UNIVERSITY OF PENNSYLVANIA
RESEARCH SUBJECT
INFORMED CONSENT AND HIPAA AUTHORIZATION FORM

Protocol Title:	Evaluating the HIV-1 Reservoir: BEAT HIV Delaney Collaborative.
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24 hr. Emergency Contact:	***Immunodeficiency Program Doctor on call*** ***(215) 662-6059***

Why am I being asked to volunteer?

White blood cells (WBCs) (cells in the body that fight infection), especially lymphocytes (a type of WBC), are responsible for the coordination of body defenses. We are asking you to donate a small portion of your WBCs through a process called leukapheresis. Leukapheresis is a procedure which involves using a machine to collect WBCs and return the rest of your blood to your body.

You are being invited to participate in a research study. 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 decide to give your WBC by leukapheresis , we ask that you read this form carefully in its entirety and that you ask as many questions as you need to fully understand the study. This form explains the procedure, potential risks and discomforts as well as benefits of undergoing leukapheresis. 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 research study?

The HIV virus, even in patients with well controlled replication, hides in WBC and is not completely eliminated. The purpose of this study is to understand better the nature of this reservoir of HIV and to study in the laboratory strategies to eliminate it.

The reason for collecting WBCs by leukapheresis for this research study is to obtain as large a number of cells as possible, which would otherwise be impossible to collect by smaller blood samples. The study will measure if we can design ways to reduce and eliminate the reservoir in the laboratory.

Researchers at PENN or collaborating institutions will also use samples collected from this study to develop standardized techniques to measure the size of the HIV reservoir that can be used in future studies involving HIV/AIDS and strategies to control HIV infection.

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How long will I be in the study? How many other people will be in the study?

You will be in the study for two visits, a screening visit to see if you are eligible and second visit when the leukapheresis procedure will be done. Approximately 20 people will take part in this study. The University of Pennsylvania is the only study center.

What am I being asked to do?

You are being asked to give your WBCs (including lymphocytes) by a procedure called Leukapheresis. Apheresis is a procedure whereby whole blood is removed from the body, a specific component is removed, and the rest is returned. Leukocytapheresis is the removal or collection of white blood cells (immune cells). In this procedure intravenous (IV, into your vein) catheters (hollow plastic tubes) will be placed in each arm for the blood collection. Blood is collected from one arm. The white blood cells are removed from your blood. The remaining blood is then returned through the other arm. This procedure usually takes about 3 hours and will be done in the Apheresis & Infusion Unit at the Hospital of the University of Pennsylvania

If you agree to participate in this study, you will come to the Hospital of the University of Pennsylvania for 2 visits: a screening visit and 1 Leukapheresis visit.

Screening Visit

You will be seen in the Infectious Diseases Clinic on 4 South PCAM for this visit.

At the screening visit:

- You will be asked to read and sign this consent form that explains the study and what will be expected of you**.**
- You will have about 4 teaspoons of blood drawn for blood tests including an HIV viral load, blood cell counts, CD4 count and a pregnancy test.
- You will have a pre-donor evaluation (PDE) performed at the Apheresis and Infusion Clinic on 3 Ravdin at the University of Pennsylvania. The purpose of the PDE is to assess your veins to make sure the procedure can be done, and to go over your medical history to determine if you have any contraindications to the leukapheresis procedure

Leukapheresis Visit

If the screening visit results show that you still qualify for the study, you will come for the leukapheresis procedure at the Apheresis and Blood Donation Center on 3 Ravdin in the main hospital.

Leukapheresis procedure:

You will sign a separate consent before you have the procedure. The time required for this procedure is approximately 3 hours. You will have to remain in a semi-reclining position for the entire time. A needle will be inserted into a vein in your arm. Your blood will be sent through a machine, filtered to separate the different types of blood cells, certain white blood cells will be taken out, and the remainder of your blood will be returned to your circulation through a second needle inserted into a vein in your other arm. This process will continue until all of your blood has been filtered about 2½ times. In addition, 100 ml of plasma (the fluid part of your blood) will be saved.

During this procedure, you will receive two solutions, saline and one of the following blood thinners to keep your blood from clotting: citrate only, citrate with heparin, or heparin only. You will be monitored during and for 30 minutes after the leukapheresis and instructed to inform the medical staff

immediately of any discomfort. Your body will make more white cells within a few days. Losing the amount of blood and the number of white blood cells that are collected does not pose a danger to you or to your health.

