HOSPITAL OF THE UNIVERSITY OF PENNSYLVANIA

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

Protocol Title:	**A5369 Version 1.0, dated 03/09/2018; Letter of Amendment #1, 9/24/2018; Letter of Amendment #2, 4/16/19 HIV-1-Gag Conserved-Element DNA Vaccine (p24CE) as Therapeutic Vaccination in HIV-Infected Persons with Viral Suppression on Antiretroviral Therapy** ***A Multicenter Trial of the AIDS Clinical Trials Group (ACTG)***
Principal Investigator:	Pablo Tebas, MD 502 Johnson Pavilion, Philadelphia PA 19104 **(215) 349-8092**
Project Manager:	Eileen Donaghy, MSN, CRNP
24 hr. Emergency Contact:	Immunodeficiency Program Doctor on call (215) 662-6059

Introduction:

You are being asked to take part in this research study because you are infected with the human immunodeficiency virus (HIV) and are currently taking anti-HIV medications. This study is sponsored by the National Institutes of Health (NIH). The doctor in charge of this study at this site is: Dr. Pablo Tebas. Before you decide if you want to be a part of this study, we want you to know about the study.

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. 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. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. The research team is going to talk to you about the research study, and they will give you this consent form to read. You may also decide to discuss it with your family, friends, or family doctor. You may find some of the medical language difficult to understand. 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.

Why Is This Study Being Done?

The study will look to see if two HIV vaccines are safe in people infected with HIV. Additionally, the study will look at whether or not the HIV vaccines improve the immune system's ability to fight HIV. This study will also look at whether the intramuscular injection of the study vaccines given along with electroporation will be well tolerated.

The HIV vaccines and injection device used in this study are experimental. This means that this vaccine has not been approved by the Food and Drug Administration (FDA).

How Many People Will Take Part in This Study?

About 40 people will take part in this study. About 5-7 people are expected to enroll at the University of Pennsylvania.

How Long Will I Be In This Study?

You will be in this study for about 12 months (48 weeks).

IRB Approved From: 06/10/2019 To: 06/09/2020

What Do I Have To Do If I Am In This Study?
To be in this study, you must continue taking your current anti-HIV drugs. Your anti-HIV drugs will not be provided to you by the study.

Screening
If you decide to take part in this research study, you will be asked to sign this consent form. You will come to the clinic to have a screening visit. Tests will be done at the screening visit to see if it is safe for you to join the study. The screening visit will take about 1 hour, but it may be shorter or longer. Prior to screening or at Screening visit, the site staff will inform you whether leukapheresis is required.
At the screening visit:

- Your HIV-1 infection will be confirmed. If there is no record available, you will have another HIV-1 test. You may have to sign a separate consent form before having this test.
- You will have a complete physical exam and will be asked questions about how you are feeling.
- You will also be asked to answer questions about your medical history and medications you are taking now and have taken in the past.
- You will have a skin pinch test to measure the thickness of the skin on your upper arm or upper thigh muscles. This test will also measure the right depth when giving the injections in the upper arm or upper thigh muscles.
- You will have a pregnancy test done, if you are a woman able to become pregnant. You cannot take part in this study if you are pregnant or breastfeeding.
- You will have a urinalysis performed to evaluate the health of your kidneys.
- You will have an electrocardiogram (EKG) test done to measure the electrical activity of your heart. You will be asked to lie down very still and breathe normally during the test.

You will have about 2 tablespoons of blood drawn from a vein in your arm:

- To measure HIV viral load (a viral load test measures how much HIV is in your blood).
- To measure CD4/CD8 T cell counts (the number of white blood cells that fight infection).
- To test for hepatitis B and hepatitis C (viruses that can infect your liver).
- To conduct routine safety tests.

You will be told the results of the tests done at the screening visit.

If you do not enroll into the study
If you decide not to take part in this study or if you do not meet the eligibility requirements, we will still use some of your information. As part of this screening visit, some demographic (for example, age, gender, race), clinical (for example, disease condition, diagnosis), and laboratory (for example, CD4 cell count, viral load) information is being collected from you so that ACTG researchers may help determine whether there are patterns or common reasons why people do not join a study. If you do not want this information to be recorded, you should not sign this consent form and not participate in the study. If you elect not to participate, all information collected thus far by the research team will be destroyed.

