INFORMED CONSENT FORM

Sponsor / Study Title:	**Public Health Vaccines, LLC / "A Phase 1 Randomized, Single-Blind, Placebo-Controlled, Ascending Dose Study to Evaluate the Safety and Immunogenicity of rVSVΔG-MARV-GP [Angola] (PHV01, MARV GP Vaccine) in Healthy Adults"**
Protocol Number:	**PHV01-C-101**
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You are invited to take part in a research study (also known as a clinical trial). A research study is designed to answer specific questions about new ways to prevent, detect, and treat disease. **Take time to decide whether you wish to participate.**

Please read this form carefully. Take your time to ask the study doctor or study staff as many questions about the study as you would like. The study doctor or study staff can explain words or information that you do not understand. Reading this form and talking to the study doctor or study staff may help you decide whether to take part or not. If you decide to take part in this study, you must sign your name at the end of this form.

Please note:

- This information sheet describes the study and what is involved to help you make an informed decision as to whether you want to take part.
- It explains the purpose of the study, your rights and responsibilities, and what to expect if you participate.
- Please take time to read the following information carefully.
- Feel free to talk with your doctor, nurse, family, or friends before deciding. Ask us if there is anything that is not clear or if you would like more information.
- Your decision to participate is completely voluntary and will have no effect on the quality of your medical care if you choose not to participate. You can also withdraw from the study at any time.

KEY INFORMATION

> Why am I being asked to participate in this study?

You have been chosen because you are a healthy adult male or non-pregnant, non-lactating adult female, ages 18 to 60 years old (inclusive) at the time of screening and have provided written informed consent.

> What are the main reasons I may not want to join this study?
Once you are screened and enrolled, the study involves a single injection with the Marburg virus study vaccine (also called PHV01 or the MARV GP study vaccine), which is an experimental vaccine that may cause some adverse reactions (side effects). Alternatively, you may get a placebo (salt water) injection. The risks are discussed in detail below. If you decide to participate and are eligible, you will need to come to the clinic for evaluation six times in the first month and then twice over the next five months. You will have blood drawn and other samples at most of the visits to make sure you are doing well, assess any side effects, and check the study vaccine impact on your immune system.

> What is the research question the study is trying to answer? Why is it relevant to me?
The study will help PHV (the Sponsor) develop a vaccine to prevent Marburg virus (MARV) disease, which is like Ebola virus disease. MARV is a highly transmissible virus that is circulating in sub-Saharan Africa, with the most recent outbreak in March 2023 in Tanzania. While these diseases are not found in the United States, they can cause outbreaks with high mortality, even in healthy people. This study vaccine could help limit the spread of an outbreak.

> What aspects of participation in this study might be unfamiliar to me, be different from my expectations, or require special attention?
PHV01 is an experimental vaccine, which means Health Authorities (like the United States 'US' Food and Drug Administration 'FDA') have not licensed it for prevention of MARV disease. However, the vaccine made with the same backbone technology to protect from Ebola (ERVEBO®) has been licensed by FDA and was given to over 300,000 people to stop the most recent epidemics in Africa.

> What information about me is being collected as part of this research?
If you agree to take part in this research study, the study doctor will first need to conduct some blood tests and ask you questions about your medical history and what medications you take, to ensure you are suitable for the study. Other information, including your age, sex and race/ethnicity (called demographics) will also be recorded. Your blood samples will be coded (by having your name replaced by a number) at the study center and sent to PHV or special laboratories working for PHV for testing. The laboratories testing your samples will not have any of your personal information; only the coded sample number will be matched to the study vaccine (or placebo) that you received.

> What are the types of activities that I will do in the research?
Apart from the initial injection, follow up visits, and the samples outlined below, there are no other activities.

> What impact will participating in this research have on me outside of the research? For example, will it reduce options for standard treatments?
The only impact that being in this study might have is to limit participation in a similar study. The study is being done in healthy people and the injection would not limit any standard treatment if you become ill in the future.

> How will my experience in this study differ from treatment outside of the study?
There are no treatments available for Marburg virus disease.

> In what ways is this research novel?
This study is designed to find out what safety effects, good or bad, the study vaccine (PHV01) has on you and to assess the immune response your body makes. The purpose of this Phase 1 study is to test the safety and immune response of 3 different dose-levels of the PHV01 vaccine in healthy subjects. Even

though the MARV GP study vaccine has not been given to humans before this trial, the FDA has reviewed the clinical study plan, the manufacturing process, and the data on testing the study vaccine in animals and has given approval for this study.

What is Marburg Virus?

Marburg virus is very closely related to Ebola virus, and it causes a similar severe hemorrhagic fever with a high mortality rate. Except for imported cases and laboratory infections, outbreaks have occurred only in sub-Saharan Africa with the most recent reported in 2023 in Tanzania. Hemorrhagic means that if you are infected, you will bleed a lot from eyes, ears, wounds, etc. in a short period of time. When a community is affected by MARV, up to 90% of the people that get infected may eventually die, so it is a very serious disease. Marburg disease is usually passed on by fruit bats. Humans are exposed to Marburg virus when they eat bats or foods that have been exposed to bat excrement then pass the virus to other people by direct contact through blood and body fluids or materials like bedding or bandages contaminated with infectious body fluids. There have been 17 recorded outbreaks since 1967 with the largest in 2004-2005 in Angola (374 cases with 329 deaths).

There is no licensed vaccine or treatment for MARV in humans. Due to the geographic distribution of the fruit bat, Marburg has been highlighted as a virus that needs attention to prevent potential future widespread infection. PHV is developing this vaccine with funding support from the Biomedical Advanced Research and Development Authority (BARDA), a US Department of Health and Human Services office responsible for developing the necessary vaccines, drugs, therapies, and diagnostic tools for public health medical emergencies (https://aspr.hhs.gov/AboutASPR/ProgramOffices/BARDA/Pages/default.aspx).

What are the criteria for enrollment?

