Prevention of Cervical Cancer Through an HPV-based Screen-and-treat Strategy in Malawi

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Consent form should be signed only between 1 July 21 and 3 June 2022
Approved by NHSRC, Malawi on 1 July 21

University of North Carolina at Chapel Hill
Consent to Participate in a Research Study
Adult Participants - Household survey

Consent Form Version Date: Version 4.0, dated 4 June 2021
IRB Study #: 19-0638
NHSRC: 19/03/2255

Title of Study: UNCPM 21904: Prevention of cervical cancer through an HPV-based screen-and-treat strategy in Malawi: a cluster randomized trial

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Funding Source and/or Sponsor: PEER/USAID

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CONCISE SUMMARY

The purpose of this study is to determine how many women received cervical cancer prevention and voluntary family planning services in the catchment areas of 16 health facilities where we have integrated cervical cancer screening into voluntary family planning services. Participants will include eligible women who have lived in these catchment areas over the past year, during the implementation of our integrated services. Participants will complete a brief household survey that asks about basic background and reproductive health information, as well as whether she has received any cervical cancer prevention services or voluntary family planning services in the past 1 year.

There are minimal risks associated with participation in this study since we will only be completing an in-person survey. You may choose not to answer any questions if you are uncomfortable with answering them. There is no direct benefit to you for participating in this study

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

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. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies. Deciding not to be in the study or leaving the study before it is completed will not affect your relationship with the researcher, your health care provider, or the University of North Carolina-Project, Lilongwe. 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 research study is to determine how many women received cervical cancer prevention and voluntary family planning services in the catchment areas of 16 health facilities where we have integrated cervical cancer screening into voluntary family planning services. Participants will include eligible women who have lived in these catchment areas over the past year, during the implementation of our integrated services. Participants will complete a brief household questionnaire that asks about basic demographic and reproductive health information, as well as whether she has received any cervical cancer prevention services or voluntary family planning services in the past 1 year.

You are being asked to be in the study because: 1) you are a woman between the ages of 15-50 years, 2) you have not had your cervix removed, and 3) you live in the catchment areas of one of the 16 health facilities where we have integrated cervical cancer screening into voluntary family planning services.

Are there any reasons you should not be in this study?

You should not be in this study if you are not between the ages of 15-50 years, you have had your cervix removed, or you do not live in the area we are integrating cervical cancer screening into voluntary family planning services.

How many people will take part in this study?

If you decide to be in this study, you will be one of approximately 8,000 women in this research study.

How long will your part in this study last?

Your participation in the study only consists of a 20-minute survey.

What will happen if you take part in the study?

If you choose to participate in this study, you will complete one 20-minute survey, which will ask you about your basic background and reproductive health information, as well as whether

you have received any cervical cancer prevention services and/or voluntary family planning services in the past 1 year.

What are the possible benefits from being in this study?
Research is designed to benefit society by bringing new knowledge. There is no direct benefit from being in this research study.

What are the possible risks or discomforts involved from being in this study?
The risks of taking part in the interview are small, if any. Some questions could make you feel uncomfortable or embarrassed. You may choose not to answer any question for any reason and you can leave the interview at any time.

How will information about you be protected?
Data collected specifically for this study will be kept in study folders and a study database. Only those individuals involved in this study will have access to the study folders and database. The study folders will be kept in a locked room and filing cabinet. The study database is secure and password protected. Information that could individually identify you will not be included in the database or study forms. You will be assigned a participant identification number, and that number will be used in the database and on the study folders and forms instead of any identifying information. The only locations where the participant identification number could be linked to information that identifies you will be in an electronic study ID linkage file, which will be stored on a secure and password-protected computer. The study files and forms will be shredded and destroyed 10 years after the study has been completed.

No participants will be identified in any report or publication about this study. Although every effort will be made to keep research records private, there may be times when the law requires the disclosure of such records, including personal information. In some cases, your information in this research study could be reviewed by the University of North Carolina at Chapel Hill Institutional Review Board (UNC-CH IRB) and the National Health Sciences Research Committee (NHSRC), representatives of the University, research sponsors, study staff, study monitors, or government agencies for purposes such as quality control **or safety.**

What will happen if you are injured by this research?
All research involves a chance that something bad might happen to you. It is unlikely that you will be injured as a result of study participation. If you are injured, the UNC Project will give you immediate necessary treatment for your injuries. You will not have to pay for this treatment. You will be referred for any additional treatment that may be required for your injuries. There is no program to pay money or give other forms of compensation for such injuries. You do not give up any legal rights by signing this consent form.

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 receive a gift up to the Malawi kwacha equivalent of US$2 for taking part in this study.

Will it cost you anything to be in this study?
It will not cost you anything to be in this study.

Who is sponsoring this study?
This research is funded by the PEER/USAID (the Sponsors). This means that the research team is being paid by the sponsors for doing the study. The researchers do not, however, 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, and have answered, any questions you may have about this research. If you have questions, complaints, concerns, or if a research-related injury occurs, you should contact the researchers listed on the first page of this form.

What if you have questions about your rights as a research participant?
All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research participant, or if you would like to obtain information or offer input, you may contact the Chairman, Dr Collins Mitambo, NHSRC Ministry OF Health, P.O. BOX 30377, Lilongwe 3, Malawi; Tel: +265 1 726 422/418; Mobile: +265 999397913; Email: mohdoccentre@gmail.com OR the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

Title of Study: UNCPM 21904: Prevention of cervical cancer through an HPV-based screen-and-treat strategy in Malawi: a cluster randomized trial

Principal Investigator: Jennifer Tang, MD, MSCR

Participant's Agreement:

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 place your thumbprint** 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

Title of Study: UNCPM 21904: Prevention of cervical cancer through an HPV-based screen-and-treat strategy in Malawi: a cluster randomized trial

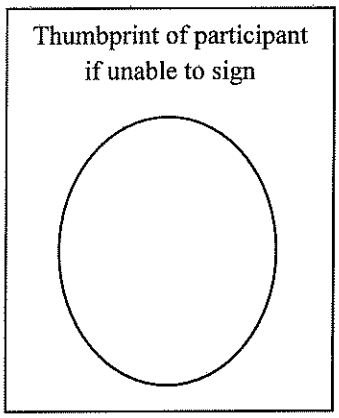
Principal Investigator: Jennifer Tang, MD, MSCR

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** on the **SHADED AREA.**



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 (print)	Impartial Witness Signature	Date