A Phase 2b randomized, open-label, controlled, single center study in *Plasmodium falciparum*-infected and uninfected adults age 18-55 years old in Kenya to evaluate the efficacy of the delayed, fractional dose RTS,S/AS01$_E$ malaria vaccine in subjects treated with artemisinin combination therapy plus primaquine

Research Team

US Army Medical Research Directorate-Africa (USAMRD-A) & Kenya Medical Research Institute (KEMRI), Kombewa, Kenya
[redacted]
[redacted]
[redacted]

Sponsor: PATH

Study Funder: PATH

You are being asked to take part in a research study. The box below tells you important things you should think about before deciding to join the study. We will provide more detailed information below the box. Please ask questions about any of the 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.

Please contact one of the research team (above) if you have any questions concerning the study or if you have any other questions or concerns.

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 take part or not. There are no penalties and you will not lose anything if you decide not to join or if you join and drop out later.
- **Purpose.** We are doing this research to test the RTS,S malaria vaccine here in western Kenya. We will test the safety of the vaccine, test how your body's immune system works when given the vaccine, and see if the vaccine helps prevent malaria in adults when used with or without drugs that kill malaria.
- **Duration.** You will take part in the study for about 14.5 to 20.5 months. This will include up to 35 visits at either the Kombewa Clinical Research Centre or your home. Visits will last from 30 minutes up to 4 hours.
- **Procedures and Activities.** The study involves:
  - Having physical exams;
  - Answering questions about yourself and your medical history;
  - Giving blood samples throughout the study;
  - Receiving either the RTS,S malaria vaccine or the rabies vaccine;
  - Reporting any problems you have after vaccination;
  - Coming to the clinic for visits and sometimes having visits in your home.

  The study will include 619 adult men and women. Each person is put into 1 of 5 study groups by chance. These groups will receive either the RTS,S or the rabies vaccine. Four of the groups will be treated with anti-malarial drugs prior to each vaccination. You will be screened with a test to see if there are any parasites in the blood and will be assigned to the different groups depending upon the results of this test.

  If you are a woman, you must avoid pregnancy until 2 months after all vaccinations are received. We will counsel you about the best way to avoid pregnancy.

  There are no costs to you to be in the study.

  We will keep your study information confidential.

  We will ask to keep your biological samples for future research. If you decline to permit us to keep your biological samples, you can still take part in the study.
- **Risks.** Most studies have some possible harms that could happen to you if you join. In this study, we expect that the risks are few. This is because all drugs and vaccines being used in this study have already been studied a lot and found to be safe. With the malaria medicines, you may have mild side effects including stomach upset, and there is a risk of anemia (a drop in red blood cells). For the vaccinations, the most likely side effect is pain or irritation where the vaccine is injected. While very rare, you can have a life-threatening allergic reaction with all medicines and vaccines.
- **Benefits.** You will receive free medical screening and medical care for acute medical problems during the study. You will also receive the rabies vaccine either during or after the study. The rabies vaccine helps protect you against rabies if you are bitten by a rabid animal. If you receive the RTS,S malaria

vaccine, the vaccine may prevent you from getting malaria. This study may benefit others because it may help to make a malaria vaccine available.
- **Alternatives.** Taking part is voluntary. The only alternative is to not take part.

1. We are asking you to be in a research study.

A research study is a way to learn new things. It is not the same as treatment or medical care. This is a study about how the vaccine, RTS,S, prevents malaria infection in adults.

Malaria comes from the bite of a mosquito that has been infected with malaria parasites. Malaria affects many people in tropical countries such as Kenya. It is a big cause of death in young children. It causes serious disease in adults in Kenya and throughout tropical countries. In areas such as Kenya, many adults have had malaria infections in childhood and into adulthood. Often adults with malaria parasites may not feel ill. Scientists are working together to understand how the RTS,S malaria vaccine provides protection in adults. Adults may have very low levels of the malaria parasite in their blood but have no other symptoms. We are trying to understand if giving anti-malarial drugs before RTS,S immunization makes the vaccine work better. In some persons, there may be no parasites in the blood and we think that the vaccine will work better in these persons.

