Form M0345

DUKE UNIVERSITY HEALTH SYSTEM

Tumaini University
Kilimanjaro Christian Medical College

ID: ___ ___ - ___ ___ ___ - ___

Name: _____

Fingerprint:

Consent to participate in a research study: **Identifying and Matching Individuals' Preferences for HIV/AIDS Counseling**
Survey Consent, Version Date 13-Dec-2019

Concise Summary

This is a research study to learn about preferences for HIV testing.

If you decide to enroll in this study, you will be asked to complete a survey administered by a study interviewer. The survey will ask you questions about your background (such as age and marital status), HIV testing history, and what you like or don't like about different HIV testing options.

At the end of the survey, we will describe several free testing options that you might want to use in the future. We will contact you periodically during the next 24 months to see if, and how, you decided to test for HIV.

There are no major risks involved with study participation.

If you are interested in learning more about this study, please continue reading below.

Introduction:
You are asked to take part in a research study about preferences for HIV testing. This study is under the direction of Dr. Bernard Njau at Kilimanjaro Christian Medical Centre and Drs. Jan Ostermann and Nathan Thielman at Duke University and the University of South Carolina in the United States. This study is sponsored by the United States' National Institutes of Health.

Research studies are voluntary. As your study staff member reads this form to you, please take your time deciding whether to participate. Please ask him/her to explain anything that you do not clearly understand. The purpose of the study, procedures, risks, and benefits are described below.

The research team will give you a copy of this form. It is important that you know:

- Your participation is entirely voluntary;
- You may decide not to take part or to withdraw from the study at any time

DUHS IRB
IRB NUMBER: Pro00075996
IRB REFERENCE DATE: 12/26/2019
IRB EXPIRATION DATE: 10/21/2021

Initials:_____

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Purpose:
The purpose of this study is to determine which characteristics of HIV testing programs influence HIV testing decisions.

Who Will Be In This Study and How Long Will This Study Last?
Approximately 2,500 persons will participate in surveys about HIV testing. After the completion of today's survey, you may be contacted again during the next 24 months with follow-up questions and offers for HIV testing.

Procedures:
The survey will last approximately 60 minutes. After you have signed and dated the consent form we will ask you questions about issues such as:

- Age and marital status,
- HIV risk behaviors,
- HIV testing, and
- Attitudes toward different HIV testing options
- Experiences with HIV treatment

Some participants will receive invitation cards to test for HIV. You may receive SMS reminders or incentives to test, and you will be periodically re-contacted to answer questions about your risk behaviors and testing decisions. You may also be offered other testing options in the future. HIV test results will be linked to your study data without your name.

Risks and discomforts:
Talking about HIV testing may cause some people to experience discomfort. You can refuse to answer any questions, and you can stop the interview at any time.

Benefits:
You will not receive any direct benefit from participating.

Confidentiality:
Study records will be kept confidential as required by law. Your records will be assigned a unique study number. If you choose to test for HIV using any of the options offered to you, only this number will be used to link your HIV test result to your study data. If we collect your fingerprints today, they may be used to verify your identity. All information is stored in a secure database. Information that links your name to the study number will be kept in a locked cabinet that can only be accessed by members of the research team. Your survey data will be shared with members of the research team at Duke University and the University of South Carolina in the U.S. When information is sent to the U.S. it is sent through a secure

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internet connection. When information from this study is presented at scientific meetings or in scientific journals, your identity will not be revealed.

A description of this clinical trial will be available on *www.ClinicalTrials.gov*, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Voluntary Participation/Right to Withdraw:
You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you agree to participate, you may refuse to answer any question or stop the interview at any time. Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits and will not affect your access to health care.

Cost to you:
There is no cost to you for taking part in this research study.

Payments to participants:
You will receive a minimum of TSH 10,000 after the completion of today's survey, and after any other survey for which you are asked to return to the study offices. After receiving the compensation you may be offered choices that could result in a higher or lower amount.

Whom do I call if I have questions or problems?
For questions about this study or if you have problems, concerns, questions, or suggestions about the research, contact Dr. Bernard Njau at KCMC (telephone number 0784-300-846). For questions about your rights as a research participant or to discuss problems or concerns related to the research contact the KCMC Ethics Committee at 027-275-3616.

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DOB: ___ ___ / ___ ___ / 19 ___ ___
(dd / mm / yyyy)

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Optional permission for future contact:
I give permission for members of the research team for this study to contact me about other components of this study, or about other studies, in the future. It will be my choice whether or not to participate in those studies at that time.

_____ Yes _____No _____Initials

STATEMENT OF CONSENT

"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

_____
Name of Participant in block letters

_____ _____ _____
Signature of Participant Date Time

_____
Name of Interviewer in block letters

_____ _____ _____
Signature of Interviewer Date Time

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