HOSPITAL OF THE UNIVERSITY OF PENNSYLVANIA

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

Protocol Title:	VRC 607/ACTG A5378: A Phase 1, Single Dose Study of the Safety and Virologic Effect of an HIV Specific Broadly Neutralizing Human Monoclonal Antibody, VRC-HIVMAB080-00-AB(VRCO1LS) or VRC-HIVMAB075-00-AB (VRC07-523LS), Administered Intravenously to HIV-Infected Adults.
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

We invite you to take part in a research study at the University of Pennsylvania. This study is a collaboration between the Vaccine Research Center (VRC), NIAID, NIH and the AIDS Clinical Trials Group (ACTG).

First, we want you to know that:

- Taking part in this study is entirely voluntary.
- You may choose not to take part, or you may withdraw from the study at any time. In either case, you will not lose any benefits to which you are otherwise entitled. You will be treated the same no matter what.
- You may receive no benefit from taking part. The research may give us knowledge that may help people in the future.
- We will tell you about new information from this study 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.

Second, some people have personal, religious or ethical beliefs that may limit the kinds of medical or research treatments they would want to receive (such as blood transfusions). If you have such beliefs, please discuss them with your health care provider or research team before you agree to the study.

Now we will describe this research study. Before you decide to take part, please take as much time as you need to ask any questions and discuss this study with the research team at PENN, or with family, friends or your personal physician or other health professional.

PURPOSE AND PLAN OF THE STUDY

In this study, we are testing two experimental products called "VRC01LS" and "VRC07-523LS". Experimental means that these products have not been approved by the U.S. Food and Drug Administration (FDA), but the FDA has allowed us to test them in research studies. VRC01LS and VRC07-523LS are antibodies directed against HIV virus. The main purpose of this study is to see if these antibodies are safe and how your body will respond to them. (An antibody is a type of protein that helps protect the body against foreign matter, such as bacteria and viruses; it can be either produced by your body or made in a laboratory.)

There are two different parts in this study (Part A and Part B). In Part A, 7 people got VRC01LS. In Part B, 7 people (up to 10 people) will get VRC07-523LS. People were put in Part A first and now Part A of the study is done. People will now be put in Part B. If you agree to take part in this study (Part B), you will get VRC07-523LS only and we will measure the amount of the drug in your body how much stays in your body over time. We will check to see if your immune system makes antibodies against the product you get.

About 14 to 20 people (7 to 10 people in each part) will take part in this study at the NIH Clinical Center in Bethesda, Maryland, at the Hospital of the University of Pennsylvania, Philadelphia, PA and sites within the ACTG Network. The study will include a total of 23 clinic visits per person over a period of about 11 months.

After you complete the day 14 study procedures, we strongly advise that you start antiviral therapy prescribed by your primary HIV physician (not study provided).

STUDY PRODUCTS

VRC01LS and VRC07-523LS are study products that contain monoclonal antibodies. "Monoclonal" means that all the antibodies in each product are exactly the same. These antibodies target the virus that causes HIV infection. As of May 10, 2018, approximately 60 people have received one of these antibodies and have not had any serious side effects or safety concerns.

In other research studies, over 840 adults with or without HIV-infection got other monoclonal antibodies similar to VRC01LS and VRC07-523LS, without serious side effects.

VRC01LS and VRC07-523LS are based on an antibody that was first found in an HIV-infected person. Both of these study products were developed by the Vaccine Research Center (VRC), NIH and made in a drug manufacturing laboratory. There are currently research studies of these products in adults without HIV infection. This is the first study to give VRC01LS or VRC07-523LS people with HIV infection.

There is currently no cure for HIV. We do not expect the products in this study to cure or control your HIV.

In laboratory and animal studies, VRC01LS and VRC07-523LS were shown to attach to and inactivate many types of HIV viruses. It is not known if these products will act the same way when given to humans. It will take many studies to learn if the products are useful for preventing or treating HIV. This study alone will not answer this question.

SCREENING VISIT

If you decide to join this study, you will be asked to sign this consent form. After you have signed the form, you will be asked some questions and will undergo some tests at the screening visit to see if it is safe for you to join the study.

