Participant ID Number

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PARTICIPANT INFORMATION AND CONSENT FORM (ICF) FOR PARTICIPATION IN THE IAVI C104 RESEARCH STUDY

Sponsor / Study Title: **International AIDS Vaccine Initiative (IAVI) / "A Phase 1 Randomized, Observer-blind, Placebo-controlled, Dose-escalation Clinical Trial to Evaluate the Safety and Immunogenicity of rVSVΔGMARV-GP Vaccine in Adults in Good General Health"**

Protocol Number: **IAVI C104**

Principal Investigator: (Study Doctor) **«PiFullName»**

Telephone: **«IcfPhoneNumber»**

Address: **«PiLocations»**

Important Information
The information provided in the table below 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.
Do I have to join this research study?	No. Taking part in this research study is voluntary. Voluntary means it is your choice. 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?	The purpose of this study is to find out if the study vaccine is safe and how your immune system responds to it. In addition, 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.
What will happen to me during the study?	During this study you will receive one study vaccine or placebo (inactive substance) injection in the upper arm. You will have physical exams conducted, blood taken to perform routine blood tests and tests for study evaluation, urine specimens taken for routine testing and, if applicable, pregnancy testing.

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How long will I participate?	Participation in this study will last approximately 7 months.
Will taking part expose me to risks?	The study vaccine or placebo used in this study may cause side effects. The side effects may include fever, chills, headache, nausea, vomiting, diarrhea, abdominal pain, muscle aches and joint pains, tiredness, skin rash, oral lesions, blisters, ulcers and local pain, swelling and tenderness at the injection site. We do not know what effect the study vaccine would have on an unborn child if given to a pregnant individual. There is a potential risk that the VSVΔG-MARV-GP vaccine virus may become present in your bodily fluids after study vaccination. This means that there is a theoretical risk that you could pass the study vaccine virus (modified vesicular stomatitis virus) to others through close personal contact or contact with your bodily fluids. Therefore, it is recommended that you avoid close contact with persons who have weakened or immature immune systems (immunocompromised persons, older adults, young children) for 3 months following study vaccination.
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. No protection from Marburg Virus Disease (MVD) should be assumed either during or after participation in this study.
What are my alternatives to participation?	Your alternative is not to be in this study.

Introduction

We are inviting you to take part in this research study of an experimental vaccine against Marburg virus. The experimental study vaccine is not approved by the United States Food and Drug Administration (FDA). There are specific criteria that the study staff will ask you about or check in order to decide whether you are able to participate in the study or not. We are inviting adults (ages 18 to 50 years of age) who are in good general health to participate in this study.

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.

The information in this document will be discussed with you by a study doctor or a member of the study clinic team but this document may contain words that you do not understand. If there is anything you do not understand you can ask the study staff to explain it before you sign this form. Feel free to ask as many questions as you need to make sure you understand the study procedures, including possible risks and benefits. If you have any questions, please ask a study staff member to give you more information.

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A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Background

Marburg Virus causes a disease that can affect multiple organ systems and reduce the body's ability to function, with a high fatality rate. There have been several outbreaks of Marburg Virus in Africa. A recent outbreak occurred in Rwanda, from September through December 2024, in which 66 illnesses and 15 deaths were reported. There is currently no specific treatment or vaccine for Marburg virus disease.

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. Before a vaccine can be used by the public, a lot of research and tests must be done to make sure it is safe and works as it is supposed to. The study vaccine used in this study is called "experimental" because it is still being tested and we do not know if it works.

This study vaccine is called rVSVΔG-MARV-GP. It uses a virus, vesicular stomatitis virus (VSV), to carry artificially made Marburg virus protein. The VSV used in this study has been changed so that it can grow a limited amount in the body and introduce a single Marburg virus protein to the body, 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 Marburg 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 to the body. We want to learn whether humans can also make antibodies against Marburg virus when given the study vaccine. We will also look in your blood for immune T cells, which may help protect you against Marburg virus. This will be the first time that this vaccine is used in humans.

