**HOSPITAL OF THE UNIVERSITY OF PENNSYLVANIA**

***CONSENT TO PARTICIPATE IN A RESEARCH STUDY AND RESEARCH SUBJECT HIPAA AUTHORIZATION***

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| **Protocol Title:** | **A5322, Version 1.0, 05/17/13; Letter of Amendment 2, dated 1/23/14**<br>Long-term Follow-up of Older HIV-infected Adults in the ACTG: Addressing Issues of Aging, HIV Infection and Inflammation |
| **Principal Investigator:** | Pablo Tebas, MD<br>502 Johnson Pavilion, Philadelphia PA 19104<br>**(215) 349-8092** |
| **Lead Study Nurse**:<br>**Research Team**: | Aleshia Thomas, RN, BSN<br>Joseph Quinn, RN, BSN<br>Wayne Wagner, RN, MSW<br>Yan Jiang, RN, BSN, MSN<br>Emily Stumm, BS<br>Arlene McGurk, BA, MEd |
| **24 hr. Emergency Contact:** | Immunodeficiency Program Doctor on call<br>(215) 662-6059 |

**Introduction:**

You are being asked to take part in this research study because you are infected with HIV, the virus that causes AIDS, are currently followed (or were recently followed) in the ALLRT (A5001) study and are 40 years of age or older. This study, A5322 (also known as the HAILO study), is a long-term follow-up study of persons who are HIV infected and received their first antiretroviral medications in selected clinical trials conducted by the AIDS Clinical Trials Group (ACTG). This study is sponsored by the National Institutes of Health (NIH). 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. 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 can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. 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. If you agree to take part in this study, you will be asked to sign this consent form. You will get a copy to keep.

**Why Is This Study Being Done?**

The purpose of this study is to look at the relationships between HIV infection, age and the immune system (how your body fights infection), and how these relate to the development of non-infectious illnesses such as heart disease, kidney disease, cancer, memory problems, and diabetes.

**How Many People Will Take Part in This Study?**

About 1550 people at Clinical Research sites throughout the U.S. will take part in this study. About 35-50 are expected to enroll at the University of Pennsylvania.

## What Do I Have To Do If I Am In This Study?

Entry visit

If you decide to enroll in this study, you will be asked to read and sign this consent form. The entry visit will take about 1.5 hours. You will need to fast before your entry visit. Fasting means nothing to eat or drink other than water and medication for 8 hours before your visit.

During this visit:

- You will have a targeted physical exam performed, at which time your body measurements (height/weight) and blood pressure will be taken.
- You will have your hip, waist, and arm measured as a baseline to compare with measurements at later visits.
- If you are a woman, you will have a gynecological assessment. This means you will be asked questions about menopausal status and symptoms, pregnancies, and contraceptive use. If you agree, we will also look at your records for details (dates and results) of any recent pelvic exams and PAP smears.
- We will look at the amount of HIV in your blood and your CD4 and CD8 T cell counts and percentages by looking at your records.
- You will have about 7 tablespoons of blood drawn. Most of this will be stored for future protocol-related tests and some of this will be used for routine laboratory tests for safety and viral hepatitis tests.
- You will be asked to provide a urine sample that will be tested for protein, and some urine will be stored for future protocol-related testing.
- You will have a frailty test. This means you will be asked to do a strength test (by squeezing a hand-held tool) and will be asked to walk a short distance (4 meters or about 12 feet).
- You will have a brief neurologic exam to test the way you think through or understand information and to test how your nerves are working. Some of these tests are paper and pencil tests. These tests are being done to find out changes that may be occurring in how you think through or understand information or in how your nerves work while on long-term treatment.

We will also ask you about:

- Your medical history and certain medications you are taking or have taken since your last ALLRT (A5001) study visit. You will be asked to give a complete history of any anti-diabetic medication you have taken and any chemotherapy you may have had. You will be asked about certain dietary supplements within the last 30 days.
- New illnesses since the last ALLRT (A5001) study visit, and possibly also some illnesses we may not have asked you about during your ALLRT (A5001) visits.
- How well you are taking your anti-HIV medication.
- Alcohol/substance/tobacco use and sexual behavior.
- How well you are able to complete usual daily activities.
- Your weight, physical activity, and energy level.
- Your family health history.
- Your health insurance coverage

On-study Visits After Entry

After your entry visit, you will come to the clinic every 24 weeks (about every 6 months) or twice per year. These study visits will last about 1.5 hours. At every study visit, you will have the evaluations listed below and at every other visit you will have the additional evaluations listed in the second list. This means that at the annual visits (week 48 (year 1), 96 (year 2), 144 (year 3), etc), you will have 14 tablespoons of blood drawn.

