

**PARTICIPANT INFORMED CONSENT FORM IN MADAGASCAR**

<b>Study Title</b>	A Phase 1b, multicenter, randomized, placebo-controlled, observer-blinded, dose escalation study to evaluate the safety, tolerability, and immunogenicity of the rSm-p80 + GLA-SE (SchistoShield®) candidate vaccine in healthy adults in Burkina Faso and Madagascar.
<b>Protocol Number</b>	IVI VASA 001
<b>Study Sponsor and address</b>	International Vaccine Institute (IVI) SNU Research Park, 1 Gwanak-ro, Gwanak-gu, Seoul, 08826 Republic of Korea
<b>Sponsor Representative</b>	Dr. Florian Marks International Vaccine Institute (IVI)/ University of Cambridge, UK
<b>Study Site</b>	University of Antananarivo established in Campus d'Ankatso, Antananarivo 101, Madagascar,
<b>Site Principal Investigator</b>	Prof. Raphael Rakotozandrindrainy
<b>ICF Version Number and Date</b>	4.0, 06 Nov 2024
<b>Participant screening Number</b>	_____

**PART I: PARTICIPANT INFORMATION SHEET****1. Introduction**

Thank you for your active participation to complete the pre-screening activities i.e. de-worming with praziquantel and albendazole treatments for 5 weeks prior to the first dosing/vaccination. You are now invited to take part in a clinical trial for a new vaccine against schistosomiasis, also known as bilharzia. A clinical trial is a study conducted in human to evaluate the safety and efficacy of a new vaccine. This form contains the information about this study to help you decide if you want to participate. This study is sponsored by International Vaccine Institute (IVI) which is based in South Korea. The vaccine tested in this study is called SchistoShield which is manufactured by a company called PAI Life Sciences Inc., (PAI Life) based in the USA.

Prof. **Raphael Rakotozandrindrainy** is the “Principal Investigator” for the study, meaning that is responsible for conducting this study. Before you decide to participate in this study, it is important that you understand why this research is being conducted and why you are invited to take part in it. Please take time to read the following information carefully and discuss it with your family and/or friends if you wish. If anything in this form is unclear, or if you have any questions, do not hesitate to ask the Principal investigator. Prof. **Raphael Rakotozandrindrainy**. Participation in this study is voluntary, i.e., it is completely your choice whether you want to be a part of this study or not.

If you do decide to take part in this study, you will receive a copy of this document, along with the signed and dated informed consent form to keep it for future reference.

This study will be conducted in Madagascar and Burkina Faso. A total of 120 participants will be asked to participate in this study, approximately 60 subjects from each country. The same vaccine was tested in adult volunteers like you, in a clinical trial much like this one in the USA where the vaccine was found to be safe.

**2. Background on the disease**

Schistosomiasis or bilharzia is a water-related disease caused by a worm called *Schistosoma*. It occurs in places with limited access to safe drinking water and inadequate sanitation programs. People become sick when they swim, work, or play in water that contains the snail that carries *Schistosoma* worms. People who are sick with schistosomiasis may experience fever, tiredness, painful muscles, a dry cough, blood in their stool, loose stools, and blood in their urine.

Like many other infectious diseases, we are trying to prevent this illness by giving a vaccine to healthy people in the areas where the disease occurs. A vaccine is a substance that stimulates the body to produce antibodies, that have the ability to prevent infection in the body. There is not yet a vaccine available against this disease. There is medicine available against this disease called Praziquantel.

**3. Why the study is being done?**

This is a “Phase 1b” research study which aims to test a new vaccine candidate (SchistoShield®) against schistosomiasis. This vaccine has been tested for the first time in phase 1a in healthy adult in the United State of America (USA). This is a “Phase 1b” clinical trial, which means that this study will be the first time the vaccine will be tested in people living in your country. The purpose of conducting this Phase 1b study is to test if this new vaccine (SchistoShield®) of 3 different dose formulations is safe, well tolerated, and if there any side effect in people living in endemic settings (who may have been infected with bilharzia in the past). We also want to study if the vaccine candidate could help people produce antibodies against schistosomiasis, that have the ability to prevent infection in the body.

**4. Who has approved this study?**

This study has been reviewed and approved by the Comité d’Ethique de la Recherche Biomédicale de Madagascar auprès du Ministère de la Santé Publique de Madagascar (CERBM) in Madagascar, as well

as by the Institutional Review Board (IRB) of the International Vaccine Institute in Korea. These committees are responsible for ensuring that research participants are protected from harm and their well-being rights are respected.

