



INFORMED CONSENT DOCUMENT

Project Title: A5332: Randomized Trial to Prevent Vascular Events in HIV

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Research Team Contact:



This consent form describes the research study and helps you decide if you want to participate. It provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights and responsibilities as a research participant. By signing this form you are agreeing to participate in this study.

- You should read and understand the information in this document including the procedures, risks and potential benefits.
- If you have questions about anything in this form, you should ask the research team for more information before you agree to participate.
- You may also wish to talk to your family or friends about your participation in this study.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. 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. 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 recommend the use of statins if someone is at risk of heart-related disease based on many different factors. People living with HIV may not be considered at high-risk for heart disease using the

current guidelines. 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 are not recommended to take statins using the current guidelines. 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.

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. In this study, Pitavastatin is considered investigational, which means that it has not been approved by the U.S. Food and Drug Administration to prevent vascular events in HIV

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.

WHAT WILL HAPPEN DURING 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. The study staff will tell you about how long each visit will be. 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				
Fasting blood tests	X	X			X	X
Pregnancy test	X	X	X	X	X	X
Electrocardiogram		X				
Pill count questionnaire			X	X	X	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.

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

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
Pill count questionnaire	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, 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 check your cholesterol (fat found in your blood) levels.

You will be told the results of these routine tests.

Will you save my samples or research data to use in future research studies?

As part of this study, we are obtaining blood samples from you. 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). These studies may provide additional information that will be helpful in understanding cardiovascular disease, HIV, inflammation, cancer or statin medications or other diseases or conditions, including research to develop investigational tests, treatments, drugs or devices that are not yet approved by the U.S. Food and Drug Administration. It is unlikely that what we learn from these studies will have a direct benefit to you. You might not receive the results of testing performed on these samples. There are no plans to provide financial compensation to you should this occur. By allowing us to use your blood you give up any property rights you may have in the blood.

If you change your mind and do not want us to store and use your blood for future research you should contact the research team member identified at the top of this document. The blood will no longer be used for research purposes. However, if some research with your blood has already been completed, the information from that research may still be used. Also, if the blood has been shared with other researchers it might not be possible to withdraw the blood to the extent it has been shared.

Please place your initials in the blank next to Yes or No for each of the questions below:

My blood may be stored and used for future research as described above.

 Yes No
Initials Initials

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

Do you agree to let us store your samples for tests to measure the levels of fat and sugar in your blood?

 YES NO Initials

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.

We would like to use some of the blood we collect to look at your genes (DNA). Do you agree to this genotyping?

_____ YES _____ NO _____ Initials

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; therefore we cannot make sure that you will be told the results of this test.

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 7 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.

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.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 100 people will take part in this study conducted by investigators at Washington University. About 6500 people will take part in this study from all study sites.

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 ARE THE RISKS OF THIS STUDY?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

Some risks described in this consent document, if severe, may cause death.

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

Less Likely / Less Common

- 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.

Rare

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 and not smoking or consuming caffeine 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 Washington University's Institutional Review Board.

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, with a spermicidal agent
- a diaphragm or cervical cap with spermicide
- an IUD (intrauterine device)
- tubal ligation
- 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.

There is a federal law called the Genetic Information Nondiscrimination Act (GINA). In general, this law makes it illegal for health insurance companies, group health plans and employers with greater than 15 employees to discriminate against you based on your genetic information. However, it does not protect you against discrimination by companies that sell life insurance, disability insurance or long term-care insurance.

Breach of Confidentiality

One risk of participating in this study is that confidential information about you may be accidentally

disclosed. We will use our best efforts to keep the information about you secure. Please see the section in this consent form titled “*How will you keep my information confidential?*” for more information.

WHAT ARE THE BENEFITS OF THIS STUDY?

You may or may not benefit from being in this study.

However, we hope that, in the future, information learned from this study may help others who have HIV and are at risk of cardiovascular disease.

WHAT OTHER TREATMENT OPTIONS ARE THERE?

- Before you decide whether or not to be in this study, your doctor will discuss the other options that are available to you. Instead of being in this study, you could have 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.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

As part of this study you will receive tests and procedures that are similar to what you would receive during routine clinical care of your condition. Your health plan/insurance company will be billed for some or all of these costs, and you will be responsible for any co-pays and deductibles that are normally required by your health plan/insurance. Not all insurance plans cover the costs associated with being in a study. Even if they do, you may be responsible for more out-of-pocket expenses, such as co-pays and deductibles, when there are more tests and procedures or more expensive tests and procedures involved in the study than if you were to receive routine clinical care outside the study.