Evaluations Performed Every 24 Weeks (about every 6 months) (± 12 weeks)
During these visits:

- You will have a targeted physical exam performed.
- You will have your hip, waist, and arm measured to learn about changes in your body shape.
- If you are a woman, you will have a gynecologic assessment, as described in the entry visit.
- You will be asked about any new medications since your last visit.
- Beginning at week 24, we will ask you questions about some of the illnesses you reported at earlier visits, including medications you may be taking for these illnesses and any changes in your condition.
- You will be asked about some new illnesses since your last visit as well as any falls.
- We will ask you how well you are talking your anti-HIV medication.
- You will be asked about your CD4 and CD8 T cell counts and percentages and your HIV-1 RNA levels measures if this information is not available in your medical chart. You may be asked to provide laboratory results from your HIV primary care provider.
- You will have about 5 tablespoons of blood drawn and stored for future protocol-related testing.

Additional Evaluations Performed Every 48 Weeks (about every year) (± 12 weeks)
You will need to fast before these visits. You will also have the additional following evaluations:

- You will be asked about your alcohol/substance/tobacco use, sexual behavior, and activities of daily living, physical activity and your health insurance coverage.
- You will have about 7 tablespoons of blood drawn. Most of this will be stored for future protocol-related tests and some of this will be used for routine laboratory tests for safety and viral hepatitis tests.
- You will have a frailty test and neurologic test, as described in the entry visit.
- You will be asked to provide a urine sample that will be tested for protein.

At weeks 48 and 96, you will be asked to provide a urine sample that will be stored for future protocol-related testing.

At weeks 144 and 336, you will be asked about your family health history.

Every 96 weeks we will draw some blood for hepatitis testing (if previous hepatitis tests have been negative). Any hepatitis tests that are done as part of routine care will be taken every 96 weeks from your medical charts when available, or obtained from laboratory reports that you provide to study staff.

Telephone Visits
If you are not able to come into the clinic because you are really sick, you may be able to have your visit over the phone. You must ask your doctor ahead of time if you want to do this. Your telephone visit schedule will be the same as if you were coming into the clinic.

Final Study Visit/Early Discontinuation
At Week 336, you will come to the clinic for the final study evaluations.. You will need to fast for this visit. At this visit:

- You will be asked about certain medications you are taking or have taken since your last study visit.
- You will have a targeted physical exam performed, where your body measurements (height/weight) and blood pressure will be taken.
- You will have your hip, waist, and arm measured to learn about changes in your body shape.

- If you are a woman, you will have a gynecological assessment, as described in the entry exam.
- We will look at the amount of HIV in your blood and your CD4 and CD8 T cell counts and percentages by looking at your records.
- You will have about 7 tablespoons of blood drawn. Most of this will be stored for future protocol-related tests and some of this will be used for routine laboratory tests for safety and viral hepatitis tests.
- You will have a frailty test and a neurologic test, as described in the entry visit.
- You will be asked to provide a urine sample that will be tested for protein.

We will ask you about:

- New illnesses since your last visit.
- How well you are taking your anti-HIV medications.
- Alcohol/substance/tobacco use and sexual behavior.
- Your weight, physical activity, and energy level.
- Your family health history.
- Your health insurance coverage.
- Falls.

If you leave the study early, you will be asked to return to the clinic within 12 weeks to complete some evaluations, as described in the final study visit. You will need to fast for the early discontinuation visit.

If you do not enroll into the study

If you decide not to take part in this study or if you do not meet the eligibility requirements, we will still use some of your information. As part of this entry visit, some demographic (eg, age, sex, race), clinical (eg, disease condition, diagnosis), and laboratory (eg, CD4 cell count, HIV-1 RNA levels) information is being collected from you so that ACTG researchers may help determine whether there are patterns or common reasons why people do not join a study. By signing this consent form you are authorizing the study staff to record your information and take blood to see if you meet the study requirements. If you do not want your information or results of blood tests to be used, you should not sign this consent form.

Other

Some of your blood that is left over after all required study testing is done may be stored (with usual protectors of identity) and used for ACTG-approved HIV-related research. These samples may be held for an indefinite length of time. We cannot ensure that you will be told of the results of the research done on these samples. Storage of leftover blood is not a requirement to participate in the study and you may withdraw your approval at anytime, and if you choose to do so this leftover blood will be destroyed.

Please indicate and initial below whether you approve the use of your leftover blood.

_____ YES _____ NO

**How Long Will I Be In This Study?**

You will be in this study for about 7 years.