You must be:

- ✓ Free of clinically significant health problems, as determined by pertinent medical history and clinical examination prior to entry in the study
- ✓ Available, able, and willing to participate in all study visits and procedures
- ✓ Able to read, understand, and complete questionnaires
- ✓ Have a negative antigen test for SARS-CoV-2 (COVID-19) on the day of dosing and no history of long COVID
- ✓ Live close enough to travel to the study site and plan to reside within the study area for the duration of the study
- ✓ Do not have children less than 1 year of age, exposure to livestock, or household contacts who are immunodeficient, on immunosuppressive medications, are human immunodeficiency virus (HIV)-positive, are pregnant or breastfeeding, or have an unstable medical condition (you can discuss this with the clinic staff), and have no plans to change these living conditions for at least the first six weeks after dosing
- ✓ Have tolerated previous injections of other vaccines without allergic reactions (anaphylaxis)
- ✓ If sexually active, be willing to practice total abstinence from sexual intercourse, or be willing to use effective methods of contraception during the first eight weeks of the study

You must not have a Body Mass Index (BMI), which is a combination of your weight and height, equal to or greater than 35, and you cannot have a history of prior infection with MARV, or having received experimental MARV vaccines or vaccines that are manufactured in the same way as the MARV vaccine (using the VSV vector). Your study nurse will explain all of this to you during the study eligibility process. Additional study participation criteria will be explained to you by your study nurse.

How many people will take part in this study?

Approximately 36 subjects will take part in this study at 1 site in the United States.

Do I have to take part?

It is up to you to decide whether to take part. If you decide to be screened, you will be asked to sign a consent form. Even if you do decide to participate, you can withdraw from the study any time without giving any reasons for doing so. If you decide not to participate, or withdraw from the study, this will not affect the standard of care you receive.

How long will I be in this study if I take part?

If you agree to take part in this research study, your participation will involve at least 9 study visits over approximately 7 months from screening to last visit.

What is involved in this study if I take part?

The results of these screening assessments will determine whether you can take part in the study. Any abnormal test results will be communicated to you by the study doctor. However, even if all your results are normal, you still may not be guaranteed participation. If we complete enrollment for the study while you are being screened, you may be asked to be a reserve subject. This means you will complete the tests and procedures required to confirm your suitability for the study and may be asked to participate if other subjects withdraw. If you are not enrolled at that visit, you may be able to join the next cohort.

If the screening assessments show that you can participate, and you are willing to take part, you will undergo further tests and procedures during the study. Your total length of time in the study, including the screening, dosing period(s), and follow-up periods, will be about 7 months.

How will the study vaccines be assigned?

If you agree to join the study and are eligible, you will be assigned to a dosing group. A dosing group is a group of people who receive a particular dose level of PHV01 vaccine or a placebo (an inactive substance), given as an injection intramuscularly (IM). You will be assigned randomly (by chance, like drawing straws or flipping a coin) to your dosing group. If you are dosed, you will stay in this group for the whole study. The study will enroll people into one of four dosing groups who get placebo or progressively higher doses of vaccine but you won't know which group you belong to (see below). A total of 36 people will be enrolled and dosed in the study.

Blinding Procedures

Neither you nor the study doctor or site staff will know which study treatment you will be receiving. However, in the event of an emergency your study doctor can find out what study treatment you are receiving. The Sponsor of the study, PHV, will be aware of which study treatment you receive and will be monitoring for events in all subjects to ensure your safety.

Who is responsible for monitoring and assuring your safety?

The study plan and study vaccine have been reviewed by the US FDA and the Institutional Review Board (IRB), for the study in which you will participate. The study doctor at the site has the primary responsibility of monitoring any adverse effects caused by the study vaccine. In addition, an experienced Medical Monitor from a different organization (called the Contract Research Organization or 'CRO') is assigned to oversee and evaluate any side effects of the study vaccine to protect your safety and well-being. The study has specific pausing and stopping rules to protect you and other subjects if an unusual side effect occurs. In addition, an important third level of oversight is provided by a Safety Review Committee or 'SRC', made up of experienced physicians from the Sponsor, the CRO and the study

center. The SRC will review and assess data after dosing to ensure that the next dose can be received safely.

What are my responsibilities?

As part of your participation in the study, you must first provide your informed consent to participate by signing this form. Before signing, it is important for you to ask questions and get answers so that you fully understand this study and how you may fit in here. It is also important for you to inform the study team of all medications and over-the-counter pills you are currently taking, any health/medical conditions you are currently experiencing, and accurately report (to the best of your ability) any changes to your health or medications for the duration of your participation in the study. It is also important that you follow the guidance on contraception (see below) and participate in all study visits detailed in the following section. If you consult another doctor for any reason while on the study, you must inform them that you are taking part in a clinical study. You should speak with the study doctor before taking any treatment prescribed by another doctor.

Prohibited Medications

Please tell us about all medications you are taking, including any herbal supplements or vitamins. The following medications may impact your health and/or the accuracy of data collected during the study. You should not use the following prohibited medications as detailed below.

- ✓ Any treatment with drugs that prevent activity of the immune system (such as cancer treatments, cytotoxic, or immunosuppressant medications) within six (6) months before enrollment and throughout the study.
- ✓ Any treatment through radiation (radiotherapy), within 60 days before enrollment and throughout the study.
- ✓ Any oral or injected corticosteroids for ≥ 7 days, within 28 days before enrollment and throughout the study.
- ✓ Any blood/plasma products (or plans to donate) or immunoglobulins within 60 days before enrollment and during the study.
- ✓ Any other (non-study) MARV or Ebola or VSV-vectored vaccines.
- ✓ Another vaccination with licensed or experimental vaccines within 14 days of planned study immunization (30 days for live vaccines).

Drugs that are used to reduce fever and pain are not allowed 24 hours prior to receipt of the injection and 24 hours after receipt of injection; these medications must be reported to the study team if you are taking them for another condition or need them after injection.

Contraception

All subjects must be willing to minimize blood and body fluid exposure of others after dosing by:

- ✓ Using effective barrier prophylaxis, such as latex condoms during penetrative sexual intercourse or oral sex with opposite-sex or same-sex partners (through eight weeks)
- ✓ Abstaining from sexual activity, including oral sex, if effective barrier prophylaxis cannot be used (through eight weeks)
- ✓ Avoiding the sharing of needles, razors, or toothbrushes (through six weeks)
- ✓ Avoiding open-mouth kissing (through six weeks)
- ✓ Covering of any open-skin lesions (through six weeks)

It is unknown whether the study vaccine affects pregnancy. Therefore, women who are pregnant or seeking to become pregnant cannot participate in the study. All women who participate in the study will complete pregnancy testing at the screening visit (blood test), before injection of study vaccine or placebo (urine test) and again 28 days after receipt of study vaccine or placebo (blood test). Female subjects will

be asked to refrain from donating reproductive tissue (eggs) from the time of informed consent until eight weeks after receipt of study injection.

