ENROLLMENT CONSENT FORM

Safety, Immunogenicity and Efficacy of Pfs230D1M-EPA/AS01 Vaccine, a Transmission Blocking Vaccine against *Plasmodium falciparum*, in an Age De-Escalation Trial of Children and a Family Compound Trial in Mali

MALI ADULTS AND CHILDREN 5 YEARS OF AGE OR OLDER COHORT (VACCINE)

NIAID Protocol #	TBD
FMPOS Protocol #:	N°2019/10/CE/FMPOS
Principal Investigator (Mali):	Issaka Sagara, MD, MSPH, PhD
Principal Investigator (USA):	Patrick Duffy, MD
Site:	Doneguebougou, and surrounding villages, Mali, West Africa

Participant's Name: _____ _____
(first) *(last)*

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

Participant's Study Screening ID Number: _____

KEY INFORMATION

- Consent is being sought for research purposes and participation is voluntary
- The purpose of this research is to evaluate how well an experimental malaria vaccine works to decrease malaria infections in your community
- Your participation in this research will last for approximately 1 year
- You will undergo screening to determine if you are a good candidate to enroll in this study
- You will receive 3 injections of either the experimental malaria vaccine or an approved vaccine that is used to prevent other germs into your muscle. Our study will use randomization to determine which type of vaccine you receive, which means that which vaccine you receive will be determined by chance.
- After the third vaccine, people who are between 9-18 years old will have mosquitoes feed off their skin 8 times
- Blood will be drawn from your vein in order to determine if you are infected with malaria and to gather other important information
- All volunteers will receive medication to kill malaria a week before receiving the first vaccine dose
- Participants in the 5-8 year old age group will also receive medication to kill malaria 2 weeks before receiving the third vaccine dose

- Some of the main risks or discomforts associated with the study include getting your blood drawn, receiving a vaccine, and for the 9-18 year old age group, having mosquitoes that are kept in a cup bite you on your forearms or calf for about 15-20 minutes
- There may be a potential for direct benefit to you if you participate in the study. This benefit may be a decrease in the number of malaria infections in the family compound. Alternatives to participation in this study are to not participate in this study

PURPOSE OF STUDY

The Malaria Research and Training Center (MRTC), Mali, and scientists from National Institute of Allergy and Infectious Diseases (NIAID)/ National Institutes of Health (NIH) in the US are conducting a study to collect information to determine whether an experimental malaria vaccine can prevent mosquitoes from spreading malaria to other humans. They will be conducting this study in Doneguebougou and surrounding areas in family compounds. Only adults and children 5 years of age or older will receive a vaccine. Children under 5 years of age will be followed during the study to see if they get malaria or not; they will not receive a vaccine.

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 diagnosed and treated promptly.

The malaria vaccine in this study is called Pfs230M-EPA/AS01. In this consent, we will call this vaccine "experimental malaria vaccine."

Pfs230M-EPA/ASO1 is an experimental malaria vaccine that has not been approved by the Food and Drug Administration (FDA) of the United States of America (USA) nor the Ministry of Health (MoH) in Mali for general use but has been reviewed by the FDA and MoH for use in this study. This vaccine contains a protein (Pfs230) that is found on the surface of the malaria germ. The other vaccine parts, EPA and AS01 are products that are added to the vaccine to improve your immune response to that protein. The Pfs230M-EPA/AS01 vaccine has already been tested in adults in Mali and it was found to be safe and able to induce good vaccine responses in adults. This study will be the first time the experimental malaria vaccine will be given to individuals under the age of 18 years old.

You are being invited to take part in this study to test if this experimental malaria vaccine is safe, can stimulate your immune system to develop a response to the vaccine, and if that immune system response is enough to prevent the malaria germ from developing in a mosquito and also to reduce the malaria infection in humans. To do this, we will look at the side effects from the vaccines, such as pain at the site where the vaccine was given, and any changes in liver, kidney, or blood cells, or your immune response and malaria infection. It is not possible to get malaria from this vaccine.

This study will enroll about 2,000 participants from Doneguebougou and surrounding villages.