At the screening visit you will have a physical exam. You will be asked about your medical history, including your HIV history, any medicines you have taken in the past and are currently taking, and if you have ever received antibodies directed against the HIV virus or taken any anti-HIV medicines. We will draw about 6 tubes of blood from you for routine blood tests, tests for Hepatitis B virus or Hepatitis C virus infection, tests for HIV antibodies and viral load (the amount of HIV in your blood), and $CD4^+/CD8^+$ T cell count (cells in your blood that fight infection). You will be informed if any tests show a medical problem. You will be advised if results show that you should seek medical care. Some medical conditions may make you not eligible for a clinical trial of an investigational product. If you are female and able to become pregnant, you will have a pregnancy test done to see if you are pregnant. You cannot participate in this study if you are pregnant. If you are not pregnant or you are having sex that could lead to pregnancy, you will be asked and must agree to use birth control before you are able to participate in this study. We will discuss effective birth control methods with you.

ELIGIBILITY

You are eligible to participate in this study because you have completed the screening process and you are:

- 18 to 70 years old
- HIV infected, have never taken antiretroviral (ARV) medications, but otherwise in good general health
- Under the care of a primary care provider for management of HIV
- Willing to let the study team give your lab test results to your primary care provider while you are in this study
- Willing to receive VRC07-523LS
- Willing to donate blood samples for future research
- Willing to use birth control for the whole study, if you are able to become pregnant

STUDY PROCEDURES

Study product infusion: If you agree to enroll in this study, you will get one dose of VRC07-523LS. The exact dose you get will depend on how much you weigh. Before you are given the study product, your temperature, blood pressure, heart rate, and weight will be taken. You may also have a brief physical exam. We will measure your weight on the day the study product is given to calculate the dose. If you are female and able to become pregnant, a pregnancy test will be done before we begin and the result of the test must be negative for you to get the study product.

VRC07-523LS will be given to you by intravenous (IV) infusion. This means we will place a thin tube or IV line into a vein in your arm. The IV line will be attached to a bag that contains the study product mixed with a liquid called "normal saline" or salt water. It will flow into your vein for about 30 minutes. If you have side effects during the infusion, it will be slowed or stopped as needed. You will be observed for at least 30 minutes immediately after receiving the study product.

If possible, we will also place an IV line in your other arm to collect blood samples. We will draw your blood before and right after the infusion, then at least 5 more times over the next 4 hours from this IV line. There are other blood draws at 8, 12 and 36 hours after infusion, which are optional. At least one IV line will stay in your arm for several hours. You will not lose any benefits if you choose not to give the optional blood samples. If you choose to get these blood draws, you may be admitted to the hospital for an overnight stay. The hospital stay is for convenience only and not to give you care or treatment.

We will give you a thermometer and ask you to check your temperature every day for 3 days after you get the study product. You will need to record your temperature and any symptoms you may have. Even if you do not feel sick, it is still very important that you record this information. You will get a password to a secure website to enter this information on an electronic form or "diary". If you do not have a computer, you may use a paper diary instead.

If you have any side effects after you get the study product, you should tell a study nurse or doctor as soon as possible. You can reach the clinic staff by phone 24 hours a day. If you have symptoms, you may be asked to come into the clinic for an examination before your next scheduled visit. It is very important that you follow the instructions you get from the clinic staff.

Follow up visits: After you get the study product, you will need to come back to the clinic 11 times over a 4-week period. During the next 9 months, you will have 10 more follow-up visits.

At most visits, we will check you for any health changes or problems. Your temperature, blood pressure, and pulse will be taken and you will have a physical exam. We will ask you how you are feeling and if you have taken any medications. We will also provide pregnancy prevention counseling (counseling to prevent pregnancy) and positive prevention counseling (counseling to prevent illness and promote good health in people who know they are HIV-positive) while you are in the study.

We will draw about 1 to 11 tubes of blood from you at each visit, depending on the type of visit. We will also ask you to provide a urine sample for a urine test at most visits. We will tell you right away if any of your test results show a health problem. You might need to have extra clinic visits and laboratory tests if you have health changes that need to be checked. The total amount of blood we draw from you will meet NIH guidelines.

We will use some blood samples to see how long the study product remains in your body and if your immune system makes antibodies against it. Results of these tests are not for checking on your health and we will not give you these results. We may also use some blood samples to check the level of ARV medications in your blood while you are in this study.

