Uganda Virus Research Institute

Information and consent form (ICF) for parents/guardians or the respective school head teacher or their authorized designate (in the absence of parents/guardians) of the male students in secondary schools participating in the MENISCUS study.

Project code: MENISCUS, version 1.1 (April 2015)

Summary (What you should know about this exploratory study):

- The MENISCUS Study is exploring the best ways to promote: knowledge of puberty and HIV/AIDS; use of HIV/AID control methods (e.g. safe male circumcision) among boys and menstrual hygiene among girls attending secondary schools in Uganda.

- This document explains the purpose of this study and what <name of participant> will be asked to do if you agree to allow them to participate.

- <Name>'s participation is completely voluntary. You or <name> have the right for <name> to take part in the study or to agree to take part now and change your mind later.

- Whatever you decide will not affect <name>'s regular healthcare and support.

- Please review this form carefully. Ask any questions before you make a decision.

You will be given a copy of this form to keep.

Part I: Information about this study

Introduction

The MENISCUS Study is led by the Uganda Virus Research Institute (UVRI) in Entebbe and the London School of Hygiene and Tropical Medicine in United Kingdom, in collaboration with a non-governmental organization called Grassroot Soccer (www.GrassrootSoccer.org) and the Ministry of Education and Sports of Uganda. We are carrying out research to guide our secondary schools and health facilities to identify practical ways of helping boys to become and stay healthier, by reducing their risk of getting sexually transmitted infections (STIs), including HIV/AIDS.

We invite you and/or <name> to be part of this research. It is optional for you to choose whether or not you want <name> to participate in this research. We have

received permission to conduct this research from your school administration, Entebbe Municipality, the Ministry of Education and Sports, and the Ethics Committees of both the UVRI and LSHTM.

If you agree to allow <name> to participate, we shall ask <name> for approval as well. Both of you have to approve before <name> can be involved.

Please feel free to ask us questions now or later using our contact information which is indicated below. We will take time to explain to you.

Purpose
The purpose of the MENISCUS Study is to help us to design a health promotion intervention that will: provide puberty and HIV/AIDS education for both boys and girls attending secondary schools in Uganda; promote use of HIV/AIDS control methods, including safe male circumcision for boys and promote menstrual hygiene for girls. We then hope to get funding to evaluate the effectiveness of these interventions through the secondary schools.

Type of Research
We will use several research methods, including interviews, group discussions and written questionnaires for yourself, <name>, his teachers, and health service providers and authorities.

Selection of Participants
We shall involve you and/or <name>.

We are seeking your consent because you are the parent/guardian of <name>.

Voluntary Participation
It is optional for you or <name> to participate in this research. You can choose to say no. That decision shall not affect any services that you and your family receive at the secondary school and/or health facilities. You can ask as many questions as you like and we shall be available to answer them. You don't have to decide today. You can think about it and tell us what you decide later. You can agree that the school head teacher or authorized designate shall provide exceptional signed consent on your behalf if you are not available or accessible for documented reasons (except for your son’s possible involvement in safe male circumcision).

Procedures
This research will take place between April/May 2015 and June/July 2016 primarily in 4 identified secondary schools in Entebbe Sub-District. It will be conducted with the support of the UVRI clinic, Entebbe hospital and The AIDS Support Organization (TASO) in Entebbe. The research has been formally approved by the: Uganda National Council for Science and Technology (UNCST); UVRI Research and Ethics Committee (UVRI REC); the Ethics Committee of the London School of Hygiene and Tropical Medicine (LSHTM), and by authorities in the Departments of Education and Sports and of Health for the local government.

1) Group discussions and/or interviews among students (of 60-90 minutes):
<Name> may be asked to take part in a discussion with 7-8 other school boys and/or in interviews. These will be conducted at school. They will be guided by our trained adolescent-friendly researchers, who will be formally introduced to the school authorities. In addition, they will wear personal identity cards.

We will discuss with adolescents their preferred sources for information about health, and whether they get the information and services they need. We will encourage them to discuss topics such as puberty; prevention of HIV/AIDS and other STIs; male circumcision; and life-skills (e.g. soccer, problem-based learning and making decisions/choices).

The discussion will take place within the school premises. The entire discussion will be tape-recorded. The tapes will be kept securely in lockable cabinets/cupboards at UVRI. The information recorded is confidential, and no one else except the researchers or other ethical eligible person(s) such as the transcribers, the sponsor or ethics review committees with regulated access to the tapes will be allowed to listen to the tapes. Nobody's name will be mentioned on the tapes.

2) Questionnaire survey among students (40-60 minutes):
<Name> may be requested to fill in a questionnaire which will be provided and collected by our trained researchers. If <name> does not wish to answer some of the questions included in the questionnaire, he may skip them and move on to the next question.

