Informed Consent Form to Take Part in a Clinical Research Study and Authorization to Disclose Health Information	
Study No. / Title:	EBS.AVA.210 / A Phase 2 Drug-Vaccine Interaction Study to Examine Whether Co-administering AV7909 with Ciprofloxacin or Doxycycline Affects Antibiotic Pharmacokinetics or AV7909 Immunogenicity in Healthy Adults
Study Sponsor:	[redacted]
Site Code:	*<Site Code>*
Principal Investigator:	*<Name>*
Site Address:	*<Address>*
Site Telephone:	*<Phone Number>*

You are being asked to take part in a research study. This Informed Consent Form will tell you about:

- The study and what will happen to you as a participant in the study,
- Possible benefits and risks to you if you choose to take part in the study, and
- Your rights as a participant in the study.

Before you agree to take part in the study, you must read, sign, and date this Informed Consent Form. Please read this form and ask as many questions as you need to be sure that you understand what will happen to you in this study. You should only sign and date this form if the study doctor or study staff have answered all your questions and you decide that you want to be part of this study. The study doctor or a member of the study staff will also sign and date this form. You will be given a copy of this signed and dated Informed Consent Form to keep. It is your choice to take part in this study because joining this study is voluntary. There will be no penalty or changes to your medical treatment if you choose not to take part in this study. Signature and date on this form does not mean you will automatically get in the study. Only after you sign and date this form can the study doctor do any tests to see if you meet all the requirements to join the study.

Participating in a research study is not the same as getting regular medical care. The purpose of regular medical care is to improve or monitor your health. The purpose of a research study is to gather information about how safe the study drug is and how well it works. Being in this study does not replace your regular medical care.

INFORMATION ABOUT THIS RESEARCH STUDY

1 INTRODUCTION

This study is being paid for by the Biomedical Advanced Research and Development Authority (BARDA; part of the United States [U.S.] Department of Health & Human Services) together with a company called Emergent Product Development Gaithersburg, Inc, hereafter called "Emergent." Emergent is the sponsor of this study and makes the study drug being tested, a study vaccine called AV7909. The AV7909 study vaccine is being developed to see if it can prevent anthrax disease. This study is being conducted to determine whether giving the vaccine interferes with how your body processes the antibiotics that are also recommended to prevent anthrax disease in exposed individuals. No one will be exposed to anthrax in this study.

1.1 What are Vaccines?

Vaccines are given to people to prevent them from getting a specific infection or disease by helping their immune system to fight off the bacteria or virus that causes the infection or disease. The immune system is the body's natural defense against germs and other invaders. Through a series of steps called the immune response, the immune system attacks germs that invade your body and cause disease. Vaccines help the immune system make special proteins called antibodies that can help fight an infection at a later point in time. This may result in a milder infection (you get better sooner) or even keep you from getting sick at all after being exposed to the bacteria or virus at a later point in time.

1.2 What is Anthrax Disease?

Anthrax is a disease that can affect both animals and humans. It is caused by the bacteria called *Bacillus anthracis* (also written as *B. anthracis*). Though very rare, people can get anthrax from direct skin contact from infected animals, wool, meat, or hides; breathing or ingesting the bacteria, or by injection (through a shot). It was also used in the US nearly 20 years ago as a bioterrorist agent.

Anthrax is usually a skin disease that results in open sores on the skin often associated with fever and tiredness. Two out of ten people who catch the skin type of anthrax die if they do not receive treatment. When *B. anthracis* is breathed in, the resulting disease (inhalation anthrax) is much more serious than the skin disease. The first symptoms may include a sore throat, mild fever and muscle aches. Within several days, these symptoms are followed by severe breathing problems, shock, and often meningitis (inflammation of the membrane that covers the brain and spinal cord). Once symptoms appear, most people who catch this form of anthrax die even if they are treated with antibiotics.

During the 2001 US terrorist attack, which spread anthrax through the mail system, 22 people were diagnosed with anthrax disease; 11 with the skin type and 11 with inhalation type. All were treated with antibiotics. There were five deaths, all of which occurred in those with inhalation anthrax.

1.3 What is AV7909 Study Vaccine?

AV7909 study vaccine is made up of the same drug substance found in an approved vaccine called BioThrax®. BioThrax vaccine, which is also made by Emergent, is a Food and Drug Administration (FDA)-approved vaccine used to prevent anthrax infection in adults who are at high risk of getting anthrax (such as certain people in the military). BioThrax vaccine helps people make antibodies against the bacteria that cause anthrax. AV7909 study vaccine also contains another substance called CPG 7909 (not found in BioThrax) that works by boosting the vaccine's effects to increase the body's immune response. Being a combination of BioThrax plus CPG 7909, it is believed that AV7909 study vaccine can work just as well if not better than BioThrax vaccine to help the body make antibodies against the bacteria that cause anthrax.

The use of AV7909 study vaccine is "investigational," meaning the study vaccine has not been approved for sale in the U.S. by the Food and Drug Administration (FDA). The study doctor is being paid to conduct this study.

1.4 What is Ciprofloxacin and Doxycycline?

Ciprofloxacin and doxycycline are both antibiotics, which are oral medicines that fight bacteria in the body. These medicines have been FDA-approved for treating different types of infections, including the treatment of post-exposure inhalation anthrax. For the purposes of this study, the ciprofloxacin will be provided as tablets at a strength of 500 mg, taken twice per day, every 12 hours. For the purposes of this study, doxycycline will be provided as tablets at a strength of 100 mg, taken twice per day, every 12 hours.

1.5 What is the Purpose of this Study?

The purpose of this study is to understand whether vaccination with AV7909 affects the levels of ciprofloxacin or doxycycline (antibiotics) in the blood when the vaccine and antibiotics are given together. Similarly, researchers want to know if taking these antibiotics will affect the immune response that your body makes when given the AV7909 vaccine.

The current treatment for suspected exposure to anthrax is 60 days with an approved antibiotic such as ciprofloxacin or doxycycline and 3 shots with the currently approved vaccine, BioThrax. An earlier study showed that the two treatments (BioThrax vaccine plus ciprofloxacin antibiotic) when given together were as safe as when given separately. This earlier study also showed that both the ciprofloxacin levels in the blood and the immune response to BioThrax were essentially the same when the two treatments were given together as when they were given separately. In the currently planned study, which is the subject of this consent form, researchers want to find out if the same results can be obtained with the AV7909 study vaccine in combination with ciprofloxacin or doxycycline. They will test the AV7909 study vaccine with and without one of the two antibiotics to

determine whether either the levels of antibiotic in the blood or the body's immune response to the vaccine are affected when the vaccine and an antibiotic are given together. You will NOT come into contact with the anthrax bacteria as part of this research study; therefore, you will NOT be at risk of anthrax infection.

