HOSPITAL OF THE UNIVERSITY OF PENNSYLVANIA

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

Protocol Title:	**A5332 FINAL Version 3.0, dated 1/28/16; Letter of Amendment 1, 8/17/16** Randomized Trial to Prevent Vascular Events in HIV (The REPRIEVE Study)
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Introduction:

You are being asked to take part in this research study because you are infected with the human immunodeficiency virus (HIV), the virus that causes AIDS, and you are taking HIV medications. 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?

Since people started taking HIV medications, illness from AIDS has decreased, but other serious diseases, like heart disease, have increased. HIV causes inflammation (irritation) inside the body that cannot be felt but can be measured. These tests will be described later in this consent form. Inflammation may contribute to diseases such as heart disease that have become some of the leading causes of death in people with HIV. HIV medications can lower inflammation somewhat, however sometimes the levels of inflammation can remain higher compared to people who are not infected with HIV.

Statins are a group of medicines used to lower the levels of cholesterol and triglycerides (fat in the blood) that people make and to prevent heart-related disease events such as heart attacks in persons with high risk for heart attacks. Studies have shown that statins may have other benefits. For example,

by decreasing levels of inflammation, statins may have an effect to protect against heart disease and its related events. In addition, statins may have some beneficial effects on some other diseases like some cancers or kidney problems.

The most recent guidelines from the American College of Cardiology and the American Heart Association (ACC/AHA) recommend the use of statins if someone is at risk of heart-related disease based on many different factors, including the use of a risk calculator based on known risk factors including gender, age, race, cholesterol levels, tobacco use, diabetes, and hypertension that estimates the 10-year risk of heart attack, stroke, or other event (the ASCVD risk score). HIV infection is not included in the risk calculator. The current risk calculators may not accurately predict the risk in HIV-infected patients. However, HIV infection, HIV medications, and chronic inflammation may put you at higher risk for these diseases, although we do not know if you would benefit from taking a statin. You are eligible for this study because you in a low to moderate risk group for heart disease under the current guidelines, and there is no consensus about whether HIV patients in this group should take statins. Your participation in this study will help us determine if the use of statins can prevent heart-related disease among people with HIV infection. The results of this study may help to create guidelines for the prevention of heart disease in HIV infection.

For HIV negative individuals with an ASCVD risk score between 7.5% and 15%, the current guidelines recommend a discussion between the health care provider and patients about the risks and benefits of statin therapy and recommend initiating statins based on available clinical trial data. However, for HIV patients with a moderate risk for heart disease (a risk score between 7.5% and 15%), no currently available data clearly tell us whether the benefits of statin therapy outweigh the risks including adverse effects and potential drug-drug interactions. Some care providers may elect to treat HIV patients in this moderate risk range with statin therapy and this option may be available to you, rather than participating in the trial. Ultimately, the results of this trial will provide data to guide the use of statins for HIV patients.

Pitavastatin is a statin that, along with a diet, has been approved by the US Food and Drug Administration for the treatment of high cholesterol. It also lowers triglyceride levels in the blood. It has not been studied to see if it reduces heart-related disease or death. Pitavastatin was chosen because there are thought to be few interactions between pitavastatin and commonly used HIV medications.

The main purpose of this clinical trial is to see if pitavastatin can prevent heart disease and heart-related deaths in people with HIV infection who are taking HIV medications. We will also study the safety of pitavastatin.

How Many People Will Take Part in This Study?
About 6500 people will take part in this study. About 150 participants are expected to enroll at the University of Pennsylvania.

How Long Will I Be In This Study?
You will be in this study about 3 ½ - 6 years (42 – 72 months) depending on when you join. As soon as the first person who joined this study completes 72 months, the study will be over**.**

What Do I Have To Do If I Am In This Study?
Study visits
If you enter the study, you will be seen in the clinic about 6 times the first year. After that, the study visits are every 4 months for the next 3 ½-5 ¾ years. This means that you will be in the study for about 3 ½ - 6 years, depending on when you enter the study. Each visit will take about one hour. More details about the visits and procedures are below.

