

*This consent form should be signed only  
between 01 Jan 2019 and 06 Jan 2020*

**FEMALE CONSENT – English** Approved by NHSRC, Malawi on 01 Jan 19

**University of North Carolina at Chapel Hill  
Consent to Participate in a Research Study  
Adult Participants – English  
Biomedical Form**

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**Consent Form Version Date:** Version 1.0 dated 11 December 2018  
**IRB Study #18-2227**  
**NHSRC Study # 18/09/2136**

**Title of Study:** UNCPM 21804 - Assessing male partner engagement in HIV testing using partner-notification slip plus oral HIV self-testing kit among male partners of HIV-negative pregnant women with syphilis

**Principal Investigator:** Maganizo B. Chagomerana, MS, PhD  
**Co-Investigators:** Nora E. Rosenberg, MSPH, PhD; William C. Miller, MD, PhD, MPH; Irving F. Hoffman, PA, MPH; Mina C. Hosseinipour, MD, MPH; Mitch M. Matoga, MBBS, MSc

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**Funding Source:** U.S. National Institute Fogarty International Center

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**What are some general things you should know about research studies?**

You are being asked to take part in a research study. To join the study is voluntary. You may refuse to join, or you may withdraw your consent to be in the study for any reason, without penalty.

Research studies are designed to obtain new knowledge that may help other people in the future. You may not receive any direct benefit from being in the research study. There may also be risks to being in research studies. Deciding not to be in the study or leaving the study before it is done will not affect your relationship with your researcher or your health care that you receive at the clinic. If you are a patient with an illness, you do not have to be in the research study in order to receive health care.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study.

You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

**What is the purpose of this study?**

The purpose of this study is to learn if offering HIV-self testing kit in addition to partner notification slip to HIV-negative pregnant women with syphilis during antenatal clinic for use by their partners has an impact on male engagement in HIV testing and return for syphilis treatment. You are being invited to participate in this study because you are receiving antenatal care at this clinic and tested positive for

syphilis. Since you tested positive for syphilis, it is important that your partner should be treated for syphilis to prevent your partner from syphilis and prevent continued transmission.

**How many people will take part in this study?**

If you decide to be in this study, you will be one of about 200 women in the study who will invite their partners for syphilis and HIV testing.

**How long will your part in this study last?**

The length of time you will be in the study will depend on how soon your partner will report to the clinic for syphilis testing and treatment but will not exceed 30 days. We will keep in contact with you once a week by phone until your male partner comes to the clinic or 30 days have passed.

**What will happen if you take part in the study?**

Today you will be assigned by chance to one of two study groups: the HIV Self-testing Intervention group or the Standard of Care group.

If you are in the HIV self-testing intervention group, you will be given a partner notification slip plus oral HIV self-testing kit with manufacturer-provided instructions for use to give to one sexual partner. You will be taught how to conduct the HIV self-test and interpret the test results. You will also be informed about the performance of the test and limitations of the product. You will also receive necessary contact information about HIV testing services if you are uncertain about how to correctly perform the self-test or interpret the result. The same information will be included in a study brochure that you will be given to take home to your partner. If your partner does not present to the clinic within one week, a community outreach worker will attempt to contact you by phone. Your partner will be required to visit the clinic only once for syphilis treatment and confirmatory HIV counselling and testing.

If you are in the Standard of Care group, you will be given a partner notification slip only inviting your partner for syphilis testing. Your partner will be required to visit the clinic only once for syphilis treatment and HIV counselling and testing.

Partners with confirmed HIV-positive results will be linked to HIV treatment and care. HIV-negative partners will be advised to retest if there is a possibility that they were exposed to HIV in the preceding six weeks, or if they are at high ongoing HIV risk.

You will also be asked to answer some questions about yourself and your sexual behavior. You can refuse to answer any of these questions. A community worker will contact you by phone once a week to remind you to tell your partner to come to the clinic until your partner comes to the clinic or 30 days have elapsed. At the end of the study, we would like to know how your partner reacted to the invitation to the clinic and/or the offer for HIV self-testing. We may therefore contact you for another interview.

**What are the possible benefits from being in this study?**

Research is designed to benefit society by gaining new knowledge. This study may help your partner to learn their syphilis and HIV status. It will help you and your partner to know each other's HIV and syphilis status. Your partner will also be treated for syphilis. If your partner is HIV-positive, he will be linked to HIV treatment and care. If your partner is also HIV-negative, you and your partners will be counselled on preventive measures to remain HIV-negative. Malawi may benefit from the results of this research by learning new knowledge about partner notification plus HIV self-testing and understanding the use of HIV self-testing within the Option B+ program.

