UNIVERSITY of MARYLAND BALTIMORE

RESEARCH CONSENT FORM AND HIPAA AUTHORIZATION

V3.0; 25 Jul 2022

Protocol Title: A Phase 1, Randomized, Parallel-Group, Double-Blind Trial of AV7909 (Liquid) and Thermostable AV7909 (Lyophilized) in Healthy Adult Volunteers

Study No.: HP-00087040

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Sponsor: National Institutes of Health (NIH) /
National Institute of Allergy and Infectious Diseases (NIAID) /
Division of Microbiology and Infectious Diseases (DMID)

CONCISE SUMMARY

This is a research study to test two formulations of AV7909, a vaccine that is meant to protect people from anthrax. By "formulation" we mean whether it comes to us "lyophilized" (as a powder) or as a liquid. Lyophilized vaccines are stored in powder form and mixed into a liquid form when the vaccine is given. We hope to find out if the lyophilized formulation is safe and if it helps improve your body's immune response to the anthrax vaccine as much as the liquid formulation. Joining this study is completely voluntary. Participants will be randomized (like the flip of a coin) to 1 of 2 study groups. Half of you will get the liquid form and half will get the lyophilized form. The study vaccine will be given as an intra-muscular (directly into the muscle) injection into your upper arm.

If you agree to take part in this study, your involvement will last for approximately 13 months. You will have 9 visits. At 2 visits, you will be vaccinated with AV7909. At all visits, you will have your blood drawn and answer questions about your health.

The risks of joining this study are described in detail below. Some of the more common risks include reactions at the injection site, flu-like symptoms, and minor pain and bruising with blood draws. A possible benefit of joining is that you may get protection from anthrax. However, you may get no benefit. You, of course, may choose not to participate or to withdraw at any time.

If you are interested in learning more about this study, please continue reading below.

PURPOSE OF THE STUDY
This is a research study. We are inviting you to participate in this research study because you are in good health and aged 18 to 45 years.

The purpose of this research is to study the safety, side effects, and immune responses (blood tests showing possible protection from anthrax) after getting an anthrax vaccine. The vaccine we are studying is called AV7909. We are comparing two "formulations." By that, we mean vaccines can come to us either already as a liquid and ready to inject, or as a dry powder. For the dry powder, we must add a liquid to it first, before injecting it. These dry powder formulations are call "lyophilized." Lyophilized vaccines have a longer shelf-life and are more easily stored than liquid vaccines.

AV7909 is a combination of a licensed anthrax vaccine, called BioThrax, and an "adjuvant". An adjuvant is a substance that may cause the body to produce more antibodies (immune proteins in the blood) when it is given with a vaccine. With more antibodies, people are often better protected. The adjuvant that was added to BioThrax to make AV7909 is called CPG7909. It is a short string of nucleotides (genetic building block molecules). This type of adjuvant has been tested in other vaccines, including one vaccine licensed in the US- a vaccine for hepatitis B.

Anthrax is a disease of animals and people. It is caused by a bacterium (germ) called *Bacillus anthracis*. Anthrax disease in humans can be cutaneous (on the skin), associated with injection drug use, gastrointestinal (in the gut), and inhalational (in the lungs). Unintentional human disease usually occurs after contact with infected animals or animal products. This type still occurs in many parts of the world, but only occurs very rarely in the United States. Other cases have been associated with certain industrial processes, as a result of laboratory accidents, and due to biological terrorism or biological warfare. "Biological terrorism" or "biological warfare" is when germs are intentionally spread by terrorists or as part of a war. That is, when they are used as a weapon. Anthrax remains one of the most likely agents to be used in bioterror or biowarfare because it is easy to grow in the lab, easy to weaponize, easy to distribute, and highly fatal.

The anthrax vaccine that is currently licensed in the US is called AVA (BioThrax). It is safe and effective, and it is given in a series of 3 doses. It was developed in the 1950s and has been used both to prevent anthrax in people at high risk, such as the military (we call this "pre-exposure prophylaxis"), and to prevent anthrax in those already exposed ("post-exposure prophylaxis"). It is possible that when this anthrax vaccine is used with an adjuvant, it will lead to faster immune responses and require fewer doses. Studies done with the liquid formulation of AV7909 support that. In this study, we want to see if the lyophilized vaccine is also just as safe, well tolerated, and good at producing immune proteins (antibodies). We plan to speak with approximately 300 potential volunteers about this study. We aim to screen up to 150 and enroll 40 who get vaccinated. If any of the 40 who join cannot finish, we might add "replacements".

