UNIVERSITY OF PENNSYLVANIA HEALTH SYSTEM

A PHASE I, OPEN LABEL STUDY TO EVALUATE THE SAFETY, TOLERABILITY AND IMMUNOGENICITY OF PENNVAX™-B (gag, pol, env) + ELECTROPORATION IN HIV-1 INFECTED ADULT PARTICIPANTS (Version 1.0, 12/10/09)

RESEARCH SUBJECT INFORMED CONSENT AND HIPAA AUTHORIZATION FORM

If you are seen at the Hospital of the University of Pennsylvania [HUP], your contacts are:

Principal Investigator:	Pablo Tebas, MD	(215) 615-4321
Coordinator:	Joseph Quinn, RN	(215) 349-8092
	Kathryn Maffei, RN	(215) 349-8092

24 Hour Emergency Number (215) 662-6059 Ask for the Immunodeficiency Program Doctor on call

INTRODUCTION:

You are being invited to participate in a research study of an anti-HIV vaccine called PENNVAX™-B because you are infected with human immunodeficiency virus (HIV) and you are currently taking potent combination antiretroviral (ARV) medications. This study is a clinical research trial to find out the effects of an investigational (not approved by the Food and Drug Administration) vaccine strategy on the immune system of HIV-infected people who are also taking anti-HIV drugs.

Before you decide if you want to be a part of this study, we want you to know about the study. The doctor in charge of this study at this site is Dr. Pablo Tebas. This study is sponsored by the pharmaceutical company named VGX Pharmaceuticals, LLC, which means that VGX designed the study. VGX is paying for this research study and for the study doctor to do this study.

Research studies like the one you are thinking about joining are done to determine whether a new treatment is safe. The University of Pennsylvania owns a patent on this new treatment being studied. If the research shows the new treatment is safe and effective, UPENN would receive a part of the profits from any sales of this treatment.

This is a consent form. It gives you information about this study. The study staff will talk with you about this information. You are free to ask questions about this study at any time. If you agree to take part in this study, you will be asked to sign this consent form. You will get a copy to keep.

Please note that your participation in this study is entirely voluntary and you may stop taking part in the study at any time without losing your standard health care.

University of Pennsylvania's Financial Interest in this Study

This research study is designed to test a product made by Inovio Pharmaceuticals, Inc. (also known as VGX Pharmaceuticals and Viral Genomix), the company sponsoring this research. The company was originally formed to further develop research technology invented at the University of Pennsylvania, including the product being tested in this study. This research technology has been licensed to Inovio, resulting in the University of Pennsylvania's receipt of a significant amount of stock in Inovio. The amount of money this stock is worth or that might result from the licensed research technology might be affected by the results of this study. This means that the University of Pennsylvania could gain or lose money depending on the results of this study.

If you would like more information, please ask the researchers or the study coordinator. **You are also encouraged to consult an advisor of your choice regarding questions you may have related to the University of Pennsylvania's financial interests related to this study.**

Please be aware that your participation is voluntary which means you can choose whether or not you want to participate. If you choose not to participate, there will be no loss of benefits to which you are otherwise entitled.

WHY IS THIS STUDY BEING DONE?

Vaccines are medicines given to create resistance or immunity against a disease. There are several different types of vaccines, including attenuated (live but weakened virus or bacteria), whole killed (inactivated virus or bacteria) or subunit (a piece of virus or bacteria). The vaccine (PENNVAX B) used in this study is new type of vaccine called a DNA vaccine. A DNA vaccine contains genes from the HIV virus in the form of a plasmid (a small circular piece of DNA).

The purpose of this study is to test the safety and the responses of your immune system to a new HIV vaccine in patients with HIV infection. The purpose of a vaccine is usually to prevent a person from getting an infection. There is no vaccine for treating HIV infection and it is not known whether making a stronger immune response with a vaccine will help you. But, the Study Team is going to look at the possibility that treating a person already infected with HIV can cause a stronger immune response against the HIV virus.