1.6 What is this Study About?

Approximately two hundred and ten (210) healthy participants who are between 18 and 45 years old will be enrolled in this study at up to 4 medical clinics across the U.S. All eligible participants (210) will receive the AV7909 study vaccine (investigational vaccine). All eligible participants will receive the AV7909 study drug (investigational vaccine) and may receive ciprofloxacin or doxycycline study drug (investigational antibiotics). Approximately 70 subjects will be assigned to each study drug (AV7909, ciprofloxacin or doxycycline). No participants will receive both ciprofloxacin and doxycycline.

This study is "open-label," which means that you and the study doctor will know what treatment you are receiving (AV7909 study vaccine, or AV7909 and ciprofloxacin, or AV7909 and doxycycline). The AV7909 study vaccine is given as two shots separated by two weeks.

Two shots of AV7909, in combination with antibiotics will be given on various study days to establish peak antibiotic levels in the blood, to evaluate if there is an effect of the antibiotics on the immune system to the vaccine.

1.7 What are the Risks of Being in this Study?

The main risks in this study are associated with the use of antibiotics, vaccines and general blood collection procedures. With the use of the vaccine the main risks to you, if you choose to participate, are side affects you may experience when a vaccine is given into your muscle such as pain, swelling and redness at the injection site, dizziness, fainting, bruising or infection. A very rare but potential risk when receiving a vaccine can also result in having a serious reaction to the study drug, which can lead to death. The main risks associated with the use of ciprofloxacin are common side effects such as diarrhea, dizziness, headache, drowsiness, nausea, vomiting and an upset stomach, however, ciprofloxacin carries rare potential risks such as tendon rupture (cords), increased or worsening of rupture tears in the aorta blood vessel, damage to nerves of your body and uncontrolled movements of the body (seizures). The most common side effects that you may experience with the use of doxycycline antibiotics may include problems with your liver, watery or bloody stools and excessive sunlight sensitivity such as sunburns and rashes. Lastly, during the process of collecting your blood for study requirements, you may feel faint, experience bruising and/or swelling at the site where blood was drawn. Please see section 5, risks and benefits for a detailed list of potential risks.

1.8 Are there any benefits to being in the study?

This study is for research purposes only. There is no direct benefit to you from your participation in the study. Information from this study might help researchers develop a new vaccine to prevent anthrax, new tests, or other medications that could help others in the future.

2 ELIGIBILITY

2.1 Who can participate in the study?

People who served in the U.S. military after 1990 cannot participate in this study because they may have already received the BioThrax vaccine. In addition, if you plan to enlist in the military from Screening through the Final Study Contact, approximately 14.5 months, you cannot participate in this study. If you are considering enlisting in the military, please tell the study doctor.

To be in this study, you must additionally meet the following requirements:

- Read, sign and date the study Informed Consent Form
- Be 18 to 45 years old at the time of this consent and considered to be in good health, with no signs of illness (within the past five years), drug or alcohol abuse
- Have a Body Mass Index (BMI) less than or equal to 35.0 kg/m^2 (the study doctor will measure your height and weight to determine your BMI)
- Be able to have blood drawn without too much difficulty
- For women able to have children:
  - Have negative pregnancy tests before enrolling in the study and before getting your first study shot
  - Not be currently breast-feeding
  - Have no intention to become pregnant at any time while participating in the study
  - Must use an acceptable form of birth control to prevent pregnancy at least one (1) month prior to Study Day 1 through Month 12

  An acceptable form of birth control for women is any of the following:

  1) No sexual intercourse;

  2) Previous bilateral tubal ligation procedure (both tubes tied);

  3) Monogamous relationship with a vasectomized partner (vasectomy performed at least six months ago); or

  4) Any of these forms of birth control: pills, intrauterine device/system (IUD/S), implantable or injectable contraceptive (for example, Norplant® or Depo-Provera®), removable device (for example, NuvaRing® or Evra® patch), or double-barrier method (condom with spermicide, diaphragm with spermicide).

  The study doctor or study staff will ask you about your preferred birth control method along with the use of a second method of birth control and review it with you at every study visit or phone call.

- Have no plans to receive a vaccine shot (for example, flu vaccine, tetanus vaccine) from seven days before your first scheduled study shot through two (2) weeks after receiving your final study shot
- Take no medications before or during the study that your study doctor determines could affect your body's immune response
- Have not previously had anthrax disease, or been exposed to anthrax, or previously received a shot of anthrax vaccine
- Has not given blood within one month prior to signing the study informed consent form and does not plan to give blood at any time during the study until after the final safety phone contact
- Have not previously had a severe allergic reaction to a vaccine, and have no known allergy to synthetic oligonucleotides, aluminum, formaldehyde, benzethonium chloride (also called phemerol), or latex
- Have no plan for elective surgery at any time while participating in study
- Have no tattoo/scar/birthmark or any other skin condition affecting the upper arm areas where the study shot will be given
- Not be participating in any other research study in which you receive an investigational product (meaning it is not FDA-approved) at the same time as this study

Tell the study doctor if you don't meet one or more of these study requirements. Before you can be enrolled in the study, the study doctor will perform a physical examination, run some laboratory tests, and ask you some questions about your health and medical history (refer to Section 4 of this Informed Consent Form). Based on the results, the study doctor will decide if you qualify for participation in the study.

3 PARTICIPANT RESPONSIBILITIES

3.1 What will happen while on the study?

You will be expected to attend all planned visits and accept all study-related phone calls as listed in the study treatment schedule described in Section 4 of this Informed Consent Form. You must additionally:

- Show up on time for all scheduled study visits, which may include overnight visits depending on the study group you are assigned to. Alert the study doctor/study staff as soon as possible if you must reschedule a visit for any reason.
- Allow the study doctor/study staff to draw blood and take urine samples on the study days listed in this Informed Consent Form.
- Tell the study doctor/study staff about all past and current health concerns/conditions for which you have received medical care or treatment.

