HOSPITAL OF THE UNIVERSITY OF PENNSYLVANIA

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

Protocol Title:	**A5361s, Version 1.0, 12/9/2016, Letter of Amendment #1, 3/30/17, Letter of Amendment 2, 3/12/18: Pitavastatin to REduce Physical Function Impairment and FRailty in HIV (PREPARE)**
Principal Investigator:	Pablo Tebas, MD 502 Johnson Pavilion, Philadelphia PA 19104 **(215) 349-8092**
Project Manager:	Eileen Donaghy, MSN, CRNP
24 hr. Emergency Contact:	Immunodeficiency Program Doctor on call (215) 662-6059

Introduction:
You are being asked to take part in this research study because you are infected with human immunodeficiency virus (HIV), the virus that causes AIDS, and are currently enrolled in the REPRIEVE (A5332) with or without co-enrollment into A5333s studies at an ACTG site. The PREPARE A5361s substudy is sponsored by the National Institutes of Health (NIH). The doctor in charge of this substudy at this site is Dr. Pablo Tebas. Before you decide if you want to be a part of this substudy, we want you to know about the substudy.

This is a consent form. It gives you information about this substudy. The study staff will talk with you about this information. You are free to ask questions about this substudy at any time. If you agree to take part in this substudy, you will be asked to sign this consent form. You will get a copy to keep.

Why Is This Sub-Study Being Done?
Aging with HIV may be related to an earlier development of frailty (weakness) or disability, including difficulties in tests of strength or walking speed. Few treatments have been shown to prevent or slow these impairments in people with or without HIV. Some studies have suggested that the class of drugs called statins (for example, pitavastatin) might be helpful in slowing frailty or disability. This might happen by decreasing fat within the muscle or by decreasing inflammation markers (substances in the blood that determine how your body reacts to infection or irritation) in the blood. Other studies have shown that statins increase the risk of muscle aches and pains. This substudy is being done to determine the impact of the drug pitavastatin on muscle.

How Many People Will Take Part in This Study?
About 600 people will take part in this study. About 40-50 participants are expected to enroll at the University of Pennsylvania.

How Long Will I Be In This Study?
You will be in this substudy for up to 48 months, depending on when you join.

What Do I Have To Do If I Am In This Study?
If you would like to take part in this substudy, you will be asked to sign this consent form.

At the study entry visit and at yearly visits coinciding with your REPRIEVE (A5332) study visits, we will measure your muscle strength and muscle function through several tests. These tests include repeated

chair rises, hand grip strength test, standing balance test, and a 4-meter (12 foot) walk and should take no more than 20 minutes to complete. You will also be asked some questions about your physical activity at the month 12, 24, 36 and 48 visits. You will be asked in an average week, how often do you: (usually/often, sometimes, rarely/never, does not apply):

- Do less than 30 total minutes of physical activity 3 days a week or more?
- Watch more than 2 hours of television or videos a day?

If you are also enrolled in A5333s, we will measure the muscle size and amount of muscle fat from the CT scan that was done as a part of your involvement in REPRIEVE (A5332) and A5333s. We will also measure changes in various substances in your blood related to inflammation and immune function (how your body reacts to infection) using blood that was collected as part of your involvement in REPRIEVE (A5332) and/or the Mechanistic Substudy of REPRIEVE (A5333s). Please note that no additional CT scans will be completed and no extra blood samples will be collected as part of this substudy.

You can receive the results of your physical function assessments at the time of your visit if you are interested. The results of the laboratory analyses and CT scans will not be reported to you.

Premature Discontinuation Evaluation
If you stop participating in the REPRIEVE (A5332) study early you will also have to stop participating in this study. You will be asked to return to the clinic to have premature study discontinuation evaluations completed. These evaluations will take about 30 minutes and include the same assessment of your physical function as you would have at other study visits.

Why Would The Doctor Take Me Off This Sub-Study Early?
The study doctor may need to take you off the study early without your permission if:

- The substudy is stopped or cancelled.
- You are not able to attend the study visits as required by the REPRIEVE (A5332) study.
- You withdraw from the REPRIEVE (A5332) study.
- Your primary care provider requests to take you off the study because the study is no longer in your best interest.

What Are The Risks Of The SubStudy?
The physical function tests are designed to be like your usual activities. These tests are associated with a small risk of tripping, slipping, or falling.

Are There Risks Related To Pregnancy?
This is an observational substudy in which no study treatment is provided, so there are no risks related to pregnancy in this study.

Are There Benefits to Taking Part in This Study?
If you take part in this substudy, there may not be a direct benefit to you. The results of your physical function assessments will be shared with you at the time of these assessments. Information learned from this study may help others who have HIV.

What Other Choices Do I Have Besides This Study?
You can choose not to be in this substudy and still participate in the REPRIEVE (A5332) study.

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. 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 the ACTG, Office for Human Research Protections (OHRP), and other US, local, and international regulatory entities as part of their duties, University of Pennsylvania institutional review board (IRB), National Institutes of Health (NIH), study staff, and study monitors. 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.

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?

- 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
- Results of tests and procedures you will undergo during this research
- Social Security Number, Medical record number

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.

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.
- Regulatory and safety oversight organizations: Data from this study will be made available to the The Office of Human Research Protections 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.

Once your personal health information is disclosed to others outside 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 use or disclose my 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 the sub-study visits, evaluations or other tests required by the study. You or your insurance company, or your health care system will be responsible for the costs of your regular medical care as well as for the costs of drugs not given by the study.

Taking part in this study may lead to added costs to you and your insurance company. In some cases it is possible that your insurance company will not pay for these costs because you are taking part in a research study.

Will I Receive Any Payment?
You will be compensated $50 for each sub-study visit you complete. This will be given on a Clincard debit card. The maximum amount of compensation for the study is $250. 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?
We will offer you the care needed to treat injuries directly resulting from taking part in this research. We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but you may also be responsible for some of them.

There are no plans for the University of Pennsylvania or the National Institutes of Health to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

If you think you have been injured as a result of taking part in this research study, tell the person in charge of the research study as soon as possible. The researcher's name and phone number are listed in the 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

This consent is a subsequent consent for this participant that does not alter the risks for investigational product or products, alternatives or benefits. Research staff will conduct the consent discussion.

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.

If you agree to join this sub-study, you will need to sign below. Before you sign this consent form, make sure of the following:

- You have read this consent form, or someone has read it to you.
- You feel that you understand what the sub-study is about and what will happen to you if you join. You understand what the possible risks and benefits are.
- You have had your questions answered and know that you can ask more.
- You agree to join this sub-study.

You will not be giving up any of your rights by signing this consent form.

_____	_____	
Name of Participant (Please Print)	Signature of Participant	Date
_____	_____	
Name of Person Conducting Consent discussion (Please Print)	Signature	Date