There are 2 parts to this study which we refer to as "pilot" and "main" study. The "pilot" study (which will include 60 children: 30 first in the age group of 9-18 years old and then 30 in the age group of 5-8 years old) will first test if the experimental malaria vaccine is safe to give to children 9 to 18 years of age, then children 5 to 8 years old. Once the pilot study is deemed safe, the main study will start and will enroll all eligible family compound members in the study for vaccination who are 5 years of age and older. Younger children, 1-4 years of age, will join the study around the time of the family compound's third vaccination and will be followed for malaria infection.

All adults and children 5 years of age and older will either be vaccinated with:

- The experimental malaria vaccine (Pfs230D1M-EPA/ASO1) for all 3 vaccinations **OR**
- Licensed vaccines for all 3 vaccinations
    - Called Havrix and Typhim Vi, or similar vaccines used to prevent hepatitis A and typhoid fever, respectively

All participants will receive 3 doses of one of these vaccines at 0, 1, 6 months and will be followed for at least 6 months following their last vaccination.

Participants in the study will be "blinded" – meaning which vaccines they receive, and which vaccine their family compound receives, will be decided by chance and that neither the study participant nor the study team will know what vaccine is administrated until the end of the study.

We would like your permission to include you in this study. If you decide you can participate, you can change your mind and take yourself off the study at any time. We will tell you about any new findings that may affect your decision to participate in the study. If you decide to withdraw from the study later, please inform any member of the study team. This decision will not affect your participation or your child's participation in other NIH or MRTC studies.

STUDY PROCEDURES

Now we will explain the study and ask you if you want to participate.

You CAN enroll in the study now if you are:

- age ≥5 years old
- in good general physical and mental health
- able to provide proof of identity and known resident in the study area
- available for the duration of the study
- willing to have blood samples stored for future research
- willing to use pregnancy prevention (**females only**)
- willing to have mosquito feeds **(for children between 9 to 18 years old)**

You CANNOT be in this study if you:

- are pregnant (**females only**)

- have received a research product (drug or vaccine) or approved vaccine within the past 30 days
- have an illness or use a medication that may make it unsafe for you to participate in the study
- have a blood or urine test or an abnormal heart tracing (called an EKG) that may make it unsafe for you to participate in the study
- have a chronic illness, psychological problems, or medical condition, including HIV
- are allergic to any of the study products, mosquito bites **(for children between 9 to 18 years old)**
- have had a serious allergic reaction in the past
- are allergic to any of the vaccines or drugs used in the study

Screening
To see if you are in good health, we will ask questions about your health, examine you, and do tests on your blood and urine to look for signs of illness in your blood, kidneys, and liver at the screening visit. Your blood will be examined for HIV. You are encouraged to ask questions about the tests being completed, and you will be counseled about HIV testing. If you test positive, you will not be able to participate in the study, but we will tell you what the results mean, how to find care, how to avoid infecting others, and how we report the infections. You will also have an EKG (electrocardiogram) test to look at the electrical activity through your heart. In order to complete the EKG, we will need to put stickers on the skin of your chest, hands, and feet.

This screening visit should not take more than 2 to 3 hours and may be completed over multiple days. At screening, you will be asked to give a small amount of blood (about 10 mL; 2 teaspoons) to make sure you are healthy. You will be told all your test results and the possible meaning of these results will be explained to you. Some of your blood test results may be used to help find out what normal results are in adults in Mali.

If we find that you are sick at the screening visit, we will provide initial care to you at the study clinic free of charge and referrals for consultation if indicated. The study team will not pay for treatment of long-term illnesses that are found during the screening visit.

Study Visits Schedule

Injections

If the screening visit(s) shows that you can take part in this research study, at your first study visit, you will be asked if there have been any changes to your health since you were in the clinic, and a physical exam will be performed if necessary. At the first study visit you will also receive the first dose of a treatment course of an anti-malarial drug called artemether/lumefantrine which you may have received before for malaria. You will be given this medication by the study staff daily for the next 2 days as well.

On the day of vaccination, before you get the vaccine, we will examine you, and a blood sample will be taken to check if you are well and to assess what responses your body may have made to previous malaria infections.

On the day of your vaccine dose, your arm will be cleaned and the vaccination will be given to you in the upper arm muscle using a sterile needle and a syringe. The vaccine will be given in the upper arm unless there is a medical reason why it cannot be.