No protection from Marburg Virus Disease (MVD) should be assumed either during or after participation in this study.

What is the purpose of the study?

The purpose of this study is to find out if the study vaccine is safe and how your immune system responds to it. In addition, 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.

About 112 participants will take part in this study. The study is taking place at 3 research centers, in 3 cities in the United States. The study doctor in charge of this study at this clinic is listed on page one of this form.

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How is this study set up?

1. How long will the study last?

Your participation in this research study will last approximately 7 months and will include 9 visits.

2. What is the study vaccine?

When participating in this research study, you will be assigned to 1 of 4 different groups, as shown below.

	Study Group*	rVSVΔG-MARV-GP Vaccine Dosage (pfu), IM Day 1	N (Active Product/ Placebo)
Dose-escalation	**1**	2×10^5	21/7
	2	2×10^6	21/7
	3	1×10^7	21/7
	4	2×10^7	21/7
			Total = 112 (84/28)

This 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, 3, and 4) gets a higher dose of the study vaccine. Participants in Group 1 will be monitored and their data reviewed to see if it is safe for participants to be enrolled in Group 2, where a higher dose of the study vaccine will be used. In the same way, participants in Groups 2 and 3 will be monitored and their data reviewed to see if it is safe before enrollment in Groups 3 and 4 is started.

Participants in all groups will have one study vaccination.

The group you are placed in will depend on when your enrollment happens during the study. You will receive either the study vaccine or placebo. The placebo used in this research study looks exactly like the study vaccine, but it does not contain any active drug. We are using a placebo to compare with the study vaccine and to ensure that the changes you report in your health, good or bad, are not only due to chance. Whether you receive the study vaccine or placebo is based on chance. At the end of the study, we will compare the results from people who received the different doses of study vaccine with the results from people who received the placebo to see how safe the study vaccine is and how their immune system responds to the study vaccine.

For Groups 1-4, 21 participants in each group will receive the study vaccine and 7 will receive placebo. This means that there is about a 3 out of 4 chance that you will receive the study vaccine, and a 1 out of 4 chance that you will receive placebo if you participate in the study.

This is an observer-blind study, which means that neither you, the study doctor, nor the study staff will know whether you received the study vaccine or placebo during this study. Only the study staff responsible for preparation of the vaccine and the sponsor of the study will know the

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identity of the vaccine given to each participant. However, in case of emergency, the study doctor will have access to this information. At the end of the study, you will find out if you received the study vaccine or placebo.

3. **What are the study procedures?**

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

DESCRIPTION OF STUDY PROCEDURES	
Procedure	**Description**
Study Vaccination	Single injection of study vaccine in the upper arm.
Full medical history	You will be asked about your general health, surgical and medical history, and about medications you are taking.
Physical exam	A physical exam to assess your overall health will be conducted, including assessment of vital signs (blood pressure, heart rate, respiratory rate, and body temperature), height, weight and lymph nodes
Counseling	Study staff will counsel you about the importance of preventing pregnancies and the use of condoms and other effective forms of contraception. You will also receive HIV test counseling before and after you are tested for HIV.
Blood draws	Blood will be taken to perform routine blood tests, and to test for HIV, hepatitis B, hepatitis C, and syphilis. Additional blood will be taken during the study to test your body's response to the study vaccine. The study doctor may be required by law to report the results of these tests to the local health authority.
Diary completion	You will use an electronic or paper diary to note any signs and symptoms you may have for 14 days after the study vaccination. You will be given a thermometer to measure your body temperature. You will also be given a ruler to measure any swelling and/or redness at the injection site. The use of the diary card, the thermometer, and the ruler will be explained to you.
Urine dipstick	A urine sample will be collected for routine standard of care testing.
Pregnancy test	A urine sample will be taken for pregnancy testing for individuals of childbearing potential.
Urine and saliva sample collection	Additional urine collection and saliva sample collection to test your body's response to the study vaccine.