Research studies follow a set schedule. This helps us answer the research questions. The visit schedule is a little flexible, but it is important that you work with the staff to follow the schedule as closely as possible. You should try not to miss any visits. You should contact the clinic staff as soon as possible if you need to change the date or time of any visit.

For the entire duration that you are on study, which will be 48 weeks or about 11 months, a maximum of about 922 mL (or about 2 pints) of blood will be collected.

HIV TESTING AND MANAGEMENT

As you take part in this study, you will have frequent testing of your HIV viral load and CD4+ T cell count for research purposes. These test results will be given to you and sent to your primary care provider. You should discuss these results and any questions about management of your HIV infection with your primary care provider.

Your personal information may be given out if required by law. If a CD4 or HIV viral load is done at a 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-of-Health/Offices%20and%20Bureaus/epidemiology/Pages/Reportable-Diseases.aspx#.V620aZ3D9eU.

This study does not include standard medical care or the management of your HIV infection. The U.S. Department of Human Services and the clinical research team recommend that all HIV-infected individuals take Antiretroviral (ARV) medication to reduce the chance of getting sick from HIV, increase life expectancy with HIV infection and prevent the spread of HIV to others.

We will not give you ARV medications as part of this research study. You must have a primary health care provider for HIV to take part in this study. If you don't have one and need help finding one or getting ARV medications, please tell a study doctor or nurse. We will help you find a qualified HIV doctor and ARV medications. You and your primary health care provider will make all decisions about starting, stopping or changing ARV medications. However, we strongly advise that you start ARV medications after you have completed the day 14 study procedures. We expect you to tell us about changes in your ARV medications. We do not expect VRC07-523LS to control HIV by itself. You should not change or stop ARV treatment without talking about it with your primary care provider. Changes in ARV treatment will not affect your continued participation in the study.

MONITORING OF THE STUDY

A group of physicians and scientists at NIH will monitor this study. This group will review the information from the study and will pay close attention to possible harmful reactions. If serious side effects occur, study product infusions may be delayed or canceled.

GENETIC TESTING

In the future, genetic research tests may be done on your stored samples to help understand how VRC07-523LS works and interacts with your body. In research studies, genetic tests are done to see if different types of immune response seem to be related to genetic differences in people. Genetic tests done in a research lab from your stored samples will not be recorded in your medical record and will not have your name on the sample. The performance of these tests is not for health care purposes.

HLA type is a genetic test. People with certain HLA types might be more likely to develop certain diseases. Simply having those HLA types does not mean they will develop those diseases. HLA typing can reveal family relationships. It is our

policy not to discuss your HLA results unless they have direct medical or reproductive implications for you or your family. Genetic information about you will not be revealed to others, including your relatives, without your permission. We will not release any information about you or your family to any insurance company or employer unless you sign a document allowing release of information.

STORED SAMPLES

We will collect blood samples from you during the study. We will keep these samples for future research to learn more about monoclonal antibodies, vaccines, the immune system, and/or other medical conditions. Results from research done with your stored samples will not be in your medical record or reported to you.

Some of your blood samples that are left over after all required study testing are done may be stored and used for VRC-approved and ACTG-approved HIV-related research.

Labeling of Stored Samples: We will label your stored samples by a code (like a number). Only the study team can link this code to you. Any identifying information about you will be kept confidential as much as the law allows. Despite protections, there is a small chance that information identifying you will be given to someone who should not get it.

Risks from Stored Samples: There is a risk of unplanned release of information from your medical records. The chance that this information will be given to an unauthorized person without your permission is very small. Possible problems with the unplanned release of information include discrimination when applying for insurance and employment. Similar problems may occur if you give information about yourself or agree to have your medical records released.

Future studies: In the future, other investigators (at NIH or outside of NIH; in the ACTG or outside of the ACTG) may wish to study your stored samples. When your stored samples are shared, they will be marked with a code. Your samples will not have any identifying information on them. Some information about you, such as your gender, age, health history, or ethnicity may also be shared with other researchers.

Any future research studies using your samples will be conducted in a way that protects the rights and privacy of study participants.

Your stored samples will be used only for research and will not be sold. The research done with your materials may be used to develop new products in the future but you will not receive payment for such products.