If you wish to know whether there are more tests and procedures or more expensive tests and procedures in the study, you should ask your study doctor.

If you wish to know whether your insurance will pay, you should contact them directly, or speak with the study team about obtaining a financial pre-certification prior to enrolling in the study.

WILL I BE PAID FOR PARTICIPATING?

You will be paid for being in this research study. You will be paid [REDACTED] at the entry visit, month 1, month 12, month 24, month 36, month 48, month 64, and month 72.

You will need to provide your social security number (SSN) in order for us to pay you. You may choose to participate without being paid if you do not wish to provide your social security number (SSN) for this purpose. You may also need to provide your address if a check will be mailed to you. You will receive a check in the mail in about 7-10 business days following each visit. If your social security number is obtained for payment purposes only, it will not be retained for research purposes.

WHO IS FUNDING THIS STUDY?

This study is sponsored by the National Institutes of Health (NIH). . This means that Washington University is receiving payments from the National Institutes of Health to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from the National Institutes of Health for conducting this study.

WHAT IF I AM INJURED AS A RESULT OF THIS STUDY?

Washington University investigators and staff will try to reduce, control, and treat any complications from this research. If you feel you are injured because of the study, please contact the investigator [REDACTED] and/or the Human Research Protection Office at [REDACTED].

Decisions about whether payment for medical treatment for injuries relating to your participation in research will be made by Washington University. The National Institutes of Health and Washington University do not have a program in place to provide monetary compensation or free medical care to you in the event of a study-related injury. If you need to seek medical care for a research-related injury, please notify the investigator as soon as possible.

HOW WILL YOU KEEP MY INFORMATION CONFIDENTIAL?

It is possible that other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

- Government representatives, (including the Office for Human Research Protections) to complete federal or state responsibilities
- The U.S. Food and Drug Administration
- NIH
- AIDS Clinical Trials Group and their monitors
- The NIH or AIDS Clinical Trials Group may also inspect any part of your medical record for the purposes of auditing the conduct of the study
- Kowa Company, Ltd, the drug company supporting this study and their designees
- Your primary care physician if a medical condition that needs urgent attention is discovered

- If you are a woman and you become pregnant while on this study, your pregnancy will be reported to the Antiretroviral Pregnancy Registry.
- Hospital or University representatives, to complete Hospital or University responsibilities
- Information about your participation in this study may be documented in your health care records and be available to your health care providers who are not part of the research team.
- The last four digits of your social security number may be used in hospital or University systems to track billing information for research procedures
- Public health agencies to complete public health reporting requirements
- Washington University's Institutional Review Board (a committee that oversees the conduct of research involving human participants.) and the Human Research Protection Office. The Institutional Review Board has reviewed and approved this study.
- A data safety monitoring board

To help protect your confidentiality, we will assign the information you give us a code number. We will protect your information, but there is a chance somebody might see it. Some of the data we share with the research team will include your date of birth and your gender and race/ethnicity. These are considered to be identifiers.

- Electronic records (computer files, electronic databases, etc.) - Any computer data is accessible only by centrally distributed and limited access passwords which are changed every 90 days
- Blood and biopsy samples – Initially labeled only with ID number, gender, DOB and date and time of draw, then barcode that has no identifying information on it.
- Paper/hard copy records (hard copy surveys, questionnaires, case report forms, pictures, etc.) - Patient information is given a code number. A master list linking the code number and subject identity will be kept separate from the research data. Only the PI and people helping him/her will be able to see the list..
- Records are not transported.
- Kept in locked, security controlled environment.

If we write a report or article about this study or share the study data set with others, we will do so in such a way that you cannot be directly identified.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. 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.

To further protect your privacy, the researchers have obtained a Certificate of Confidentiality from the Department of Health and Human Services (DHHS). This Certificate may prevent the researcher from being forced (for example by court subpoena) to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceeding. However, a

Certificate of Confidentiality does not prohibit the researcher from disclosing information about you or your involvement in this research that you have agreed to disclose or make available. For example, if you give permission in writing that information about you or your participation in the research be released to an insurance company, the researcher may not use the Certificate of Confidentiality to withhold this information. This means that you and your family should actively protect your own privacy. Finally, the researcher is not prevented from taking steps, including reporting to appropriate authorities, to prevent child abuse or serious harm to yourself or others.

