1CONSENT FORM

RAKAI COMMUNITY COHORT STUDY (RCCS)

Includes information on studies of circumcision and of ARVs, which are nested in the RCCS..

Project Title: Rakai Cohort Surveillance Study

Principal Investigators:
Ugandan Principal Investigators:

Hello, my name is _____. I work for the Rakai Health Sciences Program (formerly the Rakai Project), a collaboration between the Uganda Ministry of Health through the Uganda Virus Research Institute, Entebbe; and researchers from Makerere University, Kampala; Columbia University and Johns Hopkins University in the United States.
I would like to invite you to participate in a study of the health of people in Rakai, including a study of the virus that causes AIDS. The study is called the Rakai Community Cohort Study (RCCS).

BACKGROUND:
The acquired immunodeficiency syndrome (AIDS) is a sickness in which the body is unable to protect itself from germs because the Human Immunodeficiency Virus (HIV) has destroyed the body's protective system, known as the "immune system".. We know that HIV can be spread by having sex with people who are infected with HIV, by sharing needles, by getting an injection with a needle which has not been properly cleaned, or by a mother with HIV passing the virus to her baby during pregnancy or breastfeeding. HIV is a serious health problem in Rakai. Other infections and conditions, such as TB, malaria and STDs are also common and cause many health problems in Rakai, and can be particularly serious in persons with HIV. By studying these infections and conditions, including how they are transmitted, and how the body tries to protect itself from these conditions, we hope to provide information which will result in better ways to prevent and treat such health problems, in the general population and in groups such as pregnant women, infants and children. Problems related to pregnancy, in mothers, unborn babies, infants and children also cause serious problems in Rakai, and studying such problems may also lead to better services and prevention.

OBJECTIVES AND PLAN OF THE STUDY
The RCCS is being carried out by the Rakai Health Science Program . The Rakai Program has worked in the district for over 17 years. The study involves researchers from the Ugandan Ministry of Health through Uganda Virus Research Institute in Entebbe, Makerere University, Kampala, Columbia University and Johns Hopkins Universities in the United States of America.

The purpose of the RCCS is to study HIV; other infections such as STDs, malaria and TB; and reproductive health including pregnancy, which affect health in Rakai. We will also assess behaviors and other factors which may affect reproductive health and the risk of acquiring or transmitting HIV and other infections. The RCCS has been ongoing for over 10 years. We plan to continue the RCCS for at least 5 more years , and to continue enrolling and following all consenting residents aged 15-49 years as well as infants and young children, living in up to 60 communities in Rakai.

Within the RCCS, we are also including a number of other, related studies.

1. The Rakai Program is starting a new study to assess the effects of providing HIV antiretroviral (ARV) drugs. The study, called "ARV effects on HIV epidemiology and behaviors" will be conducted mainly through the annual surveys of the RCCS. The assessment will include HIV+ persons whether or not they are on ARVs, as well as HIV-negative people. Study goals include finding out what HIV+ and HIV-negative people know and think about ARVs; whether the availability of ARVs influences behaviors including acceptance of HIV voluntary testing and counseling; whether eligible persons accept ARVs and use them correctly; and what the effects of ARVs are on the spread of HIV, on health in HIV+ persons, and on families. As part of the ARV study, we will also identify pregnant women (both HIV+ and HIV-negative): the pregnant women will be invited to participate in an additional study of mothers' and infants' health. Pregnant women will be provided additional information and a separate consent for the mother/infant study.

2. Rakai Program is also also conducting a study to determine whether male circumcision affects the risks of HIV and STDs in men and women. Men living in about 50-60 villages are being invited to participate in this circumcision study, which has a separate procedure for male consent and enrolment.

   However, during the Rakai Community Cohort Study visits, we will ask all men, whether or not they are in the separate circumcision study, if they have been circumcised and when they underwent the procedure, and we will also ask women whether their partners have been circumcised. We will ask everyone about attitudes towards circumcision.