The Study Team will watch the safety, side effects, and immune system response of the experimental vaccine against HIV infection called PENNVAX™-B. The vaccine will be given with an investigational device (called CELLECTRA®) that will deliver a small electric charge through 5 needles. This is called electroporation and is used to increase the amount of vaccine taken up by your muscle. This investigational device has also not been approved by the U.S. Food and Drug Administration (FDA) for use in this country but may be used in clinical studies like this one. This vaccine will be studied along with the CELLECTRA® device to see if it boosts immune response in people already infected with HIV.

WHAT DO I HAVE TO DO IF I AM IN THIS STUDY?

If you qualify to be in this study, you will receive PENNVAX™-B given with the CELLECTRA® device. Every subject enrolled will receive the same treatment**.**

You will be taking your anti-HIV drugs while receiving the HIV vaccine. This study will not provide any of your anti-HIV drugs. Your primary care provider will continue to provide them to you. The vaccines, study visits and lab work will be provided free to you. Your insurance company will not be charged for these visits. You will continue to see your primary care provider for your HIV treatment. You should continue to take your HIV medicines. Each study visit will last about 1 hour. Even if you discontinue the study for any reason, you will be asked to return to all your study visits.

PENNVAX™-B is a new type of vaccine called a DNA vaccine. A DNA vaccine contains genes from the HIV virus in the form of a plasmid (a small circular piece of DNA). Genes are the pieces of DNA that act as a code of instructions to make proteins. The DNA containing genes is injected into muscle. The body then makes the vaccine protein, which may stimulate immunity in a better way than other vaccines.

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The PENNVAX™-B vaccine is made of 3 different plasmids which contain genes that produce several of the different proteins that make up some parts of the HIV virus (envelope and core). Because the vaccine is made of genes that produce only parts of the HIV virus, it can not make a live virus. In the vaccine, the DNA is mixed with bupivacaine, which helps the DNA enter cells. Bupivacaine is a licensed numbing medicine.

The PENNVAX™-B will be given you to by injection followed by electroporation (a small electric charge delivered through 5 needles from the CELLECTRA® device). This charge is meant to increase the amount of vaccine taken up by your muscle.

Procedures:

Approximately 12 subjects will participate in this study. All of them will be enrolled at the University of Pennsylvania and everyone will receive the same treatment (PENNVAX™-B + electroporation). You will be enrolled at this institution under the care of Dr. Pablo Tebas, who is in charge of this study at the University of Pennsylvania. The study will begin with only one person receiving the PENNVAX™-B vaccination. Then the study will vaccinate a few more small groups at a time before the rest of the subjects are enrolled.

The exact schedule and procedures are as follows:

Pre-entry screening: Before you can start the study, the study doctor or study staff will talk to you about the study. Then you will have to sign this form before the study doctor or study staff can begin the screening period. These screening procedures will be performed to determine if you are eligible to participate in this study. These procedures include:

Health and medication questionnaire: You will answer questions about your health, your medical history, and the medications you take

Physical Assessment: The study doctor will do a physical exam. The exam consists of obtaining your height and weight, listening to your heart and lungs, looking in your eyes, ears, and mouth. If you have a health concern or your past medical history is significant, the doctor may ask you questions or may conduct a more thorough evaluation.

Weight and Height: Study staff will see how much you weigh and how tall you are.

Vital signs: Study staff will check your blood pressure by putting a band around your arm. This will squeeze your arm for about a minute. They will also check your pulse, listen to you breathe in and out, and take your temperature. These measurements will be done several times during the study.

Electrocardiograms (ECGs): Study staff will attach leads (electrical sensing devices) to your chest to measure the electrical activity of your heart.

Collect blood for safety testing of your blood counts, chemistry, liver and kidney functions, CD4+ T-cell count, viral load and immunology testing.

Collect urine for safety testing – this is being performed as a safety lab to check for infections.

Pregnancy testing on women who are able to have children. These tests must be repeated within 24 hours of dosing and the tests must show you are not pregnant.

You will be permitted to enter the study if you meet the study criteria and if study related test results are satisfactory which will be decided by the study investigator.