Women who cannot become pregnant must be either surgically sterile (hysterectomy, fallopian tubes 'tied' or removed, and/or ovaries removed before entering the study) or postmenopausal (defined as spontaneous absence of menstruation for at least 1 year). However, medical records showing more than 1 follicle stimulating hormone (FSH) measurement (greater than 35 IU/L or mIU/mL) can be used for more menopause confirmation. Women not meeting these criteria will be considered to be of childbearing potential.

For women who cannot become pregnant and all men, the use of condoms with other adjunctive contraception will be required as a method of contact precaution for eight weeks after receipt of study vaccine.

Women who can become pregnant must agree to abstain from sexual intercourse or to use the following methods of contraception from 28 days prior to receipt of the injection and for eight weeks after receipt of study vaccine or placebo.

- One highly effective method of contraception **plus** an acceptable barrier method (condom used by male partner(s) plus spermicide).

Examples of highly effective contraceptive methods include:

- Hormonal contraceptives that inhibit ovulation (oral, intravaginal, or transdermal) for at least 12 weeks before entering the study
- Intrauterine device (IUD), or intrauterine hormone-releasing system for at least 12 weeks before entering the study.
- Bilateral tubal occlusion or vasectomized partner(s) at least 26 weeks before entering the study.
    - Note: A vasectomized partner is a highly effective method of contraception, provided that the male partner uses a condom and is the sole sexual partner of the study subject who is a woman of childbearing potential and that the vasectomized partner has received medical assessment of surgical success.
- Sexual abstinence.
    - Note: True abstinence, when in line with the preferred and usual lifestyle of the subject, is considered a highly effective method only if defined as refraining from heterosexual intercourse during the entire period of risk associated with the study drug treatment. Periodic abstinence (e.g., calendar, ovulation, symptothermal, post ovulation methods) and withdrawal are NOT acceptable methods of contraception.

All men must use a condom as a contact precaution for eight weeks after dosing. Those who are capable of causing a pregnancy must agree to completely abstain from sexual intercourse or use condoms during sexual intercourse after entering the study and for at least eight weeks after dosing. Male subjects must also ensure that any non-pregnant female partners of childbearing potential comply with the contraception requirements listed above. A surgically sterile male (vasectomy greater than 26 weeks prior to screening and medical assessment of surgical success) must use a condom during sexual intercourse as a contact precaution for eight weeks after dosing.

It is also not permitted for men participating in the study to donate sperm for 90 days after being vaccinated.

You should also understand that if you choose to be sexually active during or within eight weeks after receiving study drug, pregnancy could still result, exposing you or your partner to possible loss of the pregnancy as well as other unknown effects on your unborn child. If your partner becomes pregnant, the

study doctor will ask to contact that person. It is important to follow your partner during her pregnancy and up to two months after the birth to ensure the baby's health. A separate consent would be used by your partner in this situation.

If you think that you have become pregnant during the study, it is important that you inform the study doctor right away. The study doctor may request that you track your pregnancy and will report the pregnancy to the Sponsor and IRB.

If you are a male, you must tell the study doctor if you get someone pregnant or think that person is pregnant. The study doctor may request to track your partner's pregnancy and will report the pregnancy to the Sponsor and IRB. You should not join the study if your female partner is planning to become pregnant.

If you agree to be in the study, you will be asked to participate in the following:

During this study, you will have at least 9 visits: one (1) screening visit to see if you are eligible to participate, one (1) visit to give you the study drug, and seven (7) additional in-clinic follow-up visits to check on your health status and perform some routine assessments and provide blood, urine and saliva (oral swab) samples. After you receive study vaccine, you will be asked to stay in the clinic for 6 hours so that we can evaluate your response. The remaining in-clinic visits may last for 30 – 90 minutes. If you have a serious side effect during the study, the study doctor may extend your in-clinic stay for safety reasons or ask you to visit the office for follow-up examinations, even after you have completed your regular study visits.

A table of study visits is presented in Table 1 below.

Table 1: Summary of Study Visits

Visit # and Timing	Visit 1 -28 to -1	Visit 2 Day 1	Visit 3 Day 2	Visit 4 Day 4 ± 1 day	Visit 5 Day 8 ± 1 days	Visit 6 Day 15 ± 2 days	Visit 7 Day 29 ± 2 days	Visit 8 Day 85 ± 7 days	Visit 9 Day 181 ± 7 days
Informed consent	X								
Inclusion/exclusion	X	Review							
Demographics	X								
Medical history	X								
Vital signs	X	X × 2*	X	X	X	X	X	X	X
Physical exam (if needed after Screening)	X	X	X	X	X	X	X	X	X
Adverse Events that occur after dosing that are immediate, require medical attention, and are of special interest to researchers	X	X × 2	X	X	X	X	X		
Concomitant medications (any medications, including vitamins, that you take on a regular basis)	X	X × 2	X	X	X	X	X		
Pregnancy test	X	X					X		
Screening for HIV, HCV, Hepatitis B (1 tsp)	X								
Rapid antigen test for SARS-CoV-2		X							
Blood to evaluate liver, bone marrow, clotting, and metabolic functions (2 tsp)	X	X		X	X		X		
Blood to test for an autoimmune protein (HLA-B27)		X							
Urinalysis	X			X	X		X		
Blood for antibody tests (special proteins that help fight infection) (4 tsp)		X			X	X	X	X	X
Blood for research (7 tbsp)								X	
Blood for PBMC/T-cell Assay (tests to measure immunologic function as observed in your blood cells)		X			X		X		
Transcriptomics (a technology to study the viral genes in cells) (½ tsp)		X	X	X	X	X			
Sampling for viremia (the presence of virus in your blood) (1.5 tsp), shedding (elimination of virus in saliva or urine)		X × 2	X	X	X	X	X		
Cytokine levels (a test to measure immune status and any inflammation)		X		X	X		X		
Dosing		X							
Post-dosing observation		X							
Provision of emergency contact card		X							
Training and review of Memory Aids		X	X	X	X	X	X	X	X

* "X × 2" indicates first sample before dosing, then again at 6 hours

Screening Visit (1 to 28 days before you are dosed)

The following activities will be done during the Screening Period of the study:

