UNIVERSITY OF WASHINGTON (UW) and UNIVERSITY of NAIROBI (UoN) Collaborative Study Group

CONSENT FOR RANDOMIZED TRIAL

Evaluation of mHealth strategies to optimize adherence and efficacy of PMTCT/ART

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Researchers' statement

We are asking you to be in a research study. The purpose of this form is to give you the information you will need to help you decide whether to be in the study or not. Please read the form carefully. You may ask questions about the purpose of the research, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions, you can decide if you want to be in the study or not. This process is called "informed consent." We will give you a copy of this form for your records.

PURPOSE OF THE STUDY

Adhering to drugs called "antiretrovirals", or ARVs, to treat HIV infection in mothers is important to prevent their infants from becoming infected with HIV and keeping them healthy during their pregnancy and throughout their lives. Some women experience difficulty taking their ARVs during pregnancy, during the breastfeeding period, and after breastfeeding has stopped. We are conducting a research study to see if sending information by SMS would help women remember to take their ARVs, stay in HIV care programs, and improve maternal and infant health. We aim to enroll 825 women into the study.

STUDY PROCEDURES

This is what will happen if you agree to participate in this study. We will ask you to read, discuss, and sign or make your mark on this form. After this form is signed or marked, the study staff will ask you questions about you, your contact information, your family, and your pregnancy. A study nurse will collect blood from you. You will be assigned to one of three groups. You cannot choose which group you will be placed in. The nurse will hand you an envelope that contains your group assignment. The three groups you may be assigned to are:

1. Control Group
If you are in the control group you will continue to receive care as usual in the clinic. You will not receive any SMS from the study.

2. One–way SMS group
If you are in the one-way SMS group you will receive SMS on your mobile phone from the study. You will not be able to send SMS to the study.

3. Two-way or interactive SMS group
If you are in the two-way or interactive SMS group you will receive SMS from the study on your mobile phone. Some of the SMS will contain a question that solicits – but does not require – a response from you. We request that you respond to those questions. If you do not respond, you will receive a follow-up or "check-in" SMS after not responding for 2 weeks. The "check-in SMS" will ask if you are receiving SMS and if you are well. If no response is received from you, no further "check-in SMS" will be sent. However, you will continue to receive regular weekly SMS. You will also be able to send SMS with concerns or questions to the study nurse.

If you are assigned to the one-way OR two-way SMS groups, the SMS will contain information about general health, medication adherence, visit reminders, pregnancy support, birth preparedness, infant breastfeeding, family planning, and infant health. The SMS will be delivered weekly to your phone. None of the SMS will contain the words: HIV, antiretrovirals

or ARVs, or other HIV specific words, unless you specifically want this information and consent to receiving HIV-related information. All charges associated with the SMS will be paid by the study. You will not have to pay to receive SMS from the study. If you enroll in the study and later decide you no longer wish to receive SMS you can stop the SMS by sending an SMS containing "STOP" to the study short code.

Study visits

The study will last until 24 months after your baby is born. We will ask you to meet with the study nurse today, 6 weeks after your baby is born and every 6 months thereafter for 24 months. Each visit should take approximately 1 to 1.5 hours. At each visit we will ask you questions about you and your health. We will also collect blood to measure the amount of HIV virus in your body and immune factors that fight against infection, called "CD4 T cells". If we detect sufficient amounts of HIV virus in your blood, we will test your virus for drug resistance. If you have a resistant virus, it may not respond to ART. We will provide these results to your healthcare provider at the clinic to help them make decisions about what treatment is best for you. We will also test your baby for HIV at the end of the study.

At each study visit you will:

- Be asked questions regarding your HIV care, pregnancy or postpartum health.
- Have blood collected (14mL or about 2 tablespoons).
- Provide information regarding your adherence to your medications.
- Be asked for updated information on your phone number and where you live.

After you deliver your baby you will:

- Be asked questions about your delivery.