The RTS,S malaria vaccine is approved by Kenyan regulatory agencies for use in young children in a pilot vaccination program in Kenya, Malawi and Ghana. In a large study in young children, the RTS,S vaccine lowered the risk of getting malaria by about one-half and decreased the severity of disease by about one-third. We now want to understand how well the RTS,S vaccine prevents infection in adults.

This form explains what will happen in this study. The entire study is expected to last between 20.5 and 26.5 months, though your participation will be only 14.5 to 20.5 months.

We will tell you the risks and benefits of being in the study. Take your time to decide if joining the study is right for you. If it helps, talk to people you trust. Ask questions about anything that is not clear. If you decide to join, you will sign or make your thumbprint on this form. We will give you a copy to keep.

[redacted]

2. What do we want to learn in this study?

We want to learn these things:

- We will look at the safety of the vaccine,
- We will test how the vaccine helps your body protect itself from malaria, and
- We will see whether the vaccine helps prevent malaria infection when used with or without anti-malarial drugs.

3. Will this study benefit you?

Being in this research study may benefit you personally.

- This study may help prevent malaria infection if you receive the RTS,S vaccine.
- If you receive the rabies vaccine, you may be protected against rabies if you are bitten by a rabid animal. Rabies is a health problem in Kombewa. If you do not receive the rabies vaccine during the study, you can get it at the end of the study for free.
- The physical exams we do may help you better manage your health.
- We will screen you for HIV infection. If the results show you have HIV, we will refer you to proper care and treatment options. You can still take part in the study if the study doctor thinks you are healthy enough to complete the study.
- You will receive free medical care for new medical problems that arise from the day of the first blood draw up until the time it is determined you are not eligible for the study. If you are eligible for the study and receive the first anti-malarial drug treatment or vaccination, you will continue to receive free medical care until the completion of the study (approximately 14.5 to 20.5 months). This does not include care for chronic conditions which are not related to your taking part in the study; in these cases you will be referred to an appropriate health provider.
- We will give you a free meal during your study visits at the Kombewa Clinical Research Centre.

What we learn may help others in the future. What we learn may help improve our current or future malaria vaccines and help make a malaria vaccine available for adults.

4. How will you find out if you can be in the study?

Before you decide if you want to join the study, we will need to see if you meet the study requirements. You will need to agree to take part and sign this form before we see if you are able to be in the study. We will:

- Ask you questions about yourself.
- Take blood to test your overall health and for HIV infection. We will take blood from your arm using a needle. We will tell you the results of these tests. If the tests show you have a health concern, we will refer you for care. You can still take part in the study if the study doctor thinks you are healthy enough to complete the study.
- Take a small sample of blood from your finger (finger-stick) to see if you have malaria parasites and to place you into one of the 5 study groups.
- If you are a woman, we test your urine to see if you are pregnant. You cannot begin the study if you are pregnant or breastfeeding. If you become pregnant during the study the investigator will determine if you are able to continue.

You may be allowed to take part in the study if:

- You sign and date or thumbprint this informed consent form.
- You are willing to comply with all study procedures and are available for the entire study.
- You are a male or female between 18 and 55 years of age.

- You are in good general health as determined by the study doctor.
- You are able to take medicines by mouth and are willing to follow the treatment plan.
- If you are female, you must avoid pregnancy beginning 30 days before through 2 months after the study vaccination period. This means either you are unable to have children or you are willing to prevent pregnancy by using a family planning method. If you are not on a family planning method, the study team will be willing to assist you to obtain a method from a health facility of your choice. We will test for pregnancy before starting the study and before each study treatment course and vaccine is given.