Pre-Entry
If you qualify for the study, you will return to the clinic after your screening visit. The visit is expected to last between 3 to 4 hours.

At the pre-entry visit:

- You will have a total of about 14 tablespoons of blood drawn from a vein in your arm. NOTE: If you are having leukapheresis performed at this visit, you will have a reduced volume of additional blood collected.
- You will have blood collected and stored for future immunologic testing (to measure the body's ability to fight infection).
- You will have a pregnancy test done, if you are a woman able to become pregnant.
- You will have blood collected to measure CD4/CD8 T cell counts (the number of white blood cells that fight infection).
- You will have blood collected for human leukocyte antigen (HLA) typing and testing.
- You will have blood stored for future tests.
- If you are one of the first 3 participants to be enrolled at your site, you will have leukapheresis performed. You will also be required to have a leukapheresis performed at the week 26 visit. By collecting blood using this procedure, researchers are able to get many more white blood cells than is usually possible. If you are not required to have leukapheresis, this procedure is optional but highly recommended.
- If you agree, you will have stool samples collected to study the different kind of bacteria in your stool. These samples will be stored and will be tested after the study is over. You will not be given the results. (This test is optional)

Leukapheresis Procedure

The leukapheresis procedure may be performed at Apheresis & Infusion Unit at the Hospital of the University of Pennsylvania. The procedure will take about 2 hours and the full visit will last about 3 hours. You will have to remain in a semi-reclining or reclining position for most of this time.

Leukapheresis is a medical procedure that involves removing whole blood from an individual/donor and separating the blood into individual components so that leukocytes (white blood cells) can be removed. The remaining blood components are then put back into the bloodstream of the individual/donor. This will be done by inserting a needle attached to sterile tubing in one arm, and first sending your blood through a machine. This machine spins your blood to separate the red blood cells (cells that carry oxygen), the white blood cells (cells that fight infection) and the platelets (cells that help form clots). The white blood cells will be kept for testing. The rest of your blood will be returned to your body through another needle and tube in your other arm. Thus, there is minimal blood loss (30 mls). Not all of your white blood cells are removed, and your body will make more white cells within a few days. Losing the number of white blood cells that are collected does not pose a danger to your health.

Entry

You will return to the clinic at least 24 hours after your pre-entry visit. The entry visit (week 0) will last about 1-2 hours, but may be shorter or longer.

At the entry visit:

- You will have a brief physical exam.
- You will be asked about how you are feeling and any medications you have taken since the last visit.
- You will have a pregnancy test done, if you are a woman able to become pregnant.
- You will have a total of about 11 tablespoons of blood drawn from a vein in your arm.
- You will have blood drawn for routine safety tests.
- You will have a urinalysis performed to evaluate the health of your kidneys.
- You will have blood drawn for CD4/CD8 T cell counts, HIV viral load, and future immunologic testing.

You will be told the results of the safety tests, HIV viral load, and CD4/CD8 T cell counts done during the study.

Study Injections
When you enter the study, you will be placed into one of the three groups. You will be randomized 2:1:1 (by chance) to receive either the p24CE1/2 pDNA vaccine (an HIV vaccine that contains the gene that makes parts of the HIV protein that are the same in all samples of HIV virus) followed by p24CE1/2 + full-length Gag pDNA vaccine (a different HIV vaccine that contains the gene for the whole HIV protein, which can be slightly different from one HIV virus to the next), OR the full-length Gag pDNA vaccine alone, OR placebo (the placebo is a salt solution that does not contain any vaccine, medicine, or drugs).

Neither you nor the study staff will know whether you will receive the vaccine or placebo. You will receive the injections at the clinic at weeks 0 (entry), 4, 12, and 24.

Electroporation (EP) Procedure
To improve the effectiveness of the vaccine, instead of a regular needle and syringe, a small, hand-held device will be used to inject the vaccine or placebo into your upper arm or thigh muscle. To give the vaccine or placebo, the study staff will press the device against your skin and press a button. Although you will not be able to see them, the device will put an injection needle and four thin wires into your muscle. The vaccine or placebo will be given through the injection needle into your muscle. After the injection, the device will give a very short electrical signal to your muscle at the spot of the injection. The electrical signal will last for about one half second. You will feel twitching in your muscle, which is often painful. Previous participants have described the feeling as a short “cramp” or “punch” in their muscle. Right after the electrical signals are finished, the device will be removed from your muscle. Your muscle may be sore to the touch after the vaccination. If this occurs, it usually does not last for more than 30-60 minutes.