### 5. What Study Products will be used in this study?

The SchistoShield® [rSm-p80 (antigen); manufactured, filled, and released by PAI Life Sciences Inc. (Seattle, WA) with GLA-SE (adjuvant); manufactured and released by the Access to Advanced Health Institute (AAHI)(Seattle, WA)] vaccine, will be used as study product in the study.

### 6. What will happen if I join this study?

In order to fairly determine the safety and immune responses of the vaccine, participants will be randomized in a blinded manner (by chance-like flipping a coin) into one of the two arms, with one arm receiving the test vaccine and another arm receiving an inactive substance called a “placebo”. The placebo does not have any medical effect. We will compare the arm that receives the placebo and the arm that receives the test vaccine.

The study is blinded to the participants and the study investigators, which means that you and the study investigators observing you will not know which arm you have been randomly assigned to.

- The study will be testing three different amounts (low, medium and high doses formulations) of the test vaccine, and so there are three groups/cohorts A, B and C of participants according to the three doses formulations. In each group/cohort, participants will be assigned by chance so that 15 participants receive the test vaccine and 5 receive the placebo.
- Cohort A 10 µg SchistoShield® + 5 µg adjuvant formulation,
- Cohort B 30 µg SchistoShield® + 5 µg adjuvant formulation and
- Cohort C 100 µg SchistoShield® + 5 µg adjuvant formulation

Cohort A will receive the low-dose antigen formulation or placebo, Cohort B will receive the medium-dose antigen formulation or placebo, and Cohort C will receive the high-dose antigen formulation or placebo. The study will start with the smallest amount of vaccine, the ‘Low Dose Vaccine’ in group/cohort A. If there are no harmful effects in any of the participants in group/cohort A, the study will move on to the medium amount of vaccine, the ‘Medium Dose Vaccine’ in group/cohort B. Finally, if there are no harmful effects in any of the participants in group/cohort B, the study will move on to the highest amount of vaccine, the ‘High Dose Vaccine’ in group/cohort C. The Safety Monitoring Committee (SMC) and site investigators will review blinded safety data of each Cohort for dose escalation.

The table below shows how participants are distributed by group/cohort according to the study arms and treatment (Vaccine doses and placebo).

Group	Arm	Treatment	Number of Volunteers
Group A	A1	Low Dose Vaccine (10 µg Ag/5 µg Adjuvant)	15
	A2	Placebo	5
Group B	B1	Medium Dose Vaccine (30 µg Ag/5 µg Adjuvant)	15
	B2	Placebo	5
Group C	C1	High Dose Vaccine (100 µg Ag/5 µg Adjuvant)	15
	C2	Placebo	5
Total			60

## 7. Why should we use a placebo or a control medicine?

A 'placebo' is an inactive substance, which looks like the real vaccine, but is not. It contains no active ingredient of the schistosomiasis vaccine and is not harmful. By comparing the test vaccine to placebo, we will find out if the vaccine works as expected. To help us know the true effect of the vaccine, the doctors and nurses (except the vaccine/placebo administrator) working on this research project will NOT know what you have received until the end of the study. This does not mean that the persons in the clinic looking after you will not know your condition. Indeed, they will keep a very close watch on you. In case of any safety concern, you will be informed about vaccine/placebo administration in the study.

## 8. What is the duration of my participation in this study?

If you agree to be part in this study, you will be followed up for within a month (4 weeks) at the start of the study to check if you can join the study and then approximately 8 months (32 weeks) starting the day on which you join the study (Visit 2).

## 9. What are the study procedures if you decide to involve in?

### 9.1 Screening visit or Visit 1 (Day -28 to Day -1)

After signing the informed consent, the study staff and doctors will go through your medical history, do a physical examination, and ask you to give blood, urine, stool samples to conduct laboratory tests. You will give about 6 mL blood sample (approx. 1 teaspoon) at this visit. If you are a woman, you will also do a pregnancy test for your safety. Empty plastic stool/urine containers will be provided to you with proper instruction on how to collect your one-gram stool/urine sample for schistosomiasis and other helminthiasis tests (in the stool). Along will the study related procedures a SARS-CoV-2 rapid antigen test will be conducted.

