PRINCIPAL INVESTIGATOR (MALI): Abdoulaye Katile, MD, MSPH, PhD

STUDY TITLE: Phase 1, Dose-Escalating, Randomized, Comparator-Controlled Trial of the Safety, Tolerability, and Immunogenicity of the Co-administration of Transmission-Blocking Vaccines (R0.6C-AlOH/ Matrix-M™ with Pfs230D1-EPA/Matrix-M™) and individual comparators (R0.6C-AlOH/ Matrix-M™ ; ProC6C-AlOH/ Matrix-M™ and Pfs230D1-EPA/Matrix-M™) against *Plasmodium falciparum* in Adults in Mali (TBVax2)

STUDY SITE: Malaria Research and Training Center (MRTC) at the University of Bamako, Mali

FMPOS PROTOCOL NUMBER: N^0XXXX/XX/XX/FMPOS

Cohort: All Study Arms (1a, 1b, 1c, 2a, 2b, 2c, 2d, 2e)

Consent Version: 2.0, April 14th, 2022

Participant's Name:_____

(first) *(last)*

Participant's Census ID Number (if available): _____

Participant's Screening ID Number: _____ Study ID Number: _____

Information Sheet

What are the most important things for you to know about this research?

This consent form describes a research study and is designed to help you decide if you would like to be a part of the research study.

This section provides the information we believe is most helpful and important to you in making your decision about participating in this study. Additional information that may help you decide can be found in other sections of the document. **Participation in this research is your choice.**

Purpose of this study

Malaria is a disease that affects many people in Mali and other parts of Africa. It is caused by germs that are spread by mosquito bites. Malaria may cause only a mild illness, but it can make people feel seriously ill or can lead to death if not treated.

We are studying an experimental combination malaria vaccine called R0.6C-AlOH/ Matrix-M with Pfs230D1-EPA/Matrix-M and individual vaccine R0.6C-AlOH/ Matrix-M and ProC6C-AlOH/ Matrix-M. We want to find out if it is safe and if people who receive those vaccines develop the kind of immune responses that we have seen with other vaccines that reduce malaria transmission. The combination vaccine, and the individual vaccine we are testing is considered experimental because it has not been approved for preventing malaria transmission by the United States (US) Food and Drug Administration (FDA), or European Medicines Agency *(EMA)* or the Ministry of Health (MoH) in Mali. However, the MoH have given us permission to test it in this study. Each of the main parts of this experimental combination malaria vaccine (R0.6C-AlOH/ Matrix-M, Pfs230D1M-EPA/Matrix-M) has been tested separately in humans (expected ProC6C-AlOH/ Matrix-M study planned to start in Burkina Faso in March 2022). This study is the first time these parts will be combined and given together to humans. We will be testing 2 different dose levels on this study - low, and high.

M**ain s**tudy visits and procedures**

At all visits during the trial, appropriate measures will be taken to prevent transmission of SARS-CoV-2, the organism which causes COVID-19.

If you join this study, you will have about 23 study visits over about 1**4** to 16 months. At 3 of these visits, you will receive an injection of either the experimental malaria vaccine or a comparator vaccine. The comparator vaccine is a rabies vaccine (Verorab Rabies Vaccine **or a similar rabies vaccine**). The Verorab Rabies Vaccine is approved in Mali. You will receive only one of these vaccines on this study, not both. You will not know which vaccine you receive. In the rest of this document, we will call both the experimental malaria vaccine and the comparator rabies vaccine "study vaccines."

We will collect blood from a vein in your arm using a needle or by fingerstick at most visits. We will use your blood samples for clinical and research tests. If you can get pregnant, you will have pregnancy testing during this study. Because the experimental malaria vaccine can have risks during pregnancy, you cannot be in this study if you are pregnant **or planning to become pregnant**.

Main risks of study participation

Study vaccines: You may experience side effects or symptoms from the study vaccines. The most common side effects seen in people who received these vaccines or parts of the vaccines are the following:

- **Side effects near the injection site:** pain, swelling, redness, or small lumps under the skin near the injection site.
- **General side effects throughout the body:** fever, headache, muscle or joint pain, feeling tired or ill, nausea, vomiting, diarrhea, and swelling of lymph nodes.

Side effects from the study vaccines are generally mild and usually get better without treatment. While most symptoms are mild, it is possible that you could develop serious side effects from the vaccine or other side effects that we do not know about. We will monitor you closely for all side effects and give you treatment if needed.