Before Injection
Due to the risk of dizziness/lightheadedness or in rare cases, fainting, the injection will be given to you while you are in a secure, seated position.

After Injection
You will be observed by the study staff when coming to a standing position following the injection. You may ask for pain-relieving medication after each injection if you need it.

After each injection, you will be asked to stay at the clinic for 30 minutes to be observed and to complete a brief survey (Procedure Tolerability Questionnaire). This survey will ask you questions on the level of discomfort you may have experienced during the vaccination, including the overall acceptability of the procedure.

You will be called 2 to 3 days after each injection to see how you are doing. The telephone call will take about 5-10 minutes. If you prefer not to be contacted by telephone, then you will be asked to return to the clinic within 2 to 3 days after each vaccination. The study staff may ask you to come to the clinic if you are having any side effects from the vaccination.

Study Diary
You will be given a diary to record:
- Your temperature for 4 days after each injection.
- Any side effects for 5 days after each injection.
- Any rash or skin irritation around and/or in the middle of the injection site.
- Any medications taken.
- Any non-study vaccines received.

The diary will be given to you at the entry visit. It will take you about 10-15 minutes to complete the diary each day. You will bring the diary back to the clinic at your next visit and at every visit afterwards until the 26-week follow-up visit. The diary will be collected by the study staff at the final visit (week 48); if you stop the study early, the diary will be collected your last study visit.

During the Study
After your entry visit, the next study visits will take place over a 12-month period (weeks 4, 6, 12, 24, 26, and 48). Each study visit will last about 1-2 hours, but may be shorter or longer.

At most visits, you will be asked about how you are feeling, what medications you are taking, and have a brief physical exam. At the injection visits (weeks 4, 12, and 24), you will have a pregnancy test done, if you are a woman able to become pregnant, before you have the injection. At weeks 4, 12, and 24, you will also have a urinalysis performed.

At most visits, you will have blood drawn from a vein for routine safety tests. At some visits, you will have blood drawn for CD4/CD8 T cell counts, HIV viral load, and future immunologic testing. You will have between 2 and 14 tablespoons of blood drawn at each visit. NOTE: If you are having leukapheresis performed at the week 26 visit, you will have a reduced volume of blood collected at that visit.

If you agree, you will have stool sample collected at week 26 to study the different kind of bacteria in your stool. These samples will be stored and will be tested after the study is over. You will not be given the results. (This test is optional.)

If you agreed to have leukapheresis performed at the pre-entry visit you will be required to also have leukapheresis performed at the week 26 visit.

NOTE: Your blood that is drawn for future immunologic testing, which is required for this study, will be stored with usual protectors of your identity. Your blood samples will be processed in the laboratory to produce a certain type of white blood cells, called PBMC (peripheral blood mononuclear cells), and plasma.

Other
If you agree, some of your blood that is left over after all required study testing is done may be stored (with usual protectors of your identity) and used for future ACTG-approved HIV-related research.

You may refuse or withdraw your permission for storage of leftover samples without any impact on you taking part in the study or any penalty or loss of benefits to which you are entitled. You can withdraw your permission at any time. If you do not agree to have the leftover samples stored or withdraw your permission, the leftover samples will be destroyed. These leftover samples may be stored for an indefinite period of time. You might not receive the results of testing performed on these leftover samples.

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 stopped or cancelled.
- You do not take your anti-HIV medications as prescribed.
- You do not comply with the protocol.
- You choose to stop your participation in the study.
- Your primary care doctor feels the treatment is no longer in your best interest.
- Failure to receive the first vaccination.

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

- You miss two consecutive clinic visits.
- Continuing to receive the study vaccine may be harmful to you.
- You need a drug or treatment that you may not take while on the study.
- You are not able to receive the study vaccine as required by the study.
- You have a bad reaction to the study vaccine and need treatment.
- You become pregnant or start breast-feeding.
- You have a plasma HIV-1 RNA >1,000 copies/mL confirmed by a second consecutive reading.