At each postpartum study visit you will

- Have blood (0.5 mL, or about 5 drops) collected from your baby.
- Be asked questions about your baby's health.

At the end of the study you will:

- Be asked questions about your experiences in the study, and with SMS.
- We will collect 0.5 ml or about 5 drops of blood from your baby for a final HIV test.

Record abstraction

In between your study visits, we will also collect your and your baby's information from records in the MCH, PSC/CCC, pharmacy or lab.

Home visits

If you are comfortable having a home visit, we will visit your home after the first study visit to make sure we have an accurate way to contact you in case your phone contacts change.

If you do not return for your study visits, we will also conduct a home visit at the end of the study to check on you.

MEDICAL RECORD INFORMATION

We will ask for access to your and your baby's clinic and pharmacy records to find out more information about your pregnancy, delivery, and postpartum care. If you agree to give us access to your medical records, we will get information from the facilities where you receive antenatal and postpartum care and delivered your baby, including: any health problems, medication adherence and side effects, and your baby's health information. We will also record laboratory test results, like your CD4 and HIV viral load tests, and infant's HIV tests.

Missed visits It is very important that you come for all your scheduled visits. If you are unable to make your clinic appointment, come to the clinic as soon as you are able. If you miss a clinic visit, you will receive an SMS reminder if you are enrolled in the one-way SMS or two-way SMS groups. We will also call you 1 month, 1 year and 2 years after you deliver your baby to check how you are doing. If you do not return for all study visits, we will visit your home at the end to the study to find out how you are doing. We will not tell anyone why we are trying to reach you.

RISKS, STRESS, OR DISCOMFORT

Blood collection (venipuncture): Blood draw may be associated with discomfort, dizziness, pain or bruising.

SMS: Receiving information by your mobile phone is generally safe, but it is possible that other people could see the SMS we send you if you are in the one-way or two-way groups. The information could include things about missed appointments and medication reminders. There is a potential risk of disclosure of an individual's personal information to others in situations where phones are shared or stolen. However, we will not send any sensitive information or words that would be related to HIV by SMS, unless you want to receive this information and specifically consent to receiving HIV-related information. We also recommend that you avoid sending sensitive questions or information if possible and delete sensitive SMS you send from your phones. We will remind you to do this at each study visit.

ALTERNATIVES TO TAKING PART IN THIS STUDY

There may be other studies going on here or in the community that you or your baby may be eligible for. If you wish, we will tell you about other studies that we know about. There also may be other places where you can go for HIV counseling and testing or for medical care. We will tell you about those places if you wish. **Whether or not you decide to participate in this research study, you can continue to receive your mother-child health care at this clinic.**

BENEFITS OF THE STUDY

You may benefit from additional HIV-related tests, which may help your HIV care provider know if the ARVs are working well. If you are assigned to one of the intervention arms, you may also benefit from ARV adherence encouragement and reminders, as well as more information on pregnancy, delivery, breast-feeding, family planning, vaccinations and prevention of HIV transmission to your baby.

By participating in the study you will contribute to our understanding of how to deliver education and counseling to improve HIV ARV adherence during pregnancy and beyond.

SOURCE OF FUNDING

The study team and/or the University of Washington are receiving financial support from the National Institutes of Health in the United States; grant number R01 HD080460.

OTHER INFORMATION

Your participation is voluntary

- You do not have to be in this study if you do not want to.
- You may withdraw from the study, or decide not to have any test or answer any question without losing your regular medical care.

Reasons why you may be withdrawn from the study

You may be removed from the study without your consent for the following reasons:

- The research study is stopped or cancelled.
- The study staff feels that participating in the study would be harmful to you.

Costs to you

There is no cost to you for participation in the study. Routine clinical care and services will not be provided by the study. However, you will continue to receive your care and treatment at the MCH and and PSC/CCC.

Reimbursement

You will receive Ksh 300.00 for your transportation costs and effort at each scheduled study visit.

