HOSPITAL OF THE UNIVERSITY OF PENNSYLVANIA

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

Protocol Title:	VRC 500, Version 6.0 (11-I-0164) Screening of Volunteers for Clinical Trials of Investigational Products and Licensed Products Evaluated for Research Purposes
Principal Investigator:	Pablo Tebas, MD 502 Johnson Pavilion, Philadelphia PA 19104 **(215) 349-8092**
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24 hr. Emergency Contact:	Immunodeficiency Program Doctor on call (215) 662-6059

INTRODUCTION

We invite you to take part in a research study at Hospital of the University of Pennsylvania, Clinical Research Site. First, we want you to know that taking part in research is entirely voluntary.

The study was developed by the National Institutes of Health (NIH). It is up to you to decide if you want to be a part of this study. You may choose not to take part, or you may withdraw from the study at any time. There is no penalty or loss of benefits for choosing to not participate. Please ask questions and discuss this study with anyone you want. Take as much time as you need to decide

PURPOSE OF THE STUDY

This is a study to screen volunteers for clinical trials of investigational products such as vaccines, injection devices, and other products related to finding new vaccines. The purpose of this screening study is to see if you are eligible for such clinical trials. This screening study may enroll as many as 3,000 volunteers.

You are eligible to screen for clinical trials if you are 18 to 70 years old, available to participate, able and willing to complete the informed consent process, and agree to have blood samples stored for future research and able to tolerate repeated blood draws.

STUDY PROCEDURES

Screening for an investigational clinical trial may begin several months before the start of the study. During this time, you may come to the clinic one or more times. The clinic staff will ask you some personal questions about your health history, including sexual activity and drug use. You will have a physical exam. During the screening visits you will be asked to give blood samples. The blood samples may vary in volume from 1 to 24 tubes of blood. You may be asked to give urine samples or have other tests to check your health. 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. You may also be informed about options for other research studies. Results will be given to your primary health care provider, if you ask for records to be sent.

Women being screened who are possibly capable of getting pregnant will be given a pregnancy test. You must discontinue participation in this screening protocol if you are pregnant or breastfeeding. If you are not pregnant, you may be asked to use birth control before you are referred for participation in a clinical trial of an investigational product.

If you begin participation in a clinical trial of an investigational product, your participation in this screening study will end.

You will be told of any new information learned during screening that might cause you to change your mind about staying in the screening study. If you are eligible and decide to join an investigational product clinical trial, we will explain the study and the risks involved. You will have to sign a separate informed consent for that clinical trial.

STORED SAMPLES

During your participation in this screening study, blood will be drawn from your arm with a needle. We will perform tests and also will store some of your blood. The stored samples will be kept and used in future research to learn more about the immune system and/or other medical conditions.

The results from the research done with your stored samples will not be given to you or your private doctor. It will not be put in your medical record. This is because the research test results, unlike routine medical testing, will be experimental or preliminary. The relevance of these tests to your health care will be unknown. However, at your request, the results of any research tests will be discussed with you or your physician by one of the investigators.

Labeling of Stored Samples

Your stored samples will be labeled with a code (such as a number) that only the study team can link to you. Any identifying information about you will be kept confidential to the extent permitted by law.

Future Studies

In the future, other investigators may wish to study your stored samples. When the study team shares your materials, it will be labeled with a code. Some information about you, such as your gender, age, health history, or ethnicity may also be shared with other investigators. Any future research studies using your samples will be reviewed by a special committee that oversees medical research studies to protect the rights and welfare of human research volunteers.

Your stored materials 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.

Risks Associated with Stored Specimens

The greatest risk is the 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 disclose information yourself or agree to have your medical records released.

GENETIC TESTING

Some of the blood drawn from you as part of this study may be used for genetic tests. Genetic tests can help researchers see if people with different genes differ in their immune response to vaccines and other investigational products. The genetic tests will be done in a research lab from your stored samples. Genetic tests done in a research lab will **not** be in your medical record. Samples sent to a research lab will **not** have your name or other identifying information.

We will not discuss any of the genetic tests with you unless they have important implications for you or your family. In these cases, we will offer you additional genetic counseling and advice.

MEDICAL RECORDS

Medical records containing your information are maintained in a secure manner. 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.

RISKS

Risks Associated with Drawing Blood

Blood drawing may cause pain and bruising, and rarely, infection at the place where the blood is taken. Sometimes, drawing blood causes people to feel lightheaded or even faint. It is important to tell us if you are having blood drawn for other studies or for other reasons.

Other Risks Associated with the Study

The questions about your health history, including sexual activity and drug use might be embarrassing. You will receive information about your health status through the lab tests and physical exam. You may think of this as either a risk or a benefit, depending upon the findings.

BENEFITS

You will receive no direct benefit from study participation.

HIV TESTING

As part of your participation in this screening protocol, we may need to test your blood for Human Immunodeficiency Virus (HIV) infection, the virus that causes Acquired Immune Deficiency Syndrome (AIDS). If your test results show that you are infected with HIV, we will tell you. We will discuss with you what the test results mean, how to find care, how to avoid infecting others, how we report HIV infection, and the importance of informing your partners who are at possible risk because of your HIV infection. The results of your HIV testing may affect your eligibility for an investigational product study.

Your personal information may be given out if required by law. If you test positive for HIV or 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. We would report your name, gender, racial/ethnic background, and the month and year you were born. This is to keep track of how many people in the U.S. have HIV infection. It is also to make sure that states get enough money from the federal government to support the medical care of people living with HIV. The Health Department does not share the names of HIV infected people with anyone else. It removes all personal identifiers, such as your name, before giving information on the number of HIV infections to the federal government

REASONS FOR REMOVING YOU FROM THE STUDY WITHOUT YOUR CONSENT

You may be removed from the study without your consent for the following reasons:

- The doctor feels that staying in the study is harmful to you.
- You enroll in another study that includes investigational treatments.
- The study is cancelled or stopped.
- You become pregnant.

COSTS TO YOU FOR YOUR PARTICIPATION

There will be no charge to you or your health insurance company for any of the costs that are directly related to this study. However, the costs of any other medical care you might need during this period will be charged to you or your health insurance.

COMPENSATION

You will be compensated $50 per screening visit.

ALTERNATIVES

You can choose not to participate in this study.

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, Hospital of the University of Pennsylvania Clinical Research Site 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, Hospital of the University of Pennsylvania Clinical Research Site 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 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, or authorized hospital accreditation organizations.

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. The University of Pennsylvania Clinical Research Site will provide short-term medical care for any injury resulting from your participation in research here. In general, no long-term medical care or financial compensation for research-related injuries will be provided by the Hospital of the University of Pennsylvania Clinical Research Site, the National Institutes of Health, 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 institutional policies. Reimbursement will be offered consistent with these guidelines.

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, M.D. or the Recruiting office (Telephone: 215-349-8092).

If you have any questions about your rights as a research subject, you may call 410-706-6156.

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.

COMPLETE APPROPRIATE ITEM(S) BELOW:

A. Adult Participant's Consent

I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I hereby consent to take part in this study.

_____ _____

Signature of Adult Participant/Legal Representative Date

_____

Print Name

THIS CONSENT DOCUMENT HAS BEEN APPROVED FOR USE FROM December 2, 2016 THROUGH November 27, 2017

_____	_____ _____
_____	
Signature of Investigator or Designee obtaining consent	Signature of Witness
Date/Time	Date
_____	_____
Print Name	Print Name