- Tell the study doctor/study staff about any past [within thirty (30) days before your first study visit] or new medications you are taking.
- Tell the study doctor/study staff if you do not feel well or notice unusual changes in your mind or body while in the study.
- Allow the study staff to give you a study shot in one arm on Study Day 8 and in the opposite arm on Study Day 23.
- When at home, complete an electronic diary (e-diary) once a day for at least one week after each study shot to describe your study shot-related symptoms. If you are selected to Group 1 and 2, you will also enter the times you take your antibiotic and your temperature once a day. If you don't have a personal smartphone, tablet, or computer with internet access to do this, the study staff will loan you a mobile device, to be used only for purposes of this study and to be returned to study staff when directed.
- If you are a woman able to have children, continuously use an acceptable method of birth control (refer to Section 2) for the duration of the study and let the study doctor/staff know immediately if you know or think you may be pregnant or when there has been a change in your method of birth control.
- Agree not to receive any commercially available shot such as a flu shot, until at least two (2) weeks after the last study shot.
- Agree to lifestyle and dietary restrictions such as avoiding dairy products at certain times, limited caffeine use, avoiding the sun, and strenuous physical activity.
- Agree not to take certain medications because these medications may hide the side effects of the study shot or interact with the antibiotics. This includes any aspirin- or Tylenol-containing medications and any non-steroidal anti-inflammatory medications such as ibuprofen, naproxen, diclofenac and celecoxib.
- Respond to the study doctor/study staff when they call you 3, 6, 9, and 12 months after the last planned study shot to find out about any changes to your general health since the last study visit or phone call.
- Agree to come to the study doctor's office when requested by the study doctor or study staff outside of a scheduled study visit or phone call to undergo a medical evaluation and blood/urine tests if necessary.

4 STUDY TREATMENT SCHEDULE

If the study doctor says you can be in the study and you agree to participate, your time in the study will last about fourteen and a half months. Depending on the study group you are chosen to participate in, you will have to come to the study doctor's office at a minimum of six visits but no more than nineteen visits, during the first one and a half month of the study. The study staff will tell you when to come in for your study visits and the amount of time you are expected to stay during your visit. At the end of all the study visits, you will receive phone calls from the study doctor/staff spaced several months apart over 12 months, so they can check up on your health and well-being.

See below for more information about which tests and procedures will be done at each study visit or phone call and be sure to ask the study doctor or study staff if you have any questions.

4.1 Visit 1: Screening Visit (Day -28 to -2)

If you agree to participate in the study, you will sign and date this Informed Consent Form before any study procedures are done.

First, a screening visit will be conducted. During this first study visit, the study doctor and/or study staff will collect some information about you and do some tests to find out if you can be in the study. They will:

- Assign you a subject code number that will identify you for the study purposes so that information collected about you is kept private (also see Section 7).
- Ask questions about you (age, sex, race and ethnicity) and your medical history, including medicines you take and shots you have had. You will need to tell study staff if you take any over-the-counter or prescription medicines and any vitamins or herbs.
- Review the conditions for being in the study with you.
- Perform a complete physical exam, including an electrocardiogram (ECG) to check the health of your heart.
- Measure your height, weight, and vital signs (blood pressure, temperature, heart and breathing rates).
- Draw blood for some tests (about 3 teaspoons of blood will be collected). You will be tested for signs of illness or infection, including for HIV (human immunodeficiency virus), hepatitis B and hepatitis C. If you test positive for HIV, hepatitis B, hepatitis C or certain other illnesses or infections, you cannot be in the study. Depending on state law, you may have to sign and date a separate Informed Consent Form before this testing can start. The study doctor or study staff will tell you if the test results are positive. If required by state law, the study doctor or study staff may report a positive test result to the local health department.
- Collect a urine sample to test for signs of illness or infection and for illegal drugs. If your urine test shows illness, infection or illegal drugs, you will be told the results and you will not qualify to be in the study.
- If you are a woman who is not surgically sterile, draw blood for a pregnancy test (less than a teaspoon of blood will be collected). The study doctor or study staff will tell you if the pregnancy test results are positive; results of the pregnancy testing must be negative for you to be in the study. Pregnant women and women who are not using two forms of acceptable birth control cannot be in the study. If you have not had a period for more than twelve (12) months in a row, blood will be drawn and tested to verify if you are postmenopausal. Once you are confirmed to be postmenopausal, you will not need to have any more pregnancy tests for the rest of the study.

If you meet the conditions to be in the study, the study doctor/staff will tell you when to come back for your second visit.

Females who are of child-bearing potential must agree to use a form of birth control that the study doctor considers "adequate" and agree to use it thirty (30) days before receiving the study drug (vaccine or antibiotic or both) until the study is complete (Study Days 374 to 402). If you are assigned to Groups 1 or 2 and receive ciprofloxacin and/or doxycycline, the antibiotics can decrease the effectiveness of birth control pills or implantable or injectable contraceptives. Therefore, you will be required to add a second form of birth control:

- add a double-barrier method (condoms in combination with contraceptive jelly, cream or foam or a diaphragm in combination with contraceptive jelly) or
- use an intrauterine device (IUD), or
- practice abstinence

4.2 Visit 2: Randomization Visit

At your second visit, the study doctor will review with you the conditions for being in the study. Additionally, the following procedures will be done:

- Perform a physical exam if needed.
- Measure your vital signs (blood pressure, temperature, heart and breathing rates).
- Review your medication(s) and update your medical history, including any side effects you may have experienced.
- If you are a woman able to have children, a urine pregnancy test will be performed. If the test is positive, a blood test will be required to confirm the result.
- If you are a woman able to have children, study staff will confirm that you are on birth control and decide if the type you are taking is acceptable.
- Review your health concern/condition.

If you meet all requirements, the study doctor will assign you to one of the three study groups on a random basis, that is you could just as easily be assigned to Group 1 or to Group 2 or Group 3, all of which are described below:

- Group 1: AV7909 vaccine and ciprofloxacin antibiotic (with or without blood draw testing for ciprofloxacin blood levels)
- Group 2: AV7909 vaccine and doxycycline antibiotic (with or without blood draw testing for doxycycline blood levels)
- Group 3: AV7909 vaccine; no antibiotics given

If you are in Group 1 or Group 2, you may be randomly selected as part of a sub group for blood draw testing of ciprofloxacin blood levels (Group 1A) or doxycycline levels (Group 2A). If you are not selected as part of either sub group, you will be part of Group 1B or 2B where you do not participate in the blood draw testing for ciprofloxacin or doxycycline blood levels.

Upon your Group assignment, the following activities will occur:

- Blood will be drawn and tested for antibodies.
- You will be instructed when to return to the clinic for your overnight visit OR be provided your antibiotic and medication schedule, based on your Group assignment.
- You will be told by the study staff when to return to clinic for your shot.
- Study staff will talk to you about your diet and daily routine limitations to follow when taking antibiotics.
- You will be given instructions on how to complete an electronic diary on the internet.

