INFORMED CONSENT FORM
AND
AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

Sponsor / Study Title: **Biomedical Advanced Research and Development Authority (BARDA)/ "A RANDOMIZED, DOUBLE-BLINDED, MULTICENTER STUDY IN HEALTHY ADULTS TO EVALUATE SAFETY AND IMMUNOGENICITY OF AV7909 ADMINISTERED AT TWO DOSE LEVELS ON TWO VACCINATION SCHEDULES, INCLUDING A PRIMARY SERIES AND BOOSTER DOSES"**

Protocol Number: **ABST001**

Principal Investigator: (Study Doctor) [redacted]

Telephone: [redacted]

Address: [redacted]

KEY INFORMATION

You are invited to take part in a research study. This research study is studying AV7009 as a possible prevention for Anthrax. BARDA is sponsoring this research study.

- This study is for research purposes only.
- The reason for your participation in the study is to contribute to research rather than for your own medical treatment.
- As the vaccine is investigational, not all risks and side effects are known. Details on common side effects, the risk of allergic reaction, and risk of immune related diseases can be found in later in the form.
- There is no direct benefit of anthrax vaccination to you in the absence of an anthrax exposure.
- This study will inform preparedness planning for a bioterrorist attack with anthrax. Therefore, this study has potential to benefit society in the future.

You are invited to take part in a research study involving an experimental vaccine, AV7909 Anthrax Vaccine (henceforth AV7909) to prevent Anthrax. There is no chance that you can catch anthrax by joining this study because the study vaccine does not contain any elements of the live Anthrax virus. ***BARDA*** is sponsoring this research study.

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

BACKGROUND AND PURPOSE

This form is being provided to you because you have expressed interest in a clinical trial. Before you decide if you will be in the clinical trial, you should understand why the clinical trial is being done and what you would be expected to do during the clinical trial. Please ask as many questions as you need to before you decide if you want to be in the clinical trial. If you decide to be in the trial, you will be asked to sign this form. You should not sign this form if you have any questions that have not been answered. You will receive a copy of your signed and dated form.

What is the purpose of the study?

The US Department of Health and Human Services (HHS)/Biomedical Advanced Research and Development Authority (BARDA) has been preparing to protect the American population from potential bioterrorist attacks by testing anthrax vaccines to be used if an emergency response is needed in the US. The purpose of this clinical trial is to determine whether Emergent's AV7909 vaccine, is safe and builds immunity. The Anthrax vaccine in this trial is an investigational product called AV7909. Although it is not approved by the U.S. Food and Drug Administration (FDA), it has been used in other clinical trials. The purpose is to evaluate safety and immune response of full and half doses of AV7909 given on 2 primary series vaccination schedules, followed by 6- and 12-month boosters.

Anthrax is an infection caused by the bacteria Bacillus anthracis. These bacteria make spores, an inactive form of the germ covered by a protective shell. The spores can live for years in the soil and can become activated and multiply when they enter the body. Bacillus anthracis can enter the body in different places, such as through the skin, stomach, or lungs. The bacteria produce poisons (toxins) and can cause severe illness and death. Anthrax that is caught by breathing in the spores is the deadliest form of anthrax. Without treatment, only 10-15% of patients survive; with aggressive treatment, about 55% of patients survive. Although anthrax is rare in the United States (US), people who handle animal products and members of the US military are at a greater risk of exposure. In addition, *B. anthracis* is one of the most likely agents to be used in a bioterrorist attack. In 2001, anthrax spores were put in letters mailed through the US postal system resulting in 22 people infected, of which 5 died.

Do I have to take part?
Taking part in this research study is voluntary and entirely up to you. We will describe the study and go through this informed consent form. If you choose to take part, you will need to sign and date the consent form. You will receive a copy of this signed and dated consent form to keep.

If you choose to take part, you can change your mind and withdraw at any time without giving a reason. If you decide not to take part or to leave the study, you will not lose any medical benefits to which you are entitled. The study doctor will explain other treatment options that are available to you.