You are not allowed to take part in this study if:

- You are planning on receiving or have received any vaccine from within 30 days before the first dose of the study vaccine until 30 days after the last dose of the study vaccine.
- You have ever received any rabies vaccine or an experimental malaria vaccine.
- You have or are suspected of having a condition that limits your immune system, including clinical stage 3 or 4 HIV. Clinical stage 3 or 4 HIV means that your immune system is limited, you have an increased risk of infections and that you are not likely to respond as well to the vaccination.
- Someone in your family has a disease of the immune system that can be passed down in families.
- You have a history of certain allergic diseases including a reaction to vaccination.
- You have been diagnosed with a disease of the nervous system.
- You are actively sick, including active malaria, at the time the study starts. If you are sick on the day you are to start, you can return after recovering from the illness to be screened again if you would still like to participate.
- You have a disease of the lungs, heart, liver, or kidneys.
- You have sickle cell disease.
- You have any abnormal labs that the investigator thinks will make it unsafe for you to take part in the study.
- Your spleen has been removed.
- You have received any human blood products (e.g. blood transfusions) within 3 months of the first vaccination, or you will receive any during the study.
- If you are female, you are pregnant or breastfeeding from the start of the study through completion of vaccinations.
- If you are female, you are planning on becoming pregnant or stopping one of the approved family planning methods.
- You currently or have previously abused alcohol or drugs. Alcohol abuse includes drinking an amount of alcohol that harms your health, relationships, or job, or that causes legal problems. This includes drinking more than 3 drinks in one sitting or 7 drinks in a week for women or more than 4 drinks in one sitting or 14 drinks in a week for men.
- You are receiving medicines that impair your immune system.
- You were born with a major medical problem or have a chronic disease that the study doctor thinks will make it unsafe for you to take part in the study.
- You are part of any other clinical trial.

- You have any other findings that the investigator feels would make it unsafe for you to take part in the study.

We will review the results of the screening with you. If you meet the requirements, then you can decide if you want to join. If you do not meet the criteria, you will not be able to join the study.

5. What will happen during the study?

Being put in a study group: You will be assigned to one of 5 groups. The group to which you are assigned will be based on whether or not you have malaria parasites in your blood that are not causing you to be sick. You will be assigned to one of 5 groups by chance (like the rolling of dice). This means you that you could be assigned to any of the groups you qualify for.

- Group 1 will include people infected with malaria who will be given anti-malarial drugs and the RTS,S malaria vaccine.
- Group 2 will include people not infected with malaria who will be given anti-malarial drugs and the RTS,S malaria vaccine.
- Group 3 will include people infected with malaria who will not be given anti-malarial drugs but will be given the RTS,S malaria vaccine.
- Group 4 will include people infected with malaria who will be given anti-malarial drugs and the rabies vaccine.
- Group 5 will include people not infected with malaria who will be given anti-malarial drugs and the rabies vaccine.

The table below summarizes these groups.

Group Number	Malaria Infection?	Given Anti-malarial Drugs?	Vaccine Used
1	Yes	Yes	RTS,S malaria vaccine
2	No	Yes	RTS,S malaria vaccine
3	Yes	No	RTS,S malaria vaccine
4	Yes	Yes	Rabies vaccine
5	No	Yes	Rabies vaccine

Study visits: There will be up to 13 visits to the Kombewa Clinical Research Centre and up to 22 home visits by a field/community health worker. The staff will tell you when to come to the Kombewa Clinical Research Centre or when the field/community health workers will visit you at your home. The time at the Kombewa Clinical Research Centre may be up to 4 hours. The home visits will last less than 30 minutes.

Study procedures include:

- A study briefing with information presented about the study and time for questions and answers;
- Written informed consent form reviewed and signed or thumbprinted by you;
- Photograph taken for a study identification card;

- Answering questions about your health and any side effects you may have during the study;
- Physical examinations including measurements of temperature, heart rate, blood pressure, examination of vaccine injection site, and other examinations as needed;
- Cheek swab for HLA-typing (optional).
- Blood draws from veins and finger sticks:
    - We will not take more than 11 teaspoons (52.5 mL) at any single visit,
    - Most collections will be less than 1 teaspoon (5 mL),
    - The total blood collected will be about 57 teaspoons (281 mL);
- Vaccination given 3 times over 7 months (either RTS,S malaria vaccine or rabies vaccine).