Your chances of being assigned to one of the three AV7909 study groups will be equal, that is 1:1:1.

4.3 Vaccination (AV7909 Shot) Visits: Study Days 8 and 23

Regardless of which group you are in (Group 1, Group 2 or Group 3), you will receive two study shots in the upper arm during the study, each shot will be given two weeks apart. The first study shot will be given during your Study Day 8 visit (also called Vaccination # 1). The second study shot will be given during your Study Day 23 visit, about two (2) weeks after the first study shot (called Vaccination #2). At the Study Day 23 visit, you will get the shot in the opposite arm from the one used the last time you got a shot.

During your visit at Study Days 8 and 23, the study doctor or study staff will perform the following procedures:

- Review the conditions for being able to receive a study shot on that day (for example, you can't have a fever or be pregnant).
- Collect urine for a pregnancy test and confirm your method of birth control, if you are a woman who could become pregnant. If this test is positive, blood will be drawn for a more accurate pregnancy test. You will be told the results of this test.
- Review how you have been feeling since your last visit.
- May perform a physical exam related to your symptoms, if you have any, and measure your vital signs (blood pressure, temperature, heart and breathing rates).
- Review any medicines you have taken since the last visit.

If you still qualify for receiving the study shot after all of these tests and examinations, you will be given a study shot.

After the study shot:

- The study doctor and study staff will check up on you in the study clinic for at least 30 minutes after the study shot to see if you have any reaction to it and also measure your vital signs about 30 minutes after the study shot.
- On Study Days 8 and 23, you will be given instructions on how to complete an e-diary on the internet. The e-diary is used to record some types of side effects related to the study shot you

may have over the next seven days and any medications you are taking. You will complete an e-diary once a day for seven days after each study shot. If you still have side effects related to the study shot after seven days, you will continue to complete the e-diary until you've had no more symptoms for at least two days in a row. To help you complete the e-diary, you will be given a thermometer to record your temperature. You will also be given a measuring tool and shown how to measure the size of any redness or swelling on your arm where you recently received your study shot. If you need a mobile device in order to access the e-diary, one will be loaned to you by the study staff to be used for the purposes of this study.

- If you previously completed an e-diary, the study doctor or study staff will review it with you.
- The next study visit will be scheduled.

4.4 Group 1 and 2 Clinic Visits:

If you are assigned to Group 1 (A or B) or 2 (A or B), you will be required to take your antibiotic on certain study days, whether you are at the clinic or at home. For those in Group 1 (A or B), ciprofloxacin will be provided as tablets at a strength of 500 mg and will be taken every 12 hours in 3 courses on Study Days 4-9, 22-24 and 31-37. For those in Group 2 (A or B), doxycycline will be provided as tablets at a strength of 100 mg and will be taken every 12 hours on Study Days 2-9, 22-24 and 32-38.

For Groups 1 and 2, you will be given instructions on how to complete an electronic diary when you receive your first antibiotic course. For those in Group 1 (A or B) , you will receive instruction on Study Day 4 and those in Group 2 (A or B) will receive instruction on Study Day 2.

In addition to items described in sections 4.2, 4.3 and 4.5, participants in Group 1 (A or B) and 2 (A or B) will be required to attend the following study visits:

- *Group 1A* will have four overnight stays on Study Days 3, 7, 30, and 34. Starting in the mornings after your overnight stays (Study Days 4, 8, 31 and 35), you will have approximately fifteen (15) blood samples taken to measure your ciprofloxacin levels over a period of twelve (12) hours. During your clinic visits on Study Days 4, 5, 6, 7, 8, 23, 31, 32, 33, 34 and 35, you will receive your antibiotic. On Study Days 9, 22, 24 and 36 you will be taking your antibiotic at home. On Study Day 37 you will take your morning antibiotic at home and return to the clinic for a blood draw to test for antibodies to the vaccine. During this visit, you will be required to return any leftover antibiotic medication to the clinic staff.
- *Group 1B* will be instructed to take your ciprofloxacin at home on Study Days 4, 5, 6, 7, 8, 9, 22, 23, 24, 31, 32, 33, 34, 35, 36 and 37. You will come to the study clinic on the morning of Study Days 8 and 23 to receive your shot and morning antibiotic. On Study Day 37 you will take your morning antibiotic at home and return to the clinic for a blood draw to test for antibodies to the vaccine. During this visit, you will be required to return any leftover antibiotic medication to the clinic staff.

- *Group 2A* will have four overnight stays on Study Days 1, 7, 31 and 37. Starting in the mornings after your overnight stays (Study Days 2, 8, 32 and 38), you will have approximately fifteen (15) blood samples taken to measure your doxycycline levels over a period of twelve (12) hours. During your clinic visits on Study Days 2, 3, 4, 5, 6, 7, 8, 23, 32, 33, 34, 35, 36 and 37, you will receive your antibiotic. On Study Days 9, 22 and 24 you will be taking your antibiotic at home. On Study Day 38 you will take your morning antibiotic in the clinic and have blood drawn to test for antibodies to the vaccine. During this visit, you will be required to return any leftover antibiotic medication to the clinic staff.
- *Group 2B* will be instructed to take your doxycycline at home on Study Days 2, 3, 4, 5, 6, 7, 8, 9, 22, 23, 24, 31, 32, 33, 34 , 35 , 36 , 37 and 38. You will return to the study clinic on the morning of Study Days 8 and 23 to receive your shot and morning antibiotic. On Study Day 37 you will take your morning antibiotic at home and have blood drawn to test for antibodies to the vaccine. During this visit, you will be required to return any leftover antibiotic medication to the clinic staff.

4.5 Group 3 Clinic Visits

In addition to items described in sections 4.2 and 4.3, participants in Group 3 will return to the clinic on Day 37 for a blood draw to test for antibodies to the vaccine.

4.6 Last Clinic Visit (Study Day 51)

Regardless of which group you are in (Group 1, Group 2 or Group 3) at the last study visit (Study Day 50, 51 or 52), you will return to the clinic and the study doctor or study staff will do some or all of the following:

- Review how you have been feeling since the previous visit. Any side effects will be recorded by the study doctor.
- Perform a complete physical exam and measure your vital signs (blood pressure, temperature, heart and breathing rates).
- Collect a urine sample to test for signs of illness or infection.
- Draw blood [about three and a half (3½) teaspoons of blood will be collected] for laboratory testing. Your blood will be tested for signs of illness or infection. Your blood will also be checked for substances made by your immune system called antibodies.
- If you are a woman able to have children, a urine pregnancy test will be performed. If the test is positive, a blood test will be required to confirm the result.
- Review any medicines you have taken since the last visit.
- Review your diary entries and collect the mobile device provided to you for e-diary entry (if not already returned to the study staff).
- Collect any remaining antibiotic medication for Groups 1 and 2 if needed.

