UNIVERSITY OF PENNSYLVANIA HEALTH SYSTEM

AACTG5128, version 3.0, dated 8/9/07

PLAN FOR OBTAINING INFORMED CONSENT TO USE STORED HUMAN BIOLOGICAL MATERIALS FOR CURRENTLY UNSPECIFIED ANALYSES

CONSENT FORM & HIPAA AUTHORIZATION

Your contacts for the study are:

Principal Investigator: Pablo Tebas, MD (215) 615-4321
Study Nurses:
  Kathryn Maffei, RN, BSN (215) 349-8092
  Joseph Quinn, RN, BSN (215) 349-8092
  Wayne Wagner, RN (215) 349-8092
  Aleshia Thomas, RN (215) 349-8092
  Carol DiGiorgio, RN (215) 349-8092
  Jenna Lewis, RN, BSN (215) 349-8092

24 Hour Emergency Number (215) 662-6059 Ask for the Immunodeficiency Program Doctor on call

INTRODUCTION
You are being asked to take part in this study because you are now enrolled in or have taken part in another research study being sponsored by the Division of Acquired Immune Deficiency Syndrome (DAIDS) at the National Institutes of Allergy and Infectious Diseases (NIAID) which is part of the U.S. National Institutes of Health. The doctor in charge of this study at this site is Dr. Pablo Tebas. Before you decide if you want to be a part of this study, we want you to know about the study.

This is a consent form. It gives you information about this study. The study staff will talk with you about this information. You are free to ask questions about this study at any time. If you agree to take part in this study, you will be asked to sign this consent form. If you do not want your samples to be used in studies at a later date, and you do not want a new sample collected from you now, you can also complete and sign this consent form to make your wishes clear to the researchers. You will get a copy to keep.

WHY IS THIS STUDY BEING DONE?
Some samples (for example, blood) taken from you during this or another research study might be useful for research at some later date. This study is being done so that your samples can be stored and used at some later date for research studies, including genetic testing. These research studies are aimed at finding better ways to prevent and treat infection with HIV (the virus that causes AIDS) and AIDS complications.

WHAT DO I HAVE TO DO IF I AM IN THIS STUDY?
You are being asked to allow the researchers to use samples of yours that are left over from another ACTG research study in studies at some later date. These studies may include testing of your genetic material (DNA) at some later date. These studies may also include other testing that is not yet planned and may not have been part of your consent for the other ACTG study.

You are also being asked to agree to give one extra blood sample that will be saved for genetic testing at some later date and that is not yet planned.
HOW MANY PEOPLE WILL BE IN THIS STUDY?
We expect that up to 20,000 people will enter this study. At first, the study was only offered at 4 ACTG sites, until 160 people had enrolled. In February of 2002, the study was opened to all ACTG sites. As of June 2007, over 9,800 people had entered the study.

HOW WILL YOU GET THE SAMPLES FROM ME?
After all the study tests are done for the research study that you are or have participated in, there may be some left over samples of blood, urine, tissue, or other body fluids. If you agree by signing this consent, any left over samples will be kept and used for research at a later date, which may include genetic testing.

If you agree to allow the researchers to take an additional sample for storage through this study, you will have about one tablespoon of blood drawn one time. This additional sample will be used as a source of DNA for genetic testing that is not yet planned but may be done at a later date. If you agree to have an additional sample drawn, it is possible that the researchers may not have enough of your DNA for studies to be done at a later date. If this happens, you may be asked to sign a new consent form and provide another sample.

HOW WILL YOU USE MY SAMPLES?
Since we do not yet know the exact questions that will be studied at a later date, we cannot tell you exactly what tests will be done on your samples or what that might mean to you. Your samples may be shipped outside of your country and may be used by researchers outside of your country.

Your samples will only be used to learn more about HIV infection and its complications. The research may include studies to understand how HIV causes disease and complications, and how to best treat or prevent HIV infection and its complications. Your samples may also be used to study other problems that affect persons with HIV infection, such as liver disease, diabetes, or heart disease. Testing may include studies of HIV, studies of other diseases (like hepatitis) that affect people with HIV, studies of your cells, proteins, and other chemicals in your body, and studies of your genes (DNA).