YOU MUST TELL THE MEDICAL STAFF ALL ABOUT YOUR PREVIOUS AND CURRENT MEDICAL CONDITIONS AND ANY DRUGS (LEGAL AND ILLEGAL) YOU ARE TAKING. FAILURE TO DO SO MAY PUT YOUR HEALTH AT RISK.

Day of the first injection (Day 0 of study): you will be asked about changes in your health since the last visit, have a physical examination, have an ECG performed, have your blood drawn and urine collected for monitoring lab tests, and have a pregnancy test if you are a woman. After being given an injection and electroporation (electroporation procedure is described below), you will have another ECG performed and stay in the Clinical and Translational Research Center (CTRC) for half hour to be monitored closely for any adverse effects. You will be given a symptom diary to take home and write down any symptoms or reactions that you notice.

Day 0 + 24 hours: you and the Study Team will talk by phone to check on any symptoms noted and to describe the injection sites (where you got the shots).

Week 2: you will return for a brief physical exam, and to give a blood and urine specimen to monitor your responses. You will return your symptom diary to the study doctor or nurse.

Week 4: you will return for a physical exam, give a report of how you have felt since the last visit, have an ECG performed and give a blood and urine specimen for monitoring tests of safety and immune responses. If a woman, you will also have a urine pregnancy test. If your overall condition is unchanged (stable), you will receive your second injection and electroporation, you will have another ECG performed and will be watched for half hour as was done for your first injection. Subsequent follow-up evaluations will be as after your first injection, on:

Week 4 +24 hours: repeat of Day 0 + 24 hours

Week 6: repeat of Week 2

Week 8: you will return for a physical exam, give a report of how you have felt since the last visit, have an ECG performed and give a blood and urine specimen for monitoring tests of safety and immune responses. If a woman, you will also have a urine pregnancy test. If your overall condition is unchanged (stable), you will receive your third injection and electroporation, you will have another ECG performed and will be watched for the next half hour as was done for your first injections. Subsequent follow-up evaluations will be as after your first injection, on Week 8 + 24 hours and Week 10.

Week 8 + 24 hours: repeat of Day 0 + 24 hours

Week 10: repeat of Week 2 and you will also give a blood specimen for monitoring tests of immune responses.

Week16: you will return for a physical exam, give a report of how you have felt since the last visit, have an ECG performed and give a blood and urine specimen for monitoring tests of safety and immune responses. If a woman, you will also have a urine pregnancy test. If your overall condition is unchanged (stable), you will receive your fourth and last injection and electroporation, you will have another ECG performed and will be watched for the next half hour as was done for your first injections. Subsequent follow-up evaluations will be as after your first injection, on:

Week 16 + 24 hours: repeat of Day 0 + 24 hours

Week 18: repeat of Week 10

Week 24 (6 months after your first injection): repeat of Week 10.

Week 48(10 months after first injection): repeat of Week 10.

Between 60-90 ml (2-3 ounces or 4-6 tablespoons) of blood will be taken at most of the study visits. The Week 2 and Week 6 visits will require less blood, between 3 and 5 tablespoons.

You must agree not to engage in any high-risk behavior including intravenous drug use and unprotected sexual intercourse.

If for any reason you discontinue the study (and refuse to get more vaccinations) you will be asked to continue the study visits, or at least come to our clinic to complete the final visit, which is exactly as the Week 48 visit (see above).

CELLECTRA® Procedure:
This study procedure will occur at the Entry (Day 0), Week 4, Week 8 and Week 16 visits. The study personnel will insert the needles from the CELLECTRA® device into a muscle on your arm or leg followed by injection of the study vaccine. Then there will be 3 short pulses from the CELLECTRA® device lasting less than 1 second each. Your arm or leg will move slightly as a result of the pulse delivered into the muscle. The CELLECTRA® device will be used to get the study medication into the cells of the muscle. It gives out a specific amount of electrical current through the muscle by using an applicator with a grouping of 5 needles. A cream (EMLA cream) to numb the area of the injection may be applied prior to the procedure. In addition, you may be offered Tylenol #3 (acetaminophen with codeine) to help with pain related to the injection. The study staff will help decide which medications you need.