After you get a vaccination, you will be asked to stay in the clinic for at least 30 minutes for observation after the vaccination and you will be asked to come back after 1, 3, 7, and 14 days to check how you are feeling. Each visit will last about 1 to 2 hours and we will ask you how you are feeling and examine you. We will also ask you to come back at least every month to see if you have malaria germs in your blood, and more frequently for a short period after vaccination #3 for scheduled mosquito feeds (for children between 9 to 18 years old) and to look for malaria. Children aged 5-8 years old will also receive another treatment course of the anti-malarial drug called artemether/lumefantrine. You will be given this medication by the study staff daily for the 3 days total.

If for some reason you can't receive one of the vaccinations, you can continue to participate in the study.

During your time in this study, you will have a blood draw or a finger prick at the majority of your study visits, ranging from about 1 to 40 mL (few drops of blood to 2.5 tablespoons) per visit to check how you are feeling, check whether or not you have developed any serious medical problems, see if you are carrying malaria parasites, and to periodically check how your immune system is responding to the vaccine over time. This is much less than the recommended maximum limit of blood to be taken in adults or children over that same time period.

If you are a female and able to become pregnant, we will also check your urine or blood to make sure you are not pregnant. Pregnancy testing may occur prior to certain study procedures, such as vaccination or mosquito feeds.

If you become sick at any time, we want you to come to the clinic so that we can examine you. You do not have to wait for your scheduled visit. 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 your scheduled vaccination and have not recovered within one week, you will not receive the next 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 clinician determines you are too ill to be in the study any further.

If you develop a rash or other vaccine site issue, we may ask you to take a photo of this finding. These photographs will not include your face.

If you are enrolled into the study, a card with your name and picture may be made for you to keep, so that we can be sure to identify you correctly.

Mosquito Feeds Following Vaccination (ONLY for children between 9 to 18 years old)

We will also test several different ways of how well malaria germs grow in mosquitoes and if the experimental malaria vaccines change how well the malaria germs grow in mosquitoes. To be enrolled into this study you have to agree to participate in mosquito feeds, but we will ask you at each visit if you want to participate. In order to perform these tests, for females, we may need to periodically test that you are not pregnant around the time of the mosquito feed.

As previously explained, one of the ways to determine how well mosquitoes become infected is to have mosquitoes which we have grown in the laboratory bite someone who has malaria germs in their blood. Two feeding pints with about 30 pre-starved female mosquitoes in each will be prepared. Each participant will be exposed to the feeding pints for approximately 15-20 minutes. Two small containers with a mesh covering (to keep the mosquitoes from getting out of the container) will have about 30 mosquitoes each (60 total) and will be placed on your inner forearms or if needed/requested on your legs. Because these mosquitoes were grown in the laboratory we can be sure that they are not already infected with malaria or other diseases that can cause you to be sick. About a week after they have bitten you, we will check the mosquitoes to see if malaria germs have developed.

To see if the experimental malaria vaccines are working in blocking malaria transmission from a human to a mosquito, it is very important that we are able to complete these tests during the malaria transmission season when we will follow you closely. This would require you to come to clinic twice a month, every month for at least 4 months after the last vaccination. Each time you come to clinic you can decide whether or not you want to do these tests when we ask you.

When you participate in the mosquito bite part of the study, for safety reasons we may also want you to return for all of the study visits.

RISKS AND DISCOMFORTS

Although you will not know which vaccines you will receive, we would like to tell you some of the possible risks and discomforts you may have when receiving either the experimental malaria vaccines or the comparator vaccines. These are some of the risks and discomforts you may have if you participate in the study.

Blood Draws

Blood draws can cause pain, crying, bruising, bleeding, sometimes lightheadedness or fainting, and rarely infection. The frequency and amount of blood that will be required for this study should not put you at risk for anemia or compromise your overall health.

Study Medications

Coartem (artemether/lumefantrine)

- Coartem is a malaria medication that is safe and has been approved for the treatment of malaria in Mali. The most commonly reported side effects of Coartem include:

headache, loss of appetite, dizziness, weakness, muscle pains, and joint pains, but generally these effects do not require people to stop using the drug.