Making your Choice: You can only take part in this study if you agree to let us collect, store, and use your blood samples in future unspecified research. If you decide not to take part in this study, you may still take part in other studies at NIH.

POSSIBLE STUDY RISKS

Risks of Blood Drawing and IV insertion: The risks of drawing blood from a vein and having an IV include pain, bruising, bleeding, lightheadedness and fainting. Rarely, infection or inflammation can occur in the skin or vein. Blood clots are possible risks when using an IV for blood draw.

Risks of VRC07-523LS: This study is the first time that VRC07-523LS is being given to people with HIV infection. As of January 2018, the people who have received at least one dose of VRC07-523LS had no concerning reactions to the product. VRC07-523LS may have other unknown risks or side effects. We do not know if getting VRC07-523LS will affect how you respond to any similar monoclonal antibody against HIV.

General risks of monoclonal antibodies: Side effects to infusions of monoclonal antibodies may include fever, chills, shaking, nausea, vomiting, pain, headache, dizziness, trouble breathing, high or low blood pressure, itchiness, rash, hives, lip or face swelling, diarrhea, racing heart or chest pain. These reactions may be related to how fast the product is infused. If you have symptoms while you get VRC07-523LS, tell the nurse right away. Slowing or stopping the infusion may help improve these symptoms. Side effects may also include reactions at the injection site, such as redness, bruising, and swelling.

Some antibody products have a risk of serious allergic reactions or cytokine release syndrome that can be life-threatening.

- Anaphylaxis is one type of allergic reaction that may happen soon after an antibody product is given. This reaction can include difficulty breathing, low blood pressure, hives or rash, swelling in the mouth and face.
- Serum sickness is a delayed type of allergic reaction that may happen several days to three weeks after an antibody product is given. This reaction can include hives or rash, fever, enlarged lymph nodes, muscle pains, joint pains, chest discomfort and shortness of breath.
- Cytokine release syndrome can happen when an antibody targets a cell protein that triggers immune cells to release cytokine (proinflammatory molecules in your body).

All of these reactions are very unlikely because VRC07-523LS is a fully human antibody that attacks the HIV virus, and not your cells.

In addition to the possible risks that are listed above, the study products may have other side effects that we do not know about yet. Taking part in this study may affect your eligibility for future studies of other experimental monoclonal antibodies, antibody mixtures or other similar products.

We will give you any new information about risks or other information that becomes available that may affect your decision to continue in the study.

Risks during Pregnancy: We do not know what effects the study products may have on a fetus or nursing infant. Women must agree not to get pregnant during the study. We will discuss effective birth control methods with you. If you are able to become pregnant, you and your partner must use reliable birth control from the time you start the study until you complete the last study visit.

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. You must tell the clinic staff right away if you become pregnant during this study or think that you might be pregnant. If you become pregnant after getting the study product, we will not collect any more blood for research. However, you will be asked to continue with study follow-up visits to check on your health and to report the outcome of the pregnancy to us, which will be reported to the Antiretroviral Pregnancy Registry (http://www.apregistry.com). This report will not use your name or other information that could be used to identify you.

POSSIBLE BENEFITS

This study will not provide you with any direct health benefit. You and others may benefit in the future from the information that we learn from the study.

COSTS TO YOU FOR YOUR PARTICIPATION

There are no costs to you for taking part in this study. You or your health insurance will have to pay for all medical costs for medical care that you get outside this study. It is possible that you may have some expenses that are not covered by the study compensation provided.

COMPENSATION TO YOU FOR YOUR PARTICIPATION

You will be compensated $1300 for your study participation as follows: $150 for the infusion visit and $50 for the other 22 study required visits. This will be based on the number of study visits you attend and study injections you receive.

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.

REASONS FOR REMOVING YOU FROM THE STUDY WITHOUT YOUR CONSENT

You may be removed from the study for several different reasons, including:

- You don't keep appointments or follow study procedures.
- You get a serious illness that needs ongoing medical care.
- You enroll in another research study at the same time you are in this study.
- You become pregnant.
- The study is stopped or canceled.

A study may be stopped or canceled by a study sponsor, a regulatory agency or by the study investigators. If this happens you will be told the reason why.

You may choose to stop participating in the study at any time.