Pain Evaluation:
Following each injection, you will rate the amount of discomfort you experienced during the injection by making a mark on a piece of paper between the numbers 0 and 10, with 0 representing no pain and 10 representing the worst pain you have ever experienced

Other information
The results of all routine blood tests, including HIV viral load and CD4 cell counts, will be provided to you and, with your permission, to your primary care doctor.

Some of your blood will be stored (with a special code to protect your identity) and used for viral and immunologic testing that is required for this study.

Some of your blood that is left over after all required study testing is done may be stored (with a special code to protect your identity) and used for approved HIV-related research.

Storage of leftover blood is not a requirement to participate in the study and you may withdraw your approval for the storage of your leftover blood, at anytime. Please indicate below whether you approve the use of your leftover blood for HIV-approved research.

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_____ YES _____ NO

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
About 12 people will take part in this study.

HOW LONG WILL I BE IN THIS STUDY?
You will be in this study for about 1 year.

WHY WOULD THE DOCTOR TAKE ME OFF THIS STUDY EARLY?
The study doctor may need to take you off the study early without your permission if:

- The study is cancelled by the U.S. Food and Drug Administration (FDA), National Institutes of Health (NIH), or the site's Institutional Review Board (IRB). (An IRB is a committee that watches over the safety and rights of research subjects.)
- The sponsor stops the study
- You are not able to attend the study visits as required by the study**.**
- You become pregnant or begin breastfeeding

The study doctor may also need to take you off the study vaccinations without your permission if:

- Continuing the study vaccinations may be harmful to you
- You need a treatment that you may not take while on the study
- You are not able to take the study vaccinations as required by the study

WHAT ARE THE RISKS OF THE STUDY?

The vaccine used in this study may have side effects, some of which are discussed below. Please note that these lists include the more serious or common side effects with a known or possible relationship. If you have questions concerning additional study vaccine side effects, please ask the medical staff at your site. Your doctor will inform you of any new information that might affect your willingness to participate in the trial.

Risks of vaccine injections in the muscle

- Injection site reactions such as redness, pain, swelling, bleeding, bruising, a warm feeling, or in rare cases infection.
- Flu-like symptoms such as fever, chills, muscle aches and pains, headaches, nausea, dizziness, and fatigue.
- Allergic reactions including itchy rash, low blood pressure, sudden body swelling, breathing difficulty; in very rare cases, reactions can lead to death. Therefore, clinic staff will watch you for ½ hour after each immunization.

Risks of DNA Vaccines
It is important to know that so far, DNA vaccines against HIV and other viruses have been safe and well tolerated by test animals and humans. A total of around 1000 people have received various DNA vaccines. Risks of the various components of the study vaccinations are as follows:

Risks of PENNVAX™-B :

The HIV-containing plasmids in this vaccine are modifications of HIV DNA vaccines that investigators at Penn and elsewhere have given to more than 1000 volunteers without a vaccine-caused complication. Because of the modifications, the study will begin with only a few subjects receiving the PENNVAX™-B vaccination at a time to confirm its safety. People in the HIV DNA vaccine studies have experienced minimal bleeding, bruising, redness and swelling at the injection site. Placebo injections have resulted in a similar number of mild injection-site reactions (As commented above). No effects have been found on kidney, liver, heart, or other organ function.

Risks of CELLECTRA® :
The device used in this study may cause soreness, bruising, pain, redness, swelling, itching, hardness/stiffness, brief local muscle contractions and a small amount of bleeding or scabs at the treatment site, and/or muscle tissue damage (minor muscle cell damage).

Other possible side effects:

- 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 is 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.
- Tylenol #3: Rarely large doses or long term usage can cause liver damage, rash, itching, fever, lowered blood sugar. These side effects are unlikely at the doses being used for this study. Side effects for codeine include lightheadedness, dizziness, drowsiness, nausea, vomiting, loss of appetite and sweating. Rarely, codeine can cause allergic reactions.