**What are the possible risks or discomforts involved with being in this study?**

You may feel embarrassed to answer questions about your sexual behavior. You can refuse to answer any questions asked of you at any time.

There is a small risk of a breach of confidentiality. Your confidentiality will be protected to the greatest extent possible. If you are contacted by phone in the community, we will do our best to prevent other people from learning the reason for the call. The discussion with the community outreach worker will take place in private.

This program may cause you social, economic, legal, or physical harm but these harms are rare. It is possible that your partner could hurt or leave you as a result of study participation. Our team will do everything in our power to help you prevent these problems and resolve them if they arise. If you experience any social harm, we will provide you with further counselling and when necessary, we will refer you for further services at the District Social Welfare Office or the Police Victim Support Unit.

**If you choose not to be in the study, what other treatment options do you have?**

You do not have to be in this research study in order to receive care at this clinic.

**What if we learn about new findings or information during the study?**

We will give you any new information we learn during the study that may affect your decision to participate in the study.

**How will information about you be protected?**

If you decide to be in this study you will be assigned a study ID number. This number will be linked to your name and medical record at the antenatal clinic only through a separate log book that will be kept in a separate locked file. Only the study staff will be able to link your medical record that has your name on it and your study information that only has your study number on it. At the conclusion of the study, this link between your name and number will be destroyed.

No subjects will be identified in any report or publication about this study. In some cases, your information in this research study could be reviewed by representatives of the University of North Carolina, research sponsors, or Malawi government agencies for purposes such as quality control or safety.

**What is a Certificate of Confidentiality?**

To also help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health (NIH). With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of Federal funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an

insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

Every effort will be made to keep your participation in the study and any personal information about you private and confidential. However, absolute confidentiality cannot be guaranteed. For example, if a study staff member learns something that would immediately put you or others in danger, the study staff member is required by law to take steps to keep you and others safe. This means that study staff members have to report to the authorities (hospital, police, or social services) any information you say that suggests that you might be in danger, such as telling staff that you plan to hurt or kill yourself, hurt or kill someone else, or if someone is abusing or neglecting you.

**What will happen if you are injured by this research?**

All research involves a chance that something bad might happen to you. This may include the risk of personal injury. If such injury occurs, the researchers will help you get medical care or counseling. By signing this form you do not give up any of your legal rights.

**What if you want to stop before your part in the study is complete?**

You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. This could be because you have had an unexpected reaction or have failed to follow instructions, or because the entire study has been stopped.

**Will you receive anything for being in this study?**

You will be reimbursed for your transport expenses at each study visit. The average transport is the local equivalent of \$10USD.

**Will it cost you anything to be in this study?**

It will not cost you anything to be in this study. All tests, visits or procedures are free of charge.

**Who is sponsoring this study?**

This research is funded by the National Institutes of Health. The research team is being paid by the sponsor for doing the study. The researchers do not have a direct financial interest with the sponsor or in the final results of the study.

**What if you have questions about this study?**

You have the right to ask any questions you may have about this research. We will answer all questions that you have. If you have questions, or if a research-related problem occurs, you should contact the researchers listed on this form.

**What if you have questions about your rights as a research subject?**

All research on human volunteers is reviewed by the Malawi Health Sciences Research Committee, which works to protect your rights and welfare, and the University of North Carolina at Chapel Hill School of Medicine IRB. If you have questions or concerns about your rights as a research subject you may contact, anonymously if you wish, the head of secretariat Dr. Ben Chilima at 0995 903 514.

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**Principal Investigator:** Maganizo B. Chagomerana, PhD

### SIGNATURES

If you have read this informed consent, or have had it read and explained to you, and understand the information, and you voluntarily agree to participate in this research study, please sign your name or make your mark in the signature area at the bottom of this page.

#### PART A: LITERATE PARTICIPANT

*Participant is literate:* ☐

\_\_\_\_\_  
Participant Name (print)                      Participant Signature                      Date

\_\_\_\_\_  
Study Staff Conducting Consent Discussion (print)                      Study Staff Signature                      Date

#### PART B : ILLITERATE PARTICIPANT

*Participant is illiterate:* ☐

The study staff must complete this section, ONLY if an impartial witness is available.

The study staff must write participant's name and date of consent

\_\_\_\_\_  
Participant Name (print)                      Participant Thumbprint                      Date

Participant Name and Date Written By.....on.....

\_\_\_\_\_  
Study Staff Conducting Consent Discussion (print)                      Study Staff Signature                      Date

\_\_\_\_\_  
Impartial Witness Name                      Impartial Witness Signature                      Date