HOSPITAL OF THE UNIVERSITY OF PENNSYLVANIA

CONSENT TO PARTICIPATE IN A RESEARCH STUDY AND RESEARCH SUBJECT HIPAA AUTHORIZATION

- Protocol Title:Inovio Pharmaceuticals, Inc, EBOV-001
PHASE I, OPEN-LABEL STUDY TO EVALUATE THE SAFETY,
TOLERABILITY, AND IMMUNOGENICITY OF INO-4212 AND ITS
COMPONENTS, INO-4201 AND INO-4202, GIVEN WITH OR
WITHOUT INO-9012, ADMINISTERED IM OR ID FOLLOWED BY
ELECTROPORATION IN HEALTHY VOLUNTEERSPrincipalPablo Tebas, MD
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 24 hr. Emergency Immunodeficiency Program Doctor on call
- **Contact:** (215) 662-6059

Why Am I Being Asked to Volunteer?

You are being asked to participate in a research study. The purpose of this consent form is to help you decide if you want to be in this research study. You must read and sign this consent form before you can take part in this research study.

You should not join this research study until all of your questions are answered.

Things to know before deciding to take part in a research study:

- The main goal of a <u>research study</u> is to learn things to help patients in the future.
- The decision to join or not join the research study will not cause you to lose any medical benefits. You may withdraw from the study at any time. If you decide not to take part in this study or withdraw, your doctor will continue to treat you.
- A research study can involve experimental (investigational) drugs or procedures that are tested to treat or prevent a certain condition or illness. An investigational study agent is one that has not been approved by the U.S. Food & Drug Administration (FDA).
- Your medical records may become part of the research record. If that happens, your medical records may be looked at and/or copied by the sponsor of this study (Inovio), the Department of Defense and US Federal Regulatory Agencies, government agencies or other groups associated with the study for regulatory oversight purposes.

If you take part in this research study, you will be given a copy of this signed and dated consent form.

What is the purpose of this research study?

The purpose of this research study is to see how safe the investigational study agents INO-4212 and INO-9012 are when given to healthy volunteers, see how well they are tolerated (level of discomfort), and see if they can cause an immune response that will help your body recognize and defend itself against Ebola virus. Ebola virus disease is a rare and deadly disease caused by infection with an Ebola virus. The Ebola virus is transmitted following exposure to infected blood or body fluids through broken skin or mucosal surfaces. Symptoms of the disease appear anywhere from 2 to 21 days after exposure, and are marked by non-specific flu-like symptoms at the onset (low grade fevers, headache, and muscle aches), followed by more severe symptoms such as hemorrhage, bleeding underneath the skin, from the nose, mouth, and eyes, as well as brain damage or malfunction. There are no approved therapies or vaccines for Ebola virus infection or disease.

INO-4212, its two components, and INO-9012 are "investigational." The study agents are injected into your body using an investigational device called CELLECTRA[®] that will deliver a small electric charge through 3 or 5 needles, to get more of the study drug into your body. Several tests will determine whether or not you can take part.

This is the first time that these particular study agents and the CELLECTRA[®] device will be tested together in people. The same study device has however been tested in at least sixteen other studies to deliver other agents, without serious problems or side effects.

"Investigational" means the study agents and the study device combination being tested have not been approved by the United States Food and Drug Administration (FDA).

The study agents are known as DNA vaccines. A DNA vaccine is a synthetic vaccine that has been created in a lab using the DNA sequence for a gene of interest. Genes are the pieces of DNA that act as instructions to make proteins. In this case, the gene of interest is the gene for part of the Ebola virus. One of the study agents, INO-4212, contains two slightly different genes modelled from Ebola viruses, called INO-4201 and INO-4202. The DNA vaccine is injected into your muscle (intramuscularly, "IM") or under your skin (intradermally, "ID"). The body then turns the vaccine DNA into protein, which may stimulate immunity, that is, the process by which your body defends itself against infections. Because the vaccine is made of genes that produce only parts of the Ebola virus, it cannot create a full Ebola virus and you cannot get infected. Some participants in this study will receive only one of the Ebola genes, and others will receive both of them mixed together.