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

	Visit 1	**Visit 2**	**Visit 3**	**Visit 4**	**Visit 5**	**Visit 6**	**Visit 7**	**Visit 8**	**Visit 9**
Study Day	**Screen**	**1**	**4**	**8**	**15**	**29**	**57**	**85**	**169**
Study Vaccination		X							

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	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8	Visit 9
Study Day	**Screen**	**1**	**4**	**8**	**15**	**29**	**57**	**85**	**169**
Medical history	X	X	X	X	X	X	X	X	X
Physical exam	X	X	X	X	X	X	X	X	X
Counseling	X	X							
Blood draws	X	X	X	X	X	X	X	X	X
Diary completion		X	X	X	X				
Urine dipstick	X								
Pregnancy test	X	X						X	
Urine and saliva sample collection		X	X	X	X	X	X		

The table below provides the average blood collection over the 7 months of study participation.

	Visit 1/Screen	Each Visit (2-9) Average	Study Total Maximum
Total Blood Volume in mL*	27mL	40 mL	348 mL
Number of Tablespoons	1.82 tbsp	2.71 tbsp	23.5 tbsp

Genetic Testing

You will be asked to allow the sponsor or its designee to perform genetic (pharmacogenetic) tests on the normal cells of your body. During genetic testing we will be looking at parts of your DNA. Deoxyribonucleic acid (DNA) is inherited from your parents and may determine things like the color of your hair or eyes. People may react in different ways to medicines in their bodies because of their genes. In this study, genetic tests may be done to help us understand why different people respond differently to vaccines. These tests will be performed at some as yet undetermined date in the future. Please note that you may not be given results, however, any findings that may affect your health will be made available to you and/or your doctor. We will ensure at all times that your personal information is treated with utmost confidentiality.

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A Federal law, called the Genetic Information Non-discrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you, or when setting the terms of your employment.

Be aware that this Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

Your responsibilities as a research participant

Your duties (responsibilities) as a study participant include the following:
You should **do** the following:

- Attending all scheduled clinic visits
- Give complete and truthful information about your medical history and any signs of illness you have during the study.
- Give complete and truthful information about all medicines you take (or stop taking) during the study, including medicines from other doctors, vaccinations, and medicine you buy yourself.
- Give urine and blood samples to be tested for routine safety tests and responses to the study vaccine.
- Complete your Diary
- Tell the study doctor if you no longer want to be in the study.

You should **not do** the following:

- Do not become pregnant during the study
- Do not donate blood during the study
- Do not use certain medication when you are starting the study, including corticosteroids, immunosuppressives, anticancer, or other medications considered significant by the Investigator within the previous 6 months
- Do not receive another vaccine during the study without talking to the study staff first
- Do not participate in other clinical investigations without talking to the study staff first

Benefits

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 to prevent disease for patients.

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Risks and Discomforts

The study vaccine is experimental (it is still being tested, and we do not know if it works) and therefore we may not know all the side effects and other possible risks associated with it.

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

The study doctor and members of the study clinic team will answer any questions that you may have regarding the risks and side effects associated with this study. Also, at each visit, the study doctor, and members of the study team will ask you questions about any symptoms and side effects you may have experienced.

There is a low risk of loss of confidentiality of your personal information. However, steps have been taken to help make sure this will not happen. You will read more about the protection of your personal information later in this information sheet.

1. Risks associated with the study vaccine

- The vaccine rVSVΔG-MARV-GP or placebo used in this study may cause side effects. The side effects may include:
    - Fever
    - Chills
    - Headache
    - Nausea
    - Vomiting
    - Diarrhea
    - Abdominal pain
    - Muscle aches
    - Joint pains
    - Tiredness
    - Skin rash
    - Oral lesions
    - Blisters
    - Ulcers and local pain
    - Swelling and tenderness at the injection site

  These symptoms are usually mild to moderate, and they usually do not last long.
- There is a risk that rVSVΔG-MARV-GP, like any other vaccine, 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

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- Dizziness

The study staff will watch you for at least 30 minutes after the injection.