The samples you provide during RCCS will be used to examine whether HIV and STD rates change in individuals and the community after male circumcision and ARVs becomes available through the Rakai Project study or other sources. (Please note: we do not know if male circumcision will reduce the risk of HIV or STDs in men or their partners, so we strongly urge men and women to practice safe sex, including abstinence, faithfulness, or condom use with any partner who is HIV+ or whose HIV status is not known. Also, even if an HIV+ person is on ARVs, they may still be able to transmit HIV and they and their partners still need to practice safe sex). We strongly urge all participants to either abstain or be faithful to one partner who has been HIV tested and is HIV-negative, or to use condoms every time in any other circumstances.

From time to time, the Rakai Health Sciences S Program may recontact RCCS participants who have certain characteristics (for example, age, place of residence or health status) to invite them to participate in other studies involving components such as interviews, focus groups, sample collection or clinical studies. If you are recontacted in such a way, the additional research will be described to you and you will be asked to provide your consent to participate in the additional research. If you prefer not to participate in the additional study(ies), you will be free to decline. As is the Rakai Program policy, your RCCS data will remain confidential. At the end of this consent, you will be asked to sign whether you agree to or decline to be contacted for additional studies through the information you provide in the RCCS.

. If you have participated in other Rakai Program studies or services, the data you provide as part of the RCCS study may be linked to the data you provide or have provided in those studies or services. .

PROCEDURES

The Rakai Community Cohort Study study will last at least 5 years. The study involves procedures similar to those used in previous Rakai Project research. If you agree to participate in the study, we will visit you in the home approximately every 12 months. During the visits, we will interview you and ask you questions about yourself such as age, education and marital status; your health, particularly illness you may have had between our

visits; your understanding of ways to avoid HIV; and about personal behaviors such as sexual matters.. As I explained above, the information will also be used to assess the effects of circumcision and ARVs on behaviors, on HIV and STD rates, and on families and the community.

We will also ask you to provide a blood sample taken from a vein in your arm. This sample (approximately 15 ml or 1 and ½ tablespoon of blood) will be used to determine whether you have the HIV virus and possibly infections such as syphilis, other STDs, O'nyong-nyong, malaria, and other conditions which affect health, to study how they might affect health, and also to assess the body's ability to fight infections and other health conditions. We will also ask you to provide a urine sample in a cup which will be tested for infections, including sexually transmitted diseases. Women will be asked to provide vaginal swabs (which they can collect on themselves) and these swabs will be tested for similar infections and conditions. In some survey rounds, you may be requested to provide additional samples, over what I have described above, for research or in order that we can provide you some service. When additional samples are requested, you will be informed of the type of sample and of the reasons to collect the additional sample or samples, and where appropriate, how to access the results. You will be free to agree or decline to provide the additional samples at that time.

We will ask all RCCS participants (men and women) to provide information to help us identify their married or official partners. Such information will help us to assess questions such as what might affect the transmission of HIV, other STDs or other infections between people, determine whether a man's circumcision status affects the health of his female partner (including the risk of acquiring HIV or other STDs) and also, whether knowledge or use of ARVS affects HIV and STD risks for partners. We have asked for this type of information, such as name and address of partners, in all our previous surveys. If we are unsure whether we have identified the correct person, we may ask you to check a photograph of the individual who we think is your partner. The information you provide in your questionnaire, your HIV results, and any STD results will be kept strictly confidential (secret), unless you and your partner both agree to share this information with one another. We strongly encourage all participants who have a sexual partner .to disclose their HIV results to their partner and to receive couples' counseling, but the Rakai Program will not disclose the survey information you provide or HIV test results to a partner, family member or the community, without direct permission from a participant.

Each interview and sample collection will take approximately 1 hour. You can agree to participate in some or all of the study; even if you decline to participate in any part of the study, you will not lose your access to Rakai Project clinics or other services.

You will be given a picture identity card (if you have never got one before). The staff will retain a copy of the card used solely for identifying you at each visit.