PROCEDURES
<u>Screening Visit – approximately 1 ½ hours</u>

At the screening visit, you will be given information about the study and asked to read this informed consent. After you have read the consent and your questions have been answered, you will be asked if you wish to be in the study. If so, we will ask you to sign this consent form.

If you agree to take part in the study, the following will be done:

- You will be asked about your medical history including any medications you are taking or have taken in the last 60 days.
- You will have your temperature, pulse, and blood pressure taken. We will measure your height and weight and calculate your Body Mass Index (BMI), which compares your weight to your height.
- You will have a physical examination.
- We will collect urine to check for drug use. The drugs we may check for include amphetamines, barbiturates, benzodiazepines, cocaine, methadone, opiates, oxycodone/oxymorphone, phencyclidine (PCP), and propoxyphene.
- We will draw about 46 mL (about 9 teaspoons) of blood from a vein in your arm for lab tests. The test results may show findings that will not allow you to continue in the study. This blood collection includes blood that will be stored frozen and available for testing, in case you develop any diseases that are what we call "autoimmune." These are diseases like lupus and psoriasis.
- As part of this eligibility testing, you will be tested for HIV (human immunodeficiency virus), which is the virus that causes the acquired immunodeficiency syndrome (AIDS), hepatitis B, and hepatitis C. You will be notified of the results of the testing, and counseled as to the meaning of the results, whether they are positive or negative. If the test indicates that you are infected with HIV, hepatitis B, or hepatitis C, you will receive additional counseling about the significance of your care and possible risks to other people. We are required to report all positive results to the Maryland Department of Health. The test results will be kept confidential to the extent permissible under the law. If you do not want to be tested for HIV, hepatitis B, or hepatitis C, then you should not agree to participate in this study.
- You will have a 12-lead electrocardiogram (EKG) performed. This requires putting small adhesive tabs on your chest, arms, and legs, to look at the electrical waves of your heart.
- If you are a woman who is able to become pregnant, you will be counseled on pregnancy avoidance and must use an acceptable method of birth control from at least 30 days before your first study vaccination until at least 60 days after your second study vaccination (Day 75). You will have a blood pregnancy test at the screening visit. If your pregnancy test returns positive, you will not be able to continue in the study.

After the screening visit, if you are eligible to join the study, you will be scheduled for your study vaccination visit.

<u>Study Visit 1 (Day 1) – approximately 2½ hours: First Vaccination Visit</u>

Before you are given the first dose of study vaccination, the following will take place:

- Your screening lab results will be reviewed with you.

- You will be asked if there have been any changes in your health or medications.
- You will be asked if you have had a bad reaction to vaccines in the past.
- You will have your temperature, pulse, and blood pressure taken.
- You may have a brief physical exam, based on your health.
- If you are a woman able to become pregnant, a urine sample will be collected to test for pregnancy. If you are pregnant, you will not be able to continue. If you are not, you will be counseled to avoid pregnancy until 60 days after the second vaccination (Day 75). The study team will discuss acceptable methods with you.
- You will have approximately 20 mL (about 4 teaspoons) of blood taken for study lab tests.

If you are eligible, you will be randomly assigned to receive 1 of the 2 study treatments (see table below). This means that the study vaccines you receive will be determined purely by chance, like flipping a coin. You will have an equal chance to be placed in either of the study groups. Neither you nor the research team will know which study treatment you receive, but we will be able to get this information quickly if we need it to ensure your safety.

		Day 1	Day 15
Study Group	**No. of Participants**	**Study Vaccine**	**Study Vaccine**
1	20	AV7909 Liquid	AV7909 Liquid
2	20	AV7909 Lyophilized	AV7909 Lyophilized

- You will be given the study vaccine as an intra-muscular (directly into the muscle) injection in the deltoid muscle (upper arm) of your preferred arm.
- After the vaccination, you must remain in the clinic for at least 30 minutes to be monitored for a reaction to the vaccine.
- The study staff will give you the following:
  - ✓ Instructions on use of an electronic memory aid for you to record, once a day, any symptoms you may have, starting the day of vaccination and continuing for the next 7 days. The information will be entered by you, to a secure website. You will also be given a paper form, as a backup, in case you cannot access the electronic form.
  - ✓ A thermometer to take your daily temperature and a ruler to measure any swelling/redness at the injection site.

<u>Study Visit 2 (Day 8)– approximately 30 minutes: Follow Up Visit</u>

- You will be asked if there have been any changes to your health or medications.
- Your electronic memory aid results will be reviewed, and your injection site will be examined.
- You may have a brief physical exam, based on your health.
- We will collect about 20 mL (4 teaspoons) of blood for study lab tests.
- If you are a woman able to become pregnant, you will be counseled to avoid pregnancy until 60 days after the second vaccination (Day 75).