The other study agent, INO-9012, contains the gene for human interleukin 12 (IL-12). IL-12 is naturally produced by your body to help the immune system work better. Some participants in this study will receive INO-9012 with INO-4212 to see if it helps your body respond better to INO-4212.

INO-4212 and INO-9012 have been designed so they do not combine with your own genes and therefore, these virus genes cannot become part of your genes or be given to any children you may have.

What does this study involve?

If you qualify to be in this study, you will be assigned to receive either INO-4201 or INO-4202 alone, INO-4201 and INO-4202 mixed together (INO-4212), or INO-4212 plus INO-9012. The study agent will be delivered with the CELLECTRA[®] device described above. Most participants will receive the study agent in their muscle with the device that has 5 needles, but about 15 participants will have

the study agent injected under their skin with the device that has 3 needles. Approximately 75 people will participate in this study; about 21 persons will be enrolled at the University of Pennsylvania.

This study is comprised of three parts: screening, vaccination or administration of the study agent, and follow-up. The duration of this study is approximately 64 weeks (15 months). Each part is explained below.

Screening Visit Procedures

Screening procedures are done to see if you are eligible to take part in this study. You are being invited to take part in this study as a healthy volunteer. Before the study starts, the study doctor will do some tests during a screening visit to find out if you can be in the study. You will be asked to visit the study site to complete the following procedures, as a part of the screening part of the study:

- Sign this informed consent document before any study related procedures are done
- Review what test results will be used to determine if you can or cannot participate in the research study
- Review your medical history, surgical history, present conditions, and demographic data (for example, your age, race/ethnicity)
- Review any medications you have taken and are currently taking
- Have a physical exam, including vital signs (blood pressure, temperature, heart and breathing rates), height and weight
- Have a sample of blood taken (about 60 mLs or 4 tablespoons) to check:
 - Your overall health and organ function, including your liver,
 - HIV, Hepatitis B, and Hepatitis C If you test positive for these tests, by law we have to report the infection to the City of Philadelphia Health Department/PA Department of Health. We would report your name, gender, racial/ethnic background, and the month and year you were born. This is to keep track of how many people in the U.S. have HIV infection. It is also to make sure that states get enough money from the federal government to support the medical care of people living with HIV. The Health Department does not share the names of HIV infected people with anyone else. It removes all personal identifiers, such as your name, before giving information on the number of HIV infections to the federal government.
 - o Your immune response, and
 - If you are pregnant (for woman able to get pregnant only)
- Have a urine test done to check your kidney function
- Perform a 12-lead electrocardiogram or ECG to measure the electrical activity of your heart)

It is possible that after the results of these tests are reviewed, you will not qualify to be in the study. If you are not eligible to take part in the study, the reasons why you cannot take part will be discussed with you by the study doctor or the study staff.

If you qualify to be in the study and you choose to be in the study, you will be scheduled to return for the first procedure day.

Study Treatment Visit Procedures:

Once you qualify, you will be asked to come to the study site for 10 more study visits no matter which group you are placed in.

The first visit after screening is called "Day 0", or, the start of dosing. Study agent will be administered using the CELLECTRA[®] device at Day 0, Week 4, and Week 12. A Sponsor representative may be present during administration of the first dose of the study agent. If this makes you feel uncomfortable to have the sponsor representative there, please discuss this with your study doctor.

Before study agent is administered at Day 0, and at Weeks 4 and 12, the following tests will be performed:

- Physical assessment, including vital signs (blood pressure, temperature, heart and breathing rates)
- Review of any medications you have taken and are currently taking
- Urine pregnancy test for woman able to get pregnant
- Approximately 42 mls (or 4 tablespoons) of blood will be drawn to check your body's immune response
- Have a photograph taken of the proposed area for injection on your arm or leg if you are in the Group receiving study agent and CELLECTRA[®] under the skin.

Following the above procedures, you will be dosed with the study agent combination you have been assigned to. Depending on which group you are in, the Study Staff will either Administer study agent with the CELLECTRA[®] device with 5 needles inserted into a muscle in your arm or thigh or administer the study agent with a needle under your skin and then administer the CELLECTRA[®] device with 3 needles into your skin afterwards. If you are in the group receiving the study agent under your skin, you will receive a dose in each arm or thigh.

