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INFORMED CONSENT FORM: RANDOMISED CONTROLLED TRIAL

This document outlines the research study and expectations for potential participants. It should be written in layman terms and typed on MUST-IRC letterhead. The wording should be directed to the potential participant NOT to IRC. If a technical term must be used, define it the first time it is used. Also, any abbreviation should be spelled out the first time it is used.

NB: All the sections of this document must be completed without any editing or deletions

*Please **use a typing font** that is easily distinguishable from the questions of the form*

Study Title: *It should be the same as on all other documents related to the study*

AFFECTING THE EPIDEMIOLOGY OF HIV IN UGANDA THROUGH OLDER ADOLESCENTS

Principal Investigator(s):

Emmanuel Kyagaba, Principal Investigator, Mbarara University of Science and Technology and Internet Solutions for Kids, Uganda

Michele Ybarra, Ph.D., Principal Investigator and President, Center for Innovative Public Health Research (CiPHR)

INTRODUCTION

HIV continues to be a significant public health challenge in Uganda.

What you should know about this study:

- You are being asked to join a research study.
- This consent form explains the research study and your part in the study
- Please listen to it carefully and take as much time as you need to decide

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- You are a volunteer. You can choose not to take part. And if you join, you may quit at any time. There will be no penalty if you decide to quit the study.

Purpose of the research project: *Include a statement that the study involves research, estimated number of participants, an explanation of the purpose(s) of the research procedure and the expected duration of the subject's participation.*

Background/ Purpose

We are developing a sexual health and HIV prevention program for young adults in Uganda. The program will be sent to young people through text messages. This research study is sponsored by the National Institutes of Health in the United States. It is a collaboration between Internet Solutions for Kids – Uganda and the Center for Innovative Public Health Research, an NGO in the US. We are asking you to take part in the randomised controlled trial.

Why you are being asked to participate: *Explain why you have selected the individual to participate in the study.*

You are one of about 200 participants being asked to help test the healthy sexuality program from across Uganda. We are asking you to take part because you are between 18-22 years of age, have a mobile phone, and have used text messaging.

Procedures: *Provide a description of the procedures to be followed and identification of any procedures that are experimental, clinical etc. If there is need for storage of biological (body) specimens, explain why, and include a statement requesting for consent to store the specimens and state the duration of storage.*

There are two different text messaging programs that we are testing. We do not know which program works better to promote healthy sexual behavior. Your assignment to either program is random. This means you have an equal chance of being assigned to either program. We will not tell you which program you are assigned to until after everyone has finished the program.

If you choose to take part in the research study, here's what we will ask you to do:

1. Complete a one-hour survey either by yourself online or with program staff on the phone.

2. Then, you will receive 2-3 messages <u>per week</u> for 20 weeks OR you will receive between 2-10 text messages <u>every day</u> for 20 weeks.

3. You may also be randomly matched to an "ITG Peer," another person in this study, with whom you can send text messages to talk about the things that you are learning in the program. You may also have access to ITGenie, which would send you advice about various topics (like HIV testing) on demand.

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4. Complete two more surveys:
    a. A short survey around 8 weeks after you start the program, done either by yourself via text message or with program staff over the phone;
    b. A one-hour survey at the end of the program, done either by yourself online, or with program staff over the phone; and

Your total time in the study will be about 5 months.

Risks and Discomforts: *Describe any reasonably foreseeable risks or discomforts-physical, psychological, social, legal or other associated with the procedure, and include information about their likelihood and seriousness. Discuss the procedures for protecting against or minimizing any potential risks to the subject. Discuss the risks in relation to the anticipated benefits to the subjects and to society.*

It is possible that a question in the survey we ask or a message that we send might make you feel uncomfortable. If this happens, you can skip the survey question. If the program messages make you feel uncomfortable, you can choose to not read them or stop being in the randomised controlled trial completely.

Benefits: *Describe any benefits to the subject or other benefits that may reasonably be expected from the research. If the subject is not likely to benefit personally from the experimental protocol note this in the statement of benefits.*
We don't know if you will benefit from being part of the study, but your participation is important: You can help us design a better sexual health program, which will benefit young adults like you in the future.

Incentives / rewards for participating: *It is assumed that there are no costs to subjects enrolled in research protocols. Any payments to be made to the subject (e.g., travel expenses, token of appreciation for time spent) must also be stated, including when the payment will be made.*
You can earn up to 25,000 shillings taking part in the program. Here is how:

- After you complete the one-hour survey, you will receive 10,000 shillings of mobile data.
- When you complete the short survey at the end of 8 weeks, you will receive 5,000 shillings of mobile data.
- When you complete the one-hour survey at program end, you will receive 10,000 shillings of mobile data.

Protecting data confidentiality: *Provide a statement describing the extent, if any, to which confidentiality or records identifying the subjects will be maintained. If data is in form of tape recordings, photographs, movies or videotapes, researcher should describe period of time they will be retained before destruction. Showing or playing of such data must be disclosed, including instructional purposes.*
We will keep a copy of your answers so that we can look at them later. Only researchers involved in this study will be able to see your answers. Your name and contact information will not be used in any reports or articles we publish. We will not tell anyone else outside of the research team what you say during the randomised controlled trial.

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We will ask for your permission to mention the study in text messages we send you. No additional contact information beyond your mobile phone number will be required to enroll. We may ask you for additional contact information (e.g., your Facebook profile name) but you do not have to provide it if you do not want to.

Protecting subject privacy during data collection: *Describe how this will be ensured.*
It is possible that your privacy will be broken. For example, if someone sees your computer or mobile phone screen or hears you talking to research staff by telephone, this person may learn that you are taking part in a study about sexual health and HIV. You can reduce this risk by completing the surveys and answering our phone calls in a private place. You can reduce the risk of people seeing the program text messages by deleting the messages or by putting a password on your phone.

Right to refuse / withdraw: *Include a statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled.*

Taking part in the randomised controlled trial is your choice. If you decide not to be in the randomised controlled trial, nothing bad will happen.

What happens if you leave the study? *Include a statement that the subject may discontinue participation at any time without penalty or loss of benefits.*

If you change your mind after you have started the randomised controlled trial and you decide you don't want to continue taking part, you are free to stop. There is no penalty if you decide to stop after you have begun participating.

Who do I ask/call if I have questions or a problem? *Include contact for researcher or Faculty advisor and Chairman MUST-IRC*

If you have questions about the research project, you may contact Mr. Agaba Edgar, the Study Coordinator on telephone number: 0703902809. You may visit him at the study offices located at Internet Solutions for Kids-Uganda, Ugafode Building, Bananuka drive 2nd floor, Mbarara.

- If you have any concerns about your rights in this research, please contact the MUST-IRB office: Dr. Francis Bajunirwe**,** Chairman MUST IRC, Mbarara University of Science and Technology**,** P.O Box 1410, Mbarara, Tel. 0485433795.

An IRB is a group of people who review research studies to protect the rights and safety of research participants.

Do you have any questions about the information that I just read to you or about the research study?

Do you agree to participate in this study? [record answer]

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If yes (consent to participate):
Great! Would you like me to email you a copy of the consent form I just read you?
If yes: Ok – what is your email address please?

If no (do not consent to participate):
Thank you for your time. We respect your decision not to take part in the randomised controlled trial. To help us design future research activities, can you please tell me why you decided not to take part?
[record answer]

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