[redacted]

4.7 Early Withdrawal Visit

You can withdraw from the study at any time without penalty. The study doctor may also decide you can't receive any more study shots, antibiotics or both, if applicable (for example, if you have an allergic reaction to the study shot, or you have a fever on a day when you were supposed to receive a study shot, or you become pregnant). Once you've received at least one study shot and either you or the study doctor decides you can't receive any more study shots, you will continue with your scheduled study visits and study follow-up phone calls. You will have the tests and procedures described in Section 4. However, you won't have any more study shots, antibiotics or both, if applicable and may not have any more blood samples collected to test the amount of antibodies that could protect you against anthrax. This will allow the study doctor and study staff to check up on your health and well-being for the entire study length.

If, however, you choose not to participate in the study anymore and have not yet reached your last study visit (Study Day 51), the study doctor/study staff will ask you to come to the doctor's office for an Early Withdrawal Visit to check your health one last time.

At the Early Withdrawal Visit, the study doctor or study staff will do some or all of the following:

- Review how you have been feeling since the previous visit. Any side effects will be recorded by the study doctor.
- Perform a complete physical exam and measure your vital signs (blood pressure, temperature, heart and breathing rates).
- Review any medicines you have taken since the last visit.
- In women who are able to have children, draw blood (less than a teaspoon) for a pregnancy test and confirm your method of birth control. You will be told the results of this test.
- Draw blood (about two (2) teaspoons of blood will be collected) and collect urine for laboratory testing. Your blood and urine will be tested for signs of illness or infection.
- If you withdraw close to study Day 37, you may be asked for blood sample to check for substances made by your immune system called antibodies [about one and a half (1½) teaspoons of blood will be collected].
- Review e-diary entries.
- Collect and count left-over antibiotic supply for Groups 1 and 2 to document medication compliance.
- Collect the mobile device provided to you for e-diary entry (if not already returned to the study staff).

4.8 Phone Calls at Study Days 100-128, 191-219, 282-310 and 374-402 (Months 3, 6, 9, and 12)

Regardless of what group you are in (Group 1, Group 2 or Group 3), you will receive phone calls from the study doctor or study staff at Study Days 100-128, 191-219, 282-310 and 374-402, which will occur, at 3 months, 6 months, 9 months, and 12 months respectively, after you receive your last

scheduled study shot. You will also be asked about your health since your last visit or the last time you received a phone call. If you are a woman who could have children, you will be asked to confirm your method of birth control. You may also be asked about any medications you have taken. The study doctor may ask you more detailed questions about any side effects and possibly refer you to a specialist if more tests are needed. The study doctor may ask you to come to the study doctor's office to collect blood in order to test it for antibodies that may indicate an autoimmune response.

4.9 What will happen to any samples you give?

Samples collected for safety:

Blood and urine samples will be collected from you for safety testing. These samples will be kept until testing is completed or until the sample is no longer usable. The samples will then be destroyed. These samples will be labeled with your subject code number and will not contain your name or any other personal information.

Samples collected for future use:

If you agree, samples of your blood will be stored for possible future re-testing as part of continued research on the anthrax vaccine. Your blood samples will not be tested for gene sequencing (structure). Any blood samples left over from the immune response testing will be stored frozen at a long-term storage facility. You will not be asked to provide additional blood samples.

Samples may be stored until at least 2 years after the last marketing application is approved (AV7909 is not approved for sale), or is no longer pending, or the investigation of AV7909 is discontinued.

These samples will only be used for research purposes and will not be sold or used directly for the production of commercial products.

Allowing retention of your leftover blood samples for future research is optional. You will be asked to agree or decline to the retention of your leftover blood samples at the end of this form.

Identifiers will be removed from your private information (personal and health information collected as part of this study) and any biospecimens (blood samples). These samples will be labeled with your subject code number and will not contain your name or any other personal information. After the information or biospecimens can no longer be readily identified as yours, it may be used for future research studies or sent to another investigator for future research studies. You will not be asked to provide additional informed consent for such use.

Medical research from your subject coded blood samples, may result in new products or discoveries. These may have value to others, but you will not share in any financial or other benefits from the use of your blood samples.

You will not be informed if clinically relevant information (information that can be used to support the health care of people) is discovered during research using your samples.

5 RISKS AND BENEFITS

5.1 What are the Risks of Being in this Study?

All medicines may cause side effects. There may be side effects of the AV7909 vaccine or ciprofloxacin or doxycycline that are not yet known. AV7909 has been previously studied in people. AV7909 has already been given to about 241 people in 3 completed studies.

The known side effects for the vaccine and antibiotics in this study are listed below. By agreeing to take part in this study, you should know that you might experience any of the problems listed below or other side effects that are not known yet.

5.2 What are the possible side effects with AV7909 Vaccine?

The potential side effects listed below, whether related or not to AV7909 were reported during 3 completed clinical studies. These potential side effects may include but are not limited to:

- Reactions on your upper arm where you got the study shot, such as swelling, tenderness, redness, warmth, itching, bruising, bleeding, darker skin color, a hardened bump or lump, rash, limited arm movement, pain, burning sensation, or numbness/tingling
- Feeling very tired all over
- Headache, migraine
- Flu-like symptoms such as fever, chills, and muscle aches
- Decrease or increase in cell blood numbers, such as in the number of white blood cells
- Cold with stuffy nose
- Rapid or fast breathing
- Nausea
- Diarrhea
- Excess gassiness or flatulence
- Toothache
- Vomiting
- Flushing
- Night sweats
- Cough
- Nasal congestion or sore throat
- Upper respiratory tract infection
- Urinary tract infection
- Vaginal infection

- Increased level in liver function tests
- Changes in blood pressure
- Decreased appetite
- High or low blood sugar levels
- High or low potassium levels
- High or low magnesium blood levels
- Difficulty sleeping
- Blood, protein, or white blood cells in the urine
- Inflammation of voice box
- Slow or fast heart beat (pulse)
- Decreased hemoglobin (e.g., anemia)
- Increased level of bilirubin in the blood
- Decreased kidney function
- Abnormal size or change in shape or feel of lymph nodes
- Feeling of body temperature change
- Feeling unwell
- Stomach flu
- Hives
- Numbness and tingling
- Pain [e.g., in muscles, joints, jaw, back, neck, chest (non-cardiac), abdomen, ear]
- Skin mole
- Muscle cramps
- Discomfort in the armpit area
- Indigestion