- If you suspect that you are having an allergic reaction, call 911 or go to the closest emergency room. We know these side effects can occur with any vaccine, but they do not usually last long.
  There is a potential risk that the VSVΔG-MARV-GP vaccine virus may become present in your bodily fluids after study vaccination. This is known as “viral shedding”, and it means that there is a theoretical risk that you could pass the study vaccine virus (modified vesicular stomatitis virus) to others through close personal contact or contact with your bodily fluids. To reduce this risk, it is recommended that you practice good hygiene, such as frequent handwashing, particularly after bathroom visits, avoid sharing personal items like toothbrushes or razors with others and that you avoid close contact with persons who are more at risk, such as those who have weakened or immature immune systems (immunocompromised persons, older adults, young children) for 3 months following study vaccination. If you develop any blisters you should keep them covered and contact the study team immediately.

2. Risks associated with research procedures

- Blood draw: Taking blood may cause discomfort, bruising and, very rarely, infection at the needle insertion site where the skin is punctured by the needle. You may also experience dizziness, nausea or fainting when blood is taken. Please tell the study doctor or study staff if you do not feel well after having your blood drawn.

3. Risks associated with pregnancy

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

If you are of childbearing potential, you must undergo a pregnancy test before you start participating in the study. This test will take place again at Visit 2. 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 and until 3 months after receiving the study vaccine or placebo.

The medically accepted contraceptive methods are condoms, diaphragm or cervical cap with spermicide, intrauterine device (IUD), hormonal contraception, oral contraception, and successful vasectomy in the male partner.

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, you must 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.

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4. Possible social risks

You may experience personal problems because of participating in this study. For example, family or friends may worry, get upset or angry, or assume you have Marburg virus and treat you unfairly, especially if they are not aware of your study participation and learn about it later. 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.

Alternatives to participation

There is no alternative vaccine available for Marburg virus. Your alternative is not to be in this study.

New information about the study becomes available

The study doctor will contact you if any important new information or results becomes available that might affect your health or willingness to continue in the study. The study doctor will explain and discuss this new information or the results with you. If you decide to continue in the study, you may be asked to sign a new consent form. If you decide to leave the study, the study doctor will make arrangements for your future care as required.

In case of injury

We do not expect you to be harmed or injured by participating in this study. If you are harmed/injured by participating 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 given at no charge to you. IAVI will cover the costs of reasonable medical expenses for injuries that directly 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 vaccine or a study procedure, report them right away to the clinic staff. 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.

Voluntary participation and the right to withdraw

Your participation in this research study is voluntary. Therefore, you may refuse to participate. You may leave the study at any time, without giving any reasons, by informing the study doctor in charge of this research or a member of the study staff. You may be asked to come to the research center for one last study visit to perform a final evaluation for safety reasons. If you don’t want to join the study or wish to stop being in the study before it is over, there will be no penalty or loss of benefits and it will not affect the medical care you already have. There will be 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.

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.

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Withdrawal from study or early termination of study

You may be taken out of the study if the study doctor in charge of the research study decides this would be best for you or if you do not follow the study rules. The study sponsor, the study doctor, the institutional review board, or a government health authority could also decide to stop the study at any time. This may happen if new findings or information indicate that participation in this research study is no longer in your best interests. If the study is stopped, your study doctor would let you know and tell you why.

Oversight of the Study

This study will be overseen by the Advarra Institutional Review Board (IRB), a Protocol Safety Review Team and the study sponsor, IAVI. An independent committee of scientific experts will review the safety data collected to make sure that the safety and health of the participants are being protected.

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 study number that will be used for your data and your samples.