Researchers may use some of your stored blood to make a cell line. This cell line will be made in a laboratory and will allow your blood cells to keep dividing (or reproducing). In this way, researchers can get more DNA without having to get more of your blood.

We do not plan to contact you or your regular doctor with any results from these studies done on your stored samples. This is because research tests often use experimental procedures, so the results from one research study are generally not useful for making decisions about treatment. If a very rare situation come up where the researchers decide that a specific test result would provide extremely important information for your health, we will make every attempt to notify you and/or your doctor. If you wish to be contacted with this type of test result, you must give the study doctor or nurse any change to your address and/or phone number. If you want your regular doctor to be
told about this type of test result, you must provide the study doctor or nurse with your regular doctor’s name, address and phone number.

Your samples will not be sold or used directly to produce commercial products. Your stored samples will not be used for any specific research study unless the plans for using them are either approved by the Institutional Review Board or another similar review body that has scientific and ethical oversight responsibility for research.

**HOW LONG WILL YOU KEEP MY SAMPLES?**
There is no time limit on how long your samples will be stored.

**HOW WILL MY SAMPLES BE STORED?**
Your samples will be stored at special facilities that are designed to store samples safely and securely. These storage facilities are designed so that only approved researchers can access the samples. The employees at these storage facilities who will store and track the samples will not have information that directly identifies you. An Institutional Review Board or Ethics Committee (EC) will review the storage facility’s procedures that show that they protect the rights of research volunteers. (An IRB or EC is a committee that watches over the safety and rights of research participants.) Your DNA samples will be stored with coded identifiers that will keep your identity from being known to researchers who may use your samples.

**COULD THIS STUDY BE STOPPED EARLY?**
This study could be stopped at any time by the IRB or EC at your site, by the local or national ministry of health in your country, by the U.S. National Institute of Allergy and Infectious Diseases, by the Office for Human Research Protections, or by other government agencies, as part of their duties to protect research study participants.

**ARE THERE BENEFITS TO TAKING PART IN THIS STUDY?**
There are no direct benefits to you. The benefit of doing research on stored samples includes learning more about HIV infection and its complications in order to help people who have HIV. You will not receive any financial gain from studies done using your stored samples.

**WILL I BE PAID FOR BEING IN THIS STUDY?**
To compensate you for the additional inconvenience, you will given a $10 gift card or if these are unavailable, $10 as cash.

**WHAT ARE THE RISKS OF THE STUDY?**

*Risks of Blood Drawing*
Taking blood may cause discomfort, bleeding, or bruising where the needle enters the body, lightheadedness, and in rare cases, fainting or infection.

**Risks of Sample Storage**

There are few risks related to storing your samples. The greatest risk is to your privacy. It is possible that if others found out information about you that is learned from tests (such as information about your DNA), it could cause you problems with family members (having a family member learn about a disease that may be passed on in families or learning who is the true parent of a child) or problems with getting a job or insurance.

**WHAT OTHER CHOICES DO I HAVE BESIDES THIS STUDY?**

You may choose not to participate in this study.

**WHAT ABOUT CONFIDENTIALITY?**

We will do everything we can to protect your privacy. Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. No publication of this study will use your name or identify you personally.

In addition to the efforts of the study staff to help keep your personal information private, we have obtained a Certificate of Confidentiality from the U.S. Federal Government. This certificate means that researchers cannot be forced to tell people who are not connected with this study, such as the court system, about your participation. Also, any publication of this study will not use your name or identify you personally.

People who may review your records include: University of Pennsylvania's IRB, Ethics Committee, local regulatory agencies, National Institutes of Health (NIH), Office for Human Research Protections (OHRP), study staff, study monitors, and their designees. Having a Certificate of Confidentiality or other similar certificate does not prevent you from releasing information about yourself and your participation in the study.

Even with the Certificate of Confidentiality, if the study staff learns of possible child abuse and/or neglect or a risk of harm to yourself or others, we will be required to tell the proper authorities.