Other

Leftover blood and apheresis samples will be stored by code number or sent to collaborators and used for HIV-related research. Collaborators will not have access to any personal health information. No genetic research will be conducted. These samples may be stored for an indefinite period of time. Results of testing performed on these samples will not be given to you as they are experimental and may not have clinical meaning at this time.

	Visit 1	Visit 2
Study week	0	leukapheresis
Sign informed consent	x	
Blood tests for: complete blood count , CD4 count, HIV viral load and pregnancy test for females capable of becoming pregnant.	x	
Evaluation of veins	X	
Leukapheresis		X

What are the possible risks or discomforts?

Blood Draw:

The risks of having blood taken are discomfort, bleeding, fainting, small blood clot or swelling to the vein and area surrounding where the blood is drawn, bruising where the needle enters the skin and infection. There is also a very small chance of infection at the needle puncture site.

Leukapheresis:

Side effects that can occur during leukapheresis include nausea, vomiting, fainting or dizziness, seizures, skin rash, hives, flushing (redness and warmness of the skin, usually the face), blood loss, and infection. Tingling of the lips, muscle cramping and, very rarely, changes in the heart rhythm can occur. These can be prevented or made milder by giving calcium supplements, either by mouth or in the vein, also called intravenous (IV). Very rarely, (less than 1 in 1,000 procedures), clotting may occur in the apheresis machine or in a patient and is potentially life-threatening. To reduce the risk of clotting, you will be given a drug called ACD (acid-citrate-dextrose). This drug may increase the risk of bleeding and may cause temporary tingling of the lips and limbs, muscle cramping, seizures, or changes in the heart rhythm. After the apheresis procedure you may experience temporary discomfort, including irritation, swelling or bruising at the place where the needle was inserted into your vein to collect the blood.

intravenous catheter placement (IV):

Placement of an IV catheter involves putting a small, short plastic tube in your vein. Occasionally the procedure can cause local infections, pain or bleeding from the needle stick, bruising of the skin, inflammation or irritation of the vein (also known as phlebitis).

Risk of Stored Samples
There may be unknown risks associated with the storage and analysis of your samples or the information resulting from the analysis of your WBC samples. However, every effort will be made to maintain your confidentiality.

The research may involve risks that are currently unforeseeable.

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. However, your participation may contribute to a better understanding of HIV reservoirs in HIV+ patients who have transplant. Ultimately, the knowledge gained through this study may be useful to you and to other persons infected with HIV.

What other choices do I have if I do not participate?
If you decide not to participate in the research study, you will undergo the standard of care.

Will I be paid for being in this study?
You will be compensated $25 for the screening visit and $175 for the leukapheresis visit.. Compensation will be given on a ClinCard (debit card) or as cash. The maximum amount of compensation for the study is $200. 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.

Will I have to pay for anything?
There will be no cost to you for participating in this study. All clinical and professional services, diagnosis and laboratory works that are part of this research will be provided at no cost to you.

You and/or your health insurance may be billed for the costs of medical care during this study if these expenses would have happened even if you were not in the study, or if your insurance agrees in advance to pay

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?
This study is expected to end after all participants have completed all visits, and all information has been collected. This study may also be stopped at any time by your physician without your consent because:

- The Primary Investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- You have not followed study instructions.
- The study Principal Investigator has decided to stop the study.

If you decide to participate, you are free to leave the study at anytime. Withdrawal will not interfere with your future care.

Electronic Medical Records and Research Results

Who can see or use my information? How will my personal information be protected?

Results of laboratory tests and clinical procedures will be placed in your medical record and may be accessible to employees of the health system that are not part of the research team. This information may also be viewed by your insurance company during routine audits. We will do our best to make sure that the personal information in your medical record will be kept private. However, we cannot guarantee total privacy.

Your personal information may be given out if required by law. As part of this study, your HIV status may be confirmed and a positive test for HIV will be generated and 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.

If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. The IRB at the University of Pennsylvania will have access to the research record. All subjects will be de-identified and assigned a numerical code to track their data.

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).

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

- Name, address, telephone number, email, medical record number, date of birth
- Social security number which is needed for payment for study participation
- Personal medical history
- Results from any examinations, tests or procedures

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
- 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 investigator for the study and the 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 of the School of Medicine, might receive my information?

Oversight organizations

The Office of Human Research Protections

Once your personal health information is disclosed to others outside the School of Medicine, it may no longer be covered by federal privacy protection regulations.

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 do this by sending written notice to the investigator for the study. 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.

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 Investigator 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.

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.

When you sign this form, you are agreeing to take part in this research study and agree to have your leftover blood and apheresis product used for research. 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.

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

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