- Group one (n=15) will receive INO-4201 given by IM injection
- Group two (n=15) will receive INO-4202 given by IM injection
- Group three (n=15) will receive INO-4201 given by ID injection
- Group four (n=15) will receive INO-4212 (INO-4201 + INO-4202) given by IM injection
- Group five (n=15) will receive INO-4212 (INO-4201 + INO-4202) + INO-9012 given by IM injection

After the study agent is injected, the CELLECTRA[®] device with 5 needles will send 3 very short (approximately 1/20th of a second) pulses of electricity into your arm muscle. The CELLECTRA[®] device with 3 needles will send 2 sets of 2 short pulses into your skin after the injection. Your arm muscle is expected to twitch as a result of the pulses. These short pulses help get more of the study agent into your body's cells. If you are assigned to receive INO-4212 and INO-9012, the study agents will be mixed and given together in one injection. The arm used may be the same or different for future doses.

All participants will be offered treatment for pain management. A cream called EMLA (lidocaine 2.5% and prilocaine 2.5%) can be put on your skin before the procedure to numb the area of injection. Lorazepam (Ativan) can help make you less anxious about the injection procedure. After the procedure, you can take a pain reliever like Tylenol (acetaminophen) to help with pain. The study staff will help you decide which medicines you may need. If you are allergic to or have contraindications to EMLA, ibuprofen, ketorolac or a mild sedative may be offered a suitable alternative.

You will be asked to complete a Visual Analog Scale (VAS) immediately after the pulses and at 5 and 10 minutes following the pulses, to describe your pain. After receiving the study agents and having the study procedure, you will need to remain at the clinic for 30-90 minutes. During this time,

a member of the study team will check for any reactions you may have after receiving the study procedures. They will also photograph the injection site so we can see what the injection site looks like throughout the study. If you are given a sedative prior to the procedure, you will not be allowed to drive or perform activities that require careful attention for 3-4 hours, and you should arrange to have someone drive you after your visit.

You will be asked to keep a Participant Reminder Diary after each dose of study agent. You will be asked to take your temperature on the day you receive the study agent and for 6 days after. You will be asked to write down in the reminder diary whether or not you feel pain or swelling or see redness or bruises at the injection site, or experience itching, and you will be provided with a measuring tool to measure how big this area of redness and/or swelling is. You should also write down if you are feeling unusually tired or unwell, have muscle aches, headache, nausea, vomiting or joint pain after the study procedure. You will also be asked to write down any other side effects that you may experience. You will have to bring your reminder diary to the next visit and discuss it with the study staff.

For the non-dosing visits (Weeks 2, 6, and Weeks 14 – 60), you will have tests done according to the schedule below, and you will be asked about how you are feeling and about any new medications you have started since the previous visit. You will also be contacted by phone at Week 8 and Week 16 to ask about any side effects you may have experienced. You will be followed for safety for 48 weeks after your last dose. The schedule and procedures are described in the table below:

Time	Physical Exam/vital signs	Blood Tests	VAS & Participant Diary	Urine Pregnancy test (women only)	Urinalysis	CELLECTRA [®] procedure and study agents	Telephone contact	Injection site evaluation and photograph**
Day 0	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark		\checkmark
Week 2	\checkmark	\checkmark						\checkmark
Week 4	\checkmark	√*	\checkmark	\checkmark		\checkmark		\checkmark
Week 6	\checkmark	\checkmark						\checkmark
Week 8							\checkmark	
Week 12	\checkmark	√*	\checkmark	\checkmark		\checkmark		\checkmark
Week 14	\checkmark	\checkmark			\checkmark			\checkmark
Week 16							\checkmark	
Week 24	\checkmark	\checkmark						\checkmark
Week 36	\checkmark	\checkmark						\checkmark
Week 48	\checkmark	\checkmark						\checkmark
Week 60	\checkmark	\checkmark						\checkmark

- *Blood will only be drawn if not done at the previous visit.
- ** Group receiving study agents under the skin only

You will have about 42 mL (4 tablespoons) of blood drawn at each visit after screening to test your immune response. Blood for immunology testing will only be drawn at Week 4 and Week 12 if it was not drawn at the previous visit. An extra 15 mL (1 tablespoon) of blood will be drawn at Week 2 and Week 14 for routine blood tests. Overall, a total of about 410 mL (14 ounces) of blood will be drawn from you over the duration of the study.