If you do not enter the study
If you decide not to take part in this study after signing the consent form, or if you do not meet the eligibility requirements, we will still use some of your information. As part of this screening visit, some demographic (for example, age, gender, race), clinical (for example, disease condition, diagnosis), and laboratory (for example, safety tests) information is being collected from you so that AIDS Clinical Trials Group (ACTG) researchers may help determine whether there are patterns or common reasons why people do not join a study.

Study drugs
If you enter the study, you will be randomly assigned (as if by the toss of a coin) to get either pitavastatin or a placebo for pitavastatin. The placebo is a tablet that looks just like pitavastatin but does not contain any active medication. Therefore, there is a chance that if you are randomized to the placebo you will receive no treatment during your participation in the study. We use placebos in clinical studies to learn if the effects seen in the trial are truly from the study medicine or from other reasons. Neither you nor the study staff will know your assignment. You will not find out your assignment until after the entire study is over and the results of the study are known. You and your doctor can be told of the assignment at any point if it is necessary for your health.

You will take the study medicine (either pitavastatin or the placebo for pitavastatin) once a day, every day, throughout the study period, with or without food. The dose is 4 mg. We recommend that you take the study medicine at the same time each day. These drugs are provided by the study. It is very important that you take your medicines as directed. Antiretroviral drugs (treatment for HIV) will not be provided by the study.

Study procedures
The study staff can answer any questions you have about individual study visits and the procedures. The table below can be used as a quick reference, along with the explanations that follow.

Procedure	Screening[1]	Entry[2]	Month 1	Visits every 4 months (starting at month 4)	Annual visits (starting at month 12)	Final visit
Physical exam	X		X		X	X
Heart disease risk assessment	X					
Heart disease risk factors	X					
Diet and exercise questions		X				X
Dispense lifestyle information		X			X	X
Health and medicine questions	X	X	X	X	X	X
Blood collected	X	X	X		X	X
Urine collected		X			X[3]	
Pregnancy test	X	X	X	X	X	X
Electrocardiogram		X				
Pills dispensed and pills counted		Pills dispensed only	Pill count only	X	X	Pill count only

[1] Screening visit: before you can enter the study, you will need to come to the clinic to have evaluations done to make sure that you can take part in the study.

IRB APPROVAL FROM:
01/31/2017 TO: 01/08/2018
IC V8 26 JAN 2017

[2] Entry visit: if you meet the entry requirements, you will enroll in the study.

[3] Urine will be collected at months 12, 24 and 48

If you leave the study early, or have to stop taking the study medication before the study is over, you will have the procedures listed in the table below.

Procedure	Stopping the study or the study treatment early
Physical exam	X
Health and medicine questions	X
Pregnancy test	X
Blood collected	X
Fasting blood tests	X
Pills counted	X

Explanation of study procedures

Physical exam

You will have a physical exam at screening. At other visits after entry, the extent of the exam will depend on how you are feeling at that visit. You will have vital signs taken, including, blood pressure and pulse. You will have measurements taken of your waist and height and weight. You will be asked questions about your health and medicines.

Heart disease risk assessment

At screening we will ask specific questions to assess eligibility based on cardiovascular disease risk. At screening you will also be asked about cardiovascular risk factors including your family history, smoking, alcohol use, substance use, diet, and exercise.

Lifestyle /risk reduction counseling

If you join the study, you will be given information about a healthy diet and the importance of exercise, smoking cessation, and taking your antiretroviral therapy and study medication as prescribed. We will provide this information at all annual visits.

ECG

An electrocardiogram, or ECG, will be done at entry. An ECG is an electrical tracing of your heart that can show how hard it is working. You will have to lie very still for up to 10 minutes while the ECG is being done.