If you received the study product before you discontinue the study early, you will be asked to continue to be part of the study and return for the rest of the study visits. At the visits you will have some tests performed for safety monitoring, however samples for research purposes will not be collected.

ALTERNATIVES

This study is not designed to treat or prevent HIV infection or any disease. You may choose to not take part in this study. You may be eligible for other studies. Instead of being in this study you have the choice of:

- Treatment with prescription drug available to you
- Treatment with experimental drugs, if you qualify
- No treatment

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

CONFLICT OF INTEREST

The research staff are reviewed at least yearly for conflicts of interest. You may ask the research team for additional information.

The National Institutes of Health, including some members of the Vaccine Research Center scientific staff, developed the experimental product in this research study. The results of this study could play a role in whether the FDA will approve the experimental product for sale at some time in the future. If approved, the future sale of the vaccine could lead to payments to NIH and some NIH scientists. By U.S. law, government scientists are required to receive such payments for their inventions.

You will not get any money from the development or sale of the product.

This protocol may have investigators who are not NIH employees. Non-NIH investigators are expected to follow the principles of the Protocol Review Guide but are not required to report their personal financial holdings to the NIH.

CLINICALTRIALS.GOV

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

OTHER PERTINENT INFORMATION

1. Confidentiality. When results of an NIH research study are reported in medical journals or at scientific meetings, the people who take part are not named and identified. In most cases, the NIH will not release any information about your research involvement without your written permission. However, if you sign a release of information form, for example, for an insurance company, the NIH will give the insurance company information from your medical record. This information might affect (either favorably or unfavorably) the willingness of the insurance company to sell you insurance.

The Federal Privacy Act protects the confidentiality of your NIH medical records. However, you should know that the Act allows release of some information from your medical record without your permission, for example, if it is required by the Food and Drug Administration (FDA), members of Congress, law enforcement officials, National Institute of Allergy and Infectious Diseases institutional review board, study monitors, or other authorized people.

ACTG Clinical Research Sites: 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 gotten a Certificate of Confidentiality from the U.S. 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.

Your records may be reviewed by the U.S. Food and Drug Administration (FDA), the ACTG, the U.S. 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), National Institutes of Health (NIH), study staff, study monitors, 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.

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?

- 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
- 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
- to see if the research was done right
- to 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.

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 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:

- Vaccine Research Center (VRC)/National Institute of Allergy and Infectious Diseases (NIAID)/NIH: Data for this study will be recorded on case report forms, keyed into a central database and electronically submitted to the Data Coordinating Center. The data will be cleaned and stored at this facility until it is ready to be analyzed.
- Contract Research Organization (PPD): Monitors from PPD will review data for accuracy and completeness before the data are sent to VRC for analysis.
- Regulatory and safety oversight organizations: Data from this study will be made available to the Office of Human Research Protections, the VRC/NIAID/NIH.

Once your personal health information is disclosed to others outside of 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 use or disclose my 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.

Will I be able to access my records?
The Principal Investigator is not required to release research information to you that is not part of your medical record.

What if I decide not to give permission to use and give out my health information?
If you decide not to give permission to use and give out your 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, imaging studies 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).

2. Policy Regarding Research-Related Injuries. 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 be responsible for some of them. 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. In general, no long-term medical care or financial compensation for research-related injuries will be provided by the National Institutes of Health, the Clinical Center, or the Federal Government. However, you have the right to pursue legal remedy if you believe that your injury justifies such action.

3. Payments. The amount of payment to research volunteers is guided by the NIH policies.

4. Problems or Questions. If you have any problems or questions about this study or about any research-related injury, contact the Principal Investigator Pablo Tebas, MD, or the Study Team listed on page 1 of this consent form.

If you have any questions about your rights as a research subject, you may call the Clinical Center Patient Representative at 301-496-2626.

5. Consent Document. Please keep a copy of this document in case you want to read it again.

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.

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.

COMPLETE APPROPRIATE ITEM(S) BELOW:

A. Adult Study Participant's Consent

RESEARCH STAFF CONSENT

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

Participant's Legally Authorized Representative (print) (As appropriate)	Legally Authorized Representative's Signature and Date/Time

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

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

THIS CONSENT DOCUMENT HAS BEEN APPROVED FOR USE AUGUST 09, 2018 FROM THROUGH MAY 06, 2019.