Sometimes people may have allergic reactions to the AV7909 vaccine. If you have a very bad allergic reaction, you could die. Some things you may have during an allergic reaction are:

- A rash
- Having a hard time breathing
- Wheezing
- Sudden drop in blood pressure (making you feel dizzy or lightheaded)
- Swelling around the mouth, throat, or eyes

[redacted]

- Fast pulse
- Sweating
- Nausea and cramps
- Hard or fast heart beat or skipping heart beat(s)

Possible risks associated with getting any shot are:

- Dizziness/fainting
- Pain associated with the needle stick
- Nerve or blood vessel damage
- Infection
- Sterile abscess, which is a sore at the point of injection, can be painful and warm to the touch

You should get medical help and contact the study doctor or study staff if you have any of these or any other side effects during the study. Contact information for the study staff can be found on page one of this Informed Consent Form.

The AV7909 vaccine and ciprofloxacin or doxycycline are not recommended for anyone who previously had a severe allergic reaction. If you have had a bad allergic reaction to a vaccine or antibiotic in the past, please tell the study doctor. If you are allergic to latex, you cannot participate in this study because the lid on the vaccine container contains a dry natural rubber that could cause an allergic reaction. If you are allergic to latex, please tell the study doctor.

One of the possible risks from one of the substances in the AV7909 study vaccine is overstimulation of your body's immune response, which could result in a chronic autoimmune disease. Chronic means a disease that continues for a long time. An autoimmune disease develops when your immune system, which defends your body against disease, decides your healthy cells are foreign. As a result, your immune system attacks healthy cells. Depending on the type, an autoimmune disease can affect one or many different parts of your body. Because of this possible risk, the study doctor and study staff will check up on your medical condition throughout this study up through 12 months after the last scheduled study shot.

During this study you will be observed for any bad or harmful effects. The study doctor will decide if it is safe for you to keep taking part in the study. Tell the study doctor or study staff right away if you have any problems with your health or the way you feel during the study, whether or not you think these problems are related to the study shots.

It is possible that you could have side effects to AV7909 study vaccine, ciprofloxacin or doxycycline antibiotics that nobody knows about yet, which could even include death. If the study doctor learns any new information about AV7909, ciprofloxacin or doxycycline that might change your mind about continuing in the study, the study doctor or study staff will tell you about it in a timely manner.

It is possible that receiving AV7909, ciprofloxacin or doxycycline with your regular medications or supplements may change how AV7909, your regular medications, or your regular supplements work.

It is very important that you tell the study doctor about all medications or supplements you are taking during the study and any changes in your overall health.

5.3 What are the possible side effects with ciprofloxacin?

Ciprofloxacin is an antibiotic medication that has already been approved by the Food and Drug Administration (FDA) and is not investigational as defined in section 1.3. Ciprofloxacin can cause serious side effects which could result in death. The list below includes, some, but not all, of the side effects you may experience when taking ciprofloxacin:

- Increased risk or worsening of ruptures or tears in the main blood vessel of the body: this is a rare but serious side effect that affects the main artery of the body called aorta. These tears can lead to dangerous bleeding or even death.
- Damage of nerves to your body resulting in altered sensations (peripheric neuropathy)
- Central Nervous System side effects: seizures (uncontrolled movement/shaking of the body)
- Peripheral neuropathy (damage to nerves of your body resulting in altered sensations including pain, burning, tingling, numbness and/or weakness)
- Worsening of Myasthenia Gravis (a muscular disease the produces muscular weakness)
- Tendon Rupture (tendons are tough cords of tissue that connect muscles to bones):Symptoms associated with tendon rupture include pain, tears, and inflammation at the tendon sites
- Photosensitivity (excessive skin reactions such as sunburns and rashes when you go into the sunlight)
- Skin rashes
- Allergic reactions, even after a single swallow
- Diarrhea
- Dizziness and lightheadedness
- Nausea
- Liver injury/failure and abnormal liver function (lab values)
- Prolongation of the QT Interval (irregular heartbeats)

5.4 What are the possible side effects with doxycycline?

Doxycycline is an antibiotic medication that has already been approved by the Food and Drug Administration (FDA) and is not investigational as defined in section 1.3. Listed below include, but is not limited to, some of the side effects you may experience when taking doxycycline:

- Serious liver problems
- Diarrhea
- Watery and bloody stools

- Tooth discoloration
- Photosensitivity (excessive reactions such as sunburns and rashes when you go into the sunlight)
- Rash

5.5 What are the Possible Risks to Reproduction or to the Unborn Baby (Fetus or Embryo) or Nursing Infant?

If you are pregnant or nursing a child while receiving AV7909 study vaccine, there may be risks to your unborn baby or nursing child. It is not known what these risks are right now.

AV7909 study vaccine has not been tested in pregnant women or women who are breast-feeding. As a result, pregnant or breast-feeding women are not allowed to join the study. Also, women who want to become pregnant at any time while on the study will not be allowed to join the study. Women who join the study but are able to have children must use an acceptable and adequate form of birth control to prevent pregnancy at least one (1) month prior to Study Day 1 through Month 12 (after the last study phone call). See Section 2 of this Informed Consent Form for what is considered an acceptable form of birth control. Be aware that you can still become pregnant even if you use an acceptable birth control method.

If you join the study and are a woman who could get pregnant: The study doctor will ask about your method of contraception and also give you a pregnancy test before you join the study and during every study visit. If you become pregnant during the study or think you may be pregnant, you must immediately tell the study doctor/ study staff so that the pregnancy can be confirmed with a blood test and the study doctor knows to stop giving you any more study shots and stop antibiotic treatments as well. The study doctor will check up on your health and well-being for the length of the study, and, after the birth, also confirm the health and well-being of your child. If you choose to leave the study early, or even if you complete the study as scheduled but have not yet given birth, the study doctor/staff will contact you at the time of your labor/delivery to check up on your health and also 28 days later to check up on the health of your child.

5.6 Are there any other risks?

Are there any risks from blood collection?

Some people have discomfort or pain when blood is collected. Some people feel faint or pass out during or shortly after blood is drawn. If you feel faint, lie down right away so you don't get hurt from a fall and tell the study personnel right away. There is a risk of infection, bleeding, swelling, and/or bruising at the spot where blood was taken, or a clot may form when blood is collected.

