UNIVERSITY OF PENNSYLVANIA

RESEARCH SUBJECT
INFORMED CONSENT AND HIPAA AUTHORIZATION FORM

Protocol Title: **General Pre-trial Screening Protocol for Enrollment of Volunteers into Research Protocols**

Principal Investigator: Pablo Tebas, MD
502 Johnson Pavilion, Philadelphia PA 19104
(215) 349-8092

Emergency Contact: Infectious Disease Resident on-call
(215) 662-6059

Why am I being asked to volunteer?

You are being invited to participate in a screening protocol. 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. Please ask the study doctor and/or the research team about this form. If you decide to participate, you will be asked to sign this form.

What is the purpose of this protocol?
The purpose of this protocol is to determine if you are eligible to participate in a full screening interview for one of our research studies.

How long will I be in the study? How many other people will be in the study?
The prescreening process to determine if you are eligible to screen for a full research study can take up to one or two visits. These visits may be scheduled over a one to four week timeframe. There is no limit to the number of participants in this pre-screening protocol.

What am I being asked to do?
If you choose to participate in this prescreen interview, it may take about 60 to 90 minutes.
You will be asked the following:

- To provide contact information including your address, phone number, email address and places where you spend your time, and the addresses and phone numbers of people, such as friends and family, who can help locate you.
- Questions about your age, race, and gender identity
- Questions regarding your HIV status, drug and alcohol use.
- Questions regarding your health and any medications you may take
- You may have a brief screening physical exam. This may include your height and weight, blood pressure and other vital signs, and an examination of your body.

- You may have blood work or other laboratory tests to determine your current state of health and eligibility for different studies. The amount of blood drawn will depend on what evaluations are needed for you. Some common tests and the amount of blood drawn, include: CBC (complete blood count) 7 mls or ½ tablespoon; Chemistries (check general health and liver and kidney function) 10 mls or 2/3 tablespoon; Hepatitis B and C (no extra blood if chemistries drawn); CD4 (T-cells) 7 ml or ½ tablespoon, viral load (how much virus is in the blood) 10 mls or 2/3 tablespoons or HIV Test (confirm HIV status) 10 mls or 2/3 tablespoons. If you had all of the above tests done, the total volume of blood drawn would be 34 mls or about 2 ½ tablespoons.
- You may be tested for the CCR5 biomarker (part of your genetic makeup) by having a buccal swab taken. This test is done by taking a swab (a long Q-Tip) and swirling it inside your cheek to collect cells. The test will be run at a PENN lab and the researchers can tell you if you may be eligible for one of the gene therapy studies. This test will not become part of your medical record as there is no clinical significance.
- We will ask you questions about your pregnancy history and plans, birth control methods and may do a pregnancy test.

At the completion of today's visit we will makes plans to contact you with results either by phone, email, or an in person visit.

What are the possible risks or discomforts?

Loss of privacy: We will make every effort to protect your privacy when you participate in the prescreen interview. Your name will not be on the pre-screen questionnaire that asks about your personal health information, HIV status, drug use or your sexual practices. You will be assigned a unique number code which is recorded on all documents containing sensitive information and stored separate from documents with your name.

Local laws about communicable disease reporting: Local law requires us to report by name all persons who test positive for the HIV virus or Hepatitis B or C. If you have a positive HIV test or Hepatitis B or C, we must comply with this requirement by reporting you and your information to the City of Philadelphia Department of Health.

Risk of Blood Draw: It is possible that you may experience some discomfort, bruising, infection or minor bleeding at the blood draw site

Risk of Buccal Swab: It is possible that you may have a little discomfort in your cheek where the swab is placed.

This research includes genetic testing. Even without your name or other identifiers, your genetic information is unique to you. The researchers believe the chance that someone will identify you is very small, but the risk may change in the future as people come up with new ways of tracing information.

There can be a risk in knowing genetic information. New health information about inherited traits that might affect you or your blood relatives could be found during a research study. Even though your genes are unique, you share some of the same genes with your blood relatives. Although we are not able to know all of the risks from taking part in research on inherited traits, we believe that the risks to you and your family are very low, because your samples will be coded. Research results will not be returned to you or your doctor.

Very rarely health or genetic information could be misused by employers, insurance companies, and others. For example, it could make it harder for you to get or keep a job or insurance, or life insurance companies may charge a higher rate based on this information. We believe the chance these things will happen is very small, but we cannot make guarantees.

