University of California, San Francisco (UCSF) & Kenya Medical Research Institute (KEMRI)
Written consent for research study participation

FOR PILOT STUDY PARTICIPANTS

Study Title: Viremia Risk Study: Enhanced virologic monitoring to facilitate adherence support for pregnant and postpartum women at risk of HIV viremia

Principal Researchers:

Name	Role	Institution	Telephone number
James Ayeiko, MBChB, MPH, PhD	Principal Investigator	KEMRI	+254-720-925-262
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Researcher's Statement

I would like to tell you about a study being conducted by researchers from the Kenya Medical Research Institute (KEMRI) and the University of California, San Francisco (UCSF) in the United States. The purpose of this consent form is to give you the information you will need to help you decide whether to be in the study or not. This is a research study about implementing enhanced viral load monitoring for pregnant and postpartum women living with HIV, in order to support them with treatment adherence. The study researchers will explain this study to you. Please ask questions about any information before you decide whether to participate. You may also wish to talk to others (for example, your family, friends or your doctor) about this study before agreeing to join.

Key Information for You to Consider

- **Voluntary consent.** It is up to you whether you choose to participate or not. There are no penalties for not participating. You will not lose any benefits to which you are otherwise entitled if you decide to not to join or if you decide to stop participating after joining.

- **Purpose.** The purpose of this study is to evaluate the potential impact of enhanced virologic monitoring to support adherence for pregnant/postpartum women at risk of HIV viremia in western Kenya. You are being asked to participate because you are receiving care from this facility, and these services could impact women like you.

- **Study duration.** This study will be conducted over 6 months in 2023.

- **Procedures.** We will ask you to answer some brief questionnaires and will collect some information from your clinic file. For some participants, but not all, we will collect up to 2 additional blood samples for viral load – at enrollment and in 3 months. If you have a detectable viral load, we will offer additional counselling. Also, we will invite some participants to complete additional questionnaires about study participation after 3 months.

- **Risks.** There are no major risks to being in this study. Some of the questions may make you uncomfortable. If we collect a blood sample, you may experience mild pain and discomfort from having your blood drawn. There is a small risk of loss of privacy. Participation could increase your exposure to COVID. We will take all possible precautions to minimize these risks.

- **Benefits**. We expect no direct benefit to you from participating in this study. However, the information that you provide will help health professionals learn more about supporting HIV care services for pregnant and postpartum women. The new understanding gained from this research about how to better target services to individuals at high risk of poor outcomes has the potential to benefit HIV patients in sub-Saharan Africa broadly.

- **Alternatives**. Participation is voluntary and the alternative is not to participate.

Following is a more complete description of this study. Please read this description carefully. You can ask any questions you want to help you decide whether to join the study. If you join this study, we will give you a signed copy of this form to keep for future reference.

DETAILED STUDY INFORMATION

Research studies only include people who choose to take part. Please take your time to make your decision about participating. Discuss your decision with your family or friends if you wish. If you have any questions, you may ask the researchers.

You are being asked to participate because you are receiving care from this facility, and these services could impact women like you.

Why is this study being done?
The purpose of this study is to evaluate whether we can improve how we monitor viral load so that we can better help pregnant and postpartum women with treatment adherence. This study is funded by the National Institutes of Health in the United States.

How many people will take part in this study?
We are inviting about 275 to participate in the pilot study, and 125 women to participate as a comparison group. You would be part of the pilot study group. We will also include women in the study who are not interviewed but will just include their clinical records. Overall, up to 720 women will be included in this study.

What will happen if I take part in this research study?
If you agree to be in this study, we will ask you to answer some questionnaires which should take about 20 minutes to complete. We will ask about your mood and about feeling stressed. Some of the questions may make you feel uncomfortable or raise unpleasant memories. You are free to skip any question. One form is used to measure depression. If your answers suggest that you are at risk of depression, we will refer you for further screening and will cover the cost of that initial screen, up to KShs 2000. If you are then referred for further care, you will be responsible to cover those costs, which might be up to KShs 2000. We will also collect a blood sample to measure your viral load. If you enroll at least 3 months before our 6-month study period is over, we will collect your viral load after 3 months. The blood will be drawn by putting a needle into a vein in your arm. One small tube of blood (less than a teaspoon) will be taken. This will take about five to ten minutes. As a participant in the pilot study, you will receive additional counseling and information about your viral load results from a mentor mother. After you are done participating, we will look up your viral load that is collected in the next 6 months.

Study location:
All these procedures will be done at the clinic.

How long will I be in the study?
At baseline, participation will take about 30 minutes. If you enroll at least 3 months before our 6-month study period is over, we will collect your viral load after 3 months, and will ask you to complete additional questionnaires, which together will take about 30 minutes.