<u>Study Visit 3 (Day 15) – approximately 2 ½ hours: Second Vaccination Visit</u>

Before you are given the second dose of study vaccination, the following will take place:

- You will be asked if there have been any changes in your health or medications.
- You will be asked if you have had a bad reaction to vaccines in the past. You may have a brief physical exam, based on your health.
- If you are a woman able to become pregnant, a urine sample will be collected to test for pregnancy. If you are pregnant, you will not be allowed to get the second vaccination. If you are not pregnant, you will be counseled to avoid pregnancy until 60 days after the second vaccination (Day 75).
- You will have about 20 mL (about 4 teaspoons) of blood taken for study lab tests.

- You will be given the study vaccine as an intra-muscular (directly into the muscle) injection in the deltoid muscle (upper arm) of the arm opposite to the one that was injected the first time. After the vaccination, you must remain in the clinic for at least 30 minutes to be monitored for a reaction to the vaccine.

The study staff will give you the following:

- Reminder instructions on the use of an electronic memory aid (as you used after the first vaccination). This is where you will record, once a day, any symptoms you may have, starting the day of vaccination and continuing for the next 7 days. The information will be uploaded by you, to a secure website. You will also be given a paper form, as a backup, in case you cannot access the electronic form.
- A reminder on the use of your thermometer, to take your daily temperature, and your ruler, to measure any swelling/redness at the injection site. If you need replacements, we will provide them.

Study Visit 4 (Day 22) – approximately 30 minutes: Follow Up Visit

- You will be asked if there have been any changes in your health or medications.
- Your electronic memory aid results will be reviewed, and your injection site will be examined.
- You may have a brief physical exam, based on your health.
- We will collect about 20 mL (4 teaspoons) of blood for study lab tests.
- If you are a woman able to become pregnant, you will be counseled to avoid pregnancy until 60 days after the second vaccination (Day 75).

Study Visit 5 (Day 29) – approximately 30 minutes: Follow Up Visit

- You will be asked if there have been any changes in your health or medications.
- You may have a brief physical exam, based on your health.
- We will collect about 30 mL (about 6 teaspoons) of blood for study lab tests.
- If you are a woman able to become pregnant, you will be counseled to avoid pregnancy until 60 days after the second vaccination (Day 75).

Study Visit 6 (Day 64) – approximately 30 minutes: Follow Up Visit

- You will be asked if there have been any changes in your health or medications.
- You may have a brief physical exam, based on your health
- We will collect about 20 mL (about 4 teaspoons) of blood for study lab tests.
- If you are a woman able to become pregnant, you will be counseled to avoid pregnancy until 60 days after the second vaccination (Day 75).

Study Visit 7 (Day 195)– approximately 30 minutes: Follow Up Visit

- You will be asked if there have been any serious changes in your health or medications.
- You may have a brief physical exam, based on your health.
- We will collect about 20 mL (about 4 teaspoons) of blood for study lab tests.

Study Visit 8 (Day 380) – approximately 30 minutes: Follow Up and Last Visit

- You will be asked if there have been any serious changes in your health or medications.
- You may have a brief physical exam, based on your health.
- We will collect about 20 mL (about 4 teaspoons) of blood for study lab tests.

Early Termination Visit – approximately 30 minutes

If you need to leave the study early, we will ask you to complete a final study visit. At this visit, the following may be done:

- You will be asked about your current health and any changes in your medications.
- You may have a brief physical exam, based on your current health.
- Your temperature, pulse, and blood pressure may be taken.
- We may collect blood and urine for study lab tests.
- Other assessments may be done, depending on when this visit occurs during the study period.

Unscheduled Study Visits – approximately 30 minutes

Unscheduled visits may occur for further evaluations. At these visits, the following may be done:

- You will be asked about your current health and any changes in your medications.
- You may have a brief physical exam, based on your health.
- You may have your vital signs taken - temperature, pulse, and blood pressure.
- We may collect blood for study lab tests.
- Other assessments may be done depending on when this visit occurs during the study period.

Genetic Testing

No genetic testing on your blood samples will be done as part of this study.

Blood Storage for Future Use

As part of this study, we are obtaining blood samples from you. However, it is possible that not all the blood we collect will be used for this research study. We would like to store this extra

blood. We would possibly use this excess/leftover blood and the information collected about you during this study for future research. We would only do this if you provide permission. Types of research include new or different immunological laboratory tests, to provide information for the development of new vaccines, or for the studies of anthrax or other infections. The tests we might want to use to study your blood may not even exist at this time.