**Why Would The Doctor Take Me Off This Study Early?**

The study doctor may need to take you off the study early without your permission if:

- The study is cancelled.
- Your clinic site is no longer funded through the ACTG and you cannot continue at another ACTG site.
- Failure to attend three consecutive study visits or three telephone visits as required by the study and no contact was made with you in the span of those three visits.
- Your study doctor or regular doctor thinks the study is no longer in your best interest.
- The investigator feels that you may be at significant risk of failing to comply with the provisions of the protocol as to cause harm to self or seriously interfere with the validity of the study results

## What Are The Risks Of The Study?

Risk of Blood Draw
Taking blood may cause some discomfort, bleeding, bruising, and/or swelling where the needle enters the body, and in rare cases it may result in fainting. There is a small risk of infection.

Questionnaire Completion
Some questions the study team asks may make you uncomfortable such as questions regarding alcohol/substance use and sexual behavior.

## Are There Risks Related To Pregnancy?

If you become pregnant, you may still participate in the HAILO study. (If you are also on another study, you will need to follow the guidelines of that study.) At the end of your pregnancy, we will collect information about you and about the delivery and health of your baby (even if your participation in the study has ended). If you are taking anti-HIV drugs when you become pregnant, your pregnancy will be reported to an international database that collects information about pregnancies in women taking anti-HIV drugs. This report will not use your name or other information that could be used to identify you.

## Are There Benefits to Taking Part in This Study?

If you take part in this study, there may be no direct benefit to you. Information learned from this study may help others who have HIV.

## Will I Receive the Results of Any Tests?

You will receive the result of routine lab tests (eg, blood counts, liver and kidney tests) that are performed at the study visits. You will be told of any new information learned during the course of the study that might cause you to change your mind about staying in the study. At the end of the study, you will be told when study results may be available and how to learn about them. As with all studies, if we find out important information that may affect your care, you will be provided with those results.

## What Other Choices Do I Have Besides This Study?

You can choose not to be in this study and just be followed routinely by your regular doctor or health care provider.

Please talk to your doctor about this and other choices available to you. Your doctor will explain the risks and benefits of these choices.

**What About Confidentiality?**

We will do everything we can to protect your privacy. All laboratory specimens, evaluation forms, reports, and other records that leave the site will be kept locked and identified by coded number only, to protect your privacy. Clinical information will not be released without your written permission, except as necessary, to ensure that your privacy is protected. Also, any publication of this study will not 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. Having a Certificate of Confidentiality 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.

People who may review your records include the ACTG, Office for Human Research Protections (OHRP), other government agencies as part of their duties, University of Pennsylvania institutional review board (IRB), National Institutes of Health (NIH), study staff, study monitors, and their designees. An IRB is a committee that watches over the safety and rights of research subjects.

Your personal information may be given out if required by law. If you test positive for Hepatitis B or C, 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.

**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 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, email address, dates directly related to you such as date of birth and clinic visits.
- Personal and family medical history
- Current and past medications or therapies
- Information from questionnaires administered in the study and from the other HIV studies in which you have participated.
- Results of tests and procedures you will undergo during this research study and from the other HIV studies in which you have participated.
- Social Security Number, Medical record number

**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:

- 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 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 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.

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 the Costs To Me?**
There will be no cost to you for study-related visits, physical examinations, laboratory tests or other procedures.

**Will I Receive Any Payment?**
You will be compensated $50 for each study visit you attend. Compensation will be given as cash. The maximum amount of compensation for the study is $700 (2 visits per year for seven years). 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.

**What Happens If I Am Injured?**

If you are injured as a result of being in this study, you will be given immediate treatment for your injuries. The cost for this treatment will be charged to you or your insurance company. There is no program for compensation either through this institution or the National Institutes of Health. You will not be giving up any of your legal rights by signing this consent form.

**What Are My Rights As a Research Subject?**

Taking part in this study is completely voluntary. You may choose not to take part in this study or leave this study at any time. Your healthcare provider will treat you the same no matter what you decide.

We will tell you about new information from this or other studies that may affect your health, welfare, or willingness to stay in this study. If you want the results of the study, let the study staff know.

**What Do I Do If I Have Questions Or Problems?**

If you have questions about this study or a research-related injury, please contact the research team listed on page 1 of this consent form.

For questions about your rights as a research subject, contact:

- Director of Regulatory Affairs at the University of Pennsylvania by phoning (215) 898-2614

**CONSENT**

When you sign this form, you are agreeing to take part in this research study. 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 Health System and the School of Medicine to use your personal health information collected about you for research purposes within our institution. You are also allowing the University of Pennsylvania Health System and the School of Medicine to disclose that personal health information to outside organizations or people involved with the operations of this study.

A copy of this consent form will be given to you. You will also be given the University of Pennsylvania Health System and School of Medicine's Notice of Privacy Practices that contains more information about the privacy of your health information.

| Name of Subject (Please Print) | Signature of Subject | Date |
|---|---|---|

| Name of Person Obtaining Consent (Please Print) | Signature | Date |
|---|---|---|