead to stigma and problems, like having trouble getting or keeping a job, or even not being accepted by your family or community. The studies at this site enroll all kinds of people. Some have HIV and some do not. This may decrease the chance of people knowing about your health.

Benefits

You may benefit by being in the study. You will receive regular counseling and medical examinations. As part of counseling, you will be given information about how to reduce your risk of becoming infected with HIV and you will receive regular HIV testing. If you wish, your partner and/or family members can have counseling with you.

If you become infected with HIV during the study, tests will be done on your blood, to find out about your general health, and your CD4 counts. These results will be very helpful to you and your doctor for your care. You will also be referred for counseling and care for HIV. You or others may benefit in the future from information learned in this study. You may get some satisfaction from being part of research on HIV. If you are a woman, and you become pregnant and catch HIV, you will be referred for prenatal care and to the Prevention of Mother To Child Transmission of HIV program.

If you have any medical problems that need treatment that is not available at the clinic, we will refer you to another clinic or hospital. This study will not cover costs for care at the place of referral.

You will also learn about HIV infection, HIV vaccines and research during the study.

Injuries

We do not expect you to suffer any injury as a result of participating in this study, but if you do, the MRC/UVRI Uganda Research Unit on AIDS will give you the necessary treatment for your injuries without charge. You will be told where you can get additional treatment for your injuries. There is no program for monetary compensation or other forms of compensation for such injuries. You do not give up any legal rights by signing this consent form.

Taking you out of the Study

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

- You are not able to or do not attend study visits or complete the study visits
- If the study is stopped
- You do not want to have HIV testing or receive your HIV test results
- Other reasons in the judgment of the investigator

What happens if you do not join the study?

There may be other HIV studies going on that you may join. If you wish, we will tell you about the 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 choose not to join this study, this will not affect the care you get at other places.

New information

You will be told about any important new information during the study. You will be told when the results of the study may be available, and how to learn about them.

Supervision of the study

The conduct of the study will be supervised by the Principal Investigator. All study information will be regularly checked by independent monitors and experts who are not part of the study. The study will also get approval of the Ethics Committee before the study starts; this committee will also be informed when any big changes are made to the study.

Costs to You

There is no cost to you for being in the study. You will receive 5000 Ush for each study visit you complete. This payment is to cover the time spent in the clinic. You will also receive money to cover your transport expenses to and from the clinic for each study visit according to the prevailing transport rates.

Confidentiality

Being in the study, all information collected about you, your blood and results of all tests will be identified by a special number and not your name. All papers containing your name will be locked away safely and will only be available to the study staff. Apart from the study staff that you meet, others from National or international government bodies that ensure correct conduct of research, members of the Ethics Committee, study monitors, auditors, Government or regulatory inspectors, and representatives of the Sponsor (IAVI) will check the study papers to make sure that the study was conducted properly. They all have to keep your information private and safe.

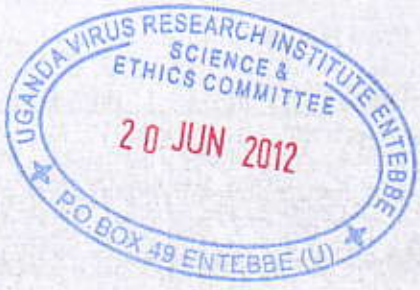
Contact Numbers

If you have any questions about the study, you can call Dr. Anatoli Kamali, the Principal Investigator at 04814 21211.

If you have a medical problem related to the study procedures received during HIV testing, please contact Dr Freddie Kibengo, Dr. Ubaldo Bahemuka or Dr. Eugene Ruzagira on Tel: 04814 21211 at the MRC/UVRI Uganda Research Unit clinic on Plot 2-5 Ntikko Road, Masaka town.

Nurse/Counselors are available at the MRC/UVRI Uganda Research Unit clinic on Plot 2-5 Ntikko Road, Masaka town and can be reached on Tel: 04814 21211.

If you have a question about your rights as a research subject you should contact Mr. Tom Lutalo, the Chairman of the Uganda Virus Research Institute Science and Ethics Committee (UVRI SE) on Tel:0414 320776 at the UVRI, Entebbe.



MRC/UVRI UGANDA RESEARCH UNIT ON AIDS - MASAKA

INFORMED CONSENT DOCUMENT

OPEN COHORT

I, (name of volunteer).....

Of (address) .....

AGREE TO TAKE PART IN THE RESEARCH PROJECT ENTITLED: A PROSPECTIVE, OPEN COHORT, OBSERVATIONAL STUDY TO DETERMINE HIV INCIDENCE IN PREPARATION FOR FUTURE PREVENTIVE HIV VACCINE CLINICAL TRIALS

I have been told in detail about all the procedures in the study and know what is required of me. I understand and accept the requirements. I understand that I am taking part in the study freely and that I can stop being part of this study at any time and for any reason. If I stop taking part, the legal rights that I have will not be affected.

□ By ticking this box, **I agree** that my specimens may be stored and sent to other expert laboratories for possible future testing to help in research for AIDS vaccines. No additional tests will be performed without the approval of the Ethics Committee.

□ By ticking this box, **I do not agree** that my specimens may be stored and sent to other expert laboratories for possible future testing to help in research for AIDS vaccines.

Volunteer:

Signature/Thumb Print: .....

Date: |__|__|/|__|__|__|/|__|__|__|__|Time: |__|__|: |__|__| (24 hours)

Person Obtaining Consent:

I have explained the nature, demands and foreseeable risks of the above study to the volunteer:

Print Name:..... Signature:.....

Date: |__|__|/|__|__|__|/|__|__|__|__|Time: |__|__|: |__|__| (24 hours)

Witness: (if volunteer was not able to read and understand the Consent Information Sheet and Informed Consent Document)

I affirm that the Informed Consent Document has been read to the volunteer, and he/she understands the study and I have witnessed the volunteer's consent to study participation.

Print Name:..... Signature:.....

Date: |__|__|/|__|__|__|/|__|__|__|__|Time: |__|__|: |__|__| (24 hours)