- Your informed consent form will be obtained, and you will be allocated a screening number
- Your eligibility criteria will be assessed
- Your demographic details (including your year of birth, sex, race, and ethnicity) will be obtained
- You will be asked about your health status, any current and past illnesses, past surgery details, medications you have taken, and the medications you are currently taking (medication and medical history)
- Vital signs will be measured including blood pressure, temperature, heart rate, and respiratory rate
- A physical examination will be done which includes overall appearance, head and face, ear, nose, throat, mouth, skin, lymph nodes, respiratory, cardiovascular, abdomen, urogenital (if necessary), musculoskeletal, nervous, and neurological systems
- Use of contraceptive will be confirmed
- Your urine will be tested for any abnormalities
- Blood collection: approximately 16 mL (or about 3 teaspoons) for the following:
    - For women of childbearing potential, blood will be taken to confirm that you are not pregnant
    - Screening assessments to test your blood for viruses: Human immunodeficiency virus (HIV)-1, HIV-2, Hepatitis B and C
    - Routine tests to evaluate metabolic function, liver, bone marrow, and clotting (routine hematology & chemistry labs).
- Procedures and expectations for communicating with the site team will be discussed

The study team will review the results from your screening tests and will decide whether you are eligible to participate in the study. Any abnormal test results will be provided and explained to you. You can only participate in the study if you have negative HIV and hepatitis B and C tests. You will be informed about these tests results. If your test result is positive, the Public Health Department will be notified as required by law. If you do not want these tests to be completed, you should not participate in this study.

If you fulfill all the inclusion criteria and none of the exclusion criteria, you will be asked to visit the study site for additional assessments and your first dose by injection of study vaccine or placebo.

Dosing Visit (Day 1)

If the screening assessments show that you can participate in the study, and you consent to take part, you will undergo some or all of the tests and procedures indicated in the Summary of Study Visits table above.

You will visit the clinic on day 1 and the following activities will be completed before you are dosed:

- Your study doctor or nurse will briefly review the study criteria for participation and use of contraceptive will be confirmed
- Vital signs will be measured including blood pressure, temperature, heart rate, and respiratory rate
- A physical examination will be done at the discretion of the study doctor
- You will be asked about any changes to your health you have experienced since your last visit
- You will be asked about the medications you are currently taking and if there were any changes to the medications you reported on your last visit
- A urine pregnancy test for female subjects of childbearing potential
- A rapid antigen test for SARS-CoV-2 will be performed (and must be negative; you may be re-scheduled if positive)
- Blood will be taken to assess the following before dosing (~7 tablespoons)

  - Routine tests to evaluate liver, bone marrow, clotting and metabolic functions (hematology & chemistry)
  - A test to measure the proteins (antibodies) your body makes to fight against Marburg virus and exploratory tests
  - A test to measure immunologic function
  - A test to measure whether an autoimmune protein is in your blood (HLA-B27)
  - A test to measure the viral genes in your cells
  - A test to measure the amount of PHV01 vaccine virus in your blood
  - A test to explore your immune response to the vaccine virus
  - A test to measure any inflammation or signs of other immune disorders
- A swab sample will be taken to see if you have vaccine virus in your saliva
- Urine sample will be taken to see how much vaccine virus you have in your urine

After all baseline assessments have been completed, you will receive an injection of either PHV01 or placebo. Your study nurse or doctor will observe you for about an hour after dosing, observe the area where you received your injection, and take your vital signs. You will be required to stay in the clinic for about 6 hours and you will be provided with lunch.

About 6 hours after you are dosed, the study team will:

- Measure vital signs including blood pressure, temperature, heart rate, and respiratory rate
- Review any changes to your health you have experienced since dosing and observe the injection site
- A swab sample will be taken to see how much study vaccine virus you have in your saliva
- A urine sample will be taken to see how much study vaccine virus you have in your urine
- A blood sample will be taken after about 6 hours to:
  - Measure the amount of PHV01 vaccine virus in your blood
  - Measure the immunologic stimulation of your cells by study vaccine virus
  - Explore the immunologic stimulation of your cells by study vaccine virus

Before you leave the site, the study team will review procedures and expectations for communication with the study team, as well as instruction for use and completion of the Memory Aids to report any symptoms for the duration of the study.

You will be given instructions for the Memory Aids, a ruler, and a digital thermometer and your study doctor or another member of the study team will teach you how to use them. You will be asked to respond to questions about your health and tell us how you are feeling and if you are taking any medications. Some of the questions will ask you to state whether your symptoms are mild, moderate, or severe. You need to enter your symptoms in the Memory Aid daily for 14 days, then 3 times a week until day 29, then weekly until the end of the study. You will be asked to do the following:

- Use the Memory Aid to make a record of certain symptoms described in the Memory Aid, any other changes in your health or medications, as well as any doctor or hospital visits for treatment of a medical condition
- Use the ruler to record the diameter (longest measurement in any direction, as if an X was drawn on the skin) of any redness or swelling at the injection site for the first 28 days
- Use the thermometer to take your temperature at least once daily and around the same time of day for the first 28 days

Follow-Up Period (First weeks after dosing: Days 2, 4, 8 and 15)

Refer to the Summary of Study Visits chart above. You will be asked to come back to the clinic on days 2, 4, 8, and 15 so that your study doctor and nurse can check your health status and monitor any changes

you may be feeling. You will undergo some or all tests and procedures described below, depending upon the visit and study day:

- Vital signs will be measured including blood pressure, temperature, heart rate, and respiratory rate
- A physical examination may be done at the discretion of the study doctor. Additional swabs will be taken of your mucous membranes or your skin if you have any blisters, mouth ulcers or skin changes. A picture might be taken if you have any rashes
- You will be asked about any changes to your health you have experienced since your last visit
- You will be asked about the medications you are currently taking and if there were any changes to the medications you reported on your last visit
- Use of contraception will be confirmed
- Blood will be taken to assess the following:
  - Routine tests to evaluate liver, bone marrow, clotting and metabolic functions hematology & chemistry (~2 teaspoons, days 4 and 8 only)
  - A test to measure the proteins (antibodies) your body makes to fight against Marburg virus and exploratory tests (~4 teaspoons, day 8 and 15 only)
  - Blood to measure immunologic function and memory (day 8 only)
  - A test to explore the immunologic stimulation of your cells by vaccine virus
  - A test to measure the amount of PHV01 vaccine virus in your blood (~1.5 teaspoons)
  - A test to measure any inflammation (~2 teaspoons)
- Swab samples will be taken to see how much study vaccine virus you have in your saliva
- Urine sample will be taken to see how much study vaccine virus you have in your urine
- Your Memory Aid will be reviewed with you to ensure that any symptoms are discussed with your study doctor

During the day 4 visit, you will be reminded to call the site within 24 hours if you experience any unusual joint-related pain or notice any rashes on your body or experience unusual headaches, dizziness, numbness, or tingling.