RISKS FROM BEING IN THE STUDY

Potential risks include:

- Some bruising or bleeding at the site of the blood collection.

- Social consequences if the answers to your questions or your HIV, STDs or other infections or conditions become known. We will minimize this risk by interviewing you in private, and keeping all information and results safe and confidential. All laboratory results will only be revealed to you in private at your only request. If you want to know the results of your HIV test we will provide them to you through the Rakai Project community counselor. We strongly encourage everyone to get their HIV results, since the information can help them protect themselves or their partners from infection, and also help them plan for their future and the future of their families. In addition, since we can now offer antiretroviral medicines (ARVs), so HIV+ persons need to find out if they are infected, in order that they can be further examined to see if they need to start the ARV medicines.

BENEFITS

The following Rakai Program services are available to all residents in RCCS communities, whether or not they agree to participate in the RCCS:

- HIV prevention and other health education.
- Access to free care, including STD symptom-based care, in Rakai mobile clinics
- Access to free treatment at the Rakai STD clinic in Kalisizo
- Access to free screening for ARV eligibility in Rakai Program clinics
- Access, with a small co-payment, to Rakai Program family planning services

The following additional services are available only to RCCS participants:

- The chance to get your HIV results and counseling, since the information and sample needed to provide this service is collected through the RCCS.
- Free condoms
- For HIV+ persons, home-based collection of blood to see if they need to start ARV treatment. .
- For all persons who are not pregnant, we will offer home-based oral treatment for worms. (Women should inform the investigator if they are pregnant.) .
- For pregnant women, pregnancy may be confirmed by a urine test and pregnant women will be offered a single dose oral treatment with Azithromycin and Cefixime. These medicines treat infections including gonorrhea, chlamydia and early syphilis, all of which can cause health problems in mothers and babies. Rakai studies have shown these medications improve the health of babies and of mothers.
- Access to free STD treatment in the Rakai Program STD clinic in Kalisizo.

Even if you decide not to participate or to leave the study at a later date, such a decision will not affect your use of the Rakai Program services which I described earlier and which are available to the whole community, including condoms, health education, family planning, and mobile clinics. .

ASSURANCE OF CONFIDENTIALITY

Research records of your participation in this study will be maintained by the Rakai Program in locked files in either Kalisizo or Entebbe. Only authorized project personnel (approved by the Ugandan Principal Investigators) will have access to these files. All data and medical information collected from you will be kept confidential, to the full extent allowed by the law.

PARTICIPATION IS VOLUNTARY

Your participation in this study is completely voluntary. You are free to withdraw at any time or decline to participate in any or all components of the study (interview, sample collection). Such a decision will not affect your medical care by the Rakai project, now or in the future.

COST OF PARTICIPATION

Medical care directly related to your participation in this study is provided at no cost to you.

COMPENSATION

Men and women in this study will receive 3,000/= UG (approximately $1.5 US) per annual visit as compensation for the time lost as a result of participation in RCCS activities.

STORED SAMPLES

The biological sample you provide in the RCCS study may be used in the trial of male circumcision, the ARV assessment study, and may also be stored and used for additional research purposes over and above those described in the current study. Storage may be indefinite: that is, at this time, we do not foresee a specific time by which samples from this study will be destroyed. Your biological samples may be used to learn more about other diseases and conditions, or may be used in new products, tests or discoveries. You will not receive any payment or financial benefit from any products, tests or discoveries. Participation in this extra research is voluntary, and if you choose not to allow your samples to be used for potential extra research, it will not in any way affect your participation in the current study or your care from the Rakai Program.

You will have an opportunity to consent to use of your samples for future research. Today, or at any time in the future, you may agree to one of the following:

- That your samples, with your identification number attached, can be used for additional future studies.
- That your samples, with your identification number removed, can be used for additional future studies. Please note that if your identification number is removed, it will not be possible for you to have access to any potential future research findings from those samples.
- That your samples cannot be used for any additional research.