The excess/leftover blood samples for future research will be stored indefinitely at a site picked by the study sponsor, the National Institutes of Health (NIH). Each blood sample will be labeled only with a barcode and a unique tracking number, to protect your confidentiality. Personnel at the storage facility and testing lab will not know your identity. They will also not know the volunteer ID code assigned to you for the study. However, the researchers who enrolled you will keep in a secure area a code key that could connect barcodes or tracking numbers to identify you, if needed.

Stored excess/leftover future research blood samples will be used only for research purposes. At any time during this study or after this study is over, stored extra blood samples may be shared with other investigators, institutions, or drug companies. The samples will not be sold or used directly for production of any commercial product or profit. No human genetic (DNA) tests will be done on these samples. There are no benefits to you in the collection, storage, and future use of your blood samples. The results of any future testing will be kept confidential in the same way as the results of other testing done for this study.

Your consent for the collection and future use of your excess/leftover blood samples is optional. You will still be a full participant in the study whether you consent to future use of your excess/leftover blood or not. Like other aspects of this study, if you give consent, during enrollment, for future use of your excess/leftover blood samples, you may change your mind and withdraw consent at any time. You will need to contact Dr. James Campbell or a research team member at 410-706-6156. Your blood samples will be removed from the study repository when the study is completed. Please feel free to ask the study staff any questions you may have about how your blood samples may be used.

Please <u>initial</u> your choice below:

_____ **YES**, I agree to allow you to store my excess/leftover blood samples for an indefinite period of time and use them for future research. I may withdraw my consent during my participation, following my first vaccination.

_____ **NO,** I do not consent to storing my excess/leftover blood for future research; however, I still wish to be a full participant in the study.

Study Results

When the study results are available, after the study is completed (generally at least several months after your last visit), a summary of the results will appear on http://www.ClinicalTrials.gov. Your individual results are important for research purposes, but not for your healthcare. We do not anticipate providing you with individual study test results or information about which group you were placed in, once the study is over. If any results are thought to be important for your healthcare, we will discuss them with you. If you have any questions or concerns about the results, please contact Dr. James Campbell at 410-706-6156.

WHAT ARE MY RESPONSIBILITIES IF I TAKE PART IN THIS RESEARCH?

If you take part in this research, you will be responsible to do the following:

- come to all study visits as scheduled
- complete an electronic memory aid to record any reactions experienced after each vaccination
- contact the study staff or doctor if you have severe symptoms (not feeling well) or are hospitalized, or feel concerned about symptoms
- avoid receiving a licensed *live* vaccine within 30 days before or after study vaccination
- avoid receiving a licensed *inactivated* vaccine within 14 days before or after study vaccination
- avoid participating in another study in which you will receive an interventional drug/agent during participation in this study (for about 13 months)
- if you are a woman who is able to have children, avoid pregnancy by using an acceptable method of birth control from at least 30 days before the first study vaccination until 60 days after the second study vaccination (Day 75)
- avoid breastfeeding through 30 days after the last study vaccination
- avoid donating blood within 4 months following the first study vaccination
- avoid having elective surgery during the study period

WHAT ARE THE POSSIBLE RISKS/DISCOMFORTS IF I TAKE PART IN THIS STUDY?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be risks which are not yet known.

The risks of participating in this trial are those related to possible reactions to AV7909, intramuscular injection, having blood drawn, and breach of confidentiality.

Risks related to the vaccine: AVA7909

AVA7909 is a combination of licensed anthrax vaccine, BioThrax, with an adjuvant, CPG7909. Since BioThrax was licensed by the FDA in 1970, more than 3.3 million individuals, primarily military personnel, have been vaccinated. Sometimes, after receiving BioThrax, people experience headache, muscle aches, and fatigue. There may also be reactions at the injection site such as redness, tenderness, swelling, itching, stiffness, difficulty with arm movements, or bruising.

Most of these reactions happen on the first day after receiving the vaccine and disappear without treatment within 1 or 2 days. Taking ibuprofen or acetaminophen and resting may relieve these side effects.

Rarely, people who have received adjuvants have developed illnesses, called autoimmune diseases, where their immune system harms their own body. Some of the autoimmune conditions observed in people who have received high doses of CPG7909 as part of treatment for cancer have included polyarthralgia (joint pains), arthritis (joint swelling), Sjögren's Syndrome (a disease with dry eyes and mouth), autoimmune thyroiditis (inflammation of the thyroid), vitiligo (loss of skin color), Guillain-Barré syndrome (a form of paralysis), and ulcerative colitis (a chronic bowel disease). These illnesses more commonly develop in people who have not received CPG7909 or vaccines with adjuvants. And, the doses of CPG7909 used in these cancer treatments were usually higher than the dose in AV7909.