If you must stop taking the study drugs before the study is over, the study doctor will ask you to continue to be part of the study and return for some study visits and procedures.

If I Have To Permanently Stop Taking Study-Provided Vaccine Or Once I Leave The Study, How Would the Vaccine Be Provided?

During the study

If you must permanently stop taking study-provided vaccine before your study participation is over, the study staff will discuss other options that may be of benefit to you.

After the study

After you have completed your study participation, the study will not be able to continue to provide you with vaccines you received on the study.

What Are The Risks Of The Study?

The vaccine or placebo used in this study may have side effects, some of which are listed below. Please note that these lists do not include all the side effects seen with the study vaccine. These lists include the more serious or common side effects with a known or possible relationship. There may be more serious or common side effects that we do not know about yet. Therefore, it is important that you report any side effects to the study staff. If you have questions concerning additional study vaccine side effects, please ask the medical staff at your site.

There is a risk of serious and/or life-threatening side effects when non-study medications are taken with the study vaccine. For your safety, you must tell the study doctor or nurse about all medications you are taking before you start the study and also before starting any new medications while on the study. Also, you must tell the study doctor or nurse before enrolling in any other clinical trials while on this study.

The following side effects can occur from either the vaccine or the placebo in this study. If you do have a reaction, it does not mean that you received the study vaccine.

General Vaccination Risks

The possible risks for vaccines in general include fever, chills, rash, aches and pains, nausea, headache, dizziness, and fatigue. We know these side effects can occur with other vaccines. They can occur whether you receive the vaccine or the placebo in this study. The side effects do not usually last long.

As with all vaccines or drugs, you could have an immediate allergic reaction, including itchy rash, hives, low blood pressure, sudden body swelling, or even difficulty breathing. Allergic reactions can be life threatening; therefore, the study staff will watch you for 30 minutes after each injection. There may be other side effects, even serious ones that we do not know about yet. Therefore, it is important that you report any side effects to the study staff as soon as they occur.

For people infected with HIV, vaccinations can cause a temporary increase in the HIV viral load, but this has not been seen when people are also taking medications that lower the amount of HIV in the blood. The long-term effects of temporary increases in HIV viral load levels are unknown.

Risks of Injections

- Arm discomfort
- Bleeding or bruising at the spot where the needle enters your body
- Small risk of fainting or infection
- Stinging, pain, soreness, redness, itching, swelling, burning, warmth at injection site
- Induration (hardness under the skin) at the site where the vaccine/placebo is given
- Brief twitching/contraction of the upper arm or thigh muscle where the injection is given.

Risks of Drawing Blood

Blood tests for screening and study visits will be done by inserting a needle into one of your veins and this can cause temporary mild pain or discomfort at the needle site (common), local bruising at needle site (rare), infection, and fainting (very rare).

Risks of HIV DNA Vaccines, including pDNA Study Vaccine

HIV-1 DNA vaccines have been studied in humans and appear to be well tolerated, but we do not have long-term follow-up on people taking part in these studies.

Possible risks related to DNA vaccines include muscle damage, or the production of antibodies (proteins made by the body's immune system in response to a foreign substance) to DNA. Other potential risks include insertion of the vaccine DNA into the body's DNA (leading to cancer) or into the DNA of a bacteria or virus in your body. None of these possible risks of DNA vaccines have been seen in laboratory tests or in animals or humans so far, but you need to be aware of these possible risks. During the study, regular blood tests and check-ups will be done to monitor these possible side effects.

The pDNA vaccine consists of artificial DNA. Since the vaccine in this study has not been given to humans for treating HIV infection, all the possible risks or side effects are not known.

The pDNA vaccine was tested in animals at doses similar to or larger than those planned to be given in this study without serious side effects. However, people may respond differently to the vaccine than animals.

Information about local injection site reactions in humans after injection of the pDNA vaccine is not available at this time. However, the local reactions related to intramuscular (IM) injections such as pain, hardness under the skin, redness, and swelling may occur and are expected to be mostly mild to moderate in severity based on results from earlier HIV clinical trials with related products. Information about systemic events (which affect your whole body, such as fever or not feeling well) with the pDNA vaccine are not available at this time. Based on results from clinical trials with related products in healthy adults and in HIV-infected persons, systemic events are expected to be mild to moderate in severity.

