Consent for Participation in a Research Study
And
Authorization to Use and Disclose Protected Health Information

Sponsor / Study Title:	**International AIDS Vaccine Initiative / "A Phase 1, Single-blind, Placebo-controlled, Dose-escalation Clinical Trial to Evaluate the Safety and Immunogenicity of rVSVΔG-SEBOV-GP Vaccine at 3 Dose Levels in Adults in Good General Health"**
Protocol Number:	**IAVI C108**
Principal Investigator: (Study Doctor)	**«PiFullName»**
Telephone:	**«IcfPhoneNumber»**
Address:	**«PiLocations»**

About this research

You are being asked to participate in a research study. This research will study a new vaccine candidate for a type of Ebola virus. The new vaccine is not approved by the United States Food and Drug Administration (FDA). The research will be looking at how the vaccine impacts the body and the immune system.

This consent form will give you information about a clinical research study to help you decide whether you want to participate. Please read this form (or have it read to you) , and ask any questions you have, before agreeing to be in the study. If you are willing to take part in the study, you will sign and then receive a copy of this document. Another copy will be kept in the clinic's files. You may choose to have somebody come with you to help you understand the study.

Important Information

This information gives you an overview of the research. More information about these topics may be found in the pages that follow.

Why am I being asked to provide my consent?	This is a research study, which is different than personal medical care. Scientists do research to answer important questions which might help change or improve the way we do things in the future. Your consent is required as you are a voluntary participant in the research study.
Do I have to join this research study?	No. Taking part in this research study is voluntary. You may choose not to take part in the study or may choose to leave the study at any time. Deciding not to participate, or deciding to leave the study later, will not result in any penalty or loss of benefits to which you are entitled.
Why is this research study being done?	This research study tests an experimental vaccine against one type of Ebola infection. The purpose of this study is to find out if the study vaccine is safe and how your immune system responds to it.
What will happen to me during the study?	During the study you will undergo screening procedures to determine whether you are eligible to participate, study vaccine administration and follow up procedures to determine how the study vaccine affects your body.
How long will I participate?	You will be in the study for approximately 6 months after the study vaccination. Your total participation including screening will last about 6.5 months.
Will taking part expose me to risks?	The possible general risks of vaccines include headache, fever, chills, nausea, skin and mouth blisters, muscle aches and joint pains, arthritis dizziness, fatigue and local pain and tenderness at the injection site, which may occur in the first few days following injection. We know these side effects can occur with any vaccine, but they do not usually last long. There is a licensed vaccine made in a similar way against a different type of Ebola vaccine, and it causes side effects like this. As with all vaccines and medicines, you could have an immediate allergic reaction, including itchy rash, low blood pressure, fainting, sudden swelling of parts of the body, or even difficulty breathing (bronchospasm). Allergic reactions can be life threatening (anaphylaxis); therefore, the study staff will watch you for at least 30 minutes after the injection. There may be other side effects, even serious ones, that we do not know about yet. This study is the first time this product is being tested in humans. It is important that you tell the study staff immediately about any alarming or unexpected signs or symptoms.
Are there any benefits to participation?	There are no benefits to you for taking part in the study except that you will get information about your health and counseling.

What are my alternatives to participation?	Taking part in this study is voluntary. Instead of being in this study you have the alternative option not to enroll in the study.

Introduction

We are inviting you to take part in this research study to help us find out if the study vaccine is safe. We hope to learn what kind of side effects you may experience after receiving the study vaccine, and how severe those side effects might be. We also hope to learn how your immune system responds to the study vaccine.

However, before you accept to take part in this study and sign this informed consent form, please take the time to read, understand and carefully examine the following information. You may also want to discuss this study with your family doctor, a family member or a close friend.

This document may contain words that you do not understand. We invite you to speak to the researcher responsible for this study (the "study doctor") or to other members of the study staff and ask them to explain to you any word or information that is unclear to you before you sign this form.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include any 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.

Background

Vaccines are products that are given to people to help their body recognize a type of infectious disease and to help their body to protect itself against that disease.