Please inform the study doctor if you decide to leave the study. To help you leave the study safely, the study doctor may ask you to have more assessments.

How long will I be in the study?
You will be in this study for about 25 months. You will have about 16 regularly scheduled visits to the study site and about 7 phone calls. There may be additional unscheduled visits and phone calls required. You may be asked to attend the research site for extra visits at any time during the study if the study doctor decides that extra assessments are needed for your safety.

How many people will be in the study?
Approximately 220 healthy subjects 18 years of age and older are expected to be enrolled across seven to eight sites in the United States only.

Study vaccine
AV7909 is being developed by Emergent Product Development Gaithersburg Inc. as a drug to protect you from developing anthrax after exposure. The drug substance used to produce AV7909 is made with the same ingredients, in the same concentrations, and using the same manufacturing process as in the approved vaccine, BioThrax. However, AV7909 has an additional component, the CPG 7909 adjuvant, a synthetic molecule called a nucleotide that is intended to increase the immune response in the body to BioThrax. The BioThrax vaccine is approved by the FDA and indicated for active immunization for the prevention of disease caused by *B. anthracis*.

There are 4 treatment groups in this study. No conflicts - Clean ICF uploaded with SS language. Neither you nor your study doctor will know which group of the study you are on, what your vaccination schedule is or whether you are receiving AV7909 or placebo (contains no active study vaccine ingredients, only sodium chloride for injection/saline) at any given point. Your study doctor and study staff will not know your study treatment regimen until all subjects have completed the study. You will be informed of your study treatment after all study information has been reviewed.

WHAT WILL HAPPEN DURING THE STUDY?

Screening:
Before any study-related tests and procedures are performed, you will be asked to read and sign this consent document. The following screening tests and procedures will then be performed to determine if you qualify to take part in this study:

- Screening will last no more than 30 days. If you provide informed consent by signing the consent form, you will have the screening procedures below to see if you are eligible to take part in this study. Several visits to the research site may be needed.
- Once you consent to the study, you will be asked to give information including, but not limited to, your medical history, age, sex, race or ethnic origin, alcohol, or recreational drug use, and if you take any over-the-counter or prescription medicines, vitamins or herbs.
- You must notify the study staff if you are currently participating in other clinical trials or have received another investigational agent within the last 30 days. You should not participate in this clinical trial if you are currently participating in or plan to enroll in another clinical trial.
- The study staff will complete some tests/procedures during a screening visit(s) to see if you can be in the clinical trial. These include:
    - Physical exam including vital signs (for example, blood pressure, temperature, heart and breathing rates, blood oxygen level), height and weight
    - A blood sample (approximately 3½ tablespoons) to check for the following:
        - Complete blood count with differential
        - Comprehensive metabolic panel
        - Viral Screening for HIV, Hepatitis B and C; The study doctor may be required by law to report the result of these tests to the local health authority.
        - Hemoglobin A1C
    - Urinalysis
    - Urine Pregnancy test for female subjects able to become pregnant
    - Electrocardiogram (ECG)

It is possible that after these test results are reviewed, you will not qualify to be in this study. If you do not qualify, the study staff will discuss the reasons with you. You will be told the test results that are relevant to your health.

If you qualify to be in the clinical trial, you will be scheduled to return for the Day 1 study visit.

This study will use competitive enrollment. This means that when a target number of subjects begins the study, all further enrollment will be closed. Therefore, it is possible that you could be in the screening phase, ready to begin the study, and be discontinued without your consent if the target number of subjects has already begun the study.

If you qualify to take part in this study and go on to receive the study treatment, then the following will happen:

Study Treatment:

Each subject will receive four doses of active study vaccine (half doses of AV7909) and one dose of placebo (saline) on 1 of 2 vaccination schedules based on their assigned study treatment group. AV7909 will be administered by intramuscular (IM) injection in the upper arm as either a full dose (0.5 mL) or half dose (0.25 mL). Placebo (0.25 mL or 0.5 mL) will be administered by IM injection in the upper arm.