Theoretical risks for DNA vaccines:
HIV DNA vaccines have been given to animals and humans without any problems being found but it cannot be certain that they will continue to be safe for humans. The possible risks related to DNA vaccines - which are theoretical (a guess as to what could happen) and haven't been observed to date include: muscle damage, antibodies to DNA, insertion of the vaccine DNA into the body's DNA, insertion of the vaccine DNA into bacteria leading to the formation of a new bacterium which might resist some antibiotics, or insertions of the vaccine into a virus leading to formation of a new virus. None of these possible risks of DNA vaccines has been seen in laboratory tests or in animals or humans so far. During the study regular blood tests will be performed to monitor some of these. It is important to know that so far, DNA vaccines have been safe and well tolerated by test animals and humans.

Special risks for bupivacaine:
All volunteers in the study will receive injections of bupivacaine, with DNA mixed in it. Bupivacaine helps the DNA get into the muscle. It is a kind of anesthetic (a medicine used to control pain), similar to the numbing medicine used by dentists when they pull teeth. Bupivacaine, like all medicines, can be associated with certain side effects. The amount of bupivicaine in the study vaccine is small but the risk may be increased if the vaccine was accidentally administered into the bloodstream. The chances of this happening are very small.

Side effects have been seen with doses of bupivacaine greater than 50 times higher than the doses that will be used in this study. The side effects are rare but include neurologic or heart problems due to high levels of bupivacaine in the blood. This may happen as a result of accidental injection into the bloodstream, overdose, or slow breakdown of the drug. Neurologic side effects can

include confusion, anxiety, dizziness, blurred vision, shaking, or seizures. Heart side effects can include decreased heart pumping, fast heart rate, low blood pressure or abnormal heartbeats. Other possible side effects include nausea, vomiting, or chills.

Allergic Reactions: As with all vaccines or drugs you could have an allergic reaction—a rash, hives or even difficulty breathing. Allergic reactions can be serious; therefore, the clinic staff will watch you for 30 minutes after each immunization. Other immune reactions could occur such as serum sickness (hives, rash, fever, abdominal pain, diarrhea, joint pain and swelling).

Risks of blood drawing

Taking blood may cause discomfort, bleeding, or bruising where the needle enters the body, and in rare cases, fainting or infection.

Other risks of being in this study

There may be risks or serious and/or life threatening side effects when other medications or herbal supplements are taken with the study vaccine. For your safety, you must tell the study doctor or nurse about all medications you are taking besides the study vaccine before you start the study, and also before starting any new medications while on the study. In addition, you must tell the doctor or nurse before enrolling in any other clinical trials while on this study.

Most studies investigating HIV vaccines exclude people who previously received an HIV vaccine. Therefore, you may be unable to participate in another trial studying an HIV vaccine if you participate in this study and receive the HIV vaccine.

Unknown/Unforeseeable Risks and Discomforts

You may have side effects while on the study. Everyone taking part in the study will be watched carefully for any side effects. However, doctors don't know all the side effects that may happen. The research may involve risks that are currently unknown. Side effects may be mild or very serious. Your health care team 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.

In addition to the risks listed above, there may be some unknown or infrequent and unforeseeable risks associated with the use of this study medication, including severe or life-threatening allergic reactions or interactions with another medication. There also is a risk of death.

You will be informed in a timely manner both verbally and in writing of any significant new information, findings or changes to the way the research will be done that might influence your willingness to continue your participation in this study.

You should talk to your study doctor about any side effects that you have while taking part in the study

Are There Risks Related To Pregnancy?

The vaccine in this study may be unsafe for unborn babies. If you are having sex that could lead to pregnancy, you must agree not to become pregnant or make a woman pregnant.

Because of the risk involved, you and your partner must use two methods of birth control that you discuss with the study staff. You must continue to use both methods until one month after you have received all vaccines. You may choose two of the birth control methods listed below:

- Birth control drugs that prevent pregnancy given by pills, shots or placed under the skin
- Male or female condoms with or without a cream or gel that kills sperm
- Diaphragm or cervical cap with a cream or gel that kills sperm
- Intrauterine device (IUD)

If you can become pregnant, you must have a pregnancy test before you enter this study. The test must show that you are not pregnant. **If you think that you have become pregnant during the study it is important that you inform the study doctor immediately. If you become pregnant or think that you may be pregnant, you will be removed from the study and the study doctor will refer you to seek obstetric care, the cost of which will be your responsibility, and may request to track your pregnancy and will report the pregnancy to the Sponsor and the IRB.** You will not be allowed to breast-feed during this study.