A total of 241 study participants have been exposed to a combination of AVA and CPG7909. No serious adverse events (SAEs) were reported that were possibly related to AV7909 in the studies so far completed. To date, no autoimmune adverse events have been reported. For the only vaccine with a CPG adjuvant licensed in the US (a vaccine called Heplisav, which contains a different CPG: CPG 1018), there was no difference in autoimmune disease rates between those who got Heplisav and those who got a similar vaccine that did not contain the adjuvant. We do not know if AV7909, the anthrax vaccine we are testing, can actually cause or worsen autoimmune diseases. If you were to develop one of these kinds of problems while in this study, we would help you find a doctor who specializes in these diseases (a rheumatologist) and help to understand if you might have gotten the disease because of the vaccine.

A small number of people (about 1 in 4 million) have immediate and serious, including fatal, allergic reactions to licensed vaccines. Such reactions are called "anaphylaxis". These reactions can cause a skin rash (hives); swelling around the mouth, throat, and eyes; shortness of breath; fast heart rate; and fainting due to a decrease in blood pressure. If these reactions occur, they can usually be stopped by the study staff, who would give you emergency medications. Most people who experience anaphylaxis recover completely.

For women participating in the study

If you are a woman who is capable of becoming pregnant, we will ask you to take a pregnancy test before beginning this study and within 24 hours prior to each study vaccination. You must use effective birth control methods and try not to become pregnant while participating in this study, from the time of screening until 60 days after the second vaccination (Day 75). If you become pregnant, there may be unknown risks to your fetus (unborn baby) associated with being in the study. There may be long-term effects of the treatment being studied that could increase the risk of harm to an unborn child.

You should not be in this study if you are breastfeeding. You should also not join if you are capable of becoming pregnant, you have sex with men, and you do not use an acceptable form of

birth control from 30 days before the first study vaccination (Day 1) until at least 60 days after you receive the second study vaccination (Day 75). Acceptable birth control methods include full abstinence from sexual intercourse with a male partner, monogamous relationship with a vasectomized partner who has been vasectomized for 180 days or more and is azoospermic (no sperm in the semen) prior to you receiving the study vaccination, barrier methods such as condoms or diaphragms/cervical cap, intrauterine devices, NuvaRing®, tubal ligation, and licensed hormonal methods such as implants, injectables, or oral contraceptives ("the pill").

If you become pregnant during this study, please contact Dr. James Campbell or his research team at 410-706-6156 as soon as possible. With your permission, you will be followed to pregnancy outcome (when your pregnancy ends or your baby is born). Blood sample(s) for study tests will continue to be collected according to the protocol, and you will continue to be followed for safety. You will not receive additional study vaccinations.

Risks related to intramuscular injections

The injection of a vaccine or drug into the deltoid muscle, as will be done in this study, is typically well tolerated. However, it often causes temporary discomfort. Intramuscular injections may cause you to feel like you might faint or to faint. Any injection could cause an abscess (infection), a hematoma (collection of blood), injury to blood vessels and nerves, or tingling or numbness. An injection too high on the shoulder could cause Shoulder Injury Related to Vaccine Administration, or SIRVA. Proper education of the study staff and injection technique should reduce the risk of these side effects.

Risks related to blood draws

Having blood taken from your arm can cause temporary discomfort, bruising, and fainting with a rare risk of infection. A possible risk of giving blood may be a low blood count (anemia). However, the total amount for this study is lower than donating a unit of blood so the risk of anemia is low. You will be providing about 224 mL (about 45 teaspoons or about half a pint) total for this study, over the course of the entire study (about 13 months). This is about half the volume of one donated unit of blood.

Risks related to loss of confidentiality

You will be asked to provide personal (protected) health information (PHI). All attempts will be made to keep this PHI confidential within the limits of the law. However, there is a chance that unauthorized persons will see your PHI. All paper study records will be kept in a locked file cabinet and/or maintained in a locked room at the CVD. Electronic files will be password-protected. Only people who are involved in the conduct, oversight, monitoring, or auditing of this trial will be allowed access to the PHI that is collected. Publications from this trial will not use information that will identify participants by name. Organizations that may inspect and/or copy research records maintained at the CVD for quality assurance and data analysis include groups such as the IRB (ethics committee), NIH (the sponsor), and the FDA (the government licensing agency).

WHAT ARE THE POSSIBLE BENEFITS IF I TAKE PART IN THIS STUDY?
You may or may not benefit by taking part in this study. There is no guarantee that you will receive direct benefit from your participation in this study. Although you may not currently be identified as a person at risk for getting anthrax, you may develop immune responses to the anthrax vaccines being studied in this protocol that are protective against anthrax. In other words, receiving the vaccine may lessen the severity of or prevent anthrax disease following exposure. However, it is also possible that you will not be protected.