Please indicate whether or not you are willing to allow extra research by signing on one of the lines at the end of the form.

MEDICAL CARE FOR INJURY OR ILLNESS

The procedures used in the RCCS are safe; we will not be testing any new drugs or medical procedures in the RCCS.. Therefore, the risk of illness due to your participation is minimal. However, if you are injured from participating in the study, no money will be available to pay you, but treatment will be available. If you experience any symptoms which you feel may be related to the study, be sure to report them immediately to the persons listed immediately below.

QUESTIONS/POINTS OF CONTACT

If you have any questions, please ask, and we will do our best to answer then. If you have additional questions or if you need to discuss any other aspect of the study, you can contact:

Drs……..Medical Officers, Rakai Project office in Kalisizo (Tel…….)

Drs…….. Ugandan Principal Investigators tel:…..

If there is any portion of this consent explanation sheet that you do not understand, ask me before signing. You will receive a copy of this consent form.

If you have any questions concerning your rights as a participant in this research, please contact Dr…….. Chairman of Science and Ethics committee of UVRI (tel ……..).

STATEMENT OF PARTICIPANT CONSENT

CONSENT OF PARENT OR GUARDIAN ***if participant is an unemancipated minor under age 18.***
I have been asked whether my son/daughter/ward may participate in the Rakai Community Cohort Study. The principal investigator Dr….. or the field medical officers Drs….. or their representative, _____ has explained the study to me, its duration, the testing that my child/ward will be asked to undergo, and possible risks. The information above has been read to me. I have been given an opportunity to ask questions about this research project. All questions were answered in a way that I understand. If I have other questions about this research, I can ask the study representative, _____ one of the field medical officers named above or Drs…..
I understand that my agreement to let my child/ward participate is voluntary, and that I can decline to let my child participate or ask that my child leave the study at any time, without losing access to Rakai project services for myself or my child. I also understand that s/he has the right to voluntarily refuse to participate in all or part of the study. I am signing my name below to indicate my assent for my child/ward participate in this project.

_____, _____
SIGNATURE OF PARENT OR GUARDIAN DATE

_____, _____
PRINTED NAME OF PARENT/GUARDIAN ADDRESS OF PARENT/GUARDIAN

_____, _____
SIGNATURE OF INVESTIGATOR ELICITING CONSENT DATE

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CONSENT OF ADULT PARTICIPANT/ ASSENT OF UNEMANCIPATED MINOR

I _____, age, _____have been asked to participate in a research study named Rakai Cohort Surveillance Study. The principal investigator Dr….. or the field medical officers Dr…. or their representative, _____ has explained the study to me, how long it will last, the testing I will undergo, and risks that I might take. The information above has been read to me. I have been given an opportunity to ask questions about this research project. All questions were answered in a way that I understand. If I have other questions about this research, I can ask the study representative, _____, the field medical officers named above or Dr…

I understand that my participation is voluntary, and that I can decline to be in the study or leave the study at any time. If I decline to participate or if I leave the study, I will not lose any benefits or access to Rakai project services. I am signing my name below to indicate my consent participate in this project. I will be given a copy of the signed consent form.

_____, _____

SIGNATURE OF PARTICIPANT (thumbprint if non-literate) DATE

_____

PRINTED NAME OF PARTICIPANT

SIGNATURE/THUMBPRINT INDICATING CONSENT
FOR USE OF STORED SAMPLES for
additional research with ID #:_____
OR: anonymous (without ID#):_____
OR: DO NOT CONSENT TO USE OF STORED SAMPLES _____

_____

ADDRESS OF PARTICIPANT

Signature/thumbprint indicating consent to be contacted for additional
Studies through RCCS interview data or lab results:
Agree to be contacted: _____
Declines to be contacted: _ _____

SIGNATURE OF WITNESS PRINTED NAME OF WITNESS DATE (same as participant's)

_____ _____

SIGNATURE OF INVESTIGATOR ELICITING CONSENT DATE