This study vaccine is called rVSVΔG-SEBOV-GP. It uses a virus, vesicular stomatitis virus (VSV), to carry artificially made Ebola virus RNA (genetic information). In humans, VSV infections may cause flu-like symptoms; they usually cause mild symptoms,such as skin and mouth blisters, muscle aches and joint pains, arthritis, dizziness, or fatigue . The VSV used in this study has been changed so that it can grow a limited amount in the body and make a single Ebola virus protein so that the body can produce an immune response.

In animals, the study vaccine has been shown to be safe and able to make antibodies against Ebola virus. An antibody is a protein in the body that can attach itself to a specific invading organism (like a virus) and tell the body to destroy it. Antibodies destroy the invader before it can cause harm in the body. We want to learn whether humans can also make antibodies against Ebola virus when given the study vaccine. This will be the first time that this vaccine is used in humans.

It is absolutely IMPOSSIBLE to get Ebola disease from the study vaccine.

About 40 participants will take part in this study. The study is taking place at 2 research centers in the US. The study doctor in charge of this study at this clinic is listed on the first page of this form.

Description of the research study procedures

1. Duration and number of visits

Your participation in this research study will last approximately 6.5 months and will include 9 visits including 2 remote visits.

2. Study design

The study is a dose-escalation study. This means that the first group (Group 1) starts with the lowest dose of the study vaccine and each subsequent group (Groups 2, and 3) gets a higher dose of the study vaccine.

The placebo used in this research study looks exactly like the study vaccine, but it does not contain any active vaccine ingredient. We are using a placebo to compare with the study vaccine to help find out if changes reported in study events are due to chance. In this Informed Consent Document, the use of "study drug" refers either to the vaccine being studied or to the placebo.

This study is randomized, which means that you will be assigned to either receive study vaccine or placebo. You are not able to choose this assignment; this process is done randomly like flipping a coin.

This is a single-blind study, which means that you will not know which study drug you will receive during this study

Tests and research study procedures

During your participation in this research study, the study doctor or a member of the study staff will conduct the following tests and procedures:

DESCRIPTION OF STUDY PROCEDURES	
Procedure	**Description**
Screening Visit	The screening visit may be completed across multiple visits, generally two. The study staff will explain the study and answer your questions. • You will read the Informed Consent Document (or have it read to you) • The study will be explained to you and you will have the opportunity to ask questions.

DESCRIPTION OF STUDY PROCEDURES	
Procedure	**Description**
	• You will have to answer questions about the study. • You will sign or mark the informed consent form if you want to join the study. If you sign the consent form and agree to join the study, the following will happen: • You will have a complete physical examination and be asked questions about your general health, medical history and about medications you are taking. • Approximately 21 mL of blood (1.5 tablespoons) will be taken to perform routine blood tests, and to test for HIV, hepatitis B, hepatitis C and syphilis. Some of the blood will also be stored for possible testing later. The study doctor may be required by law to report the result of these tests to the local health authority. • The HIV test will be explained to you, and you will be counselled about ways to reduce your chances of becoming infected with HIV. • A urine specimen will be taken for routine testing. • If you are a woman, you will also have a urine pregnancy test. • We will counsel you on family planning and contraceptives and you will be referred for services, if necessary. Once all results of the screening are available, the study doctor will determine if you are eligible for the study or not. If you are eligible, you will be asked to return for the vaccination visit. If you are not eligible, we will review the reason(s) with you, but it will not be possible for you to be part of the study.
Vaccination Visit	At the vaccination visit, the study staff will review the Informed Consent Document with you again and answer any questions you may have about the study. • You will have a short physical examination including vital signs (blood pressure, heart rate, respiratory rate and body temperature). Your lymph nodes will be checked. You may also be asked about your medical history including any medications you may be taking since the screening visit. • We will counsel you on family planning and confirm your contraceptive methods. • If you are a woman, you will also have a urine pregnancy test. • Approximately 60 mL of blood (less than 4 tablespoons)