ARE THERE BENEFITS TO TAKING PART IN THIS STUDY?

You may receive no benefit from being in this study. Information learned from this study may help others who have HIV.

WHAT OTHER CHOICES DO I HAVE BESIDES THIS STUDY?

Instead of being in this study you have the choice of not participating in this study.

WHAT ABOUT CONFIDENTIALITY?

By signing this Consent/Authorization Form you are permitting the University of Pennsylvania Health System and the School of Medicine to use your personal health information collected about you for research purposes within our institution. You are also allowing the University of Pennsylvania Health System and the School of Medicine to disclose that personal health information to outside organizations or people involved with the processing of this study.

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

Personal health and contact (phone number, address) information collected as part of this study is recorded in your clinical trial chart. This record is separate from your medical chart. Data collected for the study is reported to the study team on a case report form, which includes the information listed below, but not your name or other identifying information. Results of laboratory tests or study procedures will be copied and sent to your primary care physician by name, at your request only.

Personal health information that is collected and will be disclosed to the agencies listed on the following page as part of this research study is:

- Demographics (Race, Gender)
- Signs and symptoms you experience while on the study
- Current and past medical diagnoses; allergies
- Current and past medications and therapies
- Information from a physical exam: weight, blood pressure, heart rate, temperature
- Data from laboratory tests (pregnancy tests)

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- Data from ECG test
- Data from study questionnaires

Why is your personal health information being used?
Personal contact information, such as phone number and address, will be used only by clinical trial staff to get in touch with you while you are participating in this study. Your health information and results of tests and procedures are being collected as part of the research study and for the advancement of medicine and clinical care. The Principal Investigator will use the results to monitor your safety and ability to tolerate the study medications.

Which of our personnel may use or disclose your personal health information?
The following individuals and organizations may use or disclose your personal health information for this research project:

- The Principal Investigator and other University staff associated with this study;
- The University of Pennsylvania Institutional Review Boards (the Committees charged with overseeing research on human subjects) and the University of Pennsylvania Office of Regulatory Affairs
- Authorized members of the University of Pennsylvania and the University of Pennsylvania Health System and School of Medicine work force who may need to access your information in the performance of their duties, for example, to provide treatment, to ensure the integrity of the research, accounting or billing matters, etc.

Who, outside of the University of Pennsylvania Health System and the School of Medicine, might receive your personal health information?
As part of the study the Principal Investigator, study team and others listed above, may disclose your personal health information, including the results of the research study tests and procedures to the following:

- Pharmaceutical Sponsors: Drug companies (VGX Pharmaceuticals) who supply the CELLECTRA® device for the study will have access to safety information.
- Government Agencies: Data from this study will be made available to the Food and Drug Administration for them to evaluate the safety and efficacy of the treatments being used in this study.

Study staff will inform you if there are any changes to this list above during your active participation in the trial. Once information is disclosed to others outside the University of Pennsylvania Health System or School of Medicine the information may no longer be covered by federal privacy protection regulations.

In all disclosures outside the University of Pennsylvania Health System or School of Medicine, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier, unless disclosure of the direct identifier is required by law. Personal health information will be disclosed by a unique code number. Only study staff can break the code and identify you to your code.

How long will the University of Pennsylvania Health System and the School of Medicine be able to use or disclose your personal health information?
Your authorization for use of your personal information for this specific study does not expire. This information may be stored in a database (research repository). However, the University of

Pennsylvania Health System and the School of Medicine may not re-use or re-disclose your personal health information collected for this study for another purpose other than the research described in this consent form unless you have given written permission to the Principal Investigator to do so. However, the University of Pennsylvania Institutional Review Board may grant permission to the Principal Investigator or others to use your information for another purpose after ensuring that appropriate safeguards are in place. The Institutional Review Board is a committee whose job is to protect the safety and privacy of research subjects. Results of all tests and procedures done solely for this research study and not as part of your regular care will not be included in your medical record unless you want them to be sent to your primary care provider. You will need to complete a medical records release of information to allow us to provide study data to your doctor.