Blood draws: Side effects from blood draws may include pain, bruising, bleeding, infection or feeling lightheaded.

Study population

A total of 115 adults will participate in this study in Donegubougou, Mali.

Benefits of study participation

You will not receive direct benefits from this study. We hope that what we learn in this study will help us make an effective new malaria vaccine that will help prevent the spread of malaria.

Compensation

You will be compensated for your time.

It is your choice whether or not you join this research study

You may choose not to take part in this study for any reason.

If you join this study, you may change your mind and stop participating in the study at any time and for any reason.

In either case, you will not lose any benefits to which you are otherwise entitled. If you do choose to leave the study, please inform the study team to ensure a safe withdrawal from the research.

Why are we doing this research?

Malaria is a disease that affects many people in Africa, including Mali. Malaria is caused by small germs that are carried between people by certain mosquitoes. When a person is bitten by an infected mosquito, they may develop malaria. While some people who are infected do not show any symptoms, others may become very sick or even die.

Our goal is to develop a vaccine that will safely reduce the spread of malaria in the community by preventing mosquitos from carrying the malaria germs from person to person. The kind of vaccine we are developing could decrease the amount of malaria germs in the entire community. And we could later combine it with a vaccine that prevents people from getting infected.

The combination vaccine we are testing in this study contains a protein (Pfs230) that is found on the surface of the malaria germ, a recombinant Pfs48/45 6C domain fused with glutamate rich protein (R0.6C) and the individual vaccine ProC6C is a recombinant Pfs48/45 6C domain fused with Pfs230-Pro domain using a Circumsporozoite protein linked. The other vaccine parts, EPA, Alhydrogel and Matrix-M are products that are added to the vaccine to improve the body's immune response to that protein. The immune response is what the body uses to fight germs. We have tested Pfs230 combined with other agents in Mali before and the R0.6C and ProC6C had tested on an others sites, and it had been safe and had induced good immune responses. But this is the first time we are combining these two vaccine parts (R0.6C and Pfs230) together in one vaccine and testing it in humans. We will start the study with a low dose of the experimental malaria vaccine. If we do not have any safety concerns after testing this dose, we will continue the study with higher doses.

In this study, we want to learn if the experimental malaria vaccine is safe in Malian adults. We want to know what side effects it may cause. We also want to see if people who get the vaccine develop the kind of immune responses that we have seen with other vaccines that reduce the

spread of malaria in the community. We will give participants 3 injections of a study vaccine and follow them during the malaria transmission season. We will do physical exams and collect blood samples to study how the immune system reacts to the vaccine. We will compare the results of research tests from participants who received the experimental malaria vaccine to the results from participants who received the approved rabies vaccine to look for differences.

What will happen if you join this study?

Screening

If you decide to take part in this study, then first we must make sure that you are eligible. This is called screening. The screening visit may take 2 to 3 hours, and may happen over more than 1 day. We will do the following to see if you are eligible for this study:

- You will complete a malaria comprehension exam. This is to make sure you understand this study. Before we give you this exam, we will explain the study to you and make sure you have time to ask any questions.
- You will have a physical exam. As part of the physical exam, we will measure your vital signs (blood pressure, heart rate, body temperature), height, and weight.
- We will ask about your medical history and any medications that you are taking.
- We will assess your risk for heart disease. You cannot be in this study if you have a history of heart disease or if you are at risk for heart disease.
- We will collect about 2 teaspoons of blood from a vein in your arm using a needle. If you are female, we may also ask you for a urine sample. We will use your blood and urine for lab tests:
    - Some blood will be tested to look for signs of illness in your blood, kidney, or liver.
    - Some blood will be tested for HIV, hepatitis B, and hepatitis C infections. HIV is the virus that causes AIDS. If any of these infections or another chronic illness is discovered during screening, we will refer you to a clinic for care and treatment as needed. Long-term treatment and care will not be provided or reimbursed by this study.
    - If you are female, we will use either blood or urine to check whether you are pregnant.

If you qualify for this study and are enrolled, we will collect some information about you (called biometric measurements) so we can correctly identify you throughout the study. Common biometric measurements that you may have heard of are fingerprints, photographs, DNA and face recognition. In this study we will take your fingerprint measurements and a photograph of you so that we can correctly identify you throughout the study. Your fingerprints and photograph will be stored in a secure biometric database and kept separate from all other study data. Only the study personnel will have access to this database and it will never be shared with

anyone outside of the study personnel. A card with your name and picture may be made for you to keep.