You will give approximately a total of about 13 teaspoons (~64 mL) of blood, or less than 1 cup (~236.5 mL) throughout the duration of the study. For comparison, this is less than half the standard blood donation of about 2 cups (473 mL).

Are there any risks of injury that could result from participating in the study?

All forms of medical health diagnosis and treatment – whether routine or experimental – involve some risk of injury. There may also be risks in this study that we do not know about. Even with all the care that is taken, you may still develop medical complications from being in this study. If during this study you get hurt or sick or have any side effect to the vaccine or study procedure, please contact the study doctor. If such complications happen, the study doctor will help you get the proper medical treatment.

In the event of an injury that occurs to you as a result of receiving AV7909 vaccine, ciprofloxacin or doxycycline or undergoing study procedures, you will receive the necessary medical treatment. In the event that you suffer injury as a direct result of participating in this study, Emergent will cover the costs of reasonably necessary medical treatment not covered by your medical or hospital insurance or by third-party or governmental programs providing such coverage. Emergent or the study doctor will not cover costs for medical care for injuries or illnesses that are not a direct result of study activities. There are no plans to provide other compensation from Emergent or the study doctor.

You are not prevented from seeking to collect compensation for injury related to malpractice, fault, or blame on the part of those involved in the study, including the study clinic or Emergent.

By signing and dating this Informed Consent Form, you do not give up your legal right to look for and receive required medical treatment. You do not give up any rights to seek payment for personal injury by signing and dating this form.

6 ALTERNATIVE COURSES OF TREATMENT AVAILABLE (OR ALTERNATIVES TO BEING IN THE STUDY)

The medication given to you in this study is not intended to treat or prevent anthrax or any disease. The only option available to you is not to be in this study.

7 USE OF STUDY RESULTS AND CONFIDENTIALITY OF MEDICAL RECORDS

Your medical and treatment history will be recorded for study purposes. Any information learned about you in this study will be kept private. The study doctor, study sponsor (Emergent), third parties working on behalf of the study sponsor (including BARDA), the ethics board also known as the Institutional Review Board (IRB), and the proper national and international regulatory authorities such as FDA will be able to see your health records and test results to confirm the study data and the safety of study participants. They may copy information from your health records. Your records will be protected and kept as private as possible under local/national/international regulations. By signing and dating this Informed Consent Form, you are granting direct access to these records and test results. Subject to applicable laws, any report that is written about this study will not reveal your identity. If the results of this study are given to medical journals, your identity will not be revealed.

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.

8 AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

Privacy rights of people participating in clinical research studies are protected under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Your rights as a subject under this act include deciding who has access to your personal health information (called "Protected Health Information").

Protected Health Information is medical information about you that includes your entire historical medical records, all study doctor visits, evaluations, biospecimens (for example, blood samples), laboratory tests, diagnostic tests, procedures, treatments, medications taken, hospitalizations, etc. The study doctor may also get information about your past, present and/or future physical or mental health and/or condition from your primary care doctor. Protected Health Information contains identifiers that can link your medical records specifically to you, such as:

- Your name,
- Your address,
- Date of birth,
- Social security/insurance number,
- Dates and results of various tests and procedures,
- Basic demographic information (such as age, gender, ethnicity/race).

The study information sent to the sponsor and their representative(s) by your study doctor and/or study clinic will not include your name, address or social security/insurance number. As a safety measure to help keep confidentiality, a subject code number will be used to identify you.

The study doctor will keep this personal health information in your study-related medical records (that we will refer to as "your records") during the study and for two (2) years after the last marketing application is approved, is no longer pending, or investigation of AV7909 is discontinued.

By signing and dating this authorization form, you are allowing the study doctor and/or study clinic to have direct access to your Protected Health Information collected in this study, and to receive your Protected Health Information from either your physician or the facilities where you have received health care.

Information collected about you during this study will be used to confirm the safety and effectiveness of AV7909 study vaccine, and the study information may be published in a scientific article. You will not be personally identified in these instances. In addition, the sponsor may re-analyze the results at a later date and combine them with results of other studies.

Your signature and date on this Informed Consent Form authorizes:

- The researchers, study doctors, and/or institution to have access to your Protected Health Information collected as part of this study;
- The study doctor and/or institution to receive your Protected Health Information from your physician and/or facilities where you have received any health care;

- Your Protected Health Information to be shared with other persons or organizations involved in the conduct or oversight of this research study, including but not limited to: U.S. Food and Drug Administration (FDA); Biomedical Advanced Research and Development Authority (BARDA); Centers for Disease Control & Prevention (CDC); the IRB used by your study doctor's office; regulatory agencies in other countries; the sponsor and third parties working on behalf of the sponsor; and the laboratory(ies) handling the lab specimens for this study. The other persons and/or organizations need to see your personal health information, so they can review the data and to confirm the quality of the study conduct and/or the data collected. These other persons and/or organizations may or may not have the same obligations as the study doctor or institution to protect your Protected Health Information.

The IRB used by your study doctor's office may review your Protected Health Information.

Your Protected Health Information will not be used or given to any other person or entity, except as required by law, or for authorized oversight of this research study. Your Protected Health Information will be used for as long as the sponsor reports study information to the FDA or other countries' regulatory agencies.

You may cancel this authorization in writing at any time by contacting the study doctor listed on the first page of this Informed Consent Form. If you cancel the authorization, continued use is permitted for the Protected Health Information obtained before the cancellation, if its use is necessary in completing the research, including samples collected for future research, if you have agreed to the storage of your leftover blood samples.

If you refuse to provide this authorization, you will not be able to participate in the research study. If you cancel the authorization, then you will be withdrawn from the study.

Finally, federal regulations allow you to obtain access to your Protected Health Information collected or used in this study. However, in order to complete the research study, your access to this Protected Health Information may be temporarily suspended while the research study is in progress. When the study is completed, your right of access to this information will be reinstated.

This authorization will expire once there is no longer a need to review and analyze the information related to this study. Your authorization for the use of your Protected Health Information will not expire, but once the study is over there will be no access or link to your Protected Health Information for anything other than this study. In California and any other state that requires an expiration date, the Authorization will expire 50 years after you sign this authorization document.

_____	_____/_____/___	_____:_____
Signature of Participant	YYYY MMM DD	Time (24h clock)

_____
Print Name of Participant Here

[redacted]

9 COSTS AND SUBJECT COMPENSATION

Study shots will be provided by the sponsor. There is no cost to you for any of the study visits or tests.