DESCRIPTION OF STUDY PROCEDURES	
Procedure	**Description**
	will be taken to perform routine blood tests. Tests that will give us information to compare how your body responds to the study vaccine will also be performed. • You will receive an injection in the upper arm. • After the vaccination, you will remain in the clinic for at least 30 minutes for the study staff to observe you and check for any immediate reactions, including taking your vital signs. • You will be given instructions how to complete the electronic diary. • You will be given disposable thermometer(s) to measure your body temperature. You will also be given a ruler to measure any swelling and/or redness at the injection site and the instructions how to use it. • Enter the information into the diary system for 14 days after the vaccination. This includes the day of vaccination and then for 14 additional days thereafter for a total of 15 days.
Follow Up Visits	After the vaccination visit, you will have follow-up study visits. • You will be asked to return to the clinic on days 3, 7, 28, 84 and 168 after vaccination. • At these visits, you will have a short physical examination including vital signs (blood pressure, heart rate, respiratory rate, and body temperature). You may also be asked about your medical history including any medications you may be taking since the last visit. • Blood will be taken to perform tests that will give us information about how your body responds to the study vaccine at each follow-up visit. Blood will also be collected at some visits to perform routine blood tests. Between approximately 30 to 50 mL (2 to ~5 tablespoons) of blood will be collected at each follow-up visit. • The information you entered into the diary will be reviewed and discussed with you during the follow up visits.

The schedule of study procedures for each visit is listed below:

SCHEDULE OF STUDY PROCEDURES									
Procedure	Visit 1	Visit 2	Visit 3 (by phone)	Visit 4	Visit 5	Visit 6 (by phone)	Visit 7	Visit 8	Visit 9
Days since vaccination	Screening	0	1	3	7	14	28	84	168
Review/sign Informed Consent	X								
Comprehensive medical history	X								
Limited medical history		X	X	X	X	X	X	X	X
Blood draw	X	X			X		X	X	X
General physical exam	X								
Limited physical exam		X		X	X		X	X	X
Height and weight	X								X
Vital signs (blood pressure, pulse, rate of breathing and temperature	X	X		X	X		X	X	X
Family Planning Counseling and pregnancy test	X	X						X	
Urine sample	X	X							
HIV testing and counseling	X								
Vaccination		X							
Enter Diary Information		X	X	X	X	X			

Participant's responsibilities

If you join the study, you will have responsibilities. It is important that you:

- Come to all study visits and follow the study instructions
- Be informed about the study and ask questions if you do not understand something
- Give study staff complete and accurate study-related information including your medical history and any medications you are taking
- Update the study staff about any symptoms or illnesses you are experiencing

- Inform the study staff of any problems you experience because of your participation in the study
- Use birth control methods as described below:
    - If born female you must not be pregnant or breastfeeding, and if you are sexually active in a way that could lead you to get pregnant, you must be willing to use an effective method of contraception for at least two weeks before and at least three months after receiving the study vaccine. If you are using a hormonal form of contraception such as birth control pills or hormonal injection or implant, they must be started at least two weeks before the vaccination visit. Contraception is not necessary if you do not have the potential to get pregnant, for example, you had a hysterectomy or were surgically sterilized or are post-menopausal.
    - If born male and sexually active in a way that could lead you to cause pregnancy, you should use effective birth control (male condoms) and not make a woman pregnant until at least three months after receiving the study vaccine.
    - If you are sexually active, you must use either male or female condoms with all sexual partners starting after vaccination and continuing for three months after receiving the study vaccine.
- Stay in touch with us. Tell us if your address, phone number, or email address changes, if you are moving away, or if you want to leave the study.

During this study you should not:

- Donate blood
- Donate body parts, body fluids, or body tissues without talking to the study staff first
- Receive any experimental drug or vaccine other than our study vaccine
- Join another research study without talking to the study staff first

Benefits associated with the research study

There is no direct benefit to you for participating in this research. However, we hope that the study results will contribute to the advancement of scientific knowledge in this field and help us find a vaccine that can be used to protect against this type of Ebola virus.

Risks associated with the research study

The vaccine is experimental and therefore we may not know all the side effects and other possible risks associated with it.

Therefore, if you have any symptoms or changes in your body during this research study, you must tell the study doctor immediately, regardless of whether you think these effects are related to the study drug. Even once your participation in the study is over, do not hesitate to contact the study doctor if you experience a symptom or change in your body that may be linked to the study drug.

The study doctor and members of his or her team will answer any questions that you may have regarding the risks and side effect associated with this study. Also, at each visit, the study doctor and members of his or her team will ask you questions about any symptoms or changes in your body you may have experienced.