Based on the results of this medical check-up, study staff and doctor will conclude whether you meet all the eligibility criteria.

Broadly, you can take part in this study if:

- You are aged between 20 and 59 years old,
- You have completed pre-screening activities and taken the anti-worm medication praziquantel and albendazole at least 5 weeks prior to the first vaccination,
- You are willing and able to comply with the visit schedule, complete diaries, and provide blood samples,
- You are able to participate for the entire duration of the study,
- You are in good health, as determined through medical examination by a doctor and through tests for your blood, nasopharyngeal swab and stool/urine samples,
- If you are a woman, you test negative for pregnancy,
- You are either currently practicing or willing to practice continuous effective contraception, up to four weeks before the 1<sup>st</sup> vaccine dose and 4 weeks after the 3<sup>rd</sup> vaccine dose,
- You give your consent to be a part of the study after being fully informed about what participating means.

## 9.2 Vaccination visits (Visits 2, 4, 6)

If you are found eligible after screening, you will be enrolled in the study on the second visit (Visit 2), no later than 28 days after the screening date. At each vaccination visit, (visits 2, 4, 6), the study staff will ask about your symptoms and medications history, and you will undergo a general health examination, to check again if you can participate in the study.

Baseline blood samples will be collected approximately 9mL at visit 2 (approx. 2 teaspoons), 15 mL at visit 4 and 6 (approx. 3 teaspoons) for both the safety and antibodies assessment against schistosomiasis. In addition, a urine test will be conducted to check pregnancy for female participants as part of the safety assessment. Finally, a nasopharyngeal swab will be collected to test for a possible current SARS-CoV-2 infection.

After each vaccination and to ensure your safety, you will remain under supervision of the study staff for at least 60 minutes.

To monitor any occurrence /symptoms/sign 7 days following each vaccination, you will be provided with a diary card after each vaccination and you will be asked to complete it at home or it will be completed by study nurse during your home visit, between the visits at the study center. An explanation will be given to you on how to fill in the diary card correctly.

The completed diary card will be checked/collected during the next visit at the study center. You will then be asked to come back with the diary card to the study center during the next follow-up visit.

## 9.3 Follow-up Visits

### ➤ Visits 3, 5, 7- One week visit following each vaccination

You will undergo a general health examination including checking the vital sign. Approximately, 15 mL of blood sample at these visits (approx. 3 teaspoons) will be drawn for both antibodies test against schistosomiasis and safety assessment.

You will be asked about any reactions/symptoms that might have occurred and medications received. The completed diary card will be checked at this visit.

### ➤ Visit 8 – 4 weeks visit after third vaccination

You will be asked about any new symptoms/signs that might have occurred and medications received since last visit. The completed diary card will be collected and checked at this visit. You will undergo a physical examination. You will be asked to come back to the study center for the next site visit.

Approximately 15mL blood sample (approx. 3 teaspoons) will be drawn to test for both antibodies test against schistosomiasis and for safety assessment.

➤ **Visit 9- 6 months visit after third vaccination**

At Visit 9, you will be asked for any new symptoms/signs that might have occurred and medications received. You will undergo a physical examination. About 5 mL of blood sample (approx. 1 teaspoon) will be drawn to test for both antibodies test against schistosomiasis and safety assessment.

Participation in the study will end with this visit.

A total of approximately 110 mL of blood will be drawn during the entire study duration of 9 scheduled visits. Clinical examinations and tests related to the study procedures will be free of charge to you, the costs will be covered by the study.

A subset of five out of 20 subjects in each cohort will be sampled by convenience to enable us to further characterize the immune response using the peripheral blood mononuclear cells (PBMC). If you are part of this subset, approximately 17 mL of blood samples (approx. 3 teaspoons) will be additionally drawn at visit 2, 3, 4, 5, 6, 7 and approximately 10 mL (approx. 2 teaspoons) at visit 8 & 9 for further immunological analysis.

#### 9.4 Unscheduled Visits

If you have any intercurrent illnesses or any medical attended event you will be asked to come to the study center an unscheduled visit or to a designated hospital for and contact one of the study personnel, whose name is written at the end of this form and on the participant diary card. The study physician will ask you or your doctor some questions about the suspected disease. The blood/stool/urine/nasopharyngeal swab samples may be collected if deemed necessary by the study doctor to perform tests to ensure better care.