There may be benefits to society through the improvement of our understanding of this vaccine.

ALTERNATIVES TO PARTICIPATION
Anthrax vaccines are not typically available to the general public, only to certain higher risk persons. This is not a treatment study. Your alternative is to not take part. If you choose not to take part, your healthcare at University of Maryland, Baltimore will not be affected.

COSTS TO PARTICIPANTS
It will not cost you anything to take part in this study.

COMPENSATION TO PARTICIPANTS
You will be offered compensation for your time and inconvenience for each of the events of the study: screening visit, vaccination visits, memory aid completion, follow-up clinic visits, and study completion. The total amount you may receive is up to approximately $1,500. We will provide the compensation in four installments via checks at the visits indicated on your Payment Schedule. The amount you receive will be prorated if you do not complete the entire study.

We are required, in order for you to receive compensation, to collect your Social Security Number. We will take measures to protect that information.

We ask that you notify the Internal Revenue Service (IRS) of this income. A Form 1099-MISC (for miscellaneous income) will be mailed to you for you to report this compensation to the IRS. We will also provide you with parking vouchers or bus tokens, if appropriate.

STUDY FUNDING
The National Institutes of Health (NIH) is funding this research study. This means that the University of Maryland, Baltimore (UMB) CVD is receiving payments from the NIH to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from NIH for conducting this study.

CONFIDENTIALITY AND ACCESS TO RECORDS
We will keep your participation in this research study confidential to the extent permitted by law. However, it is possible that other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you, such as your name, address, and date of birth.

- federal government regulatory agencies,
- the U.S. Food and Drug Administration,
- the National Institutes of Health (NIH) (the sponsor) and those contracted by the NIH, e.g. Emmes Corporation, and its representatives, including any groups assisting with what is called pharmacovigilance or monitoring,
- auditing and regulatory affairs departments at the University of Maryland, Baltimore, and
- the University of Maryland, Baltimore Institutional Review Board (a committee that reviews and approves human research studies) and other representatives of this organization.

To help protect your confidentiality, we will use ID numbers on research data. Hardcopy data will be stored in locked cabinets and/or offices when not in use. Only research team members who are involved in the conduct, oversight, or auditing of this study will have access to the research data. Electronic data will be stored in password protected computers and websites. For this study, each blood sample will be labeled with a barcode and a unique tracking number to protect your confidentiality. Personnel at the central storage, testing labs, and the drug company, will not know your identity or the volunteer ID assigned to you for the study.

The data from the study may be published. However, you will not be identified by name. People designated from the institutions where the study is being conducted and people from the sponsor will be allowed to inspect sections of your medical and research records related to the study. Everyone using study information will work to keep your personal information confidential. Your personal information will not be given out unless required by law.

To help us protect your privacy, we have received a Certificate of Confidentiality from NIH. The certificate says that the investigators may not disclose research information that may identify you in any federal, state, or local, civil, criminal, administrative, legislative, or other proceedings, unless you have consented for this use. Research information protected by this certificate cannot be disclosed to anyone else who is not connected with the research unless:

- There is a law that requires disclosure (such as to report child abuse or communicable diseases, but not for legal proceedings).
- You have consented to the disclosure, including for your medical treatment.
- The research information is used for other scientific research, as allowed by federal regulations protecting research subjects.

As noted above, disclosure is required, however, for audit or program evaluation requested by the agency that is funding this project or for information that is required by the FDA.

You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

We are required to report all positive results of the HIV test to the Maryland Department of Health. The test results will be kept confidential to the extent permissible under the law. If you do not want to be tested for HIV, then you should not agree to participate in this study.

The University of Maryland, Baltimore generally requires that we document in your medical record chart that you are participating in this study. If you do not have a medical record in the UMMS system, then we will create one for you. The information included in the chart will provide contact information for the research team as well as information about the risks associated with this study. We will keep this Informed Consent Document in our research files; it will not be placed in your medical record chart.

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

WILL MY HEALTH INFORMATION BE USED DURING THIS STUDY?

The Federal Health Insurance Portability and Accountability Act (HIPAA) requires University of Maryland, Baltimore to obtain your permission for the research team to access or create "protected health information" about you for purposes of this research study. Protected health information is information that personally identifies you and relates to your past, present, or future physical or mental health condition or care. We will access or create health information about you, as described in this document, for purposes of this research study.