Blood collected

Blood will be collected from you for different tests if they are not available as part of your routine medical care or for safety reasons. These include routine tests to evaluate your blood counts, liver, and kidney function.

At screen we will use the results of your liver function tests done as part of routine care by your medical provider. At month 1, and month 12 we will collect blood from you to evaluate your liver function. This test is required as part of your participation in the study. Approximately 1 teaspoon of blood at each of these visits will be collected for this test.

At screen and the end of study visit we will use the results of your CBC (blood count) and kidney function done as part of routine care by your medical provider.

At screen and annual visits we will use the results of your CD4 T-cell count (how many infection fighting cells are in your blood) done as part of routine care by your medical provider.

At entry and annual visits we will use the results of your HIV viral load (how much HIV is in your blood) done as part of your routine care by your medical provider.

At screen we will use the results of your cholesterol (fat found in your blood) levels done as part of routine care by your medical provider.

You will be told the results of these routine tests.

Stored Samples:
At entry, all annual visits, and the end of study visit, some blood will be collected and stored for tests that will be done later on in the study or after the study is over. These tests will measure the levels of fat and sugar in your blood. Some of these tests will be used for metabolic blood tests (measures how your body uses the food that you eat). You do not need to agree to store this blood to join the study and you may change your mind about storing your blood at any time. Your blood may be stored (with usual protectors of identity) for an indefinite length of time. You will not be told of the results of the research done on your blood.

At each of these visits, approximately 2 teaspoons of your blood will be collected and stored for these purposes.

Samples for Future Research
At entry, all annual visits (as indicated in the Study Procedures table), and the end of study visit, some of your blood will be collected and stored to use for future REPRIEVE-approved research on conditions including cardiovascular disease, HIV, inflammation, cancer or statin medications. You do not need to agree to store this blood to join the study and you may change your mind about storing your blood at any time. Your blood may be stored (with the usual protectors of identity) for an indefinite length of time. You will not be told of the results of the research done on your blood.

Up to 14 teaspoons of blood will be collected at the entry, months 12, 24, 48 and end of study visit for these purposes.

Samples for Genetic Testing
Approximately 1 teaspoon of blood will be collected to look at genes that may affect your risk for cardiovascular disease and how statins work in your body. Genetic testing is a laboratory test that looks at differences in people's genes. Your body, like all living things, is made up of cells, and 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. The testing in this study will focus on certain genes that are known to have an effect on cardiovascular disease and how your body uses statins. New genes of interest may be identified in the future and may also be looked at.

Your body's genetic makeup is unique to you, so there is a risk with genetic research that even with all of the security measures in place, someone using your samples or genetic information may still find out which information is yours. However, this risk today is very small, but it may increase with time since science and technology are developing rapidly.

In the event that your genetic information becomes linked to your name, the US federal law called the Genetic Information Nondiscrimination Act (GINA) helps protect you. This law prohibits health insurance companies, group health plans, and most employers from denying services based on your

genetic information. However, GINA does not protect against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

If at a later date you change your mind and want your samples destroyed, contact the research staff. There are two ways to withdraw your permission. You could allow researchers to remove all your personal identifiers from your samples, so that they are not linked to you anymore. These samples will then become anonymous. Or, you can ask researchers to destroy your samples, so that they cannot be used for future research. However, in either case, researchers will not be able to destroy samples or information from research that is already underway.

Urine collected
Urine will be collected at entry to check for protein in your urine. The results from this test will not be known immediately as they are batched and tested later; therefore we cannot make sure that you will be told the results of this test. Urine will also be collected at month 12, 24, and 48 to check measures of kidney function.

Fasting blood tests
Before the screen, entry and all annual visits you should not eat or drink anything, including food, beverages, candy, or gum for 8 hours before your visit. You are encouraged to drink water before your visits. If you are not fasting we will ask you to return while fasting to have your blood drawn within 21 days of the study visit.

Study drugs given to you
Study drugs will be given to you at entry and every 4 months. No study drugs will be given to you at your final study visit.