Can I stop being in the study?
Yes, you can stop your participation at any time. Your care will not be impacted if you decide not to be in this study.

What risks can I expect from being in the study?
- Some of the questions may make you feel uncomfortable. If your responses suggest you are at risk of depression, or are thinking of hurting yourself, we will refer you to a social worker that same day for further counselling and support.
- The needle stick may hurt. There is a small risk of bruising and fainting, and a rare risk of infection.
- Participation could increase your exposure to COVID. To reduce your risk, you and the research staff will be screened for COVID symptoms, including a temperature check, prior to the interview. Anyone with symptoms will be referred for testing and will not participate that day.
- As with all research, there is a chance that confidentiality could be compromised; however, we are taking precautions to minimize this risk.

- Ask one of the researchers if you would like to discuss potential risks further.

Are there benefits to taking part in the study?
There will be no direct benefit to you from participating in this study. However, the information that you provide may help health professionals better understand how to target services to individuals at high risk of poor outcomes, which has the potential to benefit HIV patients in sub-Saharan Africa broadly.

What other choices do I have if I do not take part in this study?
You are free to choose not to participate in the study. If you decide not to take part in this study, there will be no penalty to you. Participation, or not, will have no impact on your care at this clinic.

How will my information be used?
Researchers will use your information to conduct this study. Once these studies are done, we may share your information with other researchers so they can use them for other studies in the future. We will not share your name or any other personal information that would let the researchers know who you are. We will not ask you for additional permission to share this de-identified information.

Research results:
The researchers hope to learn new information in this study, and plan to share that information with other researchers and care providers with the hopes that these results can improve care.

Will information about me be kept private?
We will do our best to make sure that the personal information gathered for this study is kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Authorized representatives from the following organizations may review your de-identified research data for the purpose of monitoring or managing the conduct of this study:
- Representatives of the National Institutes of Health
- Representatives of the University of California
- Representatives of the Kenya Medical Research Institute

Participation in research may involve a loss of privacy, but information about you will be handled as confidentially as possible. A study record will be created because of your participation in this study. Your consent form and the text of the focus group discussion will be included in this record. The consent form will be stored in a locked safe within a locked office. Blood samples obtained for this research will be destroyed as soon they have been tested by the lab facility that processes them.

A description of this clinical trial will be available on https://www.clinicaltrials.gov/, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Are there any costs to me for taking part in this study?
No. There are no costs to you for participation.

Will I be paid for taking part in this study?
In return for your time and travel expenses, you will be paid 500 KShs.

What are my rights if I take part in this study?
Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you in any way.

Who can answer my questions about the study?
You can talk to the researchers about any questions, concerns, or complaints you have about this study. Contact the researchers:

- James Ayieko, +254-720-925-262 (Kenya)
- Pamela Murnane, +1-415-502-1000 ext. 14614 (USA)

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please contact:
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Kenya: Committee Chairperson KEMRI Scientific and Ethics Review Unit • P. O. Box 54840-00200, Nairobi • Phone: 020-2722541, 0717719477 • Email address: seru@kemri.org	USA: Committee on Human Research at UCSF • Phone: +1-415-476-1814 • E-mail address: chr@ucsf.edu

CONSENT
You have been given a copy of this consent form to keep. PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to be in this study, or to withdraw from it at any point without penalty or loss of benefits to which you are otherwise entitled.

If you wish to participate in this study, you should sign below.

Subject's Statement
This study described above has been explained to me. I volunteer to take part in this research I have had a chance to ask questions. If I have future questions about the research, I can ask one of the investigators listed above. If I have questions about my rights as a research subject, I can contact the ethics departments listed above.

Consent to participate in the study Yes ___ No___ Date _____

Consent to have my blood drawn Yes___ No___ Date _____

Consent to complete the questionnaire Yes___ No___ Date _____

Consent to checking my records for future viral load results

Yes___ No___ Date _____

We might like to contact you in the future to see if you would be interested in participating in a follow-up research study. Please indicate if you are willing to be contacted about future research studies.

Consent for future research Yes ___ No___ Date _____

SIGNATURE OF PARTICIPANT

_____
Printed Name of Participant

_____ _____
Signature of Study Participant and Date Thumbprint of Study Participant and Date

SIGNATURE OF WITNESS

_____
Printed Name of Witness

_____ _____
Signature of Witness Date

SIGNATURE OF INDIVIDUAL ADMINISTERING CONSENT
(Can only be signed by an investigator or staff approved to administer consent)

_____
Printed Name of Administering Individual

_____ _____
Signature of Administering Individual Date