It is unknown whether receiving this HIV vaccine will change your response to any future HIV therapies or vaccines that you might receive. This might prevent you from taking part in other experimental vaccine or immune studies.

Risks of EP Procedure

This section describes the risks and restrictions we know about. There may also be unknown risks, even serious ones. If we learn about new risks during this study, we will tell you.

- Brief twitching/contraction of the upper arm or thigh muscle where the vaccination is given will occur during the EP procedure. This may result in a painful sensation, which should last only a few seconds.
- It is possible that the EP procedure could cause you to become dizzy or lightheaded. If severe enough, this could lead you to faint. Should this happen, you may require additional tests and/or hospitalization.
- After the EP device is removed, slight bleeding may occur in the skin at the vaccination site. This bleeding, if any, should only last for a few minutes.
- Delivery of the vaccine with the EP device is likely to result in muscle soreness or pain of mild to moderate severity at the vaccination site. Redness, swelling, and/or bruising in the area of the vaccination could also occur. It is possible that these reactions could persist for several days or more after administration.

Other Expected Risks

Common:

- Muscle pain with severe muscle contractions during vaccination administration
- Mild to moderate injection site pain, tenderness, redness, bruising, or edema (swelling under the skin)
- Muscle aches or headache in the first few days following vaccination

Less common:

- Severe vaccination site pain or tenderness
- Joint pain
- Vaccination site bruising (a mass of blood in the tissue caused by injury), laceration (cut or slash), or bleeding related to the vaccination procedure
- Dizziness/lightheadedness

Uncommon or rare:

- Fainting
- Severe reaction of the vaccination site including sterile abscess (lumps caused by nonliving irritants such as drugs) or secondary bacterial infection
- Allergic reaction, including rash, urticaria (hives), angioedema (swelling of the skin), bronchospasm (narrowing of the muscles that help you breathe), or anaphylaxis (life-threatening allergic reaction)

Unknown frequency or theoretical risks:

- Muscle damage at the vaccination site
- Insertional mutagenesis (a mutation caused by new genetic material put into a normal gene)
- Autoimmune reaction (a process in which your immune system attacks your body)

Risks of Bupivacaine

The HIV pDNA vaccine contains bupivacaine. Bupivacaine helps the DNA get into the muscle cells. It is an anesthetic, similar to the numbing medicine used by dentists. Bupivacaine, like all medicines, can have side effects. Bupivacaine can cause problems with the nervous system and heart. The nervous system side effects include confusion, dizziness, blurred vision, shaking, or seizures. The heart side effects can include decreased heart pumping, fast heart rate, low blood pressure, abnormal heartbeats, or even death. Other possible side effects include nausea, vomiting, or chills. All of these side effects are very rare, but may happen as a result of accidental injection into the bloodstream.

Risks of Leukapheresis
Leukapheresis has been shown to be safe in HIV-infected donors and does not affect CD4+ T-cell count or immune status of short-term donors. The needle used is larger than normal blood draw and may be uncomfortable. Rarely, a participant may feel faint during or after leukapheresis. This sort of reaction can be handled by changing the participant's position or administering intravenous fluids. You may experience chills, nausea, and heartburn caused by the citrate anticoagulant that is used during the procedure to keep the collected cells from clumping together in the bag. This chemical may use up some of the calcium in your blood stream, and tingling in the face, lips, or hands may be noted. If this happens, study staff may slow the rate of infusion of this chemical and may offer you one or two calcium carbonate tablets to correct the calcium loss. Participants will be observed closely by an experienced blood bank technician during the procedure.

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 for at least three months after the final study vaccination. Because of the risk involved, you and your partner must agree to use two methods of birth control that you discuss with the study staff. You may choose two of the birth control methods listed below:

- Condoms (male or female) with or without a spermicidal agent
- Diaphragm or cervical cap with spermicide
- Intra-uterine device (IUD)
- Hormone-based contraceptive

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 you may be pregnant at any time during the study, tell your study staff right away. The study staff will talk to you about your choices. If you become pregnant while on the study, you will be asked if you wish to continue in the study and come for study visits for routine safety evaluations. You will not receive any further injections that are scheduled.

Safety information regarding the performance of this pDNA vaccine in pregnant women is not available at this time. Therefore, this vaccine is not to be given to pregnant women or nursing mothers.