You will be randomly assigned by chance to a study treatment group. As of 13-May-2024, study treatment groups 1 and 2 are closed to enrollment. Subjects already taking part in this study had a ***25%* (1 in 4)** chance of being assigned to one of the groups below:

Table 1: Study Dosing Schedule

Study Group	AV7909 Dose	Schedule	Primary Series			Boosters	
			Dose 1 Day 1	Dose 2 Day 15	Dose 3 Day 29	Dose 4 Day 181	Dose 5 Day 366
1	Full	1	AV7909	AV7909	Placebo	AV7909	AV7909
2	Full	2	AV7909	Placebo	AV7909	AV7909	AV7909
3	Half	1	AV7909	AV7909	Placebo	AV7909	AV7909
4	Half	2	AV7909	Placebo	AV7909	AV7909	AV7909

Subjects already taking part will continue in the study in the study group they were assigned to. New subjects joining the study on or after 13-May-2024, will have a ***50%* (1 in 2)** chance of being assigned to either study group 3 or study group 4.

This is a double-blind study, which means neither you nor your study doctor will know to which of these study groups you are assigned. In case of an emergency, however, the study doctor can get this information.

You will have the following study visits and undergo the following procedures as outlined in table 2.

Table 2: Schedule of Events

Time Point	Physical Exam, Vital signs	CBC/CMP*	Urine Pregnancy Test (women only)	AV7909 or Placebo	Blood Tests for Immunogenicity	Phone Call Check In
**V1/Day 1`	X	X	X	X	X	

Time Point	Physical Exam, Vital signs	CBC/CMP*	Urine Pregnancy Test (women only)	AV7909 or Placebo	Blood Tests for Immunogenicity	Phone Call Check In
V2/Day 3	X					
V3/Day 15	X	X	X	X	X	
***C1/Day 17						X
V4/Day 29	X	X	X	X	X	
C2/Day 31						X
V5/Day 36	X	X			X	
V6/Day 43	X	X			X	
V7/Day50	X				X	
V8/Day 64	X				X	
V9/Day 85	X				X	
V10/Day 181	X	X	X	X	X	
C3/Day 183						X
V11/Day 211	X				X	
C4/Day 256						X
V12/Day 366	X	X	X	X	X	
C5/Day 368						X
V13/Day 396	X				X	
C6/Day 456						
V14/Day 546	X				X	
C7/Day 636						X
V15/Day 731	X				X	

CBC/CMP* = complete blood count/comprehensive metabolic profile; V**=visit; C***=phone calls

Procedures after vaccine dosing:

After receiving AV7909 or placebo, you will need to remain at the study site for at least 1 hour. During this time, the study staff will check for any reactions you may have after the procedure.

Subjects will be given a diary as well as rulers and thermometers to record and monitor the following information:

- Oral temperature and time taken (each daily entry before 11:59 pm)
- General symptoms
- Injection site symptoms (rulers to measure reactions)
- Current medications

The diary should be completed once daily starting on the evening of each study dose through seven days after each dose. The completed diary will be reviewed with you by the study staff during site visits and phone calls to assess for fever and other symptoms (unusually tired/feeling unwell, chills, muscle aches, joint pain, headache, nausea, vomiting and diarrhea) and injection site symptoms (site warmth, tenderness, itching, pain, restriction of range of arm motion, pain,

redness, palpable or observable bump, swelling and bruising). In addition, you should let the study staff know about any other symptoms and changes in medications.

Follow-up Visits:

You will have approximately 15 in person visits following screening. You will also be contacted by study staff for follow-up phone calls. The study doctor can give you more information about this.

The following will be conducted at every follow-up visit, unless otherwise specified:

- Physical exam and assessment of your vital signs
- Review of your medications and any side effects or symptoms you are experiencing

The following will be collected at some of your follow-up visits:

- Collection of approximately 3-4 tablespoons of blood to check your immune system's response to the study vaccine.