**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, 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:
- Individuals or organizations responsible for administering the study:
  - AACTG Data Coordinating Center (FSTRF): Data will be recorded on case report forms,
    keyed into a central database and electronically submitted to the Data Coordinating
    Center. Study data are reported by code number only and do not contain any of the
    PHI variables
  - Statistical Data Analysis Center (SDAC): Approved data will be downloaded from FSTRF
    to the statistical data center for the AACTG at the Harvard School of Public Health.
    ACTG Repository (BRI): This is the storage facility that will keep all specimens until
    they are requested by ACTG researchers. All personal information will be removed
    from your blood specimen before it is sent to the repository. Your sample will be
    identified only by a study code number (not your name or other unique identifier) and
    by study and visit date.
  - ACTG Repository (BRI): This is the storage facility that will keep all specimens until
    they are requested by ACTG researchers. All personal information will be removed
    from your blood specimen before it is sent to the repository. Your sample will be
    identified only by a study code number (not your name) and by study and visit date.
  - Contract Research Organization (PPD, Inc): Monitors from PPD will visit the study
    center on a quarterly basis to review data and correct mistakes before the data are
    sent to SDAC for analysis.
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- **DAIDS:** Data from this study will be made available to the Division of AIDS (DAIDS) of the National Institute for Allergy and Infectious Disease, for them to evaluate the safety and efficacy of the treatments being used in this study.

- **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?**
During your participation in this study, you might not be able to access some or all of your medical records. For example, access to portions of your medical records may be denied in studies where your knowledge of study results included in such records could affect the reliability of the study. You will have access to your medical record information when the study is over or earlier, if possible. The Principal Investigator is not required to release research information to you that is not part of your medical record.

**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 the address on the first page. 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.
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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.

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 ARE MY RIGHTS?

Allowing your samples to be stored for research to be done at a later date is completely voluntary. Your decision will not affect your right to take part in other studies now or in the future.

If you decide now that your samples can be stored for research to be done at a later date, you may change your mind at any time. If you change your mind, you must contact your study doctor or nurse and let them know that you do not want your samples used for research to be done at a later date. Every effort will then be made to either destroy your left-over samples.

If you have previously enrolled in A5128, but at some later date decide to change your mind regarding your enrollment status (for example, you withdraw previous consent for use of stored samples; or change from not allowing to allowing use of stored specimens), you will need to sign a new consent form to indicate your new wishes.

WHOM DO I CONTACT FOR QUESTIONS?

If you wish further information regarding your rights as a research participant, you may contact the Director of Regulatory Affairs at the University of Pennsylvania by telephoning (215) 898-2614. If you ever have questions pertaining to your participation in this research study or about research-related injuries, you may contact the investigators or study nurse listed on the first page of this form.
SIGNATURE PAGE-A5128

Please carefully read the statements below and think about your choice. No matter what you decide, it will not affect your care.

I agree to have any of my leftover samples (blood, urine, tissue, or other body fluids) stored and used for research related to HIV infection and its complications. This research will be done at a later date, and may include genetic testing. You may have already signed a consent form regarding leftover blood as part of your other ACTG study. This allows for possible genetic testing of those samples.

___ Yes
___ No

I agree to have an additional 1 tablespoon of blood taken so that DNA can be collected from it and stored for research related to HIV infection and its complications. This research will be done at a later date, and may include genetic testing.

___ Yes
___ No

If you checked both “No” spaces and sign your name below, information about your age, race, and sex will still be collected and may be shared with other researchers. If you have read this consent form (or had it explained to you), all your questions have been answered, please sign your name below.

Participant’s Name ___________________________ Participant’s Signature ___________________________ Date/Time ___________________________

Participant’s Legal Guardian ___________________________ Legal Guardian’s Signature ___________________________ Date ___________________________

Study Staff Conducting Consent Discussion ___________________________ Study Staff Signature ___________________________ Date ___________________________

IRB Approved: From: 08-Feb-2012 To: 07-Feb-2013