RISKS AND DISCOMFORTS

You must tell your study doctor or study staff about all side effects that you have. If you are not honest about your side effects, it may not be safe for you to stay in the study.

If you do not understand what any of these side effects mean, please ask your study doctor or study staff to explain these terms to you.

Below is a list of possible side effects of the study agents, based on experience with similar study agents delivered using the CELLECTRA[®] device. Since this is the first time these study agents and device are being used together in people, all side effects may not be known. As per the current information, there are no expected differences in safety and side effects between the two investigational study agents (INO-4212 and INO-9112). You will be told about any new findings that develop during the time that might change your willingness to continue in the study.

Most common side effects based on other study agents using the same device:

- Pain, redness, swelling, hardness/stiffness, brief muscle contractions and a small amount of bleeding or scabs at the injection site
- Feeling unwell or feeling tired
- o Muscle aches
- o Headache

Less common side effects based on other study agents using the same device:

- o Joint pain
- o Nausea
- o Bruising or itching at the injection site

Very rare or possible side effects based on other study agents using the same device:

- Rash at the injection site
- o Cuts or heavy bleeding at the injection site
- o Severe pain or tenderness at the injection site
- o Scarring at the injection site
- o Chills
- Dizziness or fainting
- Muscle tissue damage (minor muscle cell damage)
- Slight changes in blood values

Long term side effects:

- There have been no serious safety problems found in earlier studies with similar study agents.
- There have been no reports of autoimmune illnesses (for example Lupus, rheumatoid arthritis) or new cancers in other studies with similar study agents.

If you require EMLA, or lorazepam prior to dosing, you may experience the side effects below:

Risks of EMLA Cream:

The most common side effects of the use of EMLA cream are redness, irritation and swelling of the area to which it is applied. Other common side effects include skin pallor (skin whiteness), itching, rash, and changes in how you sense skin temperature. Allergic reactions are rare but can occur with the use of this product. This product contains lidocaine and prilocaine. You should tell the study staff if you are allergic to lidocaine or prilocaine.

Risks of Lorazepam (Ativan):

Side effects include mild drowsiness, weakness and temporary confusion. If you receive lorazepam, you will not be permitted to drive yourself after the study dosing. You must have someone else drive you. You should also avoid using stairs or working with machinery after receiving lorazepam.

Risks of Acetaminophen (Tylenol):

Side effects of Tylenol include nausea, stomach pain, loss of appetite, itching, rash, headache, dark urine, clay-colored stools, or jaundice (yellowing of skin or eyes).

The study doctor will discuss the side effects of these and other drugs/procedures with you at that time.

Other Study Related Risks

Risk of Blood Draws

During the blood collections, you may feel pain, have bruising, redness or bleeding where the needle is inserted. Although uncommon, a blood clot may form and an infection may occur at the injection site. Lightheadedness and/or fainting may also occur during or shortly after the blood draw. If you feel faint, you should lie down immediately to avoid possible injury caused by falling, and tell the study staff.

Risks of Electrocardiogram

The ECG procedure may cause discomfort on the skin of your chest, wrist and ankle areas while the ECG leads are put on and taken off. It may also cause redness, itching, and peeling of the skin. If the hair under the patches needs to be shaved, irritation from shaving also could occur.

Risks of the CELLECTRA® device

During the study device procedure, you may feel pain where the needles are inserted. Other subjects have rated the discomfort that they felt during the procedure on a scale from 0 ("No pain") to 10 ("Worst pain") and the average score was around 6 immediately after the procedure. After about 5 minutes, pain levels were between 1-3 out of 10.

Everyone taking part in this study will be monitored carefully for side effects, however the research may involve risks that are currently unknown. When you take more than one study agent at a time, the side effects can be worse or different than if you take either study agent by itself. There may be side effects that are not known at this time.