After Study Treatment:
Because this is a research study, the study vaccine will be given to you only during this study and not after the study is over.

EXPECTATIONS
If you participate in this study, you will be expected to:

- Attend each study visit
- Answer study phone calls
- Complete study diaries

RISKS, SIDE EFFECTS, AND/OR DISCOMFORTS
AV7909 is investigational, so some of the side effects may not yet be known, especially if they are rare. Some of these may be life threatening. Below is a list of possible side effects of receiving the study vaccine.

Most common

- Upper respiratory tract infection
- Injection site pain/reaction
- Headache
- Urinary tract infection
- Nausea
- Fatigue
- Nasopharyngitis (common cold)
- Back pain
- Muscle aches
- Arm motion limitation

Because CPG 7909, the vaccine adjuvant, may have the potential to cause immune related diseases, you will be closely monitored throughout the study and for at least 12 months after the last study vaccination. Immune mediated diseases include diseases such as systemic lupus, thyroiditis, rheumatoid arthritis, etc. Such events have been very infrequent with AV7909 (3 out of 3724 subjects).

As with receiving any vaccine, there is a risk of allergic reaction. If you have a very serious allergic reaction, you may be at risk of death. Some symptoms of allergic reactions are:

- Rash
- Wheezing and difficulty breathing
- Dizziness and fainting
- Swelling around the mouth, throat or eyes
- A fast pulse
- Sweating

Please seek treatment immediately and tell the study doctor and study staff if you have any of these symptoms.

RISKS OF STUDY PROCEDURES

- Blood sample collections: Possible side effects from drawing blood include faintness; inflammation of the vein; and pain, bruising, or bleeding at the site of puncture. There is also a slight possibility of infection.
- Electrocardiogram (ECG): Skin irritation is rare but could occur during an ECG from the electrodes or gel that is used.

UNFORESEEN RISKS
Since the study vaccine AV7909 is investigational, there may be other risks that are unknown.

BIRTH CONTROL RESTRICTIONS
Receiving the study vaccine may involve risks to a pregnant woman, an embryo, fetus (unborn baby) or nursing infant. Therefore, if you are pregnant, planning to become pregnant, or are breastfeeding a child, you cannot participate in this study.

Females:
In order to reduce the risk of pregnancy, you should use an effective method of birth control while you are participating in this study (approximately 2 years) and at least 2 months prior to screening. The study doctor or study staff will discuss this with you.

If you become pregnant while you are participating in this study or after you have stopped receiving the study vaccine, tell your study doctor or study staff immediately. The study vaccine will be stopped. You will continue to be followed for safety through day 731 or through completion of your pregnancy, whichever is longer.

Acceptable forms of contraception may include:

- Oral contraceptives (taking birth control pills orally; use of additional form of contraception recommended with this method)
- Condoms with contraceptive foam
- Birth control shots or patches
- Intrauterine device (IUD)

- Contraceptive hormonal implant
- Vaginal contraceptive ring
- Diaphragm with contraceptive jelly
- Diaphragm with condoms ("double barrier")

ALTERNATIVES TO PARTICIPATION
This research study is for research purposes only. The only alternative is to not participate in this study.

NEW FINDINGS
Any new important information that is discovered during the study and may influence your willingness to continue participation in the study will be provided to you.

BENEFITS
This study is for research purposes only. The purpose of your participation in the study is to contribute to research rather than for your own medical treatment. There is no direct benefit of anthrax vaccination to you in the absence of an anthrax exposure. The risk of anthrax infection in the general population is very low. It is not known if the study vaccine will offer protection against infection by the bacteria that causes anthrax at the doses and vaccination schedules being studied. If it does offer protection, it is not known how long that protection may last.

This study will inform preparedness planning for a bioterrorist attack with anthrax. Therefore, this study has potential to benefit society in the future.