Risks associated with the study vaccine

There is a risk that rVSVΔG-SEBOV-GP vaccine, like any other medication, could provoke an allergic reaction in people who receive it. This allergic reaction could range from mild to life-threatening. Symptoms of a life-threatening allergic reaction (called anaphylaxis) may include:

- Difficulty breathing
- Rapid heartbeat
- Tongue swelling
- Nausea
- Fainting
- Hives
- Fever
- Dizziness

If you suspect that you are having an allergic reaction, call 911 or go to the closest emergency room.

While this specific vaccine has not been studied in humans, a similar vaccine called ERVEBO® has been given to people for a different type of Ebola virus. The study vaccine may cause similar side effects to ERVEBO®. The most common side effects seen in people taking ERVEBO® include the following:

- Fever
- Sore muscles
- Chills
- Feeling tired
- Excessive sweating
- Headache
- Stomach pain or discomfort
- Feeling sick to your stomach
- Changes in your blood test results
- Pain in arms, legs, or joints (places that bend, such as elbows, knees or fingers) or arthritis. Sometimes joints were also swollen and/or stiff. The joint pain, swelling and stiffness usually went away in a few days or weeks, but in some people, it lasted for months. In some people, the symptoms came back after initially going away.
- Skin rash
- Skin and oral blisters
- Rarely, people had serious allergic reactions. Allergic reactions with ERVEBO® have been seen in less than 1 out of 1000 people.

Risks associated with research procedures

Potential risks of drawing blood and intramuscular injection:

- Blood will be drawn by inserting a needle into one of your veins. This can cause temporary mild pain or discomfort (common), local bruising (rare), infection and fainting (very rare).
- Intramuscular injection may cause temporary redness, swelling, pain/tenderness, warmth or itching at the injection site and fainting (very rare).

Potential risks of use of an electronic diary:

As part of this research, you may be required to use one or more of the following: a phone or web app/ site, an electronic study diary (eDiary), or a device that collects information about you. While using these, information about you may be collected and shared with the researchers or people outside of the study. This data might include personal health information, location, call logs, text message history, web browsing history, or social media use. A complete description of the data collection and sharing for an app, eDiary, or device can commonly be found in the Terms of Use, End User License Agreement, or Privacy Policy associated with the app. If you would like to read these documents, request a copy or instructions about how to access this information from the study doctor.

While the Terms of Use, End User License Agreement, or Privacy Policy may include statements limiting your rights in the relation to this app, eDiary, or device in this study, you do not release the investigator, sponsor, institution, or agents for responsibilities from mistakes. You also do not waive any of your rights as a research participant.

Other risks

Ebola disease is found in Africa unless a person who is infected travels to the United States, so it is unlikely that you will be exposed to Ebola disease. However, if that should occur, you should not assume you are protected from getting Ebola disease while in this study or after participating in this study.

Please notify the study staff if you live with children less than 1 year of age, adults over 75 years of age or someone immunocompromised as there might be a low risk of the study vaccine shedding (where you may infect others) and precautions might need to be taken.

Possible social risks

You may experience personal problems because of participating in this study. If you do, let the study staff know and we will try to help you with these issues. You may have trouble at your workplace if the study takes too much time away from your work. If you do experience any problems, let the study staff know and we will try to help you with these issues.

Risks associated with pregnancy

Participation in this study may include risks, known or unknown, for pregnant women, unborn children or to children of breastfeeding women. Consequently, pregnant or breastfeeding women cannot take part in this project.

If you are a woman of childbearing potential, you must undergo a pregnancy test before you start participating in the study. This test will take place again at the vaccination visit. In addition, if you are sexually active, and could become pregnant you must use a medically accepted contraceptive method from at least 2 weeks before, throughout your participation in the study, and 3 months after the receipt of the study vaccine.

The medically accepted contraceptive methods are oral contraception (pills), hormonal implants, hormonal patches, intrauterine device (IUD), diaphragm and spermicide, cervical cape with spermicide, and condom with spermicide.

The study doctor or the study staff will discuss your contraceptive method with you to ensure that it is medically accepted.

If you suspect that you have become pregnant during your participation in the research study, please inform the study doctor immediately. You will be asked to allow the study staff to collect information about the pregnancy, its outcome, and the health of the child after birth.