#### 10. What are the benefits of taking part in this study?

You may receive no direct benefit from this study participation. But you will be closely followed as part of the study procedures and the clinical examination and safety laboratory results will be shared with you. Findings of medical concern will be referred for appropriate care and treatment.

The test-vaccine, SchistoShield®, is an experimental vaccine, if you are vaccinated with you may develop immune response and protection against schistosomiasis, although this cannot be guaranteed. However, your participation will help generating new information for future development of the vaccine and for the society later, if the vaccine candidate gets successful. The findings of the study will be shared with all the study participants at the end of the study conduct.

#### 11. What are the possible risks in participating in this study?

**Risks of receipt of test vaccine:** As with any vaccination, there is the potential for an anaphylactic reaction (strong allergic reaction). To identify and address this potential problem, medical staff experienced in the management of anaphylactic reaction will observe patients for at least 60 minutes following each vaccination. Participants receiving any of the vaccines in this study may experience pain, tenderness, redness of the skin, hardening, swelling or itchiness at the injection site, fever, headache, fatigue, chills (an unpleasant cold feeling), muscle aches and pains, cold, cough, nausea, vomiting, dizziness, Stiffness of the joints. Three doses of Low, medium and high dose of rSm-p80 either adjuvanted with or without 5µg of GLA-SE were recently tested for the first time in adults in the USA. The product was well tolerated with a good safety profile. There were no serious adverse event (SAE), medically attended adverse event (MAAE) and potentially immune mediated medical conditions (PIMMCs) related to the study product. The most common expected systemic symptoms post any dose experienced within the 7 days post vaccination were fatigue, arthralgia (pain in joints), myalgia (body aches/muscular pain) and headache. The most common expected local symptoms and signs reported during the 7 days post vaccination included the pain, tenderness induration (hardness)/swelling. The



most common unsolicited adverse event reported with 28 days post vaccination and related to the study product was arthralgia (pain in joints). Increases in serum creatinine related to the study product were reported in study participants. Changes in hematology parameters related to the study product were reported and included decrease in white blood cell count, increase in platelet count and decrease in hemoglobin. Most of these clinical laboratory abnormalities were mild and transient (for short time). Additionally, there may be other side effects from these vaccines that at this time are not known. You will be extensively counselled to contact the study staff if you experience symptoms and signs after receiving a dose. Side effects that require medical care will be treated by a qualified medical doctor at the nearest health facility following local guidelines.

**Risk when administered during pregnancy:** There have not yet been any studies of this test vaccine in pregnant women. In other words, there is no information about the effects of these vaccines in the developing babies and the risk for occurring malformations. Therefore, pregnant women and women of child-bearing age seeking to become pregnant, should be excluded from participating in the vaccination portion of this study. Additionally, breastfeeding women will be excluded from the vaccinations as well because there is no information regarding the safety of mother and baby in this group.

**Risks when taking a blood sample:** When a blood sample is taken, you may experience slight pain from the needle puncturing the skin, and, rarely, dizziness and fainting. Additionally, abnormal blood collection outside of blood vessels due to the venipuncture, but this has minimal risk. Infection of the skin/soft tissue at the puncture site, vein, or blood stream can all occur, though are very rare with both finger sticks (A procedure in which a finger is pricked with a lancet to obtain a small quantity of capillary blood for testing) and venous blood draws. Your monitoring and aseptic techniques such as using sterile disposable blood collection apparatuses and adhering to standard medical precautions will reduce any risk to a minimum. The amount of blood to be taken for sampling will not be harmful to your health.

**Nasopharyngeal swab sample collection:** Another potential cause of discomfort while participating in the study is collecting nasopharyngeal samples. A 5 to 6 inches long bendable, one time use stick, which has a cotton swab fixed in one end will be inserted through the nasal tract and throat. This may cause mild discomfort and pain. Appropriate sterile precautions will be maintained while collecting the sample. Some discomfort can occur in the nostril during this procedure. Occasionally, this can result in a small amount of bleeding from the nose, which can be controlled with pressure to the affected area.

## 12. Sickness or injury as a result of study participation and treatment

If you become ill or are injured as a direct result of the study-related procedures or study vaccines, the participant will receive appropriate medical treatment and care as provided by a clinical trials medical insurance policy that will be obtained by the study sponsor. If you develop any serious medical problems during the study that turn out to have been caused by any study procedure(s), you will receive the necessary medical treatment (as other permitted medication) and care provided free of charge through appropriate clinical trial insurance coverage, as required under applicable laws and regulations.