COMPENSATION FOR PARTICIPATION
You will be paid up to a total of [redacted] if you complete this study. You will be paid for the visits you complete according to the following schedule:

Time Point	Compensation
Screening	[redacted]
Visit 1/Day 1`	[redacted]
V2/Day 3	[redacted]
V3/Day 15	[redacted]
C1/Day 17	[redacted]
V4/Day 29	[redacted]
C2/Day 31	[redacted]
V5/Day 36	[redacted]
V6/Day 43	[redacted]
V7/Day50	[redacted]
V8/Day 64	[redacted]
V9/Day 85	[redacted]
V10/Day 181	[redacted]
C3/Day 183	[redacted]
V11/Day 211	[redacted]

Time Point	Compensation
C4/Day 256	[redacted]
V12/Day 366	[redacted]
C5/Day 368	[redacted]
V13/Day 396	[redacted]
C6/Day 456	[redacted]
V14/Day 546	[redacted]
C7/Day 636	[redacted]
V15/Day 731	[redacted]

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

Unscheduled or an Early Withdrawal visit will be compensated at $25.00/visit.

You will be paid following each completed visit on a Visa Prepaid card that will be provided to you by the study site. If you do not finish the study, you will be reimbursed for the part of the study that you did complete. However, your expenses could be more that the amount you are reimbursed.

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

CONFIDENTIALITY

Records of your participation in this study will be held confidential except when sharing the information is required by law or as described in this informed consent. The study doctor, the sponsor or persons working on behalf of the sponsor, and under certain circumstances, the United States Food and Drug Administration (FDA) and the Institutional Review Board (IRB) will be able to inspect and copy confidential study-related records which identify you by name. This means that absolute confidentiality cannot be guaranteed. If the results of this study are published or presented at meetings, you will not be identified.

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

To make sure that the health information collected in this study is accurate, it will need to be checked from time to time against your medical records. Some persons may need to see these records in order to monitor the research and verify the accuracy of the study data, including:

- A limited number of representatives from BARDA (namely its monitors and auditors),
- The Institutional Review Board – [redacted] IRB (an independent ethics committee that reviewed the ethical aspects of this study to help protect the rights and welfare of study subjects),

- Government regulatory authorities including the US Food and Drug Administration (FDA) and other foreign regulatory agencies.

Your study records including confidential information about you collected during the study will be kept at a secure location.

While every effort will be made to protect the privacy of your information, absolute confidentiality cannot be guaranteed. This does not limit the duty of the researchers and others to protect your privacy.

HIPAA (Health Insurance Portability and Accountability Act) Regulations or applicable state law requires that you authorize the release of any health information that may revel your identity. [redacted] ("Study Doctor"), [redacted] may be collectively referred to as "Study Site", and each of its/his study staff must obtain your authorization (permission) to use and/or disclose (release) any health information that might identify you.

By signing this information and consent form, you consent to the collection, access, use and disclosure of your information as described above.

COMPENSATION FOR INJURY

If you are injured or get sick because of being in this research, call the study doctor immediately at the number listed on page one of this form. The study doctor will provide emergency medical treatment, as warranted or refer you to an appropriate health care facility. In the event of a life-threatening emergency, contact emergency services/911 and seek immediate medical care prior to contacting the study doctor. Your insurance may be billed for this treatment. No other payment is routinely available from the study doctor or sponsor. BARDA has no plans to provide medical care or financial compensation for study-related injuries. No financial compensation by the study doctors that gave you the vaccine will be offered for any discomfort suffered because of participation in this study.

The study drug and the clinical trial are covered by the Public Readiness and Emergency Preparedness (PREP) Act which limits your ability to sue if you develop a reaction to the study drug. A Federal program has been created to help pay for medical care and other specific expenses of people who have serious reactions that are caused by the study product. To be eligible for this program, you must file a claim within one year of receiving the study drug. The program is administrated by the Health Resources and Services Administration. An information sheet about the PREP Act and the Federal program, including how to file a claim, will be provided to you.

You do not give up any of your legal rights by signing this form.

Be aware that your health care payer/insurer might not cover the costs of study-related injuries or illnesses. You should contact your insurance company for more information.