Your name and other information that can directly identify you will not be included when the samples and data are analyzed. The data and samples that are sent to the sponsor and collaborating parties will only contain the study number, not your name or other information with which you can be identified. Your study data may be shared with other researchers or made public in the future but any personal information that could identify you will be removed or changed before files are shared. The data cannot be traced back to you in reports and publications about the study. While every effort will be made to protect the confidentiality of your information, absolute confidentiality cannot be guaranteed.

Protection of your personal information and rights

Your participation in the study, all personal information collected about you and all laboratory test results will be confidential. Only you and the clinic staff know your study number. Apart from the study staff you meet, other staff from national and international government regulatory agencies, such as the FDA, members of the Institutional Review Board (IRB), monitors, auditors, inspectors, and representatives of the sponsor will check the records to make sure that the trial 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 or made public in the future but any personally identifying information that could identify you will be removed or changed before files are shared.

You have the right to ask the study doctor about the data being collected on you and to see your personal health information and, if applicable, ask for corrections. However, in order to protect the reliability of the study, the study treatment you received in this study needs to remain unknown until the study data is examined.

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A Certificate of Confidentiality has been obtained from the Administration for Strategic Preparedness and Response, a US Federal Government entity under the Department of Health and Human Services. This will help further protect information that may identify you. The Certificate prevents the study doctor from being forced to disclose information that may identify you for use in court. 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).

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.

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.

Your study records will be kept at the study clinic or a designated archiving facility off-site for at least 10 years following the completion of the study. After the study is completed, you will be told whether you received the experimental study vaccine or the placebo, and you will be told the results of the study. If you decide to leave the study, you have the right to ask for no more data to be collected, but already collected data will not be deleted.

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Do I get anything for being in the research study?
«Compensation»

The research study related tests and visits are provided at no charge to you. You will be given <$XXX.XX> to cover the cost of transportation and time for scheduled visits. You will be given <$XXX.XX> 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 the study site if you receive $2,000 or more in one calendar year for taking part in one or more research studies at the study site. Questions about your own tax status should be referred to your personal tax advisor.

The use of your data and samples may lead to new tests, vaccines, drugs or other products or services with commercial value. These products or services could be patented and licensed. There are no plans to provide any payment to you should this occur.

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).

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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: Pro00092662.

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PARTICIPANT INFORMED CONSENT FORM

I have read the information sheet, or had it read to me and have discussed with the study staff the purpose of the study, the procedures involved, the number of visits to the study clinic, the anticipated risks and benefits involved, participant safety procedures and protection of rights of study participants. I have been given the opportunity to ask questions, which have been answered to my satisfaction. If I have any questions concerning my participation in this study, I may contact any of the study doctors at any time.

I understand that my participation in this study is voluntary and that I may decide not to participate. I also understand that if, for any reason, I wish to discontinue my participation in this study at any time, I will be free to do so. If I leave the study, I understand that the information and samples that were collected from me will still be used in the study.

I agree that I can be contacted by study staff during my participation. I understand that as a participant in this study, my identity, medical records, and data relating to this research study will be kept confidential, except as required by law.

By signing this document, you agree to be in this study.

We will give you a copy of this document for your records and we will keep a copy with the study records.

_____

Printed name of study participant

_____ _____

Signature of participant Date (DD/MMM/YYYY)

TMF-54957 | 3.0 | Status:Approved | 05 Mar 2026
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Participant ID Number

C	1	0	4					

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.

Printed name of person conducting consent discussion

Signature of person conducting consent discussion

Date (DD/MMM/YYYY)

Impartial witness (if participant is illiterate)

I sign here as a witness to the consent process. I have participated in the discussion and witnessed the participant's consent to study participation:

Printed name of impartial witness

Signature of impartial witness

Date (DD/MMM/YYYY)

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Signature Page for TMF-54957 v3.0

Reason for signing: Approved	Name: Lebohang Molife Role: Medical Monitor Date of signature: 05-Mar-2026 07:44:06 GMT+0000

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