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Informed Consent for Providers

TITLE: Pharmacy PrEP cRCT
Version 1.3 August 1st, 2023

INVESTIGATORS:

Investigator	Title	Institution	Telephone
Local investigators			
<Name, site Co-PI)>	Co-Site Principal Investigator	<site institution>	<telephone #>
<Name, other site Co-PI)>	Co-Site Principal Investigator	<site institution>	<telephone #>
<Name, site Co-I)>	Co-Investigator	<site institution>	<telephone #>
<Name, other site Co-I)>	Co-Investigator	<site institution>	<telephone #>
<Name, other site Co-I)>	Co-Investigator	<site institution>	<telephone #>
<Name, other site Co-I)>	Co-Investigator	<site institution>	<telephone #>
<Name, other site Co-I)>	Co-Investigator	<site institution>	<telephone #>
International investigators			
Dr. Katrina Ortblad	Principal Investigator	Fred Hutchinson Cancer Research Center	+1-2066677267

Emergency number: <emergency phone # for site>
Study location: <site in Kenya>

Key Information for You to Consider

- **Voluntary Consent**. You are being asked to volunteer for a research study. It is up to you whether you choose to participate or not. There are no penalties and you will not lose anything if you decide not to join or, if after you join, you decide to quit.
- **Purpose**. Pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP) are two medications that can help prevent HIV. Right now in Kenya, PrEP and PEP are primarily available in HIV clinics. The purpose of this study is to understand how PrEP and PEP could additionally be delivered at retail pharmacies in Kenya. This study will test four different delivery models: one in which pharmacy providers deliver PrEP and PEP to clients for a fee (model 1); one in which pharmacy providers (model 2) or an HIV Testing Services (HTS) counselor stationed at the pharmacy (model 3) deliver it for free (i.e., at no cost to clients); and one in which pharmacy providers screen and refer clients to nearby health facilities with HIV clinics (model 4).
- **Procedures and activities.** As part of the research components of this study, you will receive periodic visits from a technical assistant who will answer any questions you may have and ask you questions about how PrEP/PEP screening, delivery, and/or referrals are going at your pharmacy and document your response. Near study endline, a trained research assistant will come to your pharmacy to administer a brief survey to you about time and costs associated with PrEP/PEP screening, delivery, and referral. At baseline and approximately 60 and 270 days into the study, we will invite you to participate in an optional survey about your experience screening, delivering, and referring clients for PrEP and PEP services. You will be compensated Ksh 500/= each time you complete this survey, if you choose to do so. During this study, you may also be invited to participate in a single, confidential interview about your experience delivering PrEP/PEP services. This interview, if you decide to complete one, will take no longer than 1 hour to complete, and you will receive Ksh 500/= for completing it.
- **Duration.** The study will run for 24 months. Approximately 16 months into the study, your pharmacy may be chosen to provide a modified version of the delivery model. If this happens, the study will provide you with additional training, as needed.
- **Risks.** In this study, we expect that you may become embarrassed, worried, or anxious when talking to study staff about your experiences delivering PrEP/PEP services.
- **Benefits**. You may get no direct benefit from participating in this study. However, you will contribute to developing new delivery models for PrEP and PEP in Africa, which will help others in the future.

- **Alternatives.** Participation is voluntary. Some portions of the research are optional. If you don't want to participate in the required portion of the study, then the only alternative is to not participate.

DESCRIPTION OF RESEARCH

The primary purpose of this study is to assess different ways to deliver PrEP and PEP services at retail pharmacies in Kenya. If you decide to take part, you will engage in the following research-related activities:

- Technical assistance: During the study, you will receive periodic visits from a technical assistant (TA) with expertise in PrEP/PEP delivery who will answer any questions you may have, ask you questions about how PrEP/PEP delivery or referral is going at your pharmacy, and document their findings. These TA visits will be more frequent (e.g., every two weeks) when your pharmacy first begins delivering services, then reduce to monthly and every other month over time. Each visit will last no longer than 1 hour.
- Monitored WhatsApp Group: During the study, you may decide to consult the study's remote clinician via phone, SMS, or a WhatsApp group created specifically for this study. All WhatsApp messages between pharmacy providers and the study's remote clinician will be securely stored in an online database and used as research data to understand the kinds of questions and support pharmacy providers need to deliver PrEP and PEP services.
- Costing survey: Near study endline, an RA will come to your pharmacy to administer a one-time survey to you about time and costs associated with PrEP/PEP delivery and referral and to observe clients.
- Provider surveys: At baseline and at approximately 60 and 270 days after the study starts, we will invite you to participate in a confidential survey about your experience delivering PrEP and PEP. Each time you opt to do this survey, which will take no longer than 1 hour to complete, you will be compensated Ksh 500/=.
- Interview: You may also be invited to participate in a one-time confidential interview about your experience delivering PrEP/PEP. This interview, if you decide to complete one, will take no longer than 1 hour to complete, and you will receive Ksh 500/= for completing it.
- There are no costs to you to participate in these research activities.

