UNIVERSITY OF PENNSYLVANIA HEALTH SYSTEM
Developing Assays to Evaluate Immunologic Response to HIV and HIV Vaccines

CONSENT FORM/HIPAA AUTHORIZATION FOR VENIPUNCTURE

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24-hour emergency Number: (215) 662-6059 (ask for Infectious Diseases Fellow on call)

What is the purpose of this research project?
You are being asked to participate in a project in the Infectious Disease unit. The purpose of this study is to develop new laboratory assays to evaluate the immunologic responses against the HIV virus (Human Immunodeficiency Virus, the virus that causes AIDS). Blood from donors that are HIV positive and HIV negative will be used to develop these assays. These assays, which are tests of your blood to see how the immune system responds to HIV, are being developed in the laboratory of Dr. David Weiner and Jean Boyer at The School of Medicine of the University of Pennsylvania. These tests are being developed for research purposes only. Blood samples will be obtained from healthy (no chronic diseases such as renal failure, liver disease, diabetes or cancer) adult (18 years or older) volunteers, who are not infected with HIV. Samples will also be obtained from otherwise healthy HIV positive individuals for comparison. Before you will be able to donate, you will have an HIV test if one is not on record for you to confirm your HIV status.

You are asked to provide 80 mls (10 tubes or 18 teaspoons) of blood to be used for these assays. Before you participate in this program, it is important that you understand the purpose of the program, any risks to you, and what is expected for your participation. This process is called informed consent.

What am I being asked to do?
If you decide to volunteer, we will obtain a blood sample from a vein in your arm. A needle will be inserted in the vein and 18 teaspoons (10 tubes) of blood removed. Collection of blood samples via venipuncture from healthy, non-pregnant adults who weigh at least 110 pounds poses minimal risk. However, blood may not be drawn more than twice per week, total amount not to exceed 550 cc in an 8 week period. You may be able to participate in this quality assurance program more than once as long as these restrictions are met.

In order to confirm your HIV status, if there is no test information available, you will have a rapid HIV test done using part of the blood that has been obtained, or an oral swab test. You will be counseled about the possible outcomes of HIV testing, including the possibility of a positive test. Presumed negative participants that are tested positive will receive counseling by Dr.Tebas or one of the Infectious Disease physicians and will be directed to the appropriate referrals and resources. You should also be aware that staff have a public health responsibility with respect to identifying an HIV-positive individual. Pennsylvania state law requires health care workers report the names of people who test positive for HIV, syphilis, gonorrhea or Chlamydia to the Health Department. The reason for

this is to make sure people who have these infections get treatment and that others exposed to these infections get treatment and that other who may have been exposed to these infections get tested. If you want, the research staff will help you with talking to the Health Department staff.

What are the possible risks or discomforts?
Risks of venipuncture include some discomfort, bruising and rarely infection.

There is also a risk of loss of confidentiality because your name may need to be reported to the health department. If you are a patient in the MacGregor clinic or have participated in a clinical trial with the Infectious Disease Unit, you probably have been identified previously.

What are the possible benefits?
No direct benefit to you is expected, although we hope that developing these assays will help us understand better the responses to the immune system against HIV infection, and ultimately lead to a potentially useful vaccine.

Will I be paid for being in this study?
To compensate you for your time and inconvenience, you will be paid $50 for the 80 ml (10 tubes) sample you provide.

What happens if I am injured or hurt during the study?
Because of the very brief duration of this study (the time necessary for obtaining your blood sample), it is unlikely that you will be hurt during the study. If you have a medical emergency during the study you may contact the Principal Investigator, the nurse obtaining your blood or the Emergency contact listed on page one of this form. You may also contact your own doctor, or seek treatment outside of the University of Pennsylvania. Be sure to tell the doctor or his/her staff that you are in a research study being conducted at the University of Pennsylvania. Ask them to call the telephone numbers on the first page of this consent form for further instructions or information about your care.

In the event of any physical injury resulting from research procedures, medical treatment will be provided without cost to you, but financial compensation is not otherwise available from the University of Pennsylvania. If you have an illness or injury during this research trial that is <u>not</u> directly related to your participation in this study, you and/or your insurance will be responsible for the cost of the medical care of that illness or injury.

What personal health information is collected and used in this study, and might also be disclosed?
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, gender and date of birth
- medical history
- Results of tests and procedures you will undergo during this research study as described in the informed consent form.

Why is your personal contact and health information being used?

Your personal contact information is important for the research team to contact you during the study. Your personal health information and results of tests and procedures are being collected as part of this research study. In some situations, your personal health information might be used to help guide your medical treatment.

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

- The Principal Investigator and the Investigator's study team
- Authorized members of the workforce of the UPHS and the School of Medicine, and University of Pennsylvania support offices, who may need to access your information in the performance of their duties (for example: for research oversight and monitoring, to provide treatment, to manage accounting or billing matters, etc.).

Who, outside of UPHS and the School of Medicine, might receive your personal health 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:

- Regulatory and safety oversight organizations
  The Office of Human Research Protections

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 UPHS and 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 repository (database). However, UPHS and 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 to do so
- The University of Pennsylvania's Institutional Review Board grants permission after ensuring that appropriate privacy safeguards are in place
- As permitted by law

Will you be able to access your records?
The results of the immunological tests conducted in your blood will not be provided to you, as those tests are still investigational and we do not know the clinical relevance of those results.

Can you change your mind?
Yes, at any time you may withdraw your approval to allow the use and disclosure of your personal health information as described here. 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 to use your personal health information, you will also be withdrawn from the research study.

If you withdraw your permission to use any blood or tissue obtained for the study, the Principal Investigator will ensure that these specimens are destroyed or will ensure that any information that could identify you is removed from these specimens.

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.

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

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 about my rights as a research subject?

If you have questions regarding your participation in this research study or if you have any questions about your rights as a research subject don't hesitate to speak with the Principal Investigator listed on page one of this form. Concerning your rights as a research subject, you may also contact the Office of Regulatory Affairs at the University of Pennsylvania by calling (215) 898-2614.

By signing below, you consent to participate in the procedure described above.
Your decision to take part in this procedure is a voluntary one and your medical care will not be affected if you refuse. You may terminate your participation anytime without prejudice to present or future care at the University. You will be given a copy of this consent form.

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

_____	_____	_____
Name of Person Obtaining Consent	Signature	Date