If you experience an injury, side effect, or any other unusual health experience during this study, you should immediately phone the study doctor or the study staff. Side effects may be mild to very

serious. The study staff may give you medicines to help lessen side effects. Many side effects go away. In some cases, side effects can be serious, long lasting, or may never go away. It is important for you to attend all of your follow-up visits even after the treatment visits have been completed. Even if you decide to not to receive all of the study treatments, you should do your best to attend follow-up visits.

Reproductive Risks

You should not become pregnant or father a child while on this study because it is not known if the study agent will have a harmful effect on your sperm or eggs, and harm an unborn baby. You cannot be in the study if you are breastfeeding as it is not known whether the study agents are safe for breast feed babies. The effects of the study agents on an unborn baby are unknown.

Female Participants

If you are a woman who is able to become pregnant, you will be asked to take a pregnancy test at the beginning of the study and before each dose of study agent in order to determine if you are pregnant. If you are pregnant, you will not be able to participate in this study. You should not become pregnant while on this study, or for 3 months after your last dose of study agent. If you are able to have children, and are sexually active with the possibility of becoming pregnant, you must agree to use a medically accepted form of birth control from the beginning of the study until 3 months after your last dose of study agent. Medically accepted forms of birth control include condoms, diaphragm, cervical cap, the placement of an intrauterine device (IUD), birth control pills, hormone implants or injections, or a partner who has undergone a vasectomy (surgical sterility). Your study doctor must approve your form of birth control. Ask your study doctor about the contraceptive methods that are available and which might be the best for you.

Even when you use an approved contraceptive method, there is always a small risk that you could still become pregnant. If you become pregnant during the course of this study tell your Study Doctor immediately, and consult an obstetrician or maternal-fetal specialist. You will not be able to receive further study agent, but will return for study visits. We will ask your permission to collect information about your pregnancy and the health of your baby. This includes information related to your pregnancy/delivery and your complete obstetrical history. The data concerning your pregnancy and birth outcome will be held in a drug safety database.

Male Participants

You must agree to use a medically accepted form of birth control during the course of this study and for at least 3 months after your last dose of study agent. If your partner does become pregnant, you must inform your study doctor immediately. Medically accepted forms of birth control include condoms or vasectomy (surgical sterility). Your study doctor must approve your form of birth control. Ask your study doctor about the contraceptive methods that are available and which might be the best for you.

You should also inform your partner of the potential harm to an unborn child. She should know that if a pregnancy should occur, you will need to report it to the study doctor immediately, and she should promptly notify her doctor.

If your partner becomes pregnant over the course of this study, we will ask for permission to collect information about the pregnancy and the health of your baby. This includes information related to the pregnancy/delivery and obstetrical history. The data concerning the pregnancy and birth outcome will be held in a drug safety database.

NEW INFORMATION

You will be told about any new information that might change your decision to be in this study. You may be asked to sign a new consent form if this occurs.

BENEFITS

Since you do not need treatment with the study agents or device, you will get no medical benefit from being in this study, other than the benefit of free medical tests. While the study doctor hopes that the study agent will be of some benefit to preventing Ebola infection, there is no proof of this yet. It may cause harm. We do know that the information from this study will help the study doctor learn more about the study agents and device and their effect on the Ebola virus.

COSTS

The sponsor will provide the study agent free of charge during this study. Tests and procedures that are done only for the study will not be billed to you or your insurance company.

You might have unexpected expenses from being in this study. Ask your study doctor to discuss the costs that will or will not be covered by the Sponsor. This discussion should include who will pay the costs of treating possible side effects.

PAYMENT FOR PARTICIPATION

You will be paid \$75 cash at the end of most completed study visits. At the visits when you are administered study drug (Day 0/Week 4/Week 12) you will be compensated \$150. This will be given to you as a check in the mail and can take 4-6 weeks to process. If you complete all 11 study visits, including the 3 visits when you receive the study agent, the maximum compensation you can receive is \$1050. There is no other form of compensation available such as reimbursements for parking, tokens or child care. In order to be compensated for your participation in this study, you must provide your Social Security Number. Additionally, please note that the University of Pennsylvania is required to report to the IRS any cumulative payments for participation in research studies that exceed a total of \$600 in a calendar year.