Vaccines

Pfs230D1M/AS01 (Experimental malaria vaccine)

- Inserting a needle through the skin for any reason can cause pain, bleeding, and bruising, and, rarely, infection at the place where the needle went into the skin. Sometimes, people can feel lightheaded or faint.
- This is not the first time the malaria vaccine candidate Pfs230 has been given to healthy adults both in US and Mali. Overall, vaccinations have been well tolerated in all groups enrolled into the study, including at doses of the Pfs230 planned for this study.
- The most commonly reported side effects reported with vaccines into your muscle, including with this experimental malaria vaccine, are side effects at the site of vaccination, including redness, itching, bruising, and/or swelling at the site of injection, muscle pain in your arm, and/or small lumps at the site of injection. Other side effects like fever, chills, headache, tiredness, muscle aches, and joint pain may also occur, and may range from mild to severe. Abnormal laboratory results in blood counts (low white blood cells and low hemoglobin) have been seen but to date these findings have not been found to be consistent and those that have occurred have not had any known clinical impact to the subject. These side effects and changes in laboratory results will be monitored closely, but in the past have generally been mild and self-limiting.
- The most commonly reported side effects from AS01 vaccines have been local site reactions similar to those noted above and other systemic symptoms such as low-grade fever and short-term flu-like symptoms: tiredness, muscle aches, headache.
- With any vaccine, there is a small chance that a sudden, severe allergic reaction can occur, which can cause death. This reaction can start by tongue swelling, feeling lightheaded, or having trouble breathing. Because of this, you will be watched carefully for at least 30 minutes after you are vaccinated. We will treat you if this reaction occurs.
- A healthy 51-year-old woman enrolled in a previous transmission blocking vaccine trial in 2014 to 2016 developed symptoms of a stroke approximately a week after receiving her fourth and last vaccination of Pfs230D1M. Due to her stroke, she died the following day. This serious event was reviewed by many individuals and groups after it happened and at this time it has been determined the stroke was unrelated to the vaccine she received. Though we do not believe that the vaccine had any cause for the stroke, we want to keep you informed of major events that have occurred during similar studies prior to your participation.

TYPHIM Vi ® (typhoid vaccine)

The most commonly reported side effects include pain and redness at the vaccine site, tiredness, upset stomach, vomiting, diarrhea, and stomach pain. Rarely, feeling lightheaded or fainting can occur. As with any drug or vaccine, you could have an allergic reaction (itching, rash, hives, swelling, or difficulties breathing) to the vaccine.

Inserting a needle through the skin for any reason can cause pain, bleeding, and bruising, and, rarely, infection at the place where the needle went into the skin. Sometimes, people can feel lightheaded or faint.

Havrix® (hepatitis A vaccine)

The most commonly reported side effects include pain, redness, and induration at the vaccine injection site, fever, irritability or fussiness, sleepiness, and decreased appetite.

Inserting a needle through the skin for any reason can cause pain, bleeding, and bruising, and, rarely, infection at the place where the needle went into the skin. Sometimes, people can feel lightheaded or faint.

If TYPHIUM Vi® or Havrix® are not available at the start of the study, another approved vaccine (by U.S. FDA and/or Mali Ministry of Health) may be used.

Pregnancy

- The risk to a growing fetus if a pregnant woman receives the experimental malaria vaccines or the comparator vaccines 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 will not receive additional vaccinations if already enrolled.
- We will perform pregnancy tests before vaccination and at other times during the study. The results of these tests will be provided to you in a confidential manner.
- If you do become pregnant during this time, we will request to follow you in the clinic until the baby is born and for a short time after delivery to see if there have been any side effects to you or your baby that may be related to your participation in the study.
- You must use adequate birth control to be in the study if you are:
    - ≥18 years of age and premenopausal
    - married and/or sexually active and 12-17 years of age

  Adequate methods of birth control include:
    - documented injectable contraceptive
    - intrauterine or another type of implanted device
- If you are unable to have children, you will need to report the date of your last period or history of surgical sterility or onset of menopause. You still will have pregnancy tests performed.
- If you are 12-17 years of age, unmarried, and not sexually active you will not be required to use birth control, but you will still have pregnancy tests performed. You will also be asked frequently during the study about any changes to this status.
- If you are menstruating and 11 years of age or younger you will be excluded from the study.

- If you want to become pregnant during the course of the study or within 3 months after the last vaccine, you cannot participate. You must notify the clinic staff immediately upon learning that you have become pregnant during this study or if you want to change your pregnancy prevention method.