Study Vaccine Assignment

As part of this study, you will be randomly assigned to receive one of the two study vaccines throughout your participation. This means that whichever study vaccine you get will be decided by chance, like drawing names out of a hat. You will NOT know which study vaccine you will be getting on this study. More participants will receive the experimental malaria vaccine than the approved rabies vaccine on this study. A total of 90 participants will receive the experimental vaccine and a total of 25 participants will receive the rabies vaccine. Therefore, you will have a higher chance of being in the experimental malaria vaccine group than the approved rabies vaccine group if you join this study. The two possible study groups that you may be assigned to are the following:

- Experimental malaria vaccine

  OR

- Approved rabies vaccine

We will start by giving the low dose experimental vaccine to 5 participants. If there are no safety concerns, we will give the high dose. At every vaccination timepoint, in addition to participants who get the experimental vaccine, there will be some participants who get the rabies vaccine. You will not be told whether you are getting the rabies vaccine or the experimental vaccine, and you would not know what dose of experimental vaccine you would be receiving.

Study Visits and Procedures

If you decide to join in this study, you will have up to 23 scheduled visits in the study clinic over 14 to 16 months. At each study visit, we will give you a brief physical exam, ask how you are feeling, and ask about any medicines you are taking. You will receive 1 study vaccination at 3 separate study visits, about 1 month apart. Before each study vaccination, your arm will be cleaned, and the vaccination will be given to you as an injection in the upper arm muscle using a sterile needle and a syringe. If there is a medical reason why the injection cannot be given in your upper arm, it will be given in your thigh.

At each of the study visits we will check to see if you have any new health complaints. You will have blood drawn from a vein or by a finger prick at most of your study visits. The amount of blood collected will range from about 1 to 56 mL (a few drops of blood to 4 tablespoons) per visit. If we need more than a few drops of blood, we will collect it from a vein. We will use the blood samples for clinical and research tests to check whether or not you have developed any medical problems, see if you are carrying malaria parasites, and to periodically check how your immune system is responding to the study vaccine. Some of the blood drawn from you as part of this study may be used to test your hemoglobin type. This is a genetic test of the different types of hemoglobin, which is the part of red blood cells that carries oxygen in the blood. We will let you know the results of this test and discuss with you if it has any impact on your health or your children's health.

If you are a female and able to become pregnant, we will also test your blood or ask for a urine sample to make sure you are not pregnant. Pregnancy testing will be done at the first study visit and before you receive each study vaccination. If you get pregnant during the study, you will not have additional study vaccinations, but we will ask you to stay in the study so we can follow you for safety.

If you become sick at any time during the study, we will ask you to come to the clinic so that we can speak with you and examine you. You do not have to wait for your scheduled visit. You or the study team may decide that you need to seek care outside of the clinic after your visit with the study team. Of course, if it is a life-threatening emergency you would need to go to the nearest health facility for care right away. A study doctor will be available at the study clinic 24 hours a day throughout the study period.

If you have a fever or are sick for any reason at the time of a scheduled study vaccination and have not recovered within one week, you will not receive that study vaccination. If you are sick from malaria, you will be treated according to the Mali National Policy on Malaria Control and can continue in the study unless the study doctor determines you are too ill to stay in the study. If you are healthy by the time of your next scheduled vaccination, you will most likely be able to continue with your vaccinations; the study doctor will make the final decision. You will receive free short-term, standard medical care for acute illnesses that happen during your participation in this study. Medical care will be provided by the Doneguebougou study clinic. Treatment for chronic illnesses will not be provided. A referral will be made for care if needed.

If you develop a rash or other reaction near the study vaccination site, we may ask to take a photo of the affected area. These photographs will not include your face.

Will my specimens be used for genetic testing?

Some of the blood drawn from you as part of this study may be used for genetic tests. Genetic tests can help researchers study how health or illness is passed on to you by your parents or from you to your children.

As mentioned above, some of the blood drawn from you as part of this study will be used to test your hemoglobin type which is a genetic test of the different types of hemoglobin (substance in red blood cells that carries oxygen).