Some people will:

- If female, have urine collected for a pregnancy test at study start and before each study drug or vaccination;
- Have anti-malarial drugs given before vaccination in 4 of the 5 groups; this will include primaquine and either dihydroartemisin-piperaquine or Coartem;
- Some subjects receiving the RTS,S malaria vaccine will be given Memory Aid Cards to record side effects that will be reviewed with study staff.

You will be given a schedule of your study visits after being assigned to a study group.

The photograph we take of you for the study will be saved on a password-protected computer at our clinic. If you take part in the study, it will be used to make a study identification card, which you will keep for the entire study. If you are not eligible or choose not to take part in the study, your photograph will be deleted. If you take part in the study, your photograph will be deleted from our computer and you may destroy your identification card after the end of the study.

6. What study procedures or products are experimental?

All the anti-malaria drugs used in this study, dihydroartemisin-piperaquine, primaquine, and Coartem, have been approved for use in Kenya. The rabies vaccine, Abhayrab, is also approved for use in Kenya.

The RTS,S malaria vaccine used in this study has been approved by Kenyan regulatory agencies for use in young children in Western Kenya under a pilot program to prevent malaria disease. For adults, the RTS,S vaccine is still being investigated. This means that the drug has not yet been approved by the Kenyan regulatory agencies for adults. Our use of this vaccine in this study is experimental. The Kenyan regulatory authority has approved its use in this research study to learn more about its safety and how it works. This study will look at how the RTS,S malaria vaccine works to prevent infection when used in combination with anti-malarial drugs.

The safety of this vaccine in humans has been tested in prior research studies. Some side effects may not yet be known.

The test for malaria parasites from your finger stick blood sample is an experimental test. But this test detects malaria parasites better than other tests.

7. Will you be told any of your test results?

We will tell you the results of any standard health testing done, including the results of the HIV test at screening. If your results show that you may have a health concern, we will treat you or refer you to proper treatment.

Other tests will be for research only and will not be used for your health care. We will not tell you the results of research only tests.

8. Will you learn the results of the study?

We will share the overall results of the study with your community by informing the village chiefs and elders upon the conclusion of the study.

9. What are the risks of this study?

All research studies have some risks. Here are the risks we know about with this study and how we will manage those risks.

Risks from study medications or vaccines

Volunteers in some of the groups will take the anti-malaria drugs dihydroartemisin-piperaquine, primaquine, and Coartem, at different times during the trial. The side effects are generally mild and the majority are non-serious. Reactions such as: cough; headache; loss of appetite; dizziness; nausea; diarrhea; and anemia are usually mild and rare. If they occur, these side effects should clear up within a few days of your last dose of the anti-malarial drug.

Each time we give you a vaccine, you might have a reaction to it. If you receive the RTS,S malaria vaccine there may be mild pain or swelling where the injection was given. This should disappear after about 2 or 3 days. In addition, muscle soreness, slight fever, tiredness, or headache may occur. You may have other reactions to the malaria vaccine that at this time are not known. The same symptoms just described may occur if you receive the rabies vaccine. Other symptoms that have been reported with the rabies vaccine are: redness at the site of injection; itching; and dizziness. As may happen with any vaccine, there is a small chance that you could have an allergic reaction due to either the malaria or rabies vaccines. Allergic reactions to the anti-malaria medications are also possible. An allergic reaction may be mild, such as a rash, or may be severe and life-threatening. A life-threatening reaction to any of the anti-malaria drugs, malaria or rabies vaccine is extremely rare. Medicines and equipment needed to treat allergic reactions are available at the Clinic.

