UNIVERSITY OF PENNSYLVANIA

Blood Donation for the Immunology Quality Assessment Program
Cryopreservation Evaluation

CONSENT FORM

Investigators:	Pablo Tebas, MD	(215) 349-8092
Study Coordinator:	Joseph Quinn, RN	(215) 349-8092

24 Hr Emergency Number (215) 662-6059 Ask for the Immunodeficiency Program Doctor On Call

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INFORMED CONSENT

You are being asked to participate in a blood donor program for the National Immunology Quality Assessment Program (IQA). Blood donations from two persons, either an uninfected volunteer or infected with HIV with a CD4 count above 200 and a viral load less than 5,000 copies will be collected and processed in the clinical trials laboratory at PENN quarterly. 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.

YOUR PARTICIPATION IS VOLUNTARY

Your participation in this project is voluntary. You may refuse to participate or stop participation at any time without penalty or loss of benefits to which you are otherwise entitled. Your decision will in no way prejudice the care you receive at the Hospital of the University of Pennsylvania.

PURPOSE

ACTU (AIDS Clinical Trials Unit) laboratories throughout the United States that perform immune blood tests to follow the course of HIV disease need to be tested for the quality of their work. One of the required procedures performed by laboratory staff is cryopreservation. Cryopreservation is the process by which the cells in blood are extracted placed in a vial and frozen very quickly in a substance called liquid nitrogen. Each ACTU is required to submit samples four times a year to a central laboratory that will perform Quality Assurance testing on them. The purpose of this project is to measure the quality of cryopreservation techniques by assessing the viability (how many cells are OK after being thawed) of cells. This type of testing for quality will assure that HIV infected patients throughout the ACTU have accurate immune blood tests that monitor their disease.

Two subjects will be recruited for this study at least four times a year. This QA program will be ongoing for the duration that University of Pennsylvania remains an ACTU that cryopreserves specimens or until the sponsor, the Division of AIDS decides to discontinue the program.

SELECTION of SUBJECTS

Samples will be needed from two donors every quarter. The HIV serostatus will be noted, but documentation does not need to be provided for HIV negative donors.

If you are HIV-positive, we will need to confirm your HIV status. The results of a previous HIV test must be made available or you can be tested today. If you have already participated in an ACTU trial and were tested, you will not need to be tested again. HIV+ participants should have a recent (within 30 days) CD4

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count of greater than 200 and a viral load less than 5,000 copies/mL.

HIV negative or positive participants can give a sample only once or may give on multiple occasions for this quality assurance program.

PROCEDURES

If you decide to participate as a blood donor in this study and sign this consent, you will have an HIV test if one is not on file already, to confirm your status before your blood can be used in the program; this will require an extra tube (10 mls) of blood. Once it is determined that you qualify to participate in this project, an appointment will be made for the day that your blood will be drawn. Blood will be obtained by inserting a needle in your arm vein by trained personnel following recommended safe blood drawing guidelines that are used for all blood donations. Six tubes (60 mls or 12 tablespoons) will be taken for the cryopreservation study. You will be allowed to donate more than once and will receive payment for each blood donation.

RISKS/DISCOMFORTS

As a blood donor, you should understand that there may be some risks and side effects associated with donating blood. Drawing blood from a vein can cause local pain, bruising or bleeding from where the needle enters the skin. There is also a minimal risk of inflammation or infection of the vein, decreased blood pressure, dizziness or fainting that can occur during or after you donate blood. You should notify the ACTU office (215 349-8092) of any illness occurring in the next few days following your blood donation.

BENEFITS

As a blood donor, you will receive no benefit from this study. However, the improvement in the quality of the blood studies being performed in the laboratories throughout the United States will benefit all HIV infected patients who need to have these blood studies done as part of their routine medical care and participation in clinical drug trials.

COSTS TO YOU

There will be no cost to you for your participation in this study. If you need to be tested for HIV, this will be done free of charge.

COMPENSATION

You will receive payment for your time and inconvenience in the amount of $5.00 PER TUBE, or $30.00 each time you give a donation of blood.

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ALTERNATIVES

Since this is not a treatment study, there is no alternative, except not to participate.

NEW FINDINGS

If you are an HIV+ participant, you will be told of any new findings regarding laboratory studies of HIV infection that may improve the monitoring of your disease state or that might cause you to change your mind about participating in the study

CONFIDENTIALITY

Every attempt will be made by investigators to maintain all information collected in this study strictly confidential except as may be required by court order or by law. Authorized representatives of the sponsor (the National Institute of Allergy and Infectious Diseases, or the Division of AIDS), the University of Pennsylvania, as well as the Food and Drug Administration (FDA), will have access to and may copy, both your medical records and records from your participation in this study. This access is necessary to insure the accuracy of the findings and your safety and welfare. If any publication or presentation results from this research, you will not be identified by name.

You will be identified by a unique donor Identification plumber (ID#) for this IQA program and personal information from your records will not be released without your written permission. This number, not your name, will be on the blood tube that is sent to the Quality Assurance Laboratory and if necessary, to the laboratory that will run an HIV test. ACTG staff are the only people who can break the code, that is, match your name with your code number.

RESEARCH-RELATED INJURY

In the event of any physical injury resulting from the research procedures, medical treatment will be provided without cost to you, but financial compensation is not otherwise available from the University of Pennsylvania.

You or your third party payer, if any, may be billed for medical expenses associated with this study if they are deemed medically necessary and such expenses would have been incurred independent of the study, or if your third party payer agrees in advance to pay for such expenses.

PROBLEMS OR QUESTIONS

If you wish further information regarding your rights as a research subject, you may contact the Director of Regulatory Affairs at the University of Pennsylvania by telephoning (215) 898-2614. You can contact one of the investigators listed on the first page of this form between 8-5 on weekdays to answer any questions you may have about your participation in this study or to report a research related injury. To report a research related injury at all other times, you should contact the Immunodeficiency Program Doctor on Call at (215) 662-6059.

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UNIVERSITY OF PENNSYLVANIA
CRYOPRESERVATION QUALITY ASSURANCE PROGRAM

CONSENT FORM

AGREEMENT

I have read and understand the above sections of the consent form.

I have been given the opportunity to ask questions and they have been answered satisfactorily. I have received a copy of this consent form.

I agree to participate in this blood donation project.

Subject's Name (PRINTED)	Signature	Date/Time

Signature of Person Conducting Consent Discussion	Date

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