Pill count
After you start the study the study staff will give ask you to bring in your pill bottles at every visit. They will count the number of pills left over.

Questionnaires
You will be asked questions about your diet and exercise at entry and will be repeated the final study visit.

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 doctor thinks it is in your best interest
- the study is cancelled
- you are not able to attend the study visits as required by the study

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

- you are not able to take the study drug as required by the study
- continuing the study drug may be harmful to you
- you need a treatment that you may not take while on the study.
- you become pregnant

If you must stop taking the study drug before the study is over, we will ask you to continue to be part of the study and return for some study visits and procedures.

If You Have To Permanently Stop Taking The Study Drug, Or If You Leave The Study, How Would Pitavastatin Be Provided?

During the study:

If you must permanently stop taking study-provided pitavastatin before your study participation is over, the study staff will discuss other options that may be of benefit to you.

After the study:

After you have completed your study participation, the study will not be able to continue to provide you with the pitavastatin you received on the study. If continuing to take this or a similar drug would be of benefit to you, the study staff will discuss how you may be able to obtain the drug.

What Are The Risks Of The Study?

The drug used in this study may have side effects, some of which are listed below. Please note that these lists do not include all the side effects seen with this drug. These lists include the more serious or common side effects with a known or possible relationship. If you have questions concerning the additional study drug side effects please ask the medical staff at your site.

There is a risk of serious or life-threatening side effects when non-study medications are taken with the study drug. For your safety, you must tell the study doctor or nurse about all medications you are taking before you start the study and also before starting any new medications while on the study. Also, you must tell the study doctor or nurse before enrolling in any other clinical trials while on this study.

Risks of Pitavastatin

- Muscle problems. Pitavastatin can occasionally cause serious muscle problems that can lead to kidney problems, including kidney failure and rarely, death.
- Liver problems. Pitavastatin can occasionally cause liver problems that may rarely be serious or cause death. Your study nurse or doctor will do blood tests to check your liver before you start taking pitavastatin and while you take it.
- Be sure to let your doctor or study nurse know immediately if you have any of these problems:
    - Muscle problems like weakness, tenderness, or pains that happen without a good reason, especially if you also have a fever or feel more tired than usual.
    - Nausea and vomiting.
    - Passing brown or dark-colored urine.
    - Feeling more tired than usual.
    - Noticing the skin and whites of your eyes become yellow.
    - Having stomach pain.

Other problems that have been caused by pitavastatin include headaches, rash (which rarely may be severe or fatal), severe allergic reaction or swelling, constipation, gas, diarrhea, pain or numbness in arms or legs, tendon rupture, urinary tract infection, dizziness, memory impairment, and depression. All of these problems are uncommon to rare.

Risks of drawing blood

Taking blood may cause some discomfort, lightheadedness, bleeding, swelling, or bruising where the needle enters the body, and in rare cases, fainting, or infection.

Risks of fasting
Some people find fasting to be bothersome. It may make some individuals feel anxious, irritable, or hungry. Patients who are required to take their morning medications with food should wait until after the visit has been completed to take their medications.

Risks of ECG
You may experience mild irritation, slight redness and itching on your skin where the electrodes from the electrocardiogram machine are placed.

Genetic Testing
The results of your genetic tests are for research purposes only and no individual results will be given back to you. The results of the genetic studies will never become a part of your medical record. We will protect your confidentiality to the fullest extent. Blood samples for genetic studies will be identified in a way in order to maintain your confidentiality.

Research study results will not be given to your family members, insurance companies, employers, or third parties without your written permission and approval of the Institutional Review Board at the University of Pennsylvania.

Unknown risks
Other side effects that are not known at this time could happen during the study. All drugs have a possible risk of an allergic reaction, which if not treated right away, could become life-threatening. During the study, you will be told about any new information that may affect your decision to stay in the study. If you decide to stay in the study, you will be asked to sign an updated consent form. If you decide to leave the study early, the study staff will talk with you about your treatment options.

