

UNIVERSITY OF PENNSYLVANIA HEALTH SYSTEM

Effects of HIV and Highly Active Antiretroviral Therapy in an Aging Outpatient Population
(VERSION 1.1)
CONSENT FORM TO PARTICIPATE IN A RESEARCH STUDY
AND
RESEARCH SUBJECT AUTHORIZATION
CONFIDENTIALITY AND PRIVACY RIGHTS

Principal Investigator:	Pablo Tebas, MD	(215) 615-4321
Coordinator ID Clinic:	Amy Graziani, PharmD.	(215) 662-3638
Trials Coordinator:	Joseph Quinn, RN	(215) 349-8092
Research Assistant:	Emily Stumm, BS	(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 research study because you are infected with HIV, the virus that causes AIDS, and you are older than 50 years of age. The doctor in charge of this study at this site is Pablo Tebas, MD. 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. You will get a copy to keep.

WHY IS THIS STUDY BEING DONE?

This study is being conducted to determine if HIV-infected patients aged 50 or older have a higher risk of early declines in mental and body metabolism function compared to HIV-negative persons.

WHAT DO I HAVE TO DO IF I AM IN THIS STUDY?

Prior to your visit, the study staff contacted you regarding possible participation in this study. It was requested that you show up for your regularly scheduled visit fasting (that is drinking only water and taking any regular medications you normally take after midnight on the day of the study).

A. Clinical Exam: With your permission, data already collected as part of your routine visit will be used by the study team. This includes results of your physical exam and your vital signs. The research assistant may ask you questions about your medical history, or alternatively will review your chart to record your medical history.

B. Testing:

- 1) The study will use information from blood tests already being done as part of your clinic visit, which may include chemistries with a fasting lipid panel (cholesterol and triglycerides), hematology, TSH, testosterone levels if you are male, viral load and CD4 counts. A urine sample will be taken to look for risk of kidney disease.
- 2) A DEXA scan (a special X-ray) to look at the bone strength, muscle and fat distribution in your body will be done. This test is conducted as part of clinical care; if you have had a DEXA scan in the previous six months, the results of that test may be used for the study and another scan will not need to be done. If you have not had a DEXA in the past year, one will be ordered for

UNIVERSITY OF PENNSYLVANIA HEALTH SYSTEM

Effects of HIV and Highly Active Antiretroviral Therapy in an Aging Outpatient Population

- you after this visit. The results will be abstracted from your chart for the study team to use.
- 3) A Digit Symbol Substitution Test (DSST) will be performed. This is a test that has you match corresponding numbers and symbols over a limited (less than 5 minute) time period. This will be administered by the research assistant and is being conducted only for the study, i.e. you would not have this done as part of your routine care.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

It is estimated that up to 350 people from two centers may take part in the study. Up to 200 people may participate at PENN.

HOW LONG WILL I BE IN THIS STUDY?

You will be in the study for only 1 visit; this study portion of your clinic visit may add an extra half hour to your regular visit.

WHAT ARE THE RISKS OF THE STUDY?

Risks of blood drawing

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

Risk of Radiation from the DEXA Scans:

The DEXA scan involves a small amount of radiation. The amount of radiation dose that you will receive for a DEXA scan is roughly equivalent to two months of natural background radiation.

ARE THERE BENEFITS TO TAKING PART IN THIS STUDY?

By taking part in this study, you will help us learn more about HIV and how the treatments for HIV affect older people. This knowledge may help other people infected with HIV who are living longer.

WHAT OTHER CHOICES DO I HAVE BESIDES THIS STUDY?

The alternative is not to participate in this study.

WILL I RECEIVE PAYMENT FOR MY PARTICIPATION IN THIS STUDY?

For your time and inconvenience, you will be paid \$20 for your participation in this study.

CONFIDENTIALITY & PRIVACY RIGHTS

This section of the consent gives you more detailed information about how your health information will be protected and includes:

UNIVERSITY OF PENNSYLVANIA HEALTH SYSTEM

Effects of HIV and Highly Active Antiretroviral Therapy in an Aging Outpatient Population

- What personal health information about you will be collected in this study
- Who will use your information within the institution and why
- Who may disclose your information and to whom
- Your rights to access research information about you
- Your right to withdraw your approval for any future use of your personal health information

By signing this Authorization/Consent Form 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 processing of this study.

What personal health information is collected and used in this study, and also might be shared?

Personal health information that is collected and will be disclosed to the agencies listed on the following page as part of this research study is:

- Demographics (Race, Gender, Age)
- Current and past medical diagnoses
- Information from a physical exam: weight, blood pressure, heart rate, temperature
- Data from laboratory tests (blood chemistry and hematology tests), CD4 count, viral load
- Data from DEXA scans and DSST testing

Why is your personal health information being used?