It is not known whether the RTS,S malaria vaccine can cause birth defects or other problems in an unborn or breastfeeding child. This is why women must agree to use effective birth control during the study. If you become pregnant or think you might be pregnant, contact your personal

physician and the principal investigator of this study listed in the "Who to contact if you have questions" section at the end of this document.

Harm from taking blood

- Taking blood can cause pain and bruising. This should not last long.
- It is very rare, but sometimes taking blood can cause an infection. This is not likely to happen because we clean the skin and use trained people to take the blood.
- Sometimes people faint when blood is taken. We will make sure you are seated or lying down when we take the blood. We are trained to provide care if fainting occurs.
- Your body will make more blood to replace the blood that we take out.

Loss of confidentiality

We keep your personal information secure. However, there is always a small chance that someone who is not allowed could see your personal information by mistake. This risk will be minimized by ensuring only authorized individuals have access to your personal information. Also, we will only use your study identification number on study documents whenever possible - to further decrease the risk that you can be identified.

Other risks

There may be other risks that we do not know about yet. If we learn new information during the study that might affect your decision to stay in the study, we will tell you about it.

10. What will happen if you are hurt?

If you are hurt as a direct result of taking part in this research project, PATH will pay for health care to treat the illness/injury. If you are injured by a vaccine, medicine or treatment that you would not have been given outside our study, you may be entitled to compensation. PATH has insurance to cover the costs of research-related injuries. This is provided that you followed all the instructions and advice of the study doctor and did nothing to cause or contribute to the research-related injury. By signing this form, you do not give up any legal right you may have. The Principal Investigator for this study, Dr Nathanial Copeland, can give you more information.

Free medical care for research-related injuries will be provided at the Kombewa Clinical Research Centre. If you require medical care beyond the abilities of the Kombewa Clinical Research Centre, we will transport you to an appropriate medical facility and pay for your care there.

11. What other choices do you have besides taking part in the study?

You can choose not to join the study. You will not have any penalties or lose any benefits if you say "no".

12. How we use your samples during the study

In this study, we will take blood from you at screening to assess your general level of health and the results of these tests will be provided to you.

We will also take blood at various times during the study. We will test these samples to see how well the vaccine works. We will not tell you the results of these study tests, which are for research only and will not be used for your health care. The total amount of blood to be collected is about 57 teaspoons (281 mL) spread out over 14.5 to 20.5 months.

In addition to collecting samples of blood, we will also take a swab from inside your cheek. This is to collect cells to look at your genes involved in the immune response to the vaccine. This test is called "HLA-typing" and involves genetic testing of your samples (cells from your blood or cheek). This information about your DNA structure (genetic information) from your samples is unique to you. While genetic information can be used to look at your risk for developing certain diseases and possible changes in your future health status or life expectancy, or that of your children and other relatives, this study will not be looking at those things. We will not be giving you information on results of this testing. This genetic testing (HLA-typing) is optional. You can choose not to have this testing done, and still be a part of the study.

Your blood samples may be sent to: a PATH-designated central laboratory in the United States; and to other laboratories working with PATH, including those outside Kenya.

If you are a woman, we test your urine before the anti-malarial drug treatments and before the vaccinations to check whether you are pregnant.

13. How we use and protect your personal information

In this study, we will record some personal information about you. We need some of this information to show that you agreed to take part in this study and that you meet the study requirements. We will also need your name, location where you live, and mobile phone number to reach you during the study. If you seek medical care during the study, we may need to look at your medical records.

We will keep your personal information confidential. Here is how we protect it:

- Your name and contact information are kept in a locked cabinet. Only the study team can unlock it.
- On study forms, we will use an identification number in place of your name.
- The information using your identification number in place of your name is put into computers. These are password protected.
- The study team keeps a link between your name and your study number in case you need to be contacted in the future. After 15 years we will destroy the link and any documents that identify you.