Visit 7 (Day 29)

- Vital signs will be measured, including blood pressure, temperature, heart rate, and respiratory rate
- A physical examination will be done by the study doctor. Additional swabs will be taken of your mucous membranes or your skin if you have any blisters, mouth ulcers or skin changes. A picture might be taken if you have any rashes
- You will be asked about any changes to your health you have experienced since your last visit
- You will be asked about the medications you are currently taking and if there were any changes to the medications you reported on your last visit
- Use of contraceptive will be confirmed
- A urine pregnancy test for female subjects of childbearing potential
- Blood will be taken to assess the following (~7 tablespoons):
  - Routine tests to evaluate liver, bone marrow, clotting and metabolic functions (hematology & chemistry)
  - A test to measure the proteins (antibodies) your body makes to fight against Marburg virus
  - Blood to measure immunologic function and memory
  - A test to explore the immunologic stimulation of your cells by study vaccine virus
  - A test to measure the amount of PHV01 vaccine virus in your blood
  - A test to measure any inflammation
- Swab samples will be taken to see how much vaccine virus you have in your saliva
- Urine sample will be taken to see how much vaccine virus you have in your urine

- Your Memory Aid will be reviewed with you to ensure that any symptoms are discussed with your study doctor

Visit 8 (Day 85)

- Vital signs will be measured including blood pressure, temperature, heart rate, and respiratory rate
- A physical examination may be done at the discretion of the study doctor. Additional swabs will be taken of your mucous membranes or your skin if you have any blisters, mouth ulcers or skin changes. A picture might be taken if you have any rashes
- Your Memory Aid will be reviewed with you to ensure that your health status is discussed with your study doctor
- Blood will be taken to assess the following (~8 tablespoons):
  - A test to measure the proteins (antibodies) your body makes to fight against Marburg virus
  - Blood samples to provide serum for future studies in the lab or in animals designed to determine the antibody level required to protect against MARV disease

Visit 9 (Final Visit): Day 181

- Vital signs will be measured including blood pressure, temperature, heart rate, and respiratory rate
- A physical examination may be done at the discretion of the study doctor. Additional swabs will be taken of your mucous membranes or your skin if you have any blisters, mouth ulcers or skin changes. A picture might be taken if you have any rashes
- Your Diary will be reviewed with you to ensure that your health status is discussed with your study doctor
- Blood will be taken to assess the following (~4 teaspoons):
  - A test to measure the proteins (antibodies) your body makes to fight against Marburg virus and exploratory tests (~4 teaspoons)

Your participation in the study will be complete after your visit on day 181. If you have any ongoing problems, your study doctor will continue to follow your progress until the issues or problem is solved.

Unscheduled visit(s)

You may be asked to return to the clinic for weekly visits (or more often) if you have any new health problems or symptoms, or abnormal results in your blood counts, blood coagulation, liver function, or kidney function tests that are discovered when your blood is tested at study visits. At these visits, you may have ~2 to 4 teaspoons of blood drawn for a repeat test. At a minimum, the following activities will be completed during an unscheduled visit:

- You will be asked about the medications you are currently taking and if there were any changes to medications you reported on your last visit
- You will be asked about any changes to your health you have experienced since your last visit
- A physical examination will be done at the discretion of the study doctor. Blood may be taken to evaluate your current physical status
- Vital signs will be measured including blood pressure, temperature, heart rate, and respiratory rate
- Confirm that you are carrying your emergency contact card with you
- Procedures and expectations for communication with the site team will be reviewed

What is the total amount of blood taken during my participation in this study?

During this study, approximately 533 mL (35 tablespoons) of blood will be collected for study assessments (slightly more for women). The total amount of blood in the first month is less than 1 pint

(the amount you would give if you donated a unit of blood). Additional blood sample(s) may be collected for safety reasons if required as per the study doctor's discretion.

What will happen to the samples I give?

The Sponsor will analyze the immune responses to PHV01 vaccine and any abnormalities in clinical laboratory tests. If you withdraw consent to participate after the start of the study, you may request that your samples be destroyed; otherwise, all samples collected from you up to that time will be stored by PHV or one of the labs contracted by PHV to perform laboratory tests. By agreeing to take part in this study, you agree that your samples may be used in the following ways:

- To look for changes in your blood cell counts or blood chemistries to study the safety of the vaccine
- To measure your body's immune system (i.e., antibody) response to the study vaccine
- To see how much of the study vaccine virus is present (if at all) in your blood, saliva, and urine after dosing. We are specifically looking to see if you are excreting or "shedding" any of the study vaccine virus in your urine or saliva
- To analyze the performance of the immunological test methods employed
- To develop new or improved tests related to MARV infection exposure or detection, or the immune responses to Marburg vaccines
- To assess the role of antibodies to protect against infection in animal studies

The stored samples may be used for additional tests on immune responses to the Marburg vaccine or other, related vaccines. As for this study, any samples tested by PHV or shared with other researchers will be identified using only a code number (i.e., not revealing your identity, and no testing of your DNA will be performed). Samples may also be used for research in the future that is related to similar viral infections, which could help with development of vaccines for those diseases.

☐ Initials: _____ I consent to the future use of my samples for research related to this or similar viral infections.

☐ Initials: _____ I do not consent to the future use of my samples for research related to this or similar viral infections.

Identifiers might be removed from the identifiable private information or identifiable biospecimens and could then be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you. However, your biospecimens (even if identifiers are removed) will not be used for commercial profit. If you withdraw from the study, any sample collected prior to your withdrawal may still be analyzed as described in this informed consent form for this study, unless you specifically ask for your samples to be destroyed or local laws require destruction of the samples. Any information derived from analysis of these samples may still be used in the study report.

Could my participation in the study be stopped?

You can decide to stop participating at any time and for any reason. Inform the study doctor if you are thinking about stopping or decide to stop. The study doctor will discuss your decision with you and advise you how to safely stop participation in the study.

The study doctor can decide to stop you from taking part in this study at any time, even if you want to continue, for reasons that include but are not limited to the following:

- Your safety would be at risk if you continued in the study
- You failed to adequately follow instructions or procedures
- You need a treatment that is not allowed by the study
- The study has been terminated

When your participation ends after all follow-up visits, no new health information will be collected about you. However, the Sponsor will still be able to use any health information about you that has already been collected during this study. Note that all personal identifiers will be removed.

Will I be paid if I take part in this study?