COSTS
There will be no charge to you for your participation in this study. The study drug, study-related procedures, and study visits will be provided at no charge to you or your insurance company.

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

I agree to have a photograph of a visible injection site abnormality for the purpose of medical management and safety evaluations.

Yes ☐ No ☐

I agree to be contacted with a request to participate in future clinical studies of subjects who have been vaccinated against B. anthracis, such as longer interval booster administration studies.

Yes ☐ No ☐

I agree to store any leftover serum for future investigations unrelated to this study. Leftover serum will be stored indefinitely. Subjects who provide consent may withdraw that consent for future investigations by contacting the study doctor identified on the consent form.

Yes ☐ No ☐

After your participation in the study has ended, you can contact BARDA's Chief Medical Officer by phone at [redacted]. Leftover serum will be destroyed, but any data that have already been collected from analysis of leftover serum will remain a part of the research database.

COMMERCIAL PROFIT
Your biospecimens collected during this study may be used for commercial profit (even if identifiers are removed) and **you will not share in this profit.**

CLINICALLY RELEVANT RESULTS
Research results that are clinically relevant, including individual research results, **will not be disclosed to you.**

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

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

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

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

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

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

- By **mail**:
  [redacted]
- or call **toll free**: [redacted]
- or by **email**: [redacted]

Please reference the following number when contacting the Study Subject Adviser:
[redacted]

VOLUNTARY PARTICIPATION / WITHDRAWAL
Your decision to participate in this study is voluntary. You may choose to not participate or you may withdraw from the study for any reason without penalty or loss of benefits to which you are otherwise entitled and without any effect on your future medical care. However, please note that the FDA requires that any information collected up to the point of your withdrawal cannot be removed from the study.

The study doctor or the sponsor can stop your participation at any time without your consent for the following reasons:

- If it appears to be medically harmful to you;
- If you fail to follow directions for participating in the study;
- If it is discovered that you do not meet the study requirements;
- If the study is canceled; or
- For administrative reasons.

If you leave the study for any reason, the study doctor may ask you to have some end-of-study tests for your safety.

PRIMARY HEALTH CARE PROVIDER NOTIFICATION OPTION

I consent to having my family doctor or primary health care provider notified by the study site of my participation in this study and/or any significant findings related to my health (please check yes or no).

☐ **YES** (If yes, please complete the information below)

☐ **NO**

Name and address of family doctor or primary health care provider:	Name: Address:
Telephone and Fax Number:	Tel: Fax:

CONSENT

I have read and understand the information in this informed consent document. I have had an opportunity to ask questions and all of my questions have been answered to my satisfaction. I voluntarily agree to participate in this study until I decide otherwise. I do not give up any of my legal rights by signing this consent document. I will receive a copy of this signed consent document.

_____
Subject's Printed Name

_____ _____
Subject's Signature Date

_____
Printed Name of the Person Conducting the Consent Discussion

_____ _____
Signature of the Person Conducting the Consent Discussion Date

WITNESS SIGNATURE FOR SUBJECTS WHO CANNOT READ

The study subject has indicated that he/she is unable to read. The consent document has been read to the subject by a member of the study staff, discussed with the subject by a member of the study staff, and the subject has been given an opportunity to ask questions of the study staff.

_____
Printed Name of Impartial Witness

_____ _____
Signature of Impartial Witness Date

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

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

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

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

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

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

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

- To see if the AV7909 vaccine works and is safe.
- For other research activities related to AV7909 vaccine.

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

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

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

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

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

STATEMENT OF AUTHORIZATION

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

_____

Printed Name of Subject

_____ _____

Signature of Subject Date

WITNESS SIGNATURE FOR SUBJECTS WHO CANNOT READ

The study subject has indicated that he/she is unable to read. This Authorization document has been read to the subject by a member of the study staff, discussed with the subject by a member of the study staff, and the subject has been given an opportunity to ask questions of the study staff.

_____

Printed Name of Impartial Witness

_____ _____

Signature of Impartial Witness Date