CONFIDENTIALITY OF RESEARCH INFORMATION

Confidentiality

We will keep your identity as a research subject confidential. Your HIV test results, medical records, and responses to questions will be kept private. If we find evidence of ART resistance in your study visit blood samples, we will share this information with your healthcare provider so that they can use this information in your care. Other than this, no identifying information of any kind will be released to any other person or agency that is not working on this study, without your permission in writing. We will not publish or discuss in public anything that could identify you. Any specimens you provide, and your medical information will be identified by a code number. All of your information, including the link between your name and code number will be kept in a secure location at the clinic only. Once the study is completed, we will maintain the link for 5 years, after this time we will remove your name and all identifying information from the study files. Any publication of this study will not use your name or identify you personally. However, the study team may share identifiable information about you in the case the study team becomes aware of possible harm to yourself or others.

Although we will make every effort to keep your information confidential, no system for protecting your confidentiality can be completely secure. It is still possible that someone could find out you were in this study and could find out information about you.

Government or university staff may review studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your records may be examined. The reviewers will protect your privacy. The study records will not be used to put you at legal risk of harm.

<u>Study records may be reviewed by:</u>

- University of Washington, including the Institutional Review Board

- Kenyatta National Hospital and University of Nairobi, including the Ethics and Research Committee
- National Institutes of Health (NIH)

A description of this clinical trial will be available on http://www.clinical.trials.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 Web site at any time.

A copy of your consent form will be placed in your study record.

Research-Related Injury

If you are injured as a result of the blood draw, the study staff will give you immediate necessary treatment for your injuries, free of charge. The study staff will also tell you where you can get additional treatment for your injuries, if needed. The research study will not provide monetary compensation or other forms of compensation for such injuries. You do not give up any legal rights by signing this consent form.

Problems or Questions

If you ever have any questions about this study, or if you have a research-related injury, you should contact Dr. John Kinuthia.

If you have questions about your rights as a research participant, you should contact the Kenyatta National Hospital Ethics and Research Committee, at 2726300 Ext. 44102.

Printed name of study staff obtaining consent Signature Date

Subject's statement

This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions later about the research, I can ask one of the researchers listed above. If I have questions about my rights as a research subject, I can call the *Kenyatta National Hospital Ethics and Research Committee, at 2726300 Ext. 44102*. I give permission to the researchers to use my medical records including my baby's as described in this consent form. I will receive a copy of this consent form.

Printed name of subject Signature of subject Date

Witness Name Witness Signature Date (print)

SPECIMEN STORAGE AND USE OF YOUR SAMPLES FOR FUTURE STUDIES

We would like to save samples of your blood and your baby's blood, at the KEMRI/ CDC, University of Nairobi, the University of Washington, Seattle Children's Hospital or the Fred Hutchinson Cancer Research Center for future research on HIV and maternal and infant health.

The site study coordinator and principal investigators will be responsible for the samples. This may include testing for genes which may affect whether a person is more or less likely to get infections, or things that may affect infant and maternal health (mother's health during pregnancy, delivery, and postpartum period with special emphasis on HIV-related illnesses). Information we get from you, and your samples, may be shared with other investigators studying HIV or mother and child health. We will not share your name or any identifying information with them.

The Kenyatta National Hospital/University of Nairobi Ethics and Research Review Committee, which watches over the safety and rights of research participants, must approve future research studies in which we will use your or your baby's samples to obtain information about both of you. Permission from the University of Nairobi's Ethics Committee will be sought before any of these samples are used for future research.

These tests are for research and are not useful for your or your baby's clinical care.

Before your samples or your baby's samples leave the clinic, they will be assigned a code and your name or your baby's name will not be on them.

We will store these samples for five years after completion of the study. After this, they will be discarded. Storage of samples past this time period will only occur with approval from an Institutional Review Board and Ethics Committee.