Are There Risks Related To Pregnancy?
Pitavastatin is unsafe for unborn babies. The risks to the unborn baby include birth defects, premature delivery, or death. If you are having sex that could lead to pregnancy, you must agree not to become pregnant.

If you can become pregnant, you must have a pregnancy test before you enter this study and at every visit (1 teaspoon of blood or a urine specimen will be collected) and at any time that pregnancy is suspected. This test must show that you are not pregnant. If you become pregnant or think you may be pregnant at any time during the study, tell your study staff right away. The study staff will talk to you about your choices.

Because of the risk involved, you and your partner must use at least one accepted form of birth control that you discuss with the study staff. You must start an accepted form of birth control at least two weeks before you start study drug and continue to use an accepted form of birth control until at least 6 weeks after you stop the study drug. If you are having sex that could lead to pregnancy, and do not use an accepted form of birth control, your study doctor will take you off of the study drug. You may choose from the birth control methods listed below:

- Condoms (male or female), with or without a spermicidal agent
- a diaphragm or cervical cap with spermicide
- an IUD (intrauterine device)
- tubal ligation
- tubal micro-inserts
- hormone-based contraceptive

If you become pregnant while on study, the study staff would like to obtain information from you about the outcome of the pregnancy (even if it is after your participation in the study ends). 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.

Breastfeeding
It is not known whether the study drug pass through the breast milk and may cause harm to your infant. Women who start breastfeeding must stop taking the provided study drug.

Are There Benefits to Taking Part in This Study?

Studies have shown statins to provide a benefit in terms of preventing heart disease in HIV uninfected patients with inflammation, but the effects of statins to prevent heart disease in HIV-infected patients is not known. If you take part in this study, there may be a direct benefit to you, but no guarantee can be made. You may benefit from learning about your risk of a cardiovascular event, but it is also possible that you may receive no benefit from being in this study either because the drug may not work or because you are assigned to placebo. Information learned from this study may help others who have HIV and are at risk of cardiovascular disease.

What Other Choices Do I Have Besides This Study?

Instead of being in this study you have the choice of:

- treatment with prescription drugs available to you
- treatment with experimental drugs, if you qualify
- no treatment
- continue routine medical care from your primary care provider
- joining another trial if you qualify
- not getting medical care

Please talk to your study doctor about these and other choices available to you. Your study 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), other government agencies as part of their duties, University of Pennsylvania institutional review board (IRB), National Institutes of Health (NIH), Food and Drug Administration, study staff, study monitors, the drug company supporting this study and its designees. 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.

A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by US law. This web site will not include information that can identify you. At most, the web site will include a summary of the results. You can search this web site at any time.

Your personal information may be given out if required by law. If you test positive for HIV or if a CD4 or viral load is done at a study visit, by law we have to report the result 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. This is to keep track of how many people in the U.S. have HIV infection. It is also to make sure that states get enough money from the federal government to support the medical care of people living with HIV. The Health Department does not share the names of HIV infected people with anyone else. It removes all personal identifiers, such as your name, before giving information on the number of HIV infections to the federal government.

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
- Information from questionnaires administered in the study
- 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 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.
- Kowa Pharmaceuticals America: The pharmaceutical company that is supplying the drugs for this study.
- 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, 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.

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

Will I be able to access my records?
Since this is a blinded study (treatment or placebo is not known to participant or study team), you will be able to access some or all of your medical records after the study is over. The Principal Investigator is not required to release research information to you that is not part of your medical record.

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 If We Can No Longer Reach You During Your Study Participation?

In the event you cannot be reached after multiple attempts to contact you, study staff may try to contact you through alternate phone numbers of family, friends, case manager, or acquaintances obtained at screening and updated at each visit. If you are unable to be reached through the alternate contacts we will attempt to obtain information about you from other sources such as family members, other designated contacts, or clinic records. The purpose of obtaining this information is to determine if you have died and the cause of death since last contact.