You will be paid for your participation in this study. Compensation will be paid according to the schedule below:

- Visit 1 $100.00
- Visit 2 $500.00
- Visits 3, 4, 5, 6, 7, 8 and 9 $250.00/per visit

You will be paid $10.00 for each Diary completion for the 7 days Post Dose.

Unscheduled Visits (If required as determined by the study doctor) $100.00.

Compensation will be paid at the completion of each visit in the study. If you do not complete the study for any reason, you will be paid for each study visit you complete.

Payment received as a research subject may be considered taxable income. If payment is $600.00 or more in a calendar year, the study doctor or clinic will have to report this to the Internal Revenue Service (IRS). Personal information about you, including your name, address, social security number (SSN) or Individual Taxpayer Identification Number (TIN) may be released for the purpose of payment and for tax reporting to the Internal Revenue Service (IRS). The facility will issue you an IRS form 1099-MISC, Miscellaneous Income, listing your payment as reportable income. Without a social security number or Individual Taxpayer Identification Number (TIN), you may be subject to withholding of 24% percent of your stipend at the time of payment under Internal Revenue Code Section 1441.

If you have any questions regarding your reimbursement for participation, please contact the study investigator at the telephone number listed on page one of this consent.

Information from this study may lead to discoveries, inventions or new commercial products that will belong exclusively to PHV. This means that you will not receive any compensation or other benefits in relation to these.

Costs

There will be no charge to you for your participation in this study.

What are the alternatives if I do not take part in this study?

This study is for research purposes only and is not intended to treat or prevent any illness. Your alternative is to not take part in the study.

What are the possible risks/side effects of taking part?

You CANNOT contract MARV or MARV disease from this study vaccine because it only contains the gene for one of the MARV proteins; the VSV virus provides the remainder of the genes needed to make the study vaccine effective. However, because the PHV01 vaccine is a live, replicating virus (because of the VSV vector), it is possible you may experience symptoms like a mild or moderate flu-like illness similar to reactions following other live, attenuated vaccines or mRNA (COVID-19) vaccines. It is important that you remember that you should avoid intimate contact that will cause you to share any bodily fluids for four weeks. This is because you may pass the study vaccine virus onto others during this period.

It is expected that the potential risks of this study vaccine will include those common to other vaccine products, such as local injection site reactions (pain, swelling, and redness at the injection site) as well as

body reactions such as fever, chills, headache, fatigue, muscle aches, and nausea. For most vaccines, when they occur, these reactions usually last 1 to 4 days. Possible risks associated with vaccine administration are provided below.

Allergies

Like any vaccine or medicine, the PHV01 vaccine may cause an allergic reaction. Allergic reactions can be mild (such as an itchy rash) or severe (such as severe difficulty breathing or failure of the circulatory system with very low blood pressure). Severe allergic reactions require emergency treatment and could cause lasting disability or death. Most severe reactions occur quickly after exposure to the vaccine and can be treated effectively. This is why you will stay in the clinic for about an hour following the injection as a precaution. There are trained medical personnel and specific drugs and equipment available at the study site to treat you in the event of an allergic reaction.

You should get medical help and contact the study doctor or study team if you have any of these or any other side effects during the study.

Autoimmune Diseases

Autoimmune diseases (such as rheumatoid arthritis or lupus), which can result from an attack of the immune system on the body's own organs and tissues, can happen rarely in people who have been given various vaccines, but they can also happen in unvaccinated people. Side effects, which can sometimes be serious, include possible cases of autoimmune diseases that can involve the liver, the nervous system, blood cells, the thyroid gland, and the kidney, are possible after being given a vaccine or a drug under testing. It is unknown if this study vaccine, or any of its components, will cause these types of events. You will be monitored for these and similar side effects as part of this study.

Guillain-Barré Syndrome

Guillain-Barré Syndrome (GBS), a disorder in which the body’s immune system attacks part of the peripheral nervous system, has been observed very rarely to be related to certain vaccines. e.g., influenza and COVID-19 vaccines, but not to VSV vector vaccines. Overall, the chance of developing GBS is possible, but very unlikely. Approximately 85% of GBS patients made a complete or nearly complete recovery, although some continue to have long-term nerve damage. In order to reduce this risk, subjects with a history of GBS, other neurologic diseases, or reactions to prior vaccinations will not be allowed to participate in this study.

Additionally, there is a theoretical risk that the backbone virus used in this vaccine (called a VSV vector) could cause encephalitis (serious and potentially life-threatening infection of the brain), but this is an extremely unlikely possibility. The gene that can cause that disease has been removed from the vector. Given the way the vaccine was designed and the lack of findings in the animal safety studies that were done to prepare for human use, the risk of a neurologic illness resulting from PHV01 injection is judged to be very low. However, this study plan includes careful monitoring for any related signs and symptoms.

Arthritis

The similar VSV vector vaccine (ERVEBO®), which was licensed by FDA for prevention of Ebola infection, has been noted to cause temporary (lasting less than 2 weeks), mild-moderate arthritis in one or a few joints, with inflammation and swelling. It is possible that the VSV vector vaccine could cause similar side effects. In the case of ERVEBO, arthritis symptoms generally resolved when subjects were given non-steroidal anti-inflammatory drugs like Advil. Very rarely joint symptoms persisted for up to 2 years. The incidence of any joint pains or arthritis was less than 5% in most studies. Investigation of arthritis cases indicated that the inflammation was caused by local infection of the joint by the vaccine virus. It is unknown whether this study vaccine will have similar side-effects. If you experience joint pain five or more days after dosing, you will be asked to return to the clinic for a symptom assessment and additional blood and urine will be collected for testing. You may be referred to a second doctor for further

evaluation of your joints if the study doctor determines it is needed. If the doctor determines there may be fluid in your joint, and if acceptable to you, you may be asked to give your permission for a sample of this fluid to be taken from the joint by a needle, a procedure called "arthrocentesis." This procedure would only be done with your permission, and you would be asked to sign a separate form to provide your consent for the procedure.

Change in blood counts

A temporary drop in white blood cell counts (decrease in neutrophils or lymphocytes) may occur in the first few days, as is often common with viral replication / infections. As a healthy individual, your risk of other infections is low because the cell counts recover rapidly in other studies.