If born male and sexually active in a way that could lead you to cause pregnancy, you should use effective birth control (male condoms) and not make a partner pregnant until at least 3 months after the last study drug intake. In case of pregnancy, we might ask you to bring your partner to the clinic for an additional follow up. They will be asked to sign separate consent form to allow the study staff to collect information about the pregnancy, its outcome, and the health of the child after birth.

<u>In case of injury</u>

We do not expect you to be harmed from taking part in this study. If you are harmed because of taking part in this study, you will be given treatment (including emergency treatment) at no cost to you. If the study clinic cannot give the treatment you need, they will refer you to a clinic where treatment will be provided. IAVI will cover the costs of reasonable medical expenses for injuries that result from taking part in this study. No other form of compensation is available from IAVI. If you have any symptoms or medical problems that you think may be caused by the study vaccine or a study procedure, report them right away to the clinic staff.

If you are injured as a direct result of your participation in this study, you should contact the study doctor listed on the first page of this document using the phone number provided. You will be offered the necessary care to treat your injury. Information may be collected, either directly from you or health care providers who treated your problem or injury.

We reserve the right to bill your insurance company, if appropriate, for the care you get for the injury. We will try to get these costs paid for you, but you may be responsible for some of them. You may be responsible for co-payments and deductibles required under your insurance.

There is no plan to reimburse you for items such as lost wages or lost time from work. By signing this consent form you have not given up any other legal rights.

Voluntary participation and the right to withdraw

Your participation in this research study is voluntary. Therefore, you may refuse to participate. You may also withdraw at any time, without giving any reasons, by informing the study doctor or a member of the study staff.

Your decision not to participate in the study, or to withdraw from it, will have no impact on the quality of care and services to which you are otherwise entitled, or on your relationship with the medical teams providing them. However, before you withdraw from the study, we suggest that you take part in a final evaluation, for safety reasons.

The study doctor or the sponsor may put an end to your participation without your consent. This may happen if new findings or information indicate that participation in this research study is no longer in your best interest, if you do not follow study instructions, or if there are administrative reasons to terminate the study.

If you withdraw or are withdrawn from the study, no further data or samples will be collected. However, the study information and biological material (blood and tissue samples) already collected for the study will be stored, analyzed and used to ensure the integrity of the study, as described in this document.

Confidentiality

The collection, use and storage of your data and your samples is required to answer the questions asked in this study and to publish the results. We are asking your permission for the use of your data and samples. Your participation in the study, all personal information collected about you and all laboratory test results will be confidential. To protect your privacy, you will be given a Participant ID number that will be used for your data and samples rather than using your name or other identifying information. The clinic staff will securely store a list linking the Participant ID with your name at the site and not share this list with anyone.

Your participation in the study, all personal information collected about you and all laboratory test results will be confidential. Apart from the study staff you meet, other staff from national or international government regulatory agencies, such as the US Food and Drug Administration (FDA), members of the Institutional Review Boards (IRB), monitors, auditors, inspectors and representatives of the sponsor will check the records to make sure that the study is carried out properly and will respect your confidentiality. You also agree to allow the study doctor to get medical information about you if you need care from a doctor outside the study. Your study data may be shared with other researchers in the US or outside the US to perform tests for this study

and study data may become public in the future, but any personally identifying information that could identify you will be removed or changed before files are shared or reports/scientific papers are published. Some samples are planned to be analyzed at IAVI's Human Immunology Laboratory in London, England, which means that your data will be treated in compliance with the UK General Data Protection Regulation (UK GDPR). For further information please see the privacy notice at the end of this document.

A Certificate of Confidentiality has been obtained from the FDA. This will help further protect information that may identify you. The Certificate of Confidentiality prevents the study doctor from being forced to disclose information that may identify you for use in court. A Certificate of Confidentiality does not prevent you or anyone you tell from voluntarily releasing information about yourself or your involvement in this research. This means that you and your family must also actively protect your own privacy. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research participants.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the agency which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of, for instance, child abuse or neglect, harm to self or others, and communicable diseases.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

Reimbursement (Compensation)
«Compensation»

The information we collect from this study may help develop an effective Ebola disease vaccine for Sudan virus, however, if the study vaccine later becomes approved and sold, you are not entitled to compensation as a participant in the study.