Efforts will be made to limit your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the University of Maryland, Baltimore Institutional Review Board (IRB) and other representatives of this organization, federal government regulatory agencies, the US Food and Drug Administration, the National Institutes of Health (NIH) and those contracted by the NIH, e.g. the Emmes Corporation (data coordinating center). The monitors, auditors, the IRB, and the Food and Drug Administration will be granted direct access to your medical records for verification of the research procedures and dates. By signing this document, you are authorizing this access.

You cannot participate in this study unless you permit us to use your protected health information. Your decision will not affect your right to medical care.

Although you may not be allowed to see study information until after this study is over, you may be given access to your health care records by contacting your health care provider. Your permission for us to access or create protected health information about you for purposes of this study has no expiration date. You may withdraw your permission for us to use your health information for this research study by sending a written notice to Dr. James Campbell. However,

we may still use your health information that was collected before withdrawing your permission. Also, if we have sent your health information to a third party, such as the study sponsor, or we have removed your identifying information, it may not be possible to prevent its future use. You will receive a copy of this signed document.

RIGHT TO WITHDRAW

Your participation in this study is voluntary. You do not have to take part in this research. You are free to withdraw your consent at any time. Refusal to take part or to stop taking part in the study will involve no penalty or loss of benefits to which you are otherwise entitled. If you decide to stop taking part, or if you have questions, concerns, or complaints, or if you need to report a medical injury related to the research, please contact the investigator, Dr. James Campbell, or his research team at 410-706-6156.

If you withdraw from this study, already collected data may not be removed from the study database. You will be asked whether the investigator can collect data from your routine medical care. If you agree, these data will be handled the same as research data.

You will be told of any significant new findings that develop during the study and which may affect your willingness to participate in the study.

If you are an employee or student, your employment status or academic standing at UMB will not be affected by your participation or non-participation in this study.

If you decide to leave the study early, we will ask you to permit the study staff to contact you to follow up on any reactions you may have had and to collect blood samples, if possible.

CAN I BE REMOVED FROM THE RESEARCH?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include the following:

- Reasons related to you (for example, if you move to another city, do not agree to get your study vaccination, or do not follow study-related directions).
- Reasons related to your health (for example, if you have a serious reaction to your study vaccinations).
- Because this entire study is stopped (the sponsor may stop this study at any time).
- If you do not later consent to any future changes that may be made to how this study is done.
- If you become pregnant, we will ask you if we may follow you up and record the outcome of your pregnancy, but we will not offer you the anthrax vaccine when you are pregnant.

The sponsor, the study doctor, or the Institutional Review Board (IRB) can also end the research study early. The study doctor will tell you about this and you will have the chance to ask questions, if this were to happen.

THE PUBLIC READINESS AND EMERGENCY PREPAREDNESS (PREP) ACT

No long-term medical care or financial compensation for research-related injuries will be provided by the NIH or the Federal Government. You do not give up any of your legal rights by signing and dating this form.

The study vaccine is covered by the Public Readiness and Emergency Preparedness (PREP) Act which limits your ability to sue if you develop a reaction to the vaccine. A Federal program has been created to help pay for medical care and other expenses related to reactions that are caused by the vaccine. To be eligible for this program, you must file a claim within one year of the vaccination. The program is administrated by the Health Resources and Services Administration. An information sheet describing the PREP Act and the Countermeasure Injury Compensation Program (CICP), as well as a factsheet on how to file a Request for Benefits Package to the CICP Summary, will be provided to you.

UNIVERSITY STATEMENT CONCERNING RESEARCH RISKS

The University of Maryland, Baltimore (UMB) is committed to providing participants in its research the rights due them under state and federal law. You give up none of your legal rights by signing this consent form or by participating in the research project. This research has been reviewed and approved by the Institutional Review Board (IRB). Please call the Institutional Review Board (IRB) if you have questions about your rights as a research subject.

Participating in research may result in an injury, as explained above. If you suffer an injury directly related to your participation in this project, UMB and/or one of its affiliated institutions or health care groups will help you obtain medical treatment for the specific injury and provide referrals to other health care facilities, as appropriate. UMB and/or its affiliated institutions or health care groups will not provide you with financial compensation or reimbursement for the cost of care provided to treat a research-related injury or for other expenses arising from a research-related injury. The institution or group providing medical treatment will charge your insurance carrier, you, or any other party responsible for your treatment costs. If you incur uninsured medical costs, they are your responsibility. The study staff can give you more information about this if you have a study injury.

By signing this Consent Form, you are not giving up any legal rights. If this research project is conducted in a negligent manner and you are injured as a direct result, you may be able to recover the costs of care and other damages from the individuals or organizations responsible for your injury.