While you are in the study, you still need to get regular medical care as you normally would seek that care. You (and/or your health care payer) will still have to pay for the costs of your regular medical care that are not a part of this study.

If you are assigned to either Groups 1 or 2, you may receive up to $ _____ if you complete the whole study. If you do not complete the whole study, you may receive $_____ for each visit completed. This includes reimbursement for your time and also covers any reasonable travel expenses that are directly related to the study visits. The study staff can tell you more about when you will get paid.

If you are assigned to Group 3, you may receive up to $ _____ if you complete the whole study. If you do not complete the whole study, you may receive $_____ for each visit completed. This includes reimbursement for your time and also covers any reasonable travel expenses that are directly related to the study visits. The study staff can tell you more about when you will get paid.

10 RIGHT TO ASK QUESTIONS AND/OR WITHDRAW FROM THE STUDY

Your participation in this study is completely voluntary. You may drop out of this study at any time. Your choice to drop out of this study will not in any way affect your medical treatment from your doctor.

Please ask questions about any and every part of this study that you do not understand before you sign and date this Informed Consent Form. If you drop out of the study you cannot re-enter, but this will not affect you in any other way.

If you decide to leave this study after you receive a study shot, antibiotics or both, or are asked to leave by your study doctor once you have already received a study shot, antibiotics or both you will be asked to stay in the study to take part in only the safety tests for all remaining study visits and phone calls, or, if you refuse that, to come back to the study doctor's office one last time for safety tests (see Section 4 of this Informed Consent Form). These safety tests and follow up phone calls are to identify any unexpected side effects. Your study doctor will make sure your regular medicines are working if you were on previous medicines. Your study doctor will record your medical condition at the time you leave the study.

11 NEW INFORMATION

You will be told in a timely manner by your study doctor of any new important information about this study, AV7909 study vaccine, ciprofloxacin and doxycycline, and other therapies that may affect your health, welfare, or willingness to stay in the study. You may be asked to sign and date a new (revised) Informed Consent Form to show that you have been told of this new information. You may contact the study doctor at any time after your participation ends to find out if any new information about this study has become available.

12 STUDY DISCONTINUATION

Your study doctor, the study sponsor (Emergent), or FDA may decide to take you out of the study, without your consent, if it is in your best interest, if the IRB suspends/terminates study approval, if you are unable to meet the requirements of the study, or if the study is cancelled. You may be asked to leave the study if you do not follow study requirements or if the study shows signs of causing medical harm to you. Also, the study sponsor may decide to end the study at any time for any reason.

13 WHOM TO CONTACT ABOUT THIS STUDY

During the study, if you experience any medical problems, whether or not you think they are related to this study, suffer a research-related injury, or have questions, concerns or complaints about the study, please contact the Principal Investigator at the telephone number listed on the first page of this consent document and below. If you seek urgent/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, and/or concerns or complaints regarding this research study, you may contact the IRB below:

Name: _____Telephone: _____

This Informed Consent Form contains important information that will enable you to decide if you want to participate in this study. If you have any questions that are not answered in this form, please ask the research personnel. With your consent, your primary physician will be told of your participation in the study.

STATEMENT OF INFORMED CONSENT

NOTE: This informed consent with the "original" signatures must be retained in the subject's file by the clinical study doctor. A signed and dated copy must be given to the subject for his/her records.

Site Code:_____ Subject Identification Number: _____

Study Number: _____ Name of Investigator: _____

You (the participant) must complete the following:

Please Tick Boxes

1. I confirm that I have read this Informed Consent Form for the above study. ☐
2. I confirm that the study has been explained to my satisfaction and I have had the time and opportunity to ask any questions. I know whom to contact if I think of more questions later. ☐
3. I understand that my participation is voluntary and that I am free to withdraw at any time without giving a reason and without my medical care or legal rights being affected. ☐
4. I understand that sections of my medical notes may be looked at by responsible individuals appointed by the study sponsor (Emergent), ethics boards, such as the IRB, and regulatory authorities such as the FDA where it is relevant to my taking part in the study. I give permission for these individuals to have direct access to my records. ☐
5. By taking part in this study I agree to the transfer of my personal data to Emergent and to regulatory authorities both within and outside the U.S. ☐
6. I have been given the information about the use and disclosure of my protected health information from this research. ☐
7. By signing and dating this authorization form, I have not given up any of my legal rights. ☐
8. I authorize the use and disclosures of my health information for the purposes described above to the parties listed in this Informed Consent Form for this study. ☐
9. I understand and agree to my primary physician being notified of my participation in the study (if applicable). ☐
10. All my questions have been answered. ☐
11. I agree to take part in the above study. ☐

A copy of the signed and dated Informed Consent Form will be given to you to keep.

_____ _____/_____/___ _____:_____
Signature of Participant YYYY MMM DD Time (24h clock)

_____
Print Name of Participant Here

_____
Address of Participant

_____
Telephone No. of Participant

_____
E-mail address of Participant (if applicable)

[redacted]

Retention of blood samples for future use (*choose one*):

I agree to the storage of my leftover blood samples for future re-testing as part of continued research on the AV7909 vaccine. Please note these samples will not be tested for gene sequencing (structure).

YES, I agree to allow my blood samples to be retained for future analysis.	Participant's Signature	Date of signature _____ (YYYY/MMM/DD)
NO, I decline to allow my blood samples to be retained for future analysis.	Participant's Signature	Date of signature _____ (YYYY/MMM/DD)

_____ _____/_____/___ _____:_____
Signature of Witness (if applicable) YYYY MMM DD Time (24h clock)

_____
Print Name of Witness Here

_____ _____/_____/___ _____:_____
Signature Person Explaining Consent YYYY MMM DD Time (24h clock)

_____
Print Name of Person Explaining Consent Here

INVESTIGATOR'S STATEMENT

I, the undersigned, certify that to the best of my knowledge, the individual/participant signing and dating this consent has had the study fully and carefully explained and clearly understands the nature, risks and benefits of participating in this research project.

_____ _____/_____/___ _____:_____
Signature of Investigator YYYY MMM DD Time (24h clock)

_____
Print Name of Investigator Here

Document Approvals
Approved Date: 5/15/2019

Approval Task Verdict: Approve	[redacted] 14-May-2019 20:57:46 GMT+0000
Approval Task Verdict: Approve	[redacted] 14-May-2019 21:27:51 GMT+0000
QA Approval Task Verdict: Approve	[redacted] 15-May-2019 12:51:13 GMT+0000