Are there additional protections for my health information?

Protected Health Information (PHI) is health information that identifies you. PHI is protected by federal law under HIPAA (the Health Insurance Portability and Accountability Act). To take part in this research, you must give the research team permission to use and disclose (share) your PHI for the study as explained in this consent form. The research team will follow state and federal laws and may share your health information with the agencies and people listed under the previous section titled, "How will you keep my information confidential?"

Once your health information is shared with someone outside of the research team, it may no longer be protected by HIPAA.

The research team will only use and share your information as talked about in this form. When possible, the research team will make sure information cannot be linked to you (de-identified). Once information is de-identified, it may be used and shared for other purposes not discussed in this consent form. If you have questions or concerns about your privacy and the use of your PHI, please contact the University's Privacy Officer at [REDACTED].

Although you will not be allowed to see the study information, you may be given access to your health care records by contacting your health care provider.

If you decide not to sign this form, it will not affect

- your treatment or the care given by your health provider.
- your insurance payment or enrollment in any health plans.
- any benefits to which you are entitled.

However, it will not be possible for you to take part in the study.

If you sign this form:

- You authorize the use of your PHI for this research
- This authorization does not expire.
- You may later change your mind and not let the research team use or share your information (you may revoke your authorization).
 - To revoke your authorization, complete the withdrawal letter, found in the Participant section of the Human Research Protection Office website at <http://hrpo.wustl.edu> (or use the direct

link: <http://hrpohome.wustl.edu/participants/WithdrawalTemplate.rtf>) or you may request that the Investigator send you a copy of the letter.

- **If you revoke your authorization:**
 - The research team may only use and share information already collected for the study.
 - Your information may still be used and shared as necessary to maintain the integrity of the research, for example, to account for a participant’s withdrawal from the research study or for safety reasons.
 - You will not be allowed to continue to participate in the study.

Can we contact you by email?

We would like to contact you by email for the purposes listed below. Some of these emails may contain health information that identifies you.

- Appointment scheduling and confirming
- Questions you may have
- Lab results if you desire

Only the research team will have access to your e-mail communications. We will only communicate by email to send you the information listed above. If you have any questions or need to contact us for an urgent or emergent situation, please contact the research team member identified at the top of this document.

You should be aware that there are risks associated with sending your health information via e-mail.

- There is always a risk that the message could be intercepted or sent to the wrong e-mail address. To avoid sending messages to the wrong e-mail address, the first e-mail we send you will be a test message to ensure we have the correct e-mail address.
- When using any computer you should be careful to protect your username and password. Make sure you log-out before getting up from the computer.
- If you share a home computer with other family members, and do not want them to know you are participating in this study make sure you provide an e-mail address that only you can access.
- Your employer will have access to any e-mail communications sent or received on a work server.

Do you agree to allow us to send you protected health information via e-mail?

Yes **No**
 Initials **Initials**

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. Any data that was collected as part of your participation in the study will remain as part of the study records and cannot be removed.

If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

What if I decide to withdraw from the study?

You may withdraw by telling the study team you are no longer interested in participating in the study or you may send in a withdrawal letter. A sample withdrawal letter can be found at <http://hrpo.wustl.edu> under Information for Research Participants.

Will I receive new information about the study while participating?

If we obtain any new information during this study that might affect your willingness to continue participating in the study, we'll promptly provide you with that information.

Can someone else end my participation in this study?

- Under certain circumstances, the investigator might decide to end your participation in this research study earlier than planned. This might happen for no reason or because 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

- 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 IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: David Clifford, MD at Telephone: [REDACTED]. If you experience a research-related injury, please contact: David Clifford, MD at [REDACTED].

If you have questions, concerns, or complaints about your rights as a research participant, please contact the [REDACTED]

[REDACTED]. General information about being a research participant can be found by clicking “Participants” on the Human Research Protection Office web site, <http://hrpohome.wustl.edu>. To offer input about your experiences as a research subject or to speak to someone other than the research staff, call the Human Research Protection Office at the number above.

This consent form is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by agreeing to participate in this study. As a participant you have rights and responsibilities as described in this document and including:

- To be given enough time before signing below to weigh the risks and potential benefits and decide if you want to participate without any pressure from the research team or others.
- To understand all of the