The research study related tests and visits are at no charge to you. You will be given <enter amount and currency> to cover the cost of transportation and time for scheduled visits. You will be given <enter amount and currency> for unscheduled visits.

If you do not complete the study, for any reason, you will be paid for each study visit you do complete.

You will be paid _____ *["following each completed visit", "monthly", "quarterly", "at the end of your participation in the research study", "following each completed visit or at the end of your participation in the research study, whichever you prefer"]*.

If you have any questions regarding your compensation for participation, please contact the study staff.

Any payments made to you may be taxable income to you. This does not include any payments you may receive to reimburse you (pay you back) for certain expenses like parking fees or travel. We are required to obtain your name and social security number for preparation and submission of Internal Revenue Service (IRS) Form 1099-Misc. You may receive an Internal Revenue Service Form 1099 from your study site if you receive more than $600 or more in one calendar year for taking part in one or more research studies at your study site. Questions about your own tax status should be referred to your personal tax advisor.

Future Research Studies

Identifiers might be removed from your identifiable private information or identifiable biospecimens collected during this study and **could then be used for future research studies or distributed to another study doctor for future research studies** without additional informed consent.

Genome Sequencing

Researchers can look closely at large amounts of your genetic information by sequencing, or "reading," every letter in your DNA (your genome). Reading a person's entire genetic code is called whole genome sequencing. The research **will not include** whole genome sequencing (for example, sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

Whom to Contact About This Study

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study such as:

- Whom to contact in the case of a research-related injury or illness;
- Payment or compensation for being in the study, if any;
- Your responsibilities as a research participant;
- Eligibility to participate in the study;
- The study doctor's or study site's decision to withdraw you from participation;
- Results of tests and/or procedures;

Please contact the study doctor at the telephone number listed on the first page of this consent document.

If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research participants. If you have any questions about your rights as a research participant, contact:

- By **mail**:
  Study Subject Adviser
  Advarra IRB
  6100 Merriweather Dr., Suite 600
  Columbia, MD 21044
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00068628.

YOUR CONSENT

By signing this document, you are agreeing to be in this study. Make sure you understand what the study is about before you sign. We will give you a copy of this document for your records and we will keep a copy with the study records.

Participant giving consent:

Participant Name

Participant Signature Date

Person obtaining consent:
I have fully explained the nature and purpose of the above-described study and the risks and benefits that are involved in its performance. I have answered all questions to the best of my ability.

Name of Person Obtaining Consent

Signature of Person Obtaining Consent Date

PRIVACY NOTICE FOR SAMPLE ANALYZED IN THE UK

This privacy notice Relates to any samples that will be analyzed at IAVI's Human Immunology Laboratory in the United Kingdom. Any sample-associated personal data processed at IAVI's Human Immunology Laboratory is subject to, and will be processed in compliance with, the UK General Data Protection Regulation (UK GDPR).

Who is responsible for processing my data?
IAVI Inc., whose registered headquarters are located at 125 Broad Street, 9th Floor, New York, NY 10004, United States of America. IAVI's Data Protection Officer (DPO) can be contacted at dpo@iavi.org.

What is the purpose and legal justification for processing my data?
IAVI carries out clinical trials and research related to finding vaccines and treatments for HIV and other diseases of global public health significance. This work also provides important data for future efficacy trials to prevent HIV and other diseases of global public health significance. IAVI will process your personal data for the purpose of this scientific research as explained in the informed consent form

The reason IAVI is permitted to process your personal data, under the UK GDPR is because it is necessary for of IAVI's legitimate interests in conducting scientific research. In addition, we are alloweded to process your special category personal data (sensitive information relating to your health and race, and for example) because it is necessary for scientific research purposes and is done so with in accordance with safeguards to keep data secure.

There is a public health interest and benefit to society in IAVI's research activities and processing your data is important to achieve the objectives of our research. IAVI makes sure that your data protection rights and freedoms are maintained and not negatively affected by our research activities.

Who do you share my data with?
IAVI works with academic, government, foundation, and community-based organizations to conduct research and may share your data in connection with the purposes described in this information sheet. Wherever possible, we will de-identify your data before sharing it. This means we will remove any details that would identify you and where necessary replace them with a code (such as a unique ID number). The only exception will be where we have a legal obligation to disclose your identifiable information. Where possible, we will let you know in advance if this occurs.