When is the Study over? Can I leave the Study before it ends?

This study is expected to end after all participants have completed all visits, and all information has been collected. This study may also be stopped at any time by your physician, the study Sponsor, or the Food and Drug Administration (FDA) without your consent because:

• The Primary Investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.

• You have not followed study instructions.

• The Sponsor, the study Principal Investigator, or the Food and Drug Administration (FDA) has decided to stop the study.

If you decide to participate, you are free to leave the study at anytime. Withdrawal will not interfere with your future care.

ALTERNATIVE TREATMENT

This is not a treatment study. Your alternative is not to be in this study.

HIPAA AUTHORIZATION

The authorization part of the consent gives more detailed information about how your personal health information may be used and disclosed by the University of Pennsylvania Health System (UPHS), the School of Medicine and the individual Principal Investigator, subject to University of Pennsylvania procedures.

What personal health information is collected and used in this study and might also be disclosed?

The following personal health information will be collected, used for research, and may be disclosed during your involvement with this research study:

- Name, address, telephone number, email address
- Dates directly related to you such as date of birth and clinic visits.
- Personal and family medical history
- Current and past medications or therapies

QuestionnairesResults of tests and procedures you will

- undergo during this research
- Social Security Number, Medical record number

Why is your personal contact and health information being used?

Your personal contact information is important for the research team to contact you during the study. Your personal health information and results of tests and procedures are being collected as part of this research study. In some situations, your personal health information might be used to help guide your medical treatment.

Which of our personnel may use or disclose your personal health information?

The following individuals may use or disclose your personal health information for this research study:

- The Principal Investigator and the Investigator's study team
- Authorized members of the workforce of the UPHS and the School of Medicine, and University
 of Pennsylvania support offices, who may need to access your information in the performance
 of their duties (for example: for research oversight and monitoring, to provide treatment, to
 manage accounting or billing matters, etc.).

Who, outside of UPHS and the School of Medicine, might receive your personal health information?

As part of the study, the Principal Investigator, the study team and others listed above, may disclose your personal health information, including the results of the research study tests and procedures. This information may be disclosed to those listed below:

Individuals or organizations responsible for administering the study:

- <u>Pharmaceutical sponsor (Inovio Pharmaceuticals Inc)</u>, the company that is supplying the study agents for this study; and/or designated representatives of the Sponsor
- Government Agencies: Data from this study will be made available to
 - The U.S. Food and Drug Administration (FDA),
 - Department of Health and Human Services (DHHS) agencies,
 - The Department of Defense
 - Governmental agencies in other countries,
 - Governmental agencies to whom certain diseases (reportable diseases) must be reported

• <u>Monitors:</u> Monitors contracted to review study records on behalf of Inovio and /or the Department of Defense.

Once your personal health information is disclosed to others outside of UPHS or the School of Medicine, it may no longer be covered by federal privacy protection regulations. Data are reported to the sponsor on Case Report Forms that identify you by your unique study number and not your name, date of birth or medical record number. Information regarding your health, such as side effects of the study drug you experience will be reported only by code number. All samples collected for analysis will be labeled with your study number, visit number and date of your visit.

The Principal Investigator or study staff will inform you if there are any additions to the list above during your active participation in the trial. Any additions will be subject to University of Pennsylvania procedures developed to protect your privacy.

How long may UPHS and the School of Medicine be able to use or disclose your personal health information?

Your authorization for use of your personal health information for this specific study does not expire.

Your information may be held in a research database. However, the School of Medicine may not re-use or re-disclose information collected in this study for a purpose other than this study unless:

- You have given written authorization
- The University of Pennsylvania's Institutional Review Board grants permission
- As permitted by law

Can I change my mind about giving permission for use of my information?

Yes. You may withdraw or take away your permission to use and disclose your health information at any time. You must do so in writing to the Principal Investigator at Infectious Disease Division, 502 Johnson Pavilion Philadelphia PA 19104. Even if you withdraw your permission, your personal health information that was collected before we received your written request may still be used and disclosed, as necessary for the study. If you withdraw your permission, you will not be able to stay in this study.

What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study.