If you do not want to have your or your baby's samples saved for future research, you can still be in this study and your or your baby's samples will be destroyed once testing for the study is completed. If you agree to store your or your baby's samples now, but change your mind before the end of the study, let the study staff know and we will make sure that your or your baby's samples do not get stored for future research. We will not sell your or your baby's samples. Tests done on your or your baby's samples may lead to a new invention or discovery. We have no plans to share any money or other benefits resulting from any potential invention or discovery with you.

Please select 'Yes' or 'No' for **each** of the following options, then mark or initial and date:

YES ____ NO ____ You can store **my samples** for future research into HIV

YES ____ NO ____ You can store **my samples** for future research into maternal health

YES ____ NO ____ You can store **samples from my baby** for future research into HIV

YES ____ NO ____ You can store **samples from my baby** for future research into infant health

_____	_____
Participant Initials	Date

_____	_____	_____
Witness Name	Witness Signature	Date (print)

HIV-RELATED SMS

You have the **option** to receive SMS that contain HIV-related content if:

1. you have disclosed your HIV status to anyone who may have access to your phone, or
2. you have your own phone, and no one has access to it.

You will not receive HIV-related content if you have not disclosed your status to people who have access to your phone and you do not have your own phone.

You will only receive these SMS if you want them and consent to them, and if you are assigned to the one-way SMS or two-way SMS groups. These messages are intended to help you adhere to your HIV medications and take care of your health. They may include words such as medications, antiretrovirals, ARVs, or related terms and may contain information on topics such as medication side-effects, prevention of mother-to-child transmission (PMTCT) and infant prophylaxis. You have three possible choices regarding HIV-related messages:

1. Receive NO HIV-related SMS.
2. Receive HIV-related SMS only in response to a question about HIV that you send to the study nurse.
3. Receive HIV-related SMS from the study as part of the regular weekly SMS sent to participants and in response to a question about HIV that you send to the study nurse.

Benefits of receiving HIV-related SMS

Choosing to receive SMS that contain HIV-related terms may allow you to receive more detailed information on topics such as challenges with medications, ARV side-effects, PMTCT and infant prophylaxis. If you are assigned to the two-way SMS group, this will also allow the study nurse to respond in more detail to any questions you may have about HIV, ARVs or PMTCT.

Risks of receiving HIV-related SMS

If you choose to receive HIV-related SMS, there is a risk that your HIV status will be disclosed if your phone is shared or stolen. We will only offer the option of receiving HIV-related SMS if you have disclosed your HIV status to anyone who may have access to your phone. If you are concerned about someone reading your SMS you may want to delete sent or received SMS that may disclose your status.

Receiving HIV-related SMS is completely optional.

- If you do not want to receive HIV-related SMS, you may still participate in the study and you will not receive any SMS that contain HIV-related terms.
- If you choose to receive HIV-related SMS now but later change your mind before the end of the study, let the study staff know and we will make sure you no longer receive these SMS.
- If you choose not to receive HIV-related SMS now but later change your mind before the end of the study, let the study staff know and we will adjust the SMS you receive.

*Please select **ONE** option* then mark or initial and date*:*

☐ 1. I have my own phone and no one has access to it.

☐ 2. I share my phone and I have disclosed my HIV status to anyone who may have access to my phone.

☐ 3. I share my phone and I have NOT disclosed my HIV status to anyone who may have access to my phone.

_____ _____

Participant Initials Date

If option 3 is selected: you will not be sent any HIV-related SMS. If your disclosure status changes and you would like to receive HIV-related SMS, please let the study staff know and we will adjust the SMS you receive.

If options 1 or 2 are selected, please select ***ONE*** option then mark or initial and date:

☐ I do NOT wish to receive any HIV-related SMS.

☐ I would like to receive HIV-related SMS ONLY if they are sent in response to questions I send about HIV to the study nurse.

☐ I would like to receive HIV-related SMS as part of the regular weekly SMS AND in response to questions I send about HIV to the study nurse.

_____ _____
Participant Initials Date

_____ _____ _____
Witness Name Witness Signature Date (print)

Copies to: Researcher
Subject
Subject's Study Record