Will you be able to access your records?

You will be able to request access to your medical record when the study is completed. During your participation in the study, you will not be able to access your medical records. This will be done to prevent the knowledge of study results affecting the reliability of the study. Your information will be available should an emergency arise that would require your treating physician to know the information to best treat you. You will have access to your medical record and study information that is part of that record when the study is over. The Investigator is not required to release to you research information that is not part of your medical record.

Can you change your mind?

You may withdraw your permission for the use and disclosure of any of your personal information for research, but you must do so in writing to the Principal Investigator at 502 Johnson Pavilion. Even if you withdraw your permission, the Principal Investigator for the research study may still use your personal information that was collected prior to your written request if that information is necessary to the study. If you withdraw your permission to use your personal health information that means you will also be withdrawn from the research study.

WHAT ARE THE COSTS TO ME?

Laboratory tests, clinical evaluations, and study vaccines will be provided by the study for free.

Your anti-HIV drugs will not be provided, so you must get these drugs through your primary care provider.

WILL I RECEIVE ANY PAYMENT?

To compensate you for your time, transportation or other expenses you may incur as a participant you will receive $50 dollars for each visit that has an injection (4 visits), $20 for other visits (9) and $50 for the final study visit. Thus if you complete all visits with injections, 9 routine study visits and the final visit, you will be compensated a total of $430 for the study. You will not be compensated for any screening visits or for telephone contact for follow up.

WHAT HAPPENS IF I AM INJURED?

If you have a medical emergency during the study you should go to the nearest emergency room. You may contact the Principal Investigator or Emergency contact listed on page one of this form. You may also contact your own doctor, or seek treatment outside of the University of Pennsylvania. Be sure to tell the doctor or his/her staff that you are in a research study being conducted at the

University of Pennsylvania. Ask them to call the telephone numbers on the first page of this consent form for further instructions or information about your care.

In the event that you are hurt or injured as a result of participation in this research study, please contact the investigator listed on page one of this form.

If during the course of this study any injury occurs to you as a direct result of the administration of the study medication or study procedures, the study sponsor, VGX Pharmaceuticals, LLC, agrees to pay any reasonable medical expenses necessary to treat such injury (1) to the extent you are not otherwise reimbursed by medical insurance, (2) to the extent that such expenses are not attributable to any pre-existing abnormal medical condition or underlying disease, and (3) provided you have followed the directions of the investigators.

Financial compensation for such things as lost wages, disability or discomfort due to injury is not available. But, you DO NOT waive your legal rights by signing this form.

WHAT ARE MY RIGHTS AS A RESEARCH SUBJECT?

Taking part in this study is completely voluntary. You may choose not to take part in this study or leave this study at any time. There will be no penalty to you if you decide to leave this study. Your healthcare provider will treat you the same no matter what you decide.

We will tell you about new information from this or other studies that may affect your health, welfare, or willingness to stay in this study. If you want the results of the study, let the study staff know.

WHAT DO I DO IF I HAVE QUESTIONS OR PROBLEMS?

For questions about this study or a research-related injury, contact:

- Pablo Tebas, MD (215-615-4321)
- Clinical Trials Unit (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

CONSENT

When you sign this form, you are agreeing to take part in this research study. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer. Your signature also means that you are permitting the University of Pennsylvania Health System and the School of Medicine to use your personal health information collected about you for research purposes within our institution. You are also allowing the University of Pennsylvania Health System and the School of Medicine to disclose that personal health information to outside organizations or people involved with the operations of this study.

A copy of this consent form will be given to you. You will also be given the University of Pennsylvania Health System and School of Medicine's Notice of Privacy Practices that contains more information about the privacy of your health information.

Name of Subject (Please Print)	Signature of Subject	Date

Name of Person Obtaining Consent (Please Print)	Signature	Date

For subjects unable to give authorization, the authorization is given by the following authorized subject representative:

Authorized subject representative **[print]**	Authorized subject representative Signature	Date

Provide a brief description of above person authority to serve as the subject's authorized representative.

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