The trained researchers and research assistants will maintain safe custody of all research records of recruited participants with identification data, including contact details in lockable cabinets and/or cupboards. This will be done to preserve privacy and confidentiality of participants. Contact details will be de-linked from research reports, presentations and publications. Data will be entered by trained research assistants into a password-protected electronic database.

3) Other interviews with you, teachers and authorities (of 60-90 minutes):
You, teachers and the authorities may be asked to take part in interviews on the topics mentioned above. This discussion will be guided by our trained researchers who will formally introduce themselves to you. In addition, they will wear personal identity cards.

The discussion will take place at an agreed venue or within the school premises. The entire discussion will be tape-recorded. The tapes will be kept securely in lockable cabinets/cupboards at UVRI. The information recorded is confidential, and no one else except the researchers or other ethical eligible person(s) such as the transcribers, the sponsor or ethics review committees with regulated access to the tapes will be allowed to listen to the tapes.

Risks and Discomforts
We will be asking you and/or <name> to share with us some personal and

confidential information (e.g. related to sexual and reproductive health and HIV status). You may feel uncomfortable talking about some of these topics. There may also be a risk of wound infections which will be managed/prevented by our qualified and experienced health workers.

Benefits
There will be no immediate and direct benefit to you or <name>. However, your participation is likely to help us, the schools, health facilities and the education and health authorities of find out more about male students' health and service needs. We hope that these will help all the relevant people to meet those needs better in the future.

Reimbursements
Neither you nor your son will be paid to take part in this research. However, you and/or <name> will be given a pen, a unique/special hardcover note book and a soft drink to compensate for your and/or his time and effort. You and/or <name> will be reimbursed for any prior agreed upon study-related travel.

Sharing of research findings
During and at the end of this research, we will be sharing what we have learnt with the adolescents, parents/guardians, teachers, health workers, education and health authorities, and with the national and international community through meetings and conferences. We will also publish the results internationally in science journals and in electronic websites in order that other interested people may learn from our experiences and evidence. All results will be presented anonymously, and will never be presented in a way that would allow anyone outside the research staff to know what you or <name> has answered.

Who to Contact

You may contact any of the following about this research:

a) **Prof. Pontiano Kaleebu**, Director of MRC/UVRI Research Unit on AIDS, Plot 51-59 Nakiwogo, P.O Box 49 Entebbe, Uganda.
Tel: +256 417 704 000 or +256 414 321 461 (Office hours)
E-mail: pontiano.kaleebu@mrcuganda.org

b) **Dr. George Miiro**, Medical Officer & Project Coordinator, UVRI, Plot 51-59 Nakiwogo, P.O Box 49 Entebbe, Uganda.
Tel: +256 414 322 016 or +256 414 321 672 (Office hours)
E-mail: gmmiiro@uvri.go.ug or gmmiiro@yahoo.co.uk

If you have any questions, complaints or concerns about your rights as a party in this research, please contact:

The Chairman, Science and Ethics Committee (Independent Authority),
UVRI, Plot 51-59 Nakiwogo, P.O Box 49, Entebbe, Uganda
Tel: +256 414 321 962

Consent form for parents/guardians or the respective school head teacher or their authorized designate (in the absence of parents/guardians) of adolescent boys in secondary schools participating in the MENISCUS project.

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PART II: Consent form

I have been asked to give consent for myself and/or <name> to participate in this research study, which may involve me/him. **I have understood the information above.**

I am the parent, legal guardian, or the respective school head teacher or their authorized designate (in the absence of parents/guardians).

I consent voluntarily for myself and/or <name> to participate in this study.

Print Name of Parent or Guardian/School Head Teacher or Authorized Designate (in absence of parent/guardian):

_____

Signature of Parent or Guardian/School Head Teacher or Authorized Designate (in absence of parent/guardian):

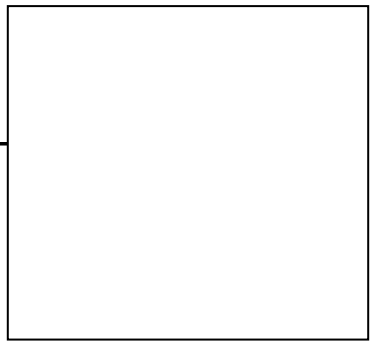
_____

Date: _____
Day/month/year

If literacy challenged
A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Literacy challenged parents/guardians should include their thumb print as well.

Print name of witness: _____

AND Thumb print of participant



Signature of witness: _____

Date: _____/_____/_____
Day/month/year

If the parent or guardian is not the person who has signed this form, document the reason(s) for the parent's/guardian's absence here:

_____

_____

Print Name of Researcher/person verifying the consent:

_____

Date: _____/_____/_____
Day/month/year

An Informed Assent Form will be completed by your son, if they themselves agree to participate in the study.