If you become pregnant while on study, the study staff would like to obtain information from you about the outcome of the pregnancy (even if it is after your participation in the study ends). If you become pregnant during the study and do not give birth by the time of the final study visit, and if you agree, you will be contacted at the end of the pregnancy regarding pregnancy outcomes.

If you are taking anti-HIV drugs when you become pregnant, your pregnancy will be reported to an international database that collects information about pregnancies in women taking anti-HIV drugs. This report will not use your name or other information that could be used to identify you.

Are There Benefits to Taking Part in This Study?

If you take part in this study, you should expect no direct benefit. 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:

- treatment with prescription drugs available to you
- treatment with experimental drugs, if you qualify
- no treatment

Please talk to your doctor about these and other choices available to you. Your doctor will explain the risks and benefits of these choices.

What About Confidentiality?

We will do everything we can to protect your privacy. In addition to the efforts of the study staff to help keep your personal information private, we have a Certificate of Confidentiality from the US Federal Government. This certificate means that researchers cannot be forced to tell people who are not connected with this study, such as the court system, about your participation. Also, any publication of this study will not use your name or identify you personally.

People who may review your records include the US Food and Drug Administration, the ACTG, Office for Human Research Protections (OHRP) or other local, US, and international regulatory entities as part of their duties, University of Pennsylvania Institutional Review Board (IRB) (a committee that protects the rights and safety of participants in research), US National Institutes of Health (NIH), study staff, study monitors, the drug company supporting this study, and their designees. Having a Certificate of Confidentiality does not prevent you from releasing information about yourself and your participation in the study.

Even with the Certificate of Confidentiality, if the study staff learns of possible child abuse and/or neglect or a risk of harm to yourself or others, we will be required to tell the proper authorities.

A description of this clinical trial will be available on www.ClinicalTrials.gov as required by US 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.

Your personal information may be given out if required by law. If you test positive for HIV, or if a CD4 or viral load is done at a research study visit, by law we have to report the result to the City of Philadelphia Health Department/PA Department of Health. Personal identifiers such as name, sex, date of birth, address, and phone number will be reported. For more information about the requirements reporting infectious diseases to the City of Philadelphia Health Department, please visit https://hip.phila.gov/ReportDisease. For more information about the requirements reporting infectious diseases to the PA Health Department, please visit: http://www.health.pa.gov/Your-Department-ofHealth/Offices%20and%20Bureaus/epidemiology/Pages/Reportable-Diseases.aspx#V620aZ3D9eU. .

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 information about me may be collected, used or shared with others?

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
- Information from questionnaires administered in the study and from the other HIV studies in which you have participated.
- Results of tests and procedures you will undergo during this research
- Social Security Number, Medical record number

Why is my information being used?
Your information is important for the research team to contact you during the study. Your information and results of tests and procedures are used to:

- do the research
- oversee the research
- see if the research was done right
- evaluate and manage research functions

Who may use and share information about me?
The following individuals may use or share your information for this research study:

- The Principal Investigator and the Investigator's study team
- Other authorized personnel at Penn, including offices that support research operations.
- Other research personnel with access to the databases for research and/or study coordination and as otherwise approved by the IRB

Who, outside the School of Medicine, might receive my 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:

- ACTG Data Coordinating Center, Frontier Science Technology Research Foundation (FSTRF): Data for this study will be keyed into a password protected, secure database.
- Statistical Data Analysis Center (SDAC): Study data will be downloaded from FSTRF to the statistical data center at the Harvard School of Public Health. Specific study reports will be periodically provided to the study team and data safety review board to monitor if the trial is safe.
- Ichor Medical Systems: The pharmaceutical company that is supplying the drug for this study.
- Contract Research Organization (PPD, Inc): Monitors from PPD will visit the site on a quarterly basis to review the individual participant records, including consent forms, eCRFs, supporting data, laboratory specimen records, and medical records (physicians' progress notes, nurses' notes, individuals' hospital charts), to ensure protection of study participants, compliance with the protocol, and accuracy and completeness of records.
- Government Agencies: Data from this study will be made available to the National Institutes of Health/Division of AIDS (DAIDS)/National Institute for Allergy and Infectious Disease (NIAID), for them to evaluate the safety and efficacy of the treatments being used in this study.