14. Who can see your personal information?

Information about your taking part in this study will remain confidential. Only Kombewa Clinical Research Centre staff have access to your study records. They are not allowed to share any personal information. All files will be kept in locked cabinets when they are not in use. The information we collect may be reviewed by:

- Representatives of the KEMRI Scientific and Ethics Review Unit (SERU);
- Representatives of PATH;
- The U.S. Department of Defense (DoD);
- U.S. Army Medical Research and Development Command (USAMRDC);
- The Walter Reed Army Institute of Research Institutional Review Board (WRAIR IRB); and the Kenya Pharmacy and Poisons Board (PPB).

They are not allowed to share any personal information about you.

Complete confidentiality cannot be guaranteed. But every effort will be made to keep the records as confidential as possible within the limits of the law. All data and medical information obtained about you as an individual will be considered important and held in confidence. All the above representatives are bound by rules of confidentiality not to reveal your identity to others.

15. What happens to your information when the study ends?

We will keep your information in a secure locked cabinet or scanned onto secure, password protected computers. We will keep the data for up to 15 years. After that time, the data may be destroyed if it is no longer needed for further research.

We will share what we learn in this study with others. We will share the study data with the Bill and Melinda Gates Foundation, which is providing support to PATH for the conduct of this study. We will remove your name and other identifying information when we share the study information with others.

Here are the ways we may share your study information:

- We may write an article or share the study results at meetings or on websites. Publications or presentations of results will not reveal your identity.
- A description of this clinical trial will be available on http://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.
- We will put the study results on a public website.
- We may put the research results in a public database. This lets other researchers see and use the results. No one can find out who are you are from this sharing.

16. Using your information and samples for future research

We want to store your samples and study information for future research to better understand malaria. You can say “no” and still take part in the study. If you agree to this storage and future use of your samples, your samples may be stored and used for up to 15 years. Research on your samples will be used to study malaria and other research areas. Future studies may involve genetic testing.

If you say yes now and change your mind later, we will destroy any extra samples and information that are in our storage. We cannot destroy samples and information that are already used or that have your code number removed.

If you say yes, we will store blood samples in a secure area at a PATH-designated central laboratory, in the United States, and at Kombewa Clinical Research Centre. Your study information will be stored on secure computers. The samples and information are labeled with a study identification number, not with your name. When we share your data or specimens for future research, we will do this in a way that other researchers will not be able to identify you.

Someone using your samples or information may make a new discovery that makes money. There are no plans to share the money with you or others.

Here is what you should know to make your decision:

- Samples are labeled only with a study identification number and will be stored securely at the PATH-designated central laboratory in the United States and at Kombewa Clinical Research Centre.
- Studies done on these samples would look further at the malaria parasite or your body's response to malaria infection or vaccination.
- Allowing us or others to use your extra samples and study information will not help you. It may help other people in the future.

17. Will you be paid for being in this study?

We will give you a minimum of [redacted] KES per scheduled visit at Kombewa Clinical Research Centre. This is to compensate you for lost wages, time, and inconvenience at approximately a day's work at minimum wage. For visits at Kombewa Clinical Research Centre, we will provide transport for you or reimburse you for transportation costs. If you are being reimbursed, you will be reimbursed between [redacted] KES for scheduled visits and between [redacted] KES for unscheduled visits, as determined by the study team on a case-by-case basis based on the distance you traveled. Other than medical care that may be provided and any other payment specifically stated in this form, you will not receive any other compensation for your taking part in this study.

18. Are there any costs to you if you join the study?

There are no costs to you if you join the study.

19. What to do you if you want to leave the study

If you want to leave the study, please tell us.

- We may ask why you are leaving the study because it is helpful for us to know. You do not have to tell us.
- We may ask to complete any study procedures that are important for your diagnostic or treatment options. You do not have to agree.
- We may refer you for medical care elsewhere. You do not have to accept this referral.

20. Can you be taken off the study?

The researchers may remove you from the study if these things happen:

- The study doctors think that staying in the study is not good for your health.
- You are not able to follow the directions of the study staff.
- The study ends early.