## 13. Alternative vaccines

As of now, there are no known effective vaccines to prevent schistosomiasis. The alternative procedure or option is to not participate in this clinical trial. If you decide not to participate in this study, it will not affect your future treatment and relationship with the site staff.

## 14. Compensation

Participants will not be compensated for participation in the study. However, each participant will receive 65.000 Ariary (approximately 15 United States Dollars (USD)) for each scheduled visit, as compensation for transportation and loss of time. A snack will be served to the participants while attending the scheduled clinic visit. No compensation will be paid for the unscheduled visit. The participant will not be charged for the study vaccines or for any of the procedures related with participation in the study. The compensation will be made according to the number of completed visits,

at respective visits even if the participant decides to withdraw from the study. In addition, the participant will get the same compensation fee even if the participant fails to meet the eligibility criteria of the study for loss of time/compensation.

### 15. Study Participant's responsibilities

Consent is a promise of trust between site staff and you. By signing the consent form and agreeing to participate, you also have the responsibility to tell the truth and to comply with the rules of the clinical trial and procedure. Maintaining a diary card is important so please be aware that you must devote time to keeping and completing the diary card. And if you feel any symptoms or discomfort, you should contact/report them to the site staff immediately and they will take the necessary steps to manage the condition. You should be available throughout the study period for follow-up visits, i.e., clinic visits or visits by phone.

### 16. Ending study participation

You can choose either not to participate or to withdraw from the study at any time without any consequence to you. However, before withdrawing from the participation, the study team would like to perform a medical examination to evaluate your health status before your study participation has come to an end.

If you would like to withdraw from this study, please contact the site Investigators or the study staff mentioned previously. You will not lose any rights, including the rights to medical treatment and others assistance.

The Site Investigator may decide to discontinue your participation in the study, but they may continue the safety follow-up under the following situations:

1. If the study has been suggested/recommended to stop by the Data Safety Monitoring Board (DSMB), IRB/Independent Ethics Committee (IEC), or by the sponsor.
2. Study sponsors or the IRB/IEC request to terminate the study for unexpected reasons.
3. You are unable to comply with the study requirement.
4. You are not willing to have blood drawn although you are still willing to participate in other processes.
5. You have a medical problem where your continuation in the study would be inconvenient to you.

The IRB/IEC, or the Sponsor also may decide to terminate the study without your prior consent. If this happens, the reason will be explained to you.

### 17. Future use of biological samples

Biological specimens (Blood samples, stool, urine, and nasopharyngeal swab) will be taken as a part of this study, for Pregnancy tests, laboratory safety tests (hematology and biochemistry) and immune responses tests and SARS-CoV-2 test. Some samples will also be sent abroad to check how well the vaccine works.

If any part of your biological samples is left over after testing, the Sponsor would like to keep it for possible use in other research for up to 15 years after the Clinical Study Report completion.

If you agree to take part in this study, you will be asked if any unused parts of your biological samples may be kept for other research purposes. Your stored samples will be used only for research and will not be sold. The research done with your samples may be used to develop new products in the future, but you will not get paid for allowing these samples to be used. No genetic testing will be performed. If you say no, these samples will be used only for the tests that are directly related to the present study. If you wish to allow your samples to be kept for research purposes, you will be asked to sign an additional Informed Consent Form in case you wish to allow us to store and use your sample for future research.



**18. Confidentiality of Personal information and data privacy**

The investigators and the study staff will maintain and protect all participant's data and confidentiality. To make sure all information collected from you is kept confidential, the following safeguards will be used: 1) access to study files and personal information will be limited to study personnel, ethics committees, regulatory authorities, and the Sponsor; 2) study information will be kept in locked rooms when not in use; and 3) all information or samples will be labeled with a unique study identification number and have no personally identifying information.

We will do everything to protect your data privacy and confidentiality. Participants will receive a study number which will be known among the study team only and it will be used to keep the confidentiality of study data. Collected specimens will not display any of your personal information.

Clinical and study data may be monitored and audited or inspected by regulatory authorities.

Participant's general and health information will be considered important and kept confidential. The regulatory and inspecting authorities will follow the restriction to keep confidential information and not reveal data to others. Publication or presentation of the data from this study will not disclose information which can identify the participant.