Regulatory and safety oversight organizations

- The Office of Human Research Protections
- the Food and Drug Administration

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 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 Informed Consent form and 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.

A clinical trial management system (CTMS) is used to register your information as a participant in a study and to allow for your research data to be entered/stored for the purposes of data analysis and any other required activity for the purpose of the conduct of the research.

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, information related to your participation in the research (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in your existing EMR maintained by UPHS. Information related to your participation in clinical research will also be contained in the CTMS.

If you have never received care within UPHS and are participating in a University of Pennsylvania research study that uses UPHS services, an EMR will be created for you for the purpose of maintaining any information produced from your participation in this research study. The creation of this EMR is required for your participation in this study. In order to create your EMR, the study team will need to obtain basic information about you that would be similar to the information you would provide the first time you visit a hospital or medical facility (i.e. your name, the name of your primary doctor, the type of insurance you have). Information related to your participation in the study (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in this EMR. 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).

What Are the Costs To Me?
Taking part in this study may lead to added costs to you and your insurance company. In some cases it is possible that your insurance company will not pay for these costs because you are taking part in a research study.

The HIV pDNA vaccine or placebo that you may receive will be supplied by the study. Your anti-HIV drugs will not be provided by the study, so you must get these drugs through your primary care provider; you must also pay for them through some other manner, such as your insurance or local AIDS Drug Assistance Program (ADAP).

Will I Receive Any Payment?
You will be compensated $50 for most study visits (screen, pre-entry, and clinic visits on Weeks 6, 26, and 48); $150 at visits when you receive a vaccination (entry and weeks 4, 12 and 24); $25 for each stool sample (Pre-entry and Week 26) (optional) and $150 for each leukapheresis (Pre-entry and Week 26) (optional). You will receive $25 for each telephone contact (following each of the 4 vaccination visits). Further, you will be compensated $25 for bringing your vaccine diary to your week 4, 6, 24, 26 so your nurse can review the information you recorded. Compensation will be given as a ClinCard (a debit card). The maximum amount of compensation for the study is $1050: $850 if all regular/vaccination study required visits are completed; $100 if all telephone contacts are completed; and $100 if study diaries are returned at visits following vaccinations. If you are required to come to the clinic for any additional visits you will be compensated $25.

If you have already completed a vaccination visit and received $50, upon signing this consent we will add $100 for each vaccine visit completed to your clincard.

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.

What Happens If I Am Injured?
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.

There are no plans for the University of Pennsylvania or the National Institutes of Health 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.

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. 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, tell the study staff.

What Do I Do If I Have Questions Or Problems?
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. 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

	This consent is the initial consent for this participant. The study staff will provide an overview of the study, required visits, treatment regimen, risk and all elements of consent. The physician investigator(s) or licensed Nurse Practitioner will conduct a focused discussion about risks, benefits and alternatives.
	This consent is a subsequent consent for this participant. The new information in IC V5 does not pertain to risk, benefits and alternatives and the study staff will conduct the re-consent discussion.

Other

Please **initial below** whether you are willing to have some of your leftover blood (that is stored at the study site and/or at a central laboratory without information that could identify you) used for future ACTG-approved HIV-related research. These samples may be stored for an indefinite period. Results of testing performed on these samples will not be given to you. You may withdraw your consent for research on stored specimens at any time and the specimens will be destroyed. No matter what you decide, it will not affect your participation in this study or loss of benefits to which you are entitled.

_____ YES, I agree to have my leftover blood stored.

_____ NO, I do not agree.

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.

RESEARCH STAFF CONSENT

_____	_____	_____
Name of Subject (Please Print)	Signature of Subject	Date/Time
_____	_____	_____
Name of Person Obtaining Consent (Please Print)	Signature	Date/Time

IRB Approved From: 06/10/2019 To: 06/09/2020

INVESTIGATOR CONSENT

The risks, alternatives, and benefits have been reviewed with me by the Investigator, and I understand what we have discussed.

_____	_____	_____
Name of Subject (Please Print)	Signature of Subject	Date/Time

I verify I have reviewed risks, alternatives, benefits with this subject, who demonstrates good understanding.

_____	_____	_____
Investigator Name (PRINTED)	Signature	Date/Time