Your health information and results of tests and procedures are being collected as part of the research study and for the advancement of medicine and clinical care. The Principal Investigator will use the results to monitor your safety and ability to tolerate the study medications.

Which of our personnel may use or disclose your personal health information?

The following individuals and organizations may use or disclose your personal health information for this research project:

- The Principal Investigator and other University staff associated with this study;
- The University of Pennsylvania Institutional Review Boards (the Committees charged with overseeing research on human subjects) and the University of Pennsylvania Office of Regulatory Affairs
- Authorized members of the University of Pennsylvania and the University of Pennsylvania Health System and School of Medicine work force who may need to access your information in the performance of their duties, for example, to provide treatment, to ensure the integrity of the research, accounting or billing matters, etc.

Who, outside of the University of Pennsylvania Health System and the School of Medicine, might receive your personal health information?

As part of the study the Principal Investigator, study team and others listed above, may disclose your personal health information, including the results of the research study tests and procedures to the following:

UNIVERSITY OF PENNSYLVANIA HEALTH SYSTEM

Effects of HIV and Highly Active Antiretroviral Therapy in an Aging Outpatient Population

- Washington University : Data from this study will be recorded on Case Report Forms and will be coded with a unique study number. The data listed earlier will be provided to the data collection facility by code number only; your name, medical record number or other personal identifier will not be on this form.

Study staff will inform you if there are any changes to this list above during your active participation in the trial. Once information is disclosed to others outside the University of Pennsylvania Health System or School of Medicine the information may no longer be covered by federal privacy protection regulations.

In all disclosures outside the University of Pennsylvania Health System or School of Medicine, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier, unless disclosure of the direct identifier is required by law. Personal health information will be disclosed by a unique code number. Only study staff can break the code and identify you to your code.

How long will the University of Pennsylvania Health System and the School of Medicine be able to use or disclose your personal health information?

Your authorization for use of your personal information for this specific study does not expire. This information may be stored in a database (research repository). However, the University of Pennsylvania Health System and the School of Medicine may not re-use or re-disclose your personal health information collected for this study for another purpose other than the research described in this consent form unless you have given written permission to the Principal Investigator to do so. However, the University of Pennsylvania Institutional Review Board may grant permission to the Principal Investigator or others to use your information for another purpose after ensuring that appropriate safeguards are in place. The Institutional Review Board is a committee whose job is to protect the safety and privacy of research subjects. Results of all tests and procedures done solely for this research study and not as part of your regular care will not be included in your medical record unless you want them to be sent to your primary care provider. You will need to complete a medical records release of information to allow us to provide study data to your doctor.

Will you be able to access your records?

You will be able to request access to your medical record when the study is completed. During your participation in the study, you will not be able to access your medical records. This will be done to prevent the knowledge of study results affecting the reliability of the study. Your information will be available should an emergency arise that would require your treating physician to know the information to best treat you. You will have access to your medical record and study information that is part of that record when the study is over. The Investigator is not required to release to you research information that is not part of your medical record.

Can you change your mind?

You may withdraw your permission for the use and disclosure of any of your personal information for research, but you must do so in writing to the Principal Investigator at 502 Johnson Pavilion. Even if you withdraw your permission, the Principal Investigator for the research study may still use your

UNIVERSITY OF PENNSYLVANIA HEALTH SYSTEM

Effects of HIV and Highly Active Antiretroviral Therapy in an Aging Outpatient Population

personal information that was collected prior to your written request if that information is necessary to the study. If you withdraw your permission to use your personal health information that means you will also be withdrawn from the research study.

WHAT HAPPENS IF I AM INJURED?

If you have a medical emergency during the study you may contact the Principal Investigator or Emergency contact listed on page one of this form. You may also contact your own doctor, or seek treatment outside of the University of Pennsylvania. Be sure to tell the doctor or his/her staff that you are in a research study being conducted at the University of Pennsylvania. Ask them to call the telephone numbers on the first page of this consent form for further instructions or information about your care.

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. You will be treated 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 would like the results of the study, let the study staff know.

WHAT DO I DO IF I HAVE QUESTIONS OR PROBLEMS?

For questions about this study or a research-related injury, contact:

- Pablo Tebas, MD
- telephone number 215-615-4321

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

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

UNIVERSITY OF PENNSYLVANIA HEALTH SYSTEM

Effects of HIV and Highly Active Antiretroviral Therapy in an Aging Outpatient Population

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.

You will be given a copy of this consent form/research subject authorization describing your participation/ confidentiality and privacy rights for the "Effects of HIV and Highly Active Antiretroviral Therapy in an Aging Outpatient Population" study. 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.

If you have read this consent form (or had it explained to you), all your questions have been answered and you agree to take part in this study, please sign your name below.

Participant's Name (print)

Participant's Signature and Date

Study Staff Conducting
Consent Discussion (print)

Study Staff Signature and Date