Any genetic information collected or discovered about you will be kept confidential. Records containing this information will be kept on password-protected computer systems and in locked and secured locations. We will not release any information about you to people outside of the study without your written permission. Some genetic information, such as the name of your diagnosis, may be on your study chart. Researchers who will have access to genetic information about you will take measures to maintain the confidentiality of your genetic information.

We are doing a type of test called “RNA sequencing”. For this testing, we are not looking at your genes, but at patterns in how information from genes is read in your body. This may help us to understand how your immune system reacts to the vaccine. This testing does not give us any information about your genetic risks for disease.

What are the possible risks from this research?

There are some of risks and discomforts you may have if you participate in the study. These may be related to the study vaccines or the study procedures.

Risks of Study Vaccines

Although you will not know which study vaccine you receive, we would like to tell you some of the possible risks and discomforts you may have when receiving either the experimental malaria vaccine or the comparator rabies vaccine.

- **Injection Risks**

  Both study vaccines are given as injections into a muscle. These types of injections can cause pain, swelling, redness, itching, and small lumps under the skin at the injection site, swollen lymph nodes, and problems moving the arm for several days. They may also cause fever, chills, headache, tiredness, feeling ill, muscle aches, and joint pain. Most side effects are mild, but they may also be severe. They usually go away without treatment, but we will monitor you closely for all side effects and give you treatment if needed.

- **Experimental Malaria Vaccine (**R0.6C-AlOH/ Matrix-M with Pfs230D1-EPA/Matrix-M , ProC6C-AlOH/ Matrix-M**)**

  The experimental malaria vaccine (R0.6C-AlOH/ Matrix-M with Pfs230D1-EPA/Matrix-M , ProC6C-AlOH/ Matrix-M) have been given separately to humans in previous studies. Some of these people had side effects. The most common side effects included pain, redness, swelling, and small lumps under the skin at the site of injection, as well as fever, headache, tiredness, feeling ill, nausea, vomiting, diarrhea, muscle aches, and joint pain. Side effects may range from mild to severe.

  Abnormal blood test results (low white blood cells and low hemoglobin) have been seen in some people who received Pfs230D1M-EPA. The changes were generally mild and came back to normal without treatment, and did not have any known impacts on the subjects' health. Safety reviews of these findings have not found clear relationships to Pfs230D1M-EPA. However, we will monitor you closely for any side effects, including changes in blood test results.

  One person in a previous study developed symptoms of a stroke and died about 1 week after receiving a fourth vaccination with Pfs230. This serious event was reviewed by individuals and groups responsible for safety oversight. They determined that the stroke was not related to the vaccine. Though we do not believe that the stroke was in any way due to the vaccine, we want to keep you informed of major events that have occurred during similar studies prior to and during your participation.

- **Comparator Vaccine (Verorab Rabies Vaccine)**

  (Verorab Rabies Vaccine **or a similar rabies vaccine approved in Mali will be the other study vaccine**).

The Verorab Rabies Vaccine is a rabies vaccine which is approved in Mali. It has been given to many people. The most common side effects of this vaccine include pain at the site of the injection, as well as swelling of lymph nodes, muscle aches, fever, and feeling ill. Other side effects include redness, itching, bruising, and small lumps under the skin at the site of the injection, rash, itching, swelling, headache, dizziness, abdominal pain, nausea, tiredness, joint pain, shivering, weakness, and flu-like symptoms.

- **General Vaccine Risks**

  With any vaccine, there is a small chance that a sudden, severe allergic reaction can occur, which can cause death. This reaction can start with tongue swelling, feeling lightheaded, or having trouble breathing. Because of this, you will be watched carefully for at least 30 minutes after you receive each study vaccination. We will treat you if this reaction occurs.

  There may be risks that we do not know about. If we learn about new risk information in the future, we will share it with you.

- **Pregnancy**

  If you want to become pregnant any time from starting the study until 1 month after the last study vaccination, you cannot participate. You must notify a member of the study team immediately if you become pregnant during this study or if you want to change your pregnancy prevention method.

  If you can get pregnant, you will need to use adequate birth control if you want to be in the study. We will talk to you frequently during the study about your sexual activity and may ask you to agree to pregnancy prevention.

  All female participants will undergo pregnancy testing prior to receipt of ANY study vaccine. The risk to a growing fetus if a pregnant woman receives the experimental malaria vaccine is unknown. For this reason, women who are pregnant or who may want to become pregnant during the study period will not be enrolled in the study, and those who become pregnant after joining the study will not receive additional vaccinations.