If you have questions, concerns, complaints, or believe you have been harmed through participation in this research study as a result of researcher negligence, you can contact members of the IRB or the Human Research Protections Office (HRPO) to ask questions, discuss

problems or concerns, obtain information, or offer input about your rights as a research participant. The contact information for the IRB and the HRPO is:

University of Maryland Baltimore
Human Research Protections Office
620 W. Lexington Street, Second Floor
Baltimore, MD 21201
410-706-5037

Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

If you agree to participate in this study, please sign your name below.

_____
Participant's Printed Name

_____
Participant's Signature

Date:_____

_____
Investigator or Designee Obtaining Consent
Signature

Date:_____ Time:_____

PID:_____

Health Insurance Portability and Accountability Act (HIPAA)
AUTHORIZATION TO OBTAIN, USE AND DISCLOSE PROTECTED HEALTH INFORMATION FOR RESEARCH

Name of Study Participant:_____

Date of Birth: _____ **Medical Record Number:** _____

NAME OF THIS RESEARCH STUDY: A Phase 1, Randomized, Parallel-Group, Double-Blind Trial of AV7909 (Liquid) and Thermostable AV7909 (Lyophilized) in Healthy Adult Volunteers

UMB IRB APPROVAL NUMBER: HP-00087040

RESEARCHER'S NAME: **JAMES D. CAMPBELL, MD, MS**

RESEARCHER'S CONTACT INFORMATION:

Center for Vaccine Development and Global Health
University of Maryland School of Medicine (UMSOM)
685 West Baltimore Street, Room 480
Baltimore, Maryland 21201
Tel: (410) 706-7284; Mobile: (443) 835-8958

This research study will use health information that identifies you. If you agree to participate, this researcher will use just the health information listed below.

THE SPECIFIC HEALTH INFORMATION TO BE USED OR SHARED:

- Health-related information you have been asked to provide for the study during interviews and via questionnaires
- Results of medical tests, laboratory tests, research procedures carried out for the purpose of the study
- Medical records from another health care facility that may be needed to determine whether a side effect or other problem is related to the study
- Billing and payment information and the medical information required to justify it.

Federal laws require this researcher to protect the privacy of this health information. He will share it only with the people and groups described here.

PEOPLE AND ORGANIZATIONS WHO WILL USE OR SHARE THIS INFORMATION:

- Dr. James Campbell and his research team, including the nursing, laboratory, and regulatory affairs staff at the Center for Vaccine Development and Global Health (CVD), and contracted affiliates of the CVD such as the Garcia Clinical Laboratory.
- The sponsor of the study, National Institute of Allergy and Infectious Diseases of the National Institutes of Health or its agents, such as data repositories or contract research organizations
- Federal and state agencies that have authority over the research, including the Department of Health and Human Services, the Food and Drug Administration, the National Institutes of Health and the Office of Human Research Protections

- University of Maryland Medical System (UMMS)
- Clinical staff not involved in the study who may become involved in your care if it is potentially relevant to treatment
- Organizations that will coordinate health care billing or compliance such as offices within UMSOM; the University of Maryland, Baltimore (UMB); University of Maryland Faculty Physicians, Inc. (FPI) and the faculty practices of the UMB; and University of Maryland Medical System (UMMS)
- Your health insurer to pay for covered treatments

THIS AUTHORIZATION WILL NOT EXPIRE. BUT YOU CAN REVOKE IT AT ANY TIME.
To revoke this Authorization, send a letter to this researcher stating your decision. He will stop collecting health information about you. This researcher might not allow you to continue in this study. He can use or share health information already gathered.

ADDITIONAL INFORMATION:
- You can refuse to sign this form. If you do not sign it, you cannot participate in this study. This will not affect the care you receive at:
    - University of Maryland Faculty Physicians, Inc. (FPI)
    - University of Maryland Medical System (UMMS)
- It will not cause any loss of benefits to which you are otherwise entitled.
- Sometimes, government agencies such as the Food and Drug Administration or the Department of Social Services request copies of health information. The law may require this researcher, the UMSOM, FPI, or UMMS to give it to them.
- This researcher will take reasonable steps to protect your health information. However, federal protection laws may not apply to people or groups outside the UMSOM, UMB, FPI, or UMMS.
- Except for certain special cases, you have the right to a copy of your health information created during this research study. You may have to wait until the study ends. Ask this research how to get a copy of this information from him/her.

My signature indicates that I authorize the use and sharing of my protected health information for the purposes described above. I also permit my doctors and other health care providers to share my protected health information with this researcher for the purposes described above.

Signature: _____Date: _____

Name (printed) _____

Privacy Questions? Call the UMSOM Privacy Official (410-706-0337) with questions about your rights and protections under privacy rules.

Other Questions? Call the researcher named on this form with any other questions.