21. Your rights

You have rights in this study:

- **You do not have to be in this study.** You can say yes or no to joining. You can leave the study at any time. If you do not join or you leave early, you will not have any penalties. You should not feel pressure to join or stay in the study.
- **By signing this consent form, you do not lose any rights you normally have.**
- **If we learn new information about the study, we will tell you.** You can decide if you want to stay in the study after you learn this new information.

22. Who has reviewed the study?

All research is reviewed by an independent group of people, called a research ethics committee. This group protects your safety, rights, well-being and dignity. This study has been reviewed and approved by the Health Authorities and has been reviewed and given a favorable opinion by the KEMRI Scientific and Ethics Review Unit, the WRAIR Institutional Review Board (IRB), and the Expert Clinical Trials Committee of the Pharmacy and Poisons Board of Kenya.

KEMRI Scientific Ethics Review Unit
P.O. Box 54840-00200, Nairobi-Kenya
Phone: (020)2722541 or 0722205901.
E-mail: SERU@kemri.org

The Director, Human Subject Protection Branch, Walter Reed Army Institute of Research (WRAIR), 503 Robert Grant Avenue, Silver Spring, MD 20910. Telephone (301-319-9940) or email (usarmy.detrick.medcom-wrair.mbx.hspb@mail.mil)

The Registrar,
Pharmacy and Poisons Board,
P.O. Box: 27663-00506,
Nairobi, Kenya
Email: cta@pharmacyboardkenya.org

23. Who to contact if you have questions

- If you have questions about this study or you believe you have been hurt as a result of the research study, please call:

[redacted]

- If you have questions about your rights in this research study, you may contact the Committee Chairperson, KEMRI Scientific and Ethics Review Unit, P.O. Box 54840-00200, Nairobi. [redacted]

Confirmation of written consent

Use of your stored samples and data for future research:

Please initial or thumb print by the sentences that reflect your choices, and then sign or thumb print below:

_____ I authorize the storage of data collected as a part of this study for use in future research studies.

OR

_____ I do not authorize the storage of data collected as a part of this study for use in future research studies.

Please initial or thumb print by the sentences that reflect your choices, and then sign or thumb print below:

_____ I authorize the storage of my biological specimens for use in future research studies.

OR

_____ I do not authorize the storage of my biological specimens for use in future research studies.

Use of your samples for genetic testing for HLA-typing:

Please initial or thumb print by the sentences that reflect your choices, and then sign or thumb print below:

_____ I authorize the genetic testing of my blood or cheek sample for HLA-typing.

OR

_____ I do not authorize the genetic testing of my blood or cheek sample for HLA-typing.

Study participant

Signing your name below means you voluntarily choose to be in this research study. It also means you:

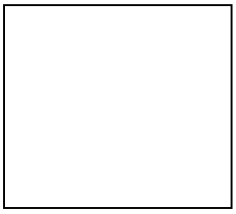
- have received an explanation of the research
- have asked any questions you want to ask and you are satisfied with the answers
- know who to contact for future questions

- agree to receive HIV counseling and testing by a study HIV counselor
- agree to having your photo taken for the study identification card
- agree to having some of your samples shipped outside of Kenya.

You will be given a copy of this signed consent form to keep.

_____ _____

Printed Name Date



_____

Signature of Participant Thumbprint of Participant

Member of research team

Signing my name below means I have explained this research study to you and answered your questions to the best of my ability. I will give you a copy of this form to keep.

_____

Printed Name

_____ _____

Signature of Person Obtaining Consent Date

Witness (*Include if enrolling participants who are illiterate and using written consent*)

Signing below means that the study participant whose thumbprint is above chose voluntarily to be in this research study. It also means I was present the whole time the study was being explained to them. I confirm that:

- the information provided to the participant was complete and accurate
- the participant had a chance to ask questions
- and that the participant appeared to understand the information provided.

The participant will get a copy of this form to keep.

_____

Printed Name

_____ _____

Signature of Witness Date