Your identifiable personal data will only be processed locally by the study site you are attending and in the United States by our data management vendor.

Data without any identifying information will eventually be transferred to IAVI Inc. (based in the USA) and shared securely with the IAVI Human Immunology Laboratory (located in the UK), along with biospecimens from the study. If you give us your permission, we may share this data with other researchers (located anywhere in the world) conducting similar research on

human health. We will ensure that the data shared is non-identifiable. You will not be informed of this in advance.

National or international monitoring or regulatory agencies involved in overseeing this study may check study records to ensure the study is carried out properly.

What happens to the data and samples?
The collection, use, and storage of your data and your blood samples is required to answer the questions we are asking in this study. This will include immunology testing.

The researchers will use your data to publish results about the study. The data cannot be traced back to you in these reports and publications about the study. Data sharing will be consistent with the GDPR as well as the data sharing policies of the study site and IAVI.

How is my data kept secure?
Data will be entered into password-protected handheld devices or computers. All identifying information is removed from the data and data is entered into a database, access to which is restricted to authorized users via username and password with additional restrictions on the corporate network. Keys linking personal identifiers to the de-identified dataset are securely stored separately from the de-identified data.

What are my rights under the UK GDPR?
You have a right to request information about the handling of your data. You have the right to request a copy of the information we hold about you and to request that we correct inaccurate or incomplete information that we hold about you. You have the right to request deletion of your data and destruction of your samples. In the event you withdraw from the study, no further data will be collected after your withdrawal. To exercise any of your rights, please contact the Principal Investigator or study team in the first instance.

What if I am not happy with how my data is being handled?
If you have concerns about the way IAVI has handled your personal data, please contact the study's Principal Investigator in the first instance. If you are unhappy with their response, you may raise a complaint with IAVI's Data Protection Officer (DPO) by contacting dpo@iavi.org. The DPO will investigate the matter and issue a response. If you are not satisfied with the DPO's response or believe IAVI is processing your personal data in a way that is not lawful, you can complain to the Information Commissioner's Office, UK via their website at https://ico.org.uk/.

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

If you decide to be in this study, the study doctor and study staff will use and share health data about you to conduct the study. Health data may include:

- Your name.
- Address.
- Phone number.
- Date of birth.
- Medical history.
- Information from your study visits, including all test results.

Health data may come from your study records or from existing records kept by your doctor or other health care workers.

For this study, the study staff may share health data about you with authorized users. Authorized users may include:

- Representatives of International AIDS Vaccine Initiative (IAVI).
- Representatives of Advarra IRB (an Institutional Review Board that reviews this study).
- The Food and Drug Administration (FDA) and other US federal and state agencies.
- Government agencies to whom certain diseases (like HIV, hepatitis, and STDs) must be reported.
- Governmental agencies of other countries.
- Outside individuals and companies, such as laboratories and data storage companies, that work with the researchers and sponsor and need to access your information to conduct this study.
- Other research doctors and medical centers participating in this study, if applicable.
- A data safety monitoring board which oversees this study, if applicable.

Your health data will be used to conduct and oversee the research, including for instance:

- To see if the study drug works and is safe.
- To compare the study drug to other drugs.
- For other research activities related to the study drug.

Once your health data has been shared with authorized users, it may no longer be protected by federal privacy law and could possibly be used or disclosed in ways other than those listed here.

Your permission to use and share health data about you will end in 50 years unless you revoke it (take it back) sooner.

You may revoke (take back) your permission to use and share health data about you at any time by writing to the study doctor at the address listed on the first page of this form. If you do this, you will not be able to stay in this study. No new health data that identifies you will be gathered after your written request is received. However, health data about you that has already been gathered may still be used and given to others as described in this form.

Your right to access your health data in the study records will be suspended during the study to keep from changing the study results. When the study is over, you can access your study health data.

If you decide not to sign this form, you will not be able to take part in the study.

STATEMENT OF AUTHORIZATION

I have read this form and its contents were explained. My questions have been answered. I voluntarily agree to allow study staff to collect, use and share my health data as specified in this form. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing this form.

_____

Printed Name of Participant

_____ _____

Signature of Participant Date