Skin rash and mouth ulcers

People who received the ERVEBO vaccine sometimes reported rashes (up to 9% in some studies) or ulcers of the mucus membranes in the mouth (less than 3%). It is possible that the VSV vector vaccine could cause similar side effects. In the case of ERVEBO, skin and mucosal side effects appear to be caused by infection of the skin by the vaccine virus. If you develop a mouth ulcer or rash, you will be asked to return to the clinic for a symptom assessment including evaluation of all skin lesions and mucosal lesions (ulcers), so swabs and additional blood and urine will be collected for testing. If the study doctor determines that you have a rash forming a bruise or blister, you may be asked to give your permission for a small piece of this rash to be taken for diagnostic purposes after numbing the skin, a procedure called "punch biopsy". If you experience a rash with a small blister, the study doctor may also ask your permission to take a sample of the blister fluid. You may also be referred to a dermatologist for further evaluation if the study doctor determines it is needed. This procedure would only be done with your permission, and you would be asked to sign a separate form to provide your consent for the procedure.

Procedure risks

Intramuscular injections may result in acute muscle damage, bruising, or injection site infection, although these are very rare. The injection site will be wiped with alcohol before the injection is given to help prevent infection.

Risks and possible discomforts you might experience from other study procedures include:

Blood Drawing

We will use a needle to take blood samples from a vein in your arm during the study. Drawing blood may cause pain where the needle is inserted, and there is a small risk of bruising at the place where the needle is inserted. However, this will resolve with time. Some people experience dizziness, upset stomach, or fainting when their blood is drawn. There is a small chance of infection by placing the cannula in your arm; every medical precaution will be taken to avoid an infection.

The study team will take blood samples from you up to 11 times. As noted above, a total of approximately 35 tablespoons will be taken from you over the approximate 7-month course of the study. For comparison, about 450 mL of blood (a little less than 2 cups) is usually taken during a blood donation. Although the total amount of blood drawn in this study meets approved safety limits, blood sampling may cause a temporary low red blood cell count, also known as anemia. You may not notice the level of anemia caused by your participation in this study or, in some cases, it may cause you to feel a little tired or fatigued. In some cases, it may cause your iron to be low. Your blood will be closely monitored by the study doctor throughout the study, and you may be asked to take iron supplements. The study doctor will also recommend other interventions if any are needed.

Unknown Risks

There may be risks that are not known at this time or that have not been reported to the scientific community. If any new risk is reported, the study doctor will let you know as soon as possible. Additionally, because of the unknown risks associated with this experimental vaccine, you should not donate blood for within 60 days of enrollment or plans to donate within the study period.

Reproductive Risks

Safety studies with the PHV01 vaccine have not yet been performed in pregnant women, and it is not known if these study agents could cause harm to an unborn baby. Generally, live-attenuated vaccines are contraindicated for pregnant women. In this research study, both men and women will be advised about using birth control. The safety of PHV01 during breastfeeding is also not known. Women who plan to become pregnant during the study or who are breastfeeding should not take part in this study.

Because of the potential reproductive risks, women of childbearing potential, and male partners of women of childbearing potential, must use an effective form of birth control for the length of the study starting from 30 days before dosing until eight weeks after dosing. Acceptable forms of birth control include abstinence or methods with a low failure rate (less than 1%) when used correctly. For this period of required contraception condoms must always be used. Acceptable birth control methods to be used with condoms include IUDs and hormonal contraceptives (birth control pills, injections, implants, patch, and vaginal ring.) If a hormonal contraceptive is being used, this method must have been used long enough for it to be effective. Ask the study doctor if you are not sure. Also, some drugs, such as certain antibiotics, may make contraceptives less effective. Please tell the study doctor other medications you are taking.

If you (or your female partner, if male) become pregnant during the study, or suspect that you or your female partner may be pregnant, you should notify the study doctor. **If you are a female subject and become pregnant, you will not take part in further study procedures, but you will continue to be followed for safety and for the outcome of your pregnancy.**

If you are a male whose female partner becomes pregnant during your participating in the study, you should notify the study doctor, who will ask to follow your partner until at least 2 months after the baby is born. The delivery date, outcome, and health status of the mother and child will be collected.

Contact Precautions

In order to minimize the risk of accidently transmitting the vaccine virus to another person as discussed above, you are asked to take additional precautions for six weeks after receiving your injection. Specifically, you should avoid sharing needles, razors, or toothbrushes, avoid open-mouth kissing, and cover any open-skin lesions for six weeks after dosing.

Safeguards

In order to minimize risks associated with this study, examinations and laboratory tests will be done frequently, as outlined previously in this consent form. A study doctor will always be available at one of the phone numbers listed on the emergency contact card. In addition, the Medical Monitor will be available for guidance and advice. You also may not enroll in any other investigational medical research for the entire duration of your participation in this study.

What if new information becomes available?

Your study doctor will be told about any new, important safety information that is learned during the study that could change your willingness to continue taking part in the study. The study doctor will be responsible for providing this information to you. You may contact the study doctor at any time during or after the study to find out if any new information has become available.

What are the possible benefits of taking part?

There is no guarantee that you will receive any benefits from taking part in this study and taking part may or may not cause your health to improve. Information from this study may help doctors learn more about PHV01 and the prevention of Marburg virus. This information may benefit other subjects with prevention of Marburg virus infection or disease, or a similar condition in the future.

At the screening visit you will undergo a medical history and physical examination and you will be tested for past exposure to viruses such as HIV, hepatitis B and hepatitis C, screened for diabetes and abnormalities of liver and kidneys and blood disorders. Any abnormalities that may be consequential to your health will be disclosed to you. The study doctor may be required by law to report the result of these tests to the local health authority.

What if something goes wrong?

At any of the study visits, the assessments performed for this study may show abnormalities that have not been previously detected. If this happens, the study doctor or your doctor will explain the results and will refer you for future care and/or treatment and provide any support you may need. If you experience any distress during the study, please let us know and we will endeavor to provide you with any support you may require.

If you should suffer any injury or illness during the study, you should tell your study team immediately, either in person or by telephone. You will be given any medical treatment necessary to help you recover from the injury or illness if the study doctors think it might be related to the study drug. An updated Declaration Under the Public Readiness and Emergency Preparedness Act for Countermeasures Against Marburgvirus and/or Marburg Disease, Document Citation 88 FR 82907 and Number 2023-26075, was issued by the Department of Health and Human Services on November 27, 2023 (effective January 1, 2024). This notice amended the former Declaration, Document Citation 85 FR 79198 and Number 2020-26972. This Declaration limits your ability to initiate a lawsuit if you are in a Marburg vaccine research study. If this study uses a drug, device or vaccine designed to treat, diagnose, cure, or prevent Marburg virus disease, you cannot sue the manufacturers, the study sponsor, healthcare providers or other professionals involved in the study for injury or harm (i.e., getting hurt) unless the injury or harm was on purpose. You may be compensated for injury or harm through a Department of Health and Human Services program called the Countermeasures Injury Compensation Program (CICP), provided you have followed the study protocol and as long as the injury or illness is not the result of any pre-existing medical conditions or related complications. For more information about this program, please contact the Health Resources and Services Administration's CICP by phone at 855-266-2427 or online at https://www.hrsa.gov/cicp/. You will not receive any other compensation for this injury.

