UNIVERSITY OF PENNSYLVANIA HEALTH SYSTEM

ACTG5128, version 4.0, dated 3/13/2013; Letter of Amendment 1, 5/17/18
PLAN FOR OBTAINING INFORMED CONSENT TO USE STORED HUMAN BIOLOGICAL MATERIALS FOR CURRENTLY UNSPECIFIED ANALYSES

CONSENT FORM & HIPAA AUTHORIZATION

Principal Investigator:	Pablo Tebas, MD	(215) 615-4321
Project Manager:	Eileen Donaghy, MSN, CRNP	(215) 615-2316

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

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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.

Your body, like all living things, is made up of cells. Cells contain deoxyribonucleic acid, also known as "DNA". DNA is like a string of information put together in a certain order. Parts of the string make up "genes". Genes contain instructions on how to make your body work and fight disease. Differences or changes in DNA explain some of the physical differences among people. These differences partly explain why some people get diseases like cancer or diabetes while others do not. Genetic testing looks at the differences in people's DNA. This testing also looks at how differences

affect health and the body's response to disease and treatment. Genes may interact with the environment, which can influence the risk of getting a disease. Many studies are done to find out about the genetic origin of common diseases.

HOW MANY PEOPLE WILL BE IN THIS STUDY?

We expect that up to 30,000 people will enter this study. As of August 24, 2017, about 15,822 people have 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 may be 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 give us permission to contact you about collecting 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 the US and may be used by researchers outside of the US.

Your samples, with the information from your other DAIDS-sponsored research study, can be used for "genetic variations" research. Some examples of genetic variations are differences in height, hair and eye color, as well as the risk of getting certain diseases.

A genome is all of your genes in total. A genome-wide association study or GWAS looks at genetic differences related to a particular disease. Many diseases can result from changes to sections of the DNA. Researchers may also study the changes to see which stretches or "sequence" of DNA may cause a certain disease. "Sequencing" is looking at the order of a person's genes to see how this order is different from the order of most people.

Results of testing done with your DNA may be put into "dbGaP". dbGaP is a research database for genetic studies. This database is available to researchers all around the world. NIH maintains this database. Your name and other health information that could identify you will never be put into this scientific database. No one will know just from looking at this database that some of the information belongs to you.

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 (IRB) or another similar review body that has scientific and ethical oversight responsibility for research. AN IRB is a committee that watches over the safety and rights of research participants.

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. 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?

For your participation, you will be given $10 on a ClinCard.

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), other local, US, and non-US regulatory entities, 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.

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?

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, email address, dates directly related to you such as date of birth and clinic visits.
-medical history
-Results of tests and procedures you will undergo during this research study as described in the informed consent form.

Why is my information being used?

Your information is important for 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.
- Other research personnel with access to the databases for research and/or study coordination and as otherwise approved by the IRB

Who, outside 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:

Individuals or organizations responsible for administering the study:

- ACTG Data Coordinating Center, Frontier Science Technology Research Foundation (FSTRF): Data for this study will be recorded on case report forms, keyed into a central database and electronically submitted to the Data Coordinating Center. The data will be cleaned and stored at this facility until it is ready to be analyzed.

- 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. Specific study reports will be periodically provided to the study team and data safety review board to monitor if the trial is safe.
- Contract Research Organization (PPD, Inc): Monitors from PPD will visit the AACTG on a quarterly basis to review data and correct mistakes before the data are sent to SDAC for analysis.
- Government Agencies: Data from this study will be made available to the Food and Drug Administration and to the National Institutes of Health/Division of AIDS (DAIDS)/National Institute for Allergy and Infectious Disease (NIAID), 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

Once your personal health information is disclosed to others outside of UPHS or 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 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 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. 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.

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.

A clinical trial management system (CTMS) is used to register your information as a participant in a study and to allow for your research data to be entered/stored for the purposes of data analysis and any other required activity for the purpose of the conduct of the research.

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, information related to your participation in the research (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in your existing EMR maintained by UPHS. Information related to your participation in clinical research will also be contained in the CTMS.

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 information produced from your participation in 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). Information related to 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).

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 let the site staff know; and in some cases, you may be asked to sign a new consent form to document your 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. No publication based on samples collected on this study will use your name or identify you personally. In addition, this study is conducted under a Certificate of Confidentiality from the Federal Government. This means that researchers cannot be forced to tell people who are not connected with this study, such as the court system, about your participation.

I agree to have any of my left over 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.

____ (initials) Yes, I agree ___ (initials) No, I do not agree

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.

____ (initials) Yes, I agree ____ (initials) No, I do not agree

I agree to allow researchers to use my samples in research involving (1) genetic differences that may be important for human health; (2) all my genes in studies that may be important for human health, including genome-wide association studies (GWAS); and (3) the sequencing or order of my DNA to determine changes that may be important for human health.

____ (initials) Yes, I agree. ____ (initials) No, I do not agree.

I agree to allow researchers to use cells from my body to make cell lines for research to do research that may be important for human health.

____ (initials) Yes, I agree. ____ (initials) No, I do not agree.

I agree to allow researchers to share my genetic information with other researchers around the world, so that they can learn more about the causes and treatment of diseases. They may store this information in a database called dbGaP as well as in other databases. dbGaP is a genetic database maintained by NIH.

____ (initials) Yes, I agree. ____ (initials) No, I do not agree.

In very rare cases where specific test results provide extremely important information for your health, we will try to contact you. If you do not want to be contacted with this information, please indicate this by marking/initialing the space below.

Please do not contact me _____ (initials)

Note that if you agree to be contacted but then are not contacted, this does NOT mean that your samples have been tested and found to be fine. No assumptions should be made either about testing or the results of testing.

If you checked both or put your initials in all of the "No" spaces above and then 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

The row immediately below will be used only in the event that a subject is under legal guardianship.

_____	_____	_____
Participant's Legal Guardian	Legal Guardian's Signature	Date

_____	_____	_____
Study Staff Conducting Consent Discussion	Study Staff Signature	Date