Contacting Your Health Care Providers

As mentioned above, we do not currently have data to tell us if HIV patients with moderate cardiovascular disease risk by the ASCVD risk calculator should be treated with statins. If you are in this moderate risk group, with a risk score between 7.5% and 15%, we would like to inform your provider about the rationale for the trial but we need your permission to share this information.

Also, with your permission, for which you would need to sign a waiver, study staff may contact your health care providers regarding any clinical diagnoses you may develop during the study, including heart related diagnoses and other diagnoses, such as HIV, kidney, liver or cancer diagnoses.

What Are the Costs To Me?

There will be no cost to you for the study drugs, the study visits, physical examinations, laboratory tests 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 the screening visit and thereafter, $25 for all study visits (entry and months 1, 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44, 48, 52, 56, 60, 64, 68 and 72). In addition if you bring all of your medication bottles to your study visits you will be compensated $25 at each visit..

Compensation will be given as cash. The maximum amount of compensation for the study is $1050 if all 21 study required visits are completed and medications are returned at each visit.. 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

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.

Stored Samples

On page 5 of this form, we told you about storing samples for tests to measure the levels of fat and sugar in your blood. **Please write your initials in the boxes next to the option you choose.**

☐ I agree to have my stored samples tested for fat and sugar.

☐ I do not agree to have my stored samples tested for fat and sugar.

Future Tests

On page 5 of this form we told you about storing your leftover blood and using it for future ACTG-approved research on conditions including cardiovascular disease, HIV, inflammation, cancer or statin medications. These samples may be stored for an indefinite period of time. Results of testing done on these samples may not be given to you because they will be done in the future. **Please write your initials in the box next to the option you choose.**

☐ I allow my leftover samples to be stored and used for research on conditions including cardiovascular disease, HIV, inflammation, cancer or statin medications.

OR

☐ I do not allow my leftover samples to be used research on conditions including cardiovascular disease, HIV, inflammation, cancer or statin medications.

Genetic Testing

On page 5 of this form we told you about using some of the blood collected to look at your genes (DNA). **Please write your initials in the box next to the option you choose.**

☐ I allow my samples to be stored and used for genotyping

OR

☐ I do not allow my samples to be stored and used for genotyping.

Health Care Provider Contact

On page 12 of this form, we told you about study staff contacting your health care providers to share information regarding your cardiovascular risk score and rationale for the trial, and to provide information regarding clinical diagnoses and to let your doctor know that he/she could object to your taking part in this study since you have a chance of getting placebo instead of treatment with statins. **Please write your initials in the box next to the option you choose.**

☐ I agree to allow the research staff to contact my health care providers to share information regarding my cardiovascular risk score and rationale for the trial, and to provide information regarding clinical diagnoses and to let my doctor know that he/she could object to my taking part in this study since I have a chance of getting placebo instead of treatment with statins. In addition to giving my permission here, a waiver will also be signed.

OR

☐ I do not allow the research staff to contact my health care providers to share information regarding your cardiovascular risk score and rationale for the trial, and to provide information regarding clinical diagnoses and to let my doctor know that he/she could object to my taking part in this study since I have a chance of getting placebo instead of treatment with statins.

Laboratory Results

There are several evaluations performed as part of the study that will be stored and tested in batches at the end of the study. Therefore it is important to not rely on the study for test results and continue to see your primary care provider for ongoing monitoring of your health. Please initial the box to the left of the statement.

☐ I have been informed that some of the results for tests done as part of this study will not be given to me by the study team as the samples are stored and the tests are performed at a later date.

If you agree to join this 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 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 study.

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

_____	_____	
Name of Subject (Please Print)	Signature of Subject	Date/Time
_____	_____	
Name of Person Obtaining Consent (Please Print)	Signature	Date/Time

IRB APPROVAL FROM:
01/31/2017 TO: 01/08/2018