

Study title: Kupewa: Optimizing Implementation Strategies for Cervical
Cancer Prevention

NCT number: NCT07015957

Document date: 2 July 2025

This consent form should be signed only
between _____ and _____
Approved by NHRCC, Malawi on _____

CLIENT CONSENT OVER 18 YEARS (ENGLISH)

Informed Consent Form English Version

Research Study Title: Kupewa: Optimizing Strategies to Implement Provider Recommendation of HPV Vaccination for Adolescent Girls and Young Women with HIV in Malawi

Introduction:

Hello. My name is _____. I work for Partners in Hope (PIH), and we are studying HPV vaccination in Malawi. We are carrying out this research in collaboration with researchers at New York University (NYU) and the University of California, Los Angeles (UCLA). We would like to see if you would be interested in participating in this study.

Purpose: We are carrying out this research to learn about uptake of HPV vaccine in Malawi. The study aims to increase health workers' knowledge, skills, and memory to recommend HPV vaccination to girls and young women.

Procedures: Hospitals and health centers that participate in this study will participate in an intervention that includes one or some combination of: 1) trainings for health workers, 2) coaching for health workers, or 3) a reminder system for health workers. Prior to beginning the study, each health facility was randomly assigned to one or more of these interventions. You will not know which of these interventions this health facility is participating in.

If you agree to take part in the research, you will participate in an interviewer-administered survey. We will ask you questions about your visit today, and your attitudes about HPV vaccination. We will also ask for some background information about yourself and other members of your household. This survey will last approximately 20 minutes.

In addition, after your next scheduled HIV care visit, we will conduct up to two follow-up phone call surveys and ask similar questions. The follow-up surveys will last approximately 10 minutes each. You will be given MK18,000 for your time on the surveys, MK6,000 for each survey; you must complete each survey in order to receive the associated payment, although you may skip any survey questions that you wish. We will connect the information you give across all these surveys for data analysis.

At the end of the study, we will also review your medical records from the health center to understand what your health care has looked like over the past year. Specifically, we will look at your HIV medications (prescribed and pill counts at your visits), your HIV-related test results, like viral loads and CD4 measurements when available, and any infections or other complications that may have arisen for you. We may ask you for some of this information from your health passport if we are unable to locate it on your health center mastercard.

Risks: There are minimal risks in participating in this research. To minimize the possibility that others can hear our conversation, we will go somewhere private where we can speak. Before you decide whether you want to participate, it is important to listen to the following information carefully and discuss it with others if you wish.

This consent form should be signed only
between _____ and _____
Approved by NHSRC, Malawi on _____

Benefits: If you choose to answer these questions, there will not be a direct benefit to you, but you will help us to understand if and how to improve health services. Please ask me if there is anything that is not clear or if you would like more information.

Privacy and confidentiality: The information you provide will be kept confidential. We will collect your name, your date of birth, the name of the village/area where you live, and your phone number(s) (to contact you for the follow-up surveys), but if you do not want to answer any of these questions, you may skip it and will not be penalized for doing so.

By continuing this survey, you freely provide consent for PIH to collect, process, and transfer information you share with us for the purposes of this research project. There are no anticipated risks from taking part in this survey. If you do not want to answer any question, you may skip it and will not be penalized for doing so.

PIH commits to comply with the principles of data protection in Malawi. You have the right to be informed on PIH's use of your data, access to your data that PIH holds, and request that PIH update, correct, or delete your data, or opt-out at any time.

We will collect the following data from you:

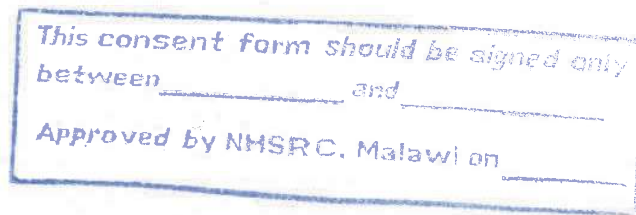
- General information about your household and about your background including your date of birth and the village/area where you live
- Contact information including your name and phone number(s)
- Information on your vaccination against HPV (if you received it and if yes, when and where)
- Knowledge and attitudes about HPV vaccination
- Information from your vaccine card and health passport

PIH may transfer your personal data inside Malawi or to the United States for the purposes of this research project. PIH has in place security measures, such as encrypted software, and limits access to your personal data on a need-to-know basis. Your personal data will only be retained as long as reasonably necessary for this research. Afterwards, PIH will either delete your personal data or anonymize your data to ensure you are no longer identifiable. These de-identified data may be kept for use in future research, and may be shared with the research community to advance scholarly knowledge. We plan to deposit the de-identified data in the Qualitative Data Repository, which is an online database that helps researchers share the information that they learn from their studies with one another, so we can all keep learning together. All information that could identify you will be removed before sharing the data or using it for other research studies. We will not ask you for additional permission before sharing the information.

Withdrawal: Participation in this research is completely voluntary. Choosing not to take part will not disadvantage you in any way. It is up to you to decide whether to take part or not. If you decide to take part, you are free to withdraw at any time and without giving a reason. You are also free to not answer any question that you do not wish to answer.

Questions and contacts: You can ask me any questions that you have about the research. If you have any questions or concerns at a later time about your rights as a research subject or concerns regarding ethical issues, you may contact the National Health Sciences Research Committee by calling:

Dr Evelyn Chitsa Banda
P.O. Box 30377
Lilongwe 3, Malawi.
Telephone 0999-936-937



This committee has reviewed research protocol in Malawi and can guide participants on how to report any matters that perceived violation of any of their rights as participants.

If you have questions about your rights as a research participant or if you believe you have been harmed from the research, please contact the NYU Human Research Protection Program at +1-212-998-4808 or ask.humansubjects@nyu.edu

Do you have any further questions at this time?

Consent

I have read (or someone has read to me) the information provided above. I have been given an opportunity to ask questions and all of my questions have been answered to my satisfaction. I have been given a copy of this form.

BY SIGNING THIS FORM, I WILLINGLY AGREE TO PARTICIPATE IN THE RESEARCH:

Name of Subject

Name of Legal Representative (if applicable)

DATE (DAY/MO/YR):

Signature of Subject or Legal Representative

OR



Thumb print of subject

SIGNATURE OF INVESTIGATOR OR DESIGNEE

I have explained the research to the subject or his/her legal representative and answered all of his/her questions. I believe that he/she understands the information described in this document and freely consents to participate.

*This consent form should be signed only
between _____ and _____
Approved by NHSRC, Malawi on _____*

Name of Investigator or Designee _____

Signature of Investigator or Designee _____

Date (must be the same as subject's) _____

Study Site _____

IF NO END THE SURVEY AND THANK THE RESPONDENT FOR HER TIME.

Do you feel that you can answer these questions privately now? ☐ Yes ☐ No
If not, schedule a time to re-visit.