You should submit any such treatment costs to the study site, who will make sure that the responsible party takes appropriate action.

If you are injured or harmed during the study due to negligence or intentional misconduct, then you may have grounds for legal action. You will not lose any of your legal rights by signing this form or by participating in the study.

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 subject;

- 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 subjects. If you have any questions about your rights as a research subject, 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: Pro00076276.

Will my taking part in this study be kept confidential?

Yes, your participation in the study and any information that might identify you will be kept strictly confidential by the clinic site. While every effort will be made to protect the privacy of your information, absolute confidentiality cannot be guaranteed.

The Sponsor will be using information from you to conduct this study and will act as the data controller. This means that they are responsible for looking after your information and using it properly and lawfully. Your rights to access or change the information about you that is collected are limited, so that we can ensure that the research is reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained up to the point of your withdrawal.

To safeguard your rights, the information we collect about you will be anonymized. This means that information such as your name has been removed to maintain your privacy. However, general demographic information such as your gender and age, will be provided to the Sponsor and their partners on this study, who will not be able to identify you personally and will not be able to find out your name, contact details, or other personal information.

The study doctor will collect information from you in accordance with the Sponsor's instructions. The study doctor will keep information about you related to this study after the study has finished for the period required by the local laws.

People working for the Sponsor on this study, as well as regulatory organizations including the US FDA, BARDA, and independent ethics committees, may view your medical records to check the accuracy of the information being collected. They will also ensure that the study is being conducted properly and that your rights are being protected.

Information will be collected from you directly during study visits, telephone calls, through interviews, questionnaires, medical examinations and medical records.

Your data is being processed to:

- Perform activities outlined in this informed consent form
- Conduct and determine the results of the study in accordance with the protocol (a document that describes how this study will be performed)
- Prepare reports or publications about the research study
- Monitor safety obligations and reporting requirements

The data recorded from this study may be held on a computer or as paper records by the Sponsor or by other authorized entities on their behalf. The anonymous data collected from all the subjects in this study may be sent to other countries for the purposes of analysis and submission to their health authorities. The data protection laws in these countries vary; however, all the parties involved in this study process have a duty to protect your identity and use the study data for legitimate healthcare and study purposes only. If your data is sent to a third party, all appropriate measures will be taken to protect your identity.

In the event of an unexpected breach of confidentiality, a US federal law (Genetic Information Non-Discrimination Act, GINA) will help protect against health insurance or employment discrimination based on genetic information obtained about you through research such as this. If you have questions about GINA or the risks of research on genetic information, please ask study team members.

From time to time the Sponsor may notify you about new information relating to your participation in the study, including how it handles your personal information. If that happens, the changes will be discussed with you by your study doctor. If any updates are made to the subject information that may impact your decision to participate in this study, you will be asked to review these and sign an updated informed consent form to confirm that you are willing to continue participating.

Will my General Physician (GP) be informed of my participation in the study?

With your permission, your GP will be informed of your participation in the study. You will need to give permission for this in the consent form. Should we be concerned about your health or wellbeing, we may discuss this with your GP / healthcare provider if you have given consent.

What will happen to the results of the research study?

The results of the research are likely to be published in a peer-reviewed scientific journal. You will not be identified in any report/publication. If you wish, feedback will be sent to you from the research doctor with the results, which will be in a manner understandable to a non-medical person. Please be aware that data analysis can take a long time, so you may not hear the results of the study for several months after participation.

A description of this clinical trial will be available on https:/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.

Who is organizing and funding the research?

The study is funded and sponsored by the Sponsor (PHV). They will provide appropriate compensation to **Research Centers of America,** for including you in this study at their clinical study site.

Who has reviewed the study?

All clinical trials in the US are reviewed by an independent group of people, called an Institutional Review Board (IRB), an ethical committee, to protect your interests. This study has been reviewed by the Advarra IRB.

Contact for Further Information

If you have any questions about this study or if there is anything you wish to discuss, please contact the study team.

If you agree to participate in this study, please sign the consent form. You will be given a copy of this information sheet and a signed consent form to keep for your records. Thank you for your time and willingness to help with this research! This is an important study vaccine that has the potential to save many lives if there is a future MARV epidemic.

Consent

I **confirm the following statements to be true:**

1. I have read the Informed Consent for this study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
2. I understand that this is a research study and that the primary purpose of the study is to study the safety and immune response to an experimental vaccine.
3. I understand that data collected during my participation in this research project may be stored electronically on one or more research databases at PHV, their partners for this study and at Research Centers of America. These data will be stored for a minimum of 15 years. I understand such data will not contain any identifying information and will be stored in an anonymized form so that I cannot be identified on the database. All data so stored will be treated in compliance with applicable privacy laws.
4. I understand that my pseudonymized data may be used in future ethically approved research studies.
5. I agree to relevant sections of my medical notes and data collected during the study being accessed by responsible individuals from the study Sponsor (PHV), their partners for this study or by or regulatory authorities or Independent Ethics Committees at Research Centers of America. I give permission for these individuals to access my records.
6. The study has been explained to me by: Prof/Dr/Mr/Mrs/Ms_____
7. I understand that I am free to withdraw from the study at any time, without having to give a reason for withdrawing and without affecting my medical care.
8. I agree to take part in this study.
9. I agree for my Primary Health Provider to be informed that I am taking part in this study and in an event of any incidental findings. You will be able to take part in this study regardless of which option you choose.

☐	YES	My study doctor can tell my Primary Health Provider that I am taking part in this study.
☐	NO	My study doctor cannot tell my Primary Health Provider that I am taking part in this study.
☐	NOT APPLICABLE	I do not have a Primary Healthcare Provider

_____
Subject Name (BLOCK CAPITALS)

_____ _____
Subject Signature Date

I, the undersigned, have fully explained this informed consent to the subject named above.

_____
Printed name of the person obtaining consent (BLOCK CAPITALS)

_____ _____
Signature of person obtaining consent *Date*

_____
Investigator name (BLOCK CAPITALS)

_____ _____
Investigator signature *Date*