Genetic Testing

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

Mosquito Feeds (ONLY for children between 9 to 18 years old)

- In Bancoumana and Doneguebougou, thousands of mosquito feeds have been performed on people older than 5 years old since 2011. Side effects are extremely rare, with a very small number of people reporting redness and/or itching at the site of the mosquito bites with no other side effects.
- Mosquitoes also can transmit other diseases besides malaria. However, the mosquitoes we use for our mosquito feeds have been grown in a laboratory and have never bitten a person before, so your risk for other infections is extremely low.

Other Risks

It is unknown if the study vaccine may alter your response if you ever have malaria infection in the future. You will be made aware of any significant health effects of the vaccine and serious side effects if they occur in other subjects, and will be updated during the trial as needed.

ALTERNATIVE TO PARTICIPATION IN THIS STUDY

Your alternative is to not participate in this study.

BENEFITS

Given you will enroll into the study with the majority of your other family compound members, there may be a potential for direct benefit to you participating in the study. This benefit could be a decrease in the number of malaria infections in the family compound receiving experimental malaria vaccine. Your participation in this study will also help researchers learn how malaria is transmitted in the focused communities, such as a family compound.

NUMBER OF PEOPLE IN THE STUDY

Approximately two thousand (~2000) healthy children and adults aged of 5 years or above will be enrolled into the study.

DURATION OF STUDY FOR EACH PARTICIPANT

Participants will be followed for 6 months after receiving their last vaccination.

COMPENSATION

You will be given compensation in kind (for example, rice or millet) or cash equivalent to a total value of approximately 72000-88500 (USD $144-177) depending on your age group if you are followed up throughout the study period (12 months). The amount of USD $6 for each scheduled visit with lab procedures, USD $3 for each scheduled visit without lab procedures, and USD $6 for weekly visits (study visits assessing for mosquito feed participation) occurring in the period following Vaccination #3 is proposed to compensate for lost time, since visits with blood drawn or mosquito feeds require more time than visits without blood drawn. Additionally, twice monthly mosquito feeds require subjects to commit a significant amount of their time to this study.

CONFIDENTIALITY

We will keep your health information private. All files with information that could identify you will be kept in locked cabinets. Samples of blood that are collected from you will be marked with a number that tells the study team that it is your blood. These samples will not be marked with your name.

People responsible for making sure that the research is done properly may look at your study records. This might include people or their representatives from the Malaria Research Training Center (MRTC) at the University of Bamako, NIAID, the Mali regulatory body, the United States Food and Drug Administration (FDA) and the World Health Organization. All of these people will also keep your identity private as much as possible.

COMPENSATION FOR INJURY

If you are enrolled in this study, you will receive free medical care for acute illnesses during the duration of the study (maximum of one year) at the site's study clinic. Treatment for malaria and other illnesses will be given to you according to the standard of care that is available in Mali and it will be free. Treatment for chronic illnesses will not be provided. A referral will be made for care if needed. 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 health problems, and for any problems resulting from your participation. Insurance is available to take care of you in case of injury or illness related to this study.

STORED SAMPLES AND FUTURE RESEARCH

We may take extra blood and tissue samples and store them for future research. These samples will help us learn more about malaria or other health problems. The research tests we will use may not be like medical tests. We may not know how the results relate to your care. Therefore, we may not put future test results in your medical record or study chart. However, if you ask, someone on the study team will discuss the test results with you. We will not share these test

results with your private doctor unless you ask us to do so. The blood that is stored will be what is left over from the tests that are done during the study. Some of these tests will tell us about how your body fights malaria. Your blood will be stored at the MRTC in Bamako, or at the NIAID in the United States.

By agreeing to participate in this study, you do not give up any rights that you have regarding access to and disclosure of your records. For further information on those rights, please contact Dr. Issaka Sagara (Tel: 76 45 90 79).

Labeling of Stored Samples
We will label your stored samples with a code that only the study team can link to you. We will keep any information that can be traced back to you private to the extent permitted by law.

Future Studies
Other investigators may want to study your stored samples. If so, the study team may send your samples to them without any information that can be traced to you. The study team may also share information such as your gender, age, health history, or ethnicity. In some cases, an Institutional Review Board (IRB) will review new research that uses your samples. The IRB is a committee that oversees medical research studies to protect volunteers' rights and welfare.

Investigators will use your samples *only* for research. We will not sell them. Future research that uses your samples may lead to new products, but you will not receive payment for these products. Some future studies may need health information (such as smoking history or present health status) that we don't already have. If so, the study team may contact you for this information and to obtain permission to access your medical records.

