Enhancing HIV-assisted Contact Tracing in Malawi Through Blended Learning: an Implementation Science Study

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Consent to Participate in a Research Study
Adult Subjects—Health Worker Consent Form (English)

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Title: UNCPM 22009-Enhancing HIV assisted contact tracing in Malawi through blended learning: an implementation science study (UNC IRB # 20-1810; NHSRC #20/06/2566)
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CONCISE SUMMARY
This is a research study to test different approaches to implementing Malawi's HIV assisted contact-tracing program. Your participation is expected to last approximately two years. You will also be asked questions about yourself and your approach to HIV testing and HIV contact tracing. You may be observed and recorded while talking to patients who receive these services. You may be asked to participate in small group discussions about these topics with your colleagues. You might find that participating in the study helps you to talk with patients about HIV testing and contact tracing services. There is a small risk of a breach of confidentiality. If you are interested in learning more about this study, please continue reading.

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

You are being asked to take part in a research study. Research studies are designed to obtain new knowledge that may help other people in the future. Taking part in this study is voluntary. You may not receive any direct benefit from being in the research study. There may also be risks to being in research studies. You may refuse to join this study or you may withdraw your consent to be in the study for any reason. Your decision to not participate in the study or leave the study before it is done will not affect your relationship with the researcher or your employment. 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. If you have any questions about this study, ask the researchers named above, or staff members who may assist you at any time.

What is the purpose of this study?

The Malawi Ministry of Health wishes to provide HIV testing to persons who come to the clinic as well as their family members and sexual contacts. The purpose of this study is to learn about the implementation of this testing program and evaluate different ways of implementing the program. You are being invited to participate in this study because you are a health worker supporting these services.

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

You should not participate in this study if you are: (a) Not working full time at one of the health facilities included in the study (b) Not involved in Malawi's HIV program and (c) are less than 18 years old.

How many people will take part in this study?

There will be up to 400 health workers participating in this study.

How long will your part in this study last?

Your participation in this study will last for approximately 2 years from today.

What will happen if you take part in the study?

If you choose to be in this study, you will be asked to sign this consent form. Your facility will be assigned to one of two different implementation and training approaches. You will be asked to participate in the implementation and training approach that your facility was assigned to. Persons in all facilities will attend a 2-day in-person training. Persons in some facilities will also complete additional electronic training and small-group meetings designed to improve implementation. We will monitor your progress in the approach your facility was assigned to. You will also be asked to complete several surveys about yourself, your approach to HIV testing, and your

perceptions of HIV testing implementation. Over the study period, you may be observed and recorded while talking to patients who receive HIV testing services. You may be asked to participate in up to three small group discussions or interviews with a study team member and these discussions will be recorded.

What are the possible benefits from being in this study?
Research is designed to benefit society by gaining new knowledge. You might find that participating in the study helps your ability to talk with patients about HIV testing services. Malawi may benefit from the results of this research by learning new information about how to make HIV services better.

What are the possible risks or discomforts involved with being in this study?
You may feel uncomfortable with being observed or discussing your experiences in a group setting. You can refuse to answer any questions asked of you at any time. If you feel discomfort with any aspect of participation, you can end your participation early and withdraw from the study. There is also a small risk of a breach of confidentiality. Your confidentiality will be protected to the greatest extent possible.

If you choose not to be in the study, what other options do you have?
You do not have to be in this research study in order to work at this clinic.

What if we learn about new findings or information during the study?
You will be given any new information gained during the course of the study that might affect your willingness to continue your participation.

How will your privacy be protected?
All information you provide will remain confidential and used only for the purpose of the study. If you decide to be in this study, you will be assigned a study ID number. This number will be linked to your name only through a separate logbook that will be kept in a separate locked file that is only accessible to study staff. At the conclusion of the study, the link between your name and study ID will be destroyed. All recordings will be transcribed and deleted at study end. Any personal identifiers (for example, your name) will be deleted from the transcript. Recordings and study-related data will be stored on password-protected encrypted platforms. Recordings will be kept for one year after study completion and then deleted. No subjects will be identified in any report or publication about this study. De-identified data from this study may be used for future research. 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?
Most people outside the research team will not see your name on your research information. This includes people who try to get your information using a court order in the United States. One exception is if you agree that we can give out research information with your name on it or for research projects that have been approved under applicable rules. Other exceptions are for information that is required to be reported under law, such as information about child or disabled abuse or neglect or certain harmful diseases that can be spread from one person to another. Personnel of a government agency sponsoring the study may also be provided information about your involvement in the research study.

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 you have failed to follow instructions, or because the entire study has been stopped. If you withdraw or are withdrawn from this study all data collected up until the point of withdrawal will be retained. However, no additional information will be collected unless you provide additional written permission for further data collection at the time of your withdrawal.

Will you receive anything for being in this study?
You will receive the local equivalent of US$10 as compensation for each study visit and each time you participate in a small-group discussion.

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 National Institutes of Health. 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 and have answered any questions you may have about this research. If you have questions, or if a research-related problem occurs, you should contact the researchers listed on this form. 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.

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 IRB. If you have questions or concerns about your rights as a research subject you may contact, anonymously if you wish, the NHSRC secretariat at 01726 422 or 01726 418.

Signature Page: Health Worker Consent Form
Title: Enhancing HIV assisted contact tracing in Malawi through blended learning: an implementation science study
Principal Investigator: Nora E. Rosenberg, PhD. Tapiwa Tembo, Maria Kim, MD

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 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 (DD/MM/YY)
_____	_____	_____
Study Staff Conducting Consent Discussion (print)	Study Staff Signature	Date (DD/MM/YY)

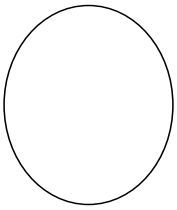
PART B : ILLITERATE PARTICIPANT

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** below**.**

Mark or Thumbprint of participant if unable to sign



_____ _____
Participant Name (print) Participant Thumbprint
Date (DD/MM/YY)

_____		_____
Participant Name and Date Written By		Date (DD/MM/YY)
_____	_____	_____
Study Staff Conducting Consent Discussion (print)	Study Staff Signature	Date (DD/MM/YY)
_____	_____	_____
Impartial Witness Name (print)	Impartial Witness Signature	Date (DD/MM/YY)