You will be given a copy of this Research Subject HIPAA Authorization describing your confidentiality and privacy rights for this study. You will also be given the UPHS and School of Medicine's Notice of Privacy Practices that contains more information about the privacy of your personal health information.

What is an Electronic Medical Record?

An Electronic Medical Record (EMR) is an electronic version of the record of your care within a health system. An EMR is simply a computerized version of a paper medical record.

If you are receiving care or have received care within the University of Pennsylvania Health System (UPHS) (outpatient or inpatient) and are participating in a University of Pennsylvania research study, results of research-related procedures (i.e. laboratory tests and clinical procedures) may be placed in your existing EMR maintained by UPHS.

Once placed in your EMR, these results are accessible to appropriate UPHS workforce members that are not part of the research team. Information within your EMR may also be shared with others who are determined by UPHS to be appropriate to have access to your EMR (e.g. health insurance company, disability provider, etc).

INTEREST OF THE MEDIA AND OTHERS IN THE RESEARCH

Because of the new nature of these study agents and study device, it is possible that the media may exhibit interest in the study and its participants. This interest may result in a greater risk than usual for information concerning your study participation to appear publicly without your consent. We make every possible effort to protect the identity of you and your family.

COMPENSATION FOR INJURY

We will offer you the care needed to treat injuries directly resulting from taking part in this research. We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but you may also be responsible for some of them. The sponsor will offer to pay for medical expenses that are not covered by your third-party payer (for example, your health insurance plan). The sponsor does not routinely offer any other financial compensation. Be aware that your health insurance plan may not cover the cost of study-related injuries or illnesses. You or your third-party payer may also be billed for medical expenses the study staff or sponsor decides are medically necessary and that would have been paid even if you were never in the study.

Medical treatment will be offered if you need it.

The above statement does not limit your legal rights. To ask questions about this, talk to the study doctor or study staff.

Please be aware that some insurance plans may not pay for research-related injuries. You should contact your insurance company for more information.

There are no plans for the University of Pennsylvania to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

If you think you have been injured as a result of taking part in this research study, tell the person in charge of the research study as soon as possible. The researcher's name and phone number are listed in the consent form.

AUTOPSY

Because you are in this study, your family may be asked for permission to do an autopsy (or obtain results of one) after your death, even though this may be years after the study. This may add to what is known about the effects of the study agent and of gene-based therapy. You should talk about this request with your family and advise them of your wishes. Signing this consent form does not force your family to agree to this.

VOLUNTARY PARTICIPATION AND WITHDRAWAL

Your participation in this study is voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled.

Your participation in this study may be stopped at any time by the study doctor or the sponsor without your consent for any reason, including:

- if it is in your best interest;
- you do not consent to continue in the study after being told of changes in the research that may affect you;
- If you do not follow your study doctor's instructions
- Pregnancy
- If we find out you should not be in the study
- If the study is stopped or cancelled
- Unanticipated circumstances

If you leave the study before the planned final visit, you may be asked by the study doctor to have some tests or procedures done so that you leave the study safely; you have the right to refuse these tests or procedures.

SOURCE OF FUNDING FOR THE STUDY

The sponsor, Inovio Pharmaceuticals, Inc., will pay for this research study. This study is funded by the Department of Defense.

QUESTIONS

If you have questions about this study or a research-related injury, please contact the research team listed on page 1 of this consent form at 215 349-8092.

For questions about your rights as a research subject, contact:

• Director of Regulatory Affairs at the University of Pennsylvania by phoning (215) 898-2614

Do not sign this consent form unless you have had a chance to ask questions and have gotten satisfactory answers.

If you agree to be in this study, you will receive a signed and dated copy of this consent form for your records.

A description of this clinical trial will be available on <u>http://www.ClinicalTrials.gov</u>, 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.

CONSENT

I have read this consent form (or it has been read to me). All my questions about the study and my part in it have been answered. I freely consent to be in this research study.

I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above.

By signing this consent form, I have not given up any of my legal rights.

Consent Instructions:

Consent: Subjects able to provide consent must sign on the subject line below

Subject Name (printed)

CONSENT SIGNATURES:

Signature of Subject

Date

Name of Person Obtaining Consent (Please Print) Signature

Date