  If you do become pregnant, we will ask permission to follow you in the clinic until the baby is born and for a short time after delivery. We may do some clinical tests to see if you or your baby have any side effects that may be related to your participation in the study.

<u>Study Procedures and Treatments</u>

- **Blood Draws**

  Blood draws can cause pain, bruising, uncontrolled bleeding, and infection at the site of the needle stick. You may also feel lightheaded or dizzy. Rarely, some people faint.

- **Malaria Treatment**

If you get malaria during this study, we will treat you according to current Malian government guidelines.

- **Risks of Genetic Testing**

  There is the possible risk of discovering a genetic characteristic (such as hemoglobin typing) that may suggest a risk of disease for you or your family.

- **Risks of Photography**

  You may refuse photographs or place any restrictions on how we use photos of you. We invite you to talk with us about any concerns you have related to photography.

What are the possible benefits of this research?

You will not receive direct benefit from being in this study.

In the future, other people might benefit from the study. We hope the information learned in this study will allow us to develop a safe and effective malaria vaccine.

What else might I do if I choose not to join this research?

You may choose not to participate in this study.

Will I be paid for being in this research?

You will be compensated for the time spent as part of study participation. You will receive cash or an equal amount of rice or millet) to a total value of approximately 63,000 CFA for the whole study. The exact amount will depend on how many visits you completed throughout the study period (14 - 16 months) and if you have any unscheduled visits with research blood draws. The amount of 3000 CFA for each scheduled visit that takes more time such as venipuncture, and 1500 CFA for scheduled visits that do not take more time such as visits without venipuncture. Compensation will be divided into 3 to 6 payments throughout the study.

Will it cost me anything for being part of this research?

Participating in the study will not cost anything to you.

Will my medical information be kept private?

We will do our best to make sure that the personal information in your medical record will be kept private. However, we cannot guarantee total privacy. Organizations that may look at and/or copy your medical records include:

- The study sponsor University of Sciences, Techniques, & Technologies of Bamako (USTTB)
- People or representatives from the PfTBV EDCTP Consortium (University of Bamako)
- People or representatives from the MRTC at the University of Bamako.
- The Faculty of Medicine of Pharmacy and Odonto-Stomatology (FMPOS) ethics committee.
- The Mali regulatory body

The researchers conducting this study and MRTC follow important laws and policies to keep your identifying information as private as possible. However, there is always a chance that, despite our best efforts, your identity and/or information from your medical records may be released by mistake or seen by unauthorized persons.

In most cases, the MRTC will not release any identifiable information collected about you without your written permission. However, your information may be shared as described in the section of this document on sharing of specimens and data, and as further outlined in the following sections.

What will happen if I get hurt because of this research?

A study doctor will be available at all times while you are in the study to check on you and treat you for any short-term problems resulting from the research procedures on this study. Insurance will be provided to take care of you in case of injury or illness related to this study.

What will happen with your information and/or specimens collected on this study?

As part of this study, we are obtaining specimens and information (data) from you. Your blood will be stored at the MRTC in Bamako, or at the NIAID laboratory in the United States or at other laboratory designated by USTTB. Your data will be stored on secure computers at the MRTC in Bamako, or at the NIAID in the United States.

We will remove all the identifiers, such as your name, date of birth, address, or medical record number and label your specimens and data with a code so that you cannot easily be identified. However, the code will be linked through a key to information that can identify you. The key to the code will be stored securely at MRTC in Bamako.

We plan to store and use these specimens and data indefinitely for studies other than the ones described in this consent form that are going on right now, as well as studies that may be conducted in the future. These studies may provide additional information that will be helpful in understanding malaria, or other diseases or conditions. This could include studies to develop other research tests, treatments, drugs, or devices, that may lead to the development of a commercial product by the NIH and/or its research or commercial partners. There are no plans to provide financial compensation to you if this happens. Also, it is unlikely that we will learn anything from these studies that may directly benefit you, and we will not share the results of these studies with you.

We may share your coded specimens and data with other researchers. If we do, while we will maintain the code key, we will not share it, so the other researchers will not be able to identify you. They may be doing research in areas that are similar to this study or in other unrelated areas. These researchers may be at NIH, other research centers and institutions, or commercial entities.