USING YOUR DATA FOR FUTURE RESEARCH

The information that we obtain from you for this study might be used for future studies. Your information will be assigned a unique identification code and any identifying information linking you to this code will be stored in a secure location at the research site. If we use the information you give us or if we give it to another investigator for future research studies we will not share any information that can identify you, but only use the unique identification code. In that case, we will not get additional permissions from you.

RISKS AND/OR DISCOMFORTS

Sharing your experience with and attitudes towards pharmacy-based delivery of PrEP and PEP with study staff may be uncomfortable.

BENEFITS

You may get no direct benefit from participating in this study. However, you will contribute to developing new delivery models for PrEP and PEP in Kenya, which will help others in the future.

CONFIDENTIALITY OF RESEARCH INFORMATION

Your information will be kept private and any publication of this study will not use your name or identify you personally. Some organizations may need to look at your research records for quality assurance or data analysis. These include:

- Agencies or data monitoring boards, who need it in order to check and assess the research.

- To the funding agency and groups involved in the research, if they need the information to make sure the research is being done correctly.

• Institutional Review Boards (IRB) or Ethics Review Boards. An IRB is a group that reviews the study to protect your rights as a research participant.

A description of this clinical trial will be available on http://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.

REIMBURSEMENT FOR SELECT RESEARCH ACTIVITIES

You will be invited to complete a survey at study baseline and at 60 days and 270 days into the study. Each time you complete a survey, you will receive Ksh 500/= for your time and effort. You may be invited to participate in a one-time interview; if you decide to participate in this interview, you will receive Ksh 500/=.

YOUR PARTICIPATION IS VOLUNTARY

It is important that you know the following:

- You do not have to be in this study if you do not want to join.
- You may decide not to take part in this study, or to withdraw from the study at any time, without any repercussions to you.
- If you decide not to take part in this study, you can still join another research study later, if one is available and you qualify.

SOURCE OF FUNDING

The study team is receiving financial support from the Bill & Melinda Gates Foundation.

YOUR RIGHTS UNDER DATA PROTECTION LAWS

You have the right to access, correct, and restrict the use of your data at any time during the study. You also have the right to report a complaint to your local data protection authority: Data Protection Commissioner, Ministry of ICT, Innovation and Youth Affairs, Teleposta Towers, Kenyatta Avenue off Koinange Street, P.O Box 30025-00100, Nairobi – Kenya, Telephone: (+254) 020 4920000 / 1. Email: info@information.go.ke. You can object at any time to your data being used for the study, however, in that case, you will also have to stop your participation in the study. You can exercise those rights through the study staff.

PROBLEMS OR QUESTIONS

If you ever have any questions about this research or if you think you have been harmed by research participation, you should contact <site co-PI> on <emergency phone #>.

If you have questions about your rights as a participant, contact the Committee Chairperson, KEMRI Scientific and Ethics Review Unit, P.O. Box 54840-00200, Nairobi, Telephone number 020272-2541, 0717719477. Email address: seru@kemri.go.ke. You can also contact the Director of the Fred Hutch Institutional Review Office at 001 206-667-5900 or email irodirector@fredhutch.org.

STATEMENT OF CONSENT AND SIGNATURES

I have read this form or had it read to me. I have discussed the information with study staff. My questions have been answered. I understand that my decision whether or not to take part in the study is voluntary. I understand that if I decide to participate, I may withdraw at any time. By signing this form, I do not give up any rights that I have as a research participant.

_____	_____	_____
Participant Name (print)	Participant Signature/Thumbprint	Date

_____	_____	_____
Study Staff Conducting Study Consent Discussion (print)	Staff Signature	Date
_____	_____	_____
Witness Name (print)	Witness Signature	Date

Copies to: 1. Investigators
2. Study participant