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. 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.

Some of the blood drawn from you as part of this study may 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). We will let you know the results of these test and if it has any impact on your health or your children's health.

Some of the blood drawn from you as part of this study may be used for a test for HLA type, which is a genetic test of markers of the immune system. For research, HLA testing might be used to try to identify factors associated with the development or severity of diseases. Some

HLA types have been associated with an increased risk of certain diseases like arthritis and other rheumatologic problems. However, simply having those HLA types doesn't mean you will develop these diseases.

Benefits
In general, future research that uses your samples will not help you, but it may help us learn what causes malaria or related conditions. This research may also help us learn how to prevent or treat malaria.

Risks
The risk is that someone may take information from your medical records without your permission. The chances of this happening are very low. If this information becomes available, you may face discrimination when you apply for insurance or a job. You may also have similar problems if you share the information yourself or allow us to release your medical records.

Data Sharing
Researchers can perform studies that are more powerful when they share with each other the data or information they get from studying human samples. They share this information with each other by putting it into scientific databases. There are different kinds of databases, some are able to be seen by anyone on the internet (public) while others are controlled (limited access). Data from this study will only be made available in a de-identified form, so the data posted will be in a form that protects your confidentiality and will not be able to be linked back to you.

Making Your Choice
If you agree to participate in this study, you also agree to let us store your blood samples and data for future research. If you agree to let us store your samples now, you can change your mind later. If you wish to withdraw your consent for your samples to be used in future research, please contact us and say that you do not want us to use your samples for future research.

Conflict of Interest
The National Institutes of Health (NIH) reviews NIH researchers at least yearly for conflicts of interest to be sure that research is not influenced by the financial interests of the researchers. NIH researchers are allowed to own small amounts of stock in the companies which make experimental products but if the amount is small this is not considered a conflict of interest. This protocol may have investigators who are not NIH employees. Non-NIH investigators are expected to adhere to the principles of the NIH Protocol Review Guide but are not required to report their personal financial holdings to the NIH. If you would like to get more information, you may ask your research team for additional information or a copy of the Protocol Review Guide.

QUESTIONS

If you want to talk to anyone about this research study because you think you have been hurt by being part of the study, or you if have any other questions about the study, you should tell the study team. They will ask the **Principal Investigator, Dr. Issaka Sagara (Tel 20 22 81 09), Dr. Mahamadou S Sissoko (Tel: 66 72 22 66) or Dr. Abdoulaye Katilé (Tel: 76 25 33 04).**

Also, you can contact the people at the **Faculty of Medicine of Pharmacy and Odonto-Stomatology (FMPOS) Ethical Review Committee** at Point G, Bamako (Tel: 20 22 52 77) for example, the President of the Ethics Committee, **Pr. Mamadou Marouf Keita (Tel 66 72 20 22)**; or the Permanent Secretary, **Pr. Mahamadou Diakité**, (Telephone: 20 22 52 77, Cell: 76 23 11 91) to answer questions you may have about being part of this study and your rights as a research participant.

A description of this trial will be posted on http://www.clinicaltrials.gov as required by U.S. law. The website will include a summary of the results of the trial; and will not include any information that can identify you.

If you have any questions about this research study, you may ask someone on the study team. You can also ask questions in the future if you do not understand something that is being done to you.

Consent Sheet

If you agree or you (the adult) agree for your child/dependent to participate in this study, please sign or put your fingerprint below.

Printed name of Volunteer (or Parent/Guardian): _____

Date: ___ / ___ / ____ *(first)* *(last)*

dd mmm yy

Signature or fingerprint of Volunteer (or Parent/Guardian):_____

Printed name of Parent/Guardian #2 (if 17 years of age or younger): _____

Date: ___ / ___ / ____ *(first)* *(last)*

dd mmm yy

Signature or fingerprint of Parent/Guardian #2 (if 17 years of age or younger):

_____

Printed name of Investigator: _____Date:___ / ___ / ___
(first) *(last)* *dd mmm yy*

Signature of Investigator: _____

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 subject, and the subject indicated that his/her questions and concerns were adequately addressed.

Printed name of Witness: _____Date: ___ / ___ / __
(first) *(last)* *dd mmm yy*

Signature of Witness: _____