The International Vaccine Institute will ensure that your personal protected information is protected under local and (if applicable) international law to include (but not limited to) Law No. 2014-038 (DP Law) which states that you have the right to object to data processing; the right to access one's personal data; the right to rectification of one's personal data; and the right to get information about a data controller and processing of personal data relating to a person.

**19. If there is a new finding**

The study team will contact you and let you know in a timely manner if there is any new information during the study that may affect your willingness to participate in the study.

**20. If you need more information/questions/ have any study-related injury**

If you have any questions about this study related to your rights and responsibility as a volunteer in this study, or if you have any study-related injury or questions regarding the work of the study staff, you can ask or contact the site Principal Investigator or designee at any time;

Name	Prof. Raphael Rakotozandrindrainy
Telephone Number	
Email	

**21. If you have any inquiries regarding the rights of the volunteer, you can contact:**

If you have any questions or requests regarding the rights and safety in the study, you can ask or contact the person below:

<b>SITE IEC (INDEPENDENT ETHICS COMMITTEE)</b>	
Name	Comité d'Ethique de la Recherche Biomédicale de Madagascar auprès du Ministère de la Santé Publique de Madagascar
Telephone Number	

<b>IVI IRB (INSTITUTIONAL REVIEW BOARD)</b>	
Name	IVI IRB Coordinator Institutional Review Board, International Vaccine Institute

Telephone Number	
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This clinical trial will be registered and will be available on the national registry of clinical trials according to the country's requirements (e.g., <https://clinicaltrials.gov/>; <https://pactr.samrc.ac.za/>). This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this study on website at any time.

Thank you for your interest, taking time to read this information or listen to it.

## **PART II: INFORMED CONSENT FORM**

### **Study Participant:**

*By signing this form, I certify to all the following:*

Sr No.	Declaration of informed consent	Subject Initials
1	I have read the participant information sheet (or had the information read to me) and received explanations regarding what will be done to me and what I am being asked to do. I have had the opportunity to ask questions, and I understand that I may ask additional questions about this study at any time.	
2	I voluntarily consent to take part in this study. I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.	
3	I confirm that I authorize the use and sharing of my health information as described in the participant information sheet.	
4	I consent to make my confidential personal information available for review by the Sponsor or its representative, the Ethics Committee and the Regulatory Authorities or to any health authorities, institutions, or governmental agencies assigned this task in this country or in another country where the study vaccine may be considered for approval, or, if applicable, the IRB or Ethics Committee.	
6	I confirm that I also know that I will not experience any disadvantage even if I withdraw(s) participation in the research.	
7	I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s). I understand that my identity will not be revealed in any information released to third parties or published.	
8	I have not waived any of my legal rights or released the parties involved in this study from liability for negligence.	
9	I confirm that I allow the study team to draw the blood samples as mentioned in the participant information sheet and to analyze the samples in the context of study even if I withdraw consent.	
10	I have been given a copy of this Informed Consent Form to keep for my reference.	
11	I understand that I will be informed of any new information that may affect my willingness to continue my participation in this study.	

Can you please confirm if you are willing to participate in the subset group to provide additional blood for further immunological analysis ("Page 6")?

☐ Yes, I confirm to participate in subset

☐ No, I do not confirm to participate in subset but I will continue to participate in the study

Printed Name of Participant in full		
Signature of Participant	Date (DD-MMM-YYYY)	Time (HH:MM)
Thumb impression (For illiterate participant)		

**Impartial Witness (if applicable)****Statement:**

I hereby confirmed that I was present during the entire process of informing the participant and I confirm that the information in the consent form has been accurately explained to and apparently understood by the participant and the participant has been provided with the necessary information and has agreed to participate in the study.

Printed Name of Impartial Witness, in full		
Signature of Impartial Witness	Date (DD-MMM-YYYY)	Time (HH:MM)

**Study Staff who obtained the Informed Consent****Statement:**

I certify that I have explained the nature and purpose of this study, and the potential benefits and reasonably foreseeable risks associated with participation, to the participant/legally authorized representative of the above volunteer, on the date stated on this consent form. I have answered any questions that have been raised and have witnessed the above signature.

Printed Name of Person Obtaining Consent		
Signature of Person Obtaining Consent	Date (DD-MMM-YYYY)	Time (HH:MM)