A federal law (Genetic Information Non-Discrimination Act, GINA) helps reduce the risk from health insurance or employment discrimination. The law does not include other types of misuse by life insurance or long term care insurance. If you want to learn more about GINA, you can find information about it on the internet or ask the study staff.

It is possible that there may be other risks which are not yet known.

What if new information becomes available about the study?
During the course of this study, we may find more information that could be important to you. This includes information that, once learned, might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

What are the possible benefits of the study?
You are not expected to get any benefit from being in this research study. At the completion of the prescreening procedures, you may learn of clinical trials that you may be eligible for, or entered into a database of people who are interested in our future research studies.

What other choices do I have if I do not participate?
You may choose not to participate.

Will I be paid for being in this study?
We will $25 for each completed in office visit.

Will I have to pay for anything?
You will not have to pay for any of the labs or evaluations associated with this protocol.

What happens if I am injured from being in the study?
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 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.

When is the Study over? Can I leave the Study before it ends?
The prescreen process is over after it is determined if you are eligible to screen for a full research study or if you are referred to a research study conducted by another University of Pennsylvania Division. However, if you are interested in learning about future research opportunities we will ask you to give us permission to keep your contact information on file. If you decide to participate, you are free to leave the study at anytime. Withdrawal will not interfere with your future care.

Who can see or use my information? How will my personal information be protected?
We will do our best to make sure that the personal information obtained during the course of this research study will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. If this study is being overseen by the Food and Drug Administration (FDA), they may review your research records.

If you test positive for HIV, Hepatitis B or C, by law we have to report the infection to the City of Philadelphia Health Department/PA Department of Health. We would report your name, gender, racial/ethnic background, and the month and year you were born.

This is to keep track of how many people in the U.S. have HIV infection. It is also to make sure that states get enough money from the federal government to support the medical care of people living with HIV. The Health Department does not share the names of HIV infected people with anyone else. It removes all personal identifiers, such as your name, before giving information on the number of HIV infections to the federal government.

Every attempt will be made by the investigators and study staff to keep all information collected strictly confidential, except as may be required by court order or by law. Personal information from your prescreen for eligibility interview study records will not be released without your written permission. All contact to inform or remind you about follow-up research visits will be handled carefully to keep your participation in research studies confidential. Your chart will be stored in locked filing systems.

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?
We will collect the following information for this prescreen research process:

- Name, address, telephone number, date of birth, address, and email address
- Personal and family medical history
- Results from a physical examinations, tests or procedures
- HIV status

Why is my information being used?
Your information is used by 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 of 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:

- Staff of the study sponsor, the Division of AIDS (DAIDS). A Division of the National Institute of Allergies and Infectious Diseases (NIAID) of the US National Institutes of Health and people or companies working for the sponsor
- The US Office of Human Research Protections (OHRP), a government agency that oversees the safety and effectiveness of this research

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.

What if I decide not to give permission to use and give out my health information?
Then you will not be able to be in this research study.

You will be given a copy of this Research Subject HIPAA Authorization describing your confidentiality and privacy rights for this study.

By signing this document you are permitting the School of Medicine to use and disclose personal health information collected about you for research purposes as described above.

Electronic Medical Records and Research Results

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.

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 results of procedures performed as part of 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). Results of research procedures performed as part of 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).

Who can I call with questions, complaints or if I'm concerned about my rights as a research subject?
If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigators listed on page one of this form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Office of Regulatory Affairs with any question, concerns or complaints at the University of Pennsylvania by calling (215) 898-2614.

When you sign this form, you are agreeing to take part in this screening protocol. 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 to use your personal health information collected about you for research purposes within our institution. You are also allowing the University of Pennsylvania 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.

Decisions

1. Telephone contact (initial your selection):
   - ☐ I grant permission for you to leave a voice mail for me.
   - ☐ I do not grant permission for you to leave a voice mail for me.

2. Email contact (initial your selection):
   - ☐ I grant permission for you to contact me by email.
   - ☐ I do not grant permission for you to contact me by email.

3. TEXT message contact (initial your selection)
   - ☐ I grant permission for you to send me a TEXT message.
   - ☐ I do not grant permission for you to send me a TEXT message.

4. Participant Database (initial your selection):
   - ☐ I grant permission for you to keep my information in a secure database and contact me in the future if a study I may be eligible for becomes available.
   - ☐ I do not grant permission for you to keep my information in a secure database and contact me in the future if a study I may be eligible for becomes available.

_____ _____

Name of Subject (Please Print) Signature of Subject Date

_____ _____

Name of Person Obtaining Consent (Please Print) Signature Date