If you change your mind and do not want us to store and use your specimens and data for future research, you should contact the research team member identified at the bottom of this document. We will do our best to comply with your request but cannot guarantee that we will always be able to destroy your specimens and data. For example, if some research with your specimens and data has already been completed, the information from that research may still be used. Also, for

example, if the specimens and data have been shared already with other researchers, it might not be possible to withdraw them.

In addition to the planned use and sharing described above, we might remove all identifiers and codes from your specimens and data and use or share them with other researchers for future research at the NIH or other places. When we or the other researchers access that data, there will be no way to link the specimens or data back to you. We will not contact you to ask your permission or otherwise inform you before we do this. If we do this, we would not be able to remove your specimens or data to prevent their use in future research studies, even if you asked, because we will not be able to tell which are your specimens or data.

Risks of Storage and Sharing of Specimens and Data

When we store your specimens and data, we take precautions to protect your information from others that should not have access to it. When we share your specimens and data, we will do everything we can to protect your identity, for example, when appropriate, we remove information that can identify you. Even with the safeguards we put in place, we cannot guarantee that your identity will never become known or someone may gain unauthorized access to your information. New methods may be created in the future that could make it possible to re-identify your specimens and data.

Reasons why your participation may be terminated without your consent

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

- You miss scheduled visits or do not follow study procedures.
- The study sponsor, doctor, Malian ethics committee, or a regulatory body decides to stop or cancel the study.
- You can no longer consent to stay on the study.
- You develop a serious illness that prevents you from participating.
- You receive treatment with a medication that affects your immune system (such as steroids).
- The study doctor feels it is not in your best medical interest to continue

However, in general, if you cannot continue with vaccinations for any reason, we will ask you to continue with safety follow-up visits if possible.

What will happen if I withdraw from the research?

If you decide that you will no longer wish to participate, you can withdraw from the study at any time. If you decide to withdraw from the study, please tell any member of the study team. This decision will not affect your participation in other MRTC or NIH studies.

If you are withdrawn from the study (by your choice or by the investigator), you will not have any more visits for this study.

Will you tell me if you learn anything new that might change my decision to be in the research?

If we find out any new information that may affect your choice to participate in this study, we will get in touch with you to explain what we have learned. This may be information we have learned while doing this study, or information we have learned from other scientists doing similar research in other places.

How many people will be in the research?

We plan to have approximately 115 adults to participate in this study at the Doneguebougou site in Mali.

Will my specimens be used for commercial profit and will I share in the profit?

Results of this study may be used to support development of a commercial malaria vaccine. You will not receive any payment if this happens. No investigator involved in this study receives payments or other benefits from any company whose drug, product, or device is being tested.

Will you tell me about any research results that might be important for my health?

This study involves standard medical tests. We will share the results of these medical tests with you. We will typically not return results of research tests to you. This is because research tests are not like standard medical tests, and we may not know how the results relate to your health or your medical care.

Will the clinical trial be registered and the results reported?

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

Who do I contact if I have any problems or questions?

If you have any problems or questions about this study, contact the site Principal Investigator, **Dr. Abdoulaye Katile and Pr. Issaka Sagara** (Tel: +223-2022-8109).

Also, you can contact the people at **the FMPOS** Ethical Review Committee to answer any questions you have about being part of this study and your rights as a research participant.

- FMPOS Ethical Review Committee at Point G, Bamako (Tel: +223-2022- 5277)
- President of the Ethics Committee, **Pr. Mamadou Marouf Keita** (Tel +223-6672- 2022)
- Permanent Secretary, **Pr. Mahamadou Diakité**, (Telephone: +223-2022- 5277, Cell: +223-7623-1191)

Consent Sheet

If ***you*** agree to participate in this study, please sign or put your fingerprint below.

_____
Printed name of participant

_____ Date: ___ / ___ / __
Signature or fingerprint of participant *dd mm yy*

_____
Printed name of Investigator

_____ Date: ___ / ___ / ___
Signature of Investigator *dd mm yy*

Complete below if participant is illiterate:

Witness to Consent Interview

On the date given next to my signature, I witnessed the consent interview for the Research Study named above in this document. I attest that the information in this consent form was explained to the participant, and the participant indicated that his/her questions and concerns were adequately addressed.

_____
Printed name of Witness

_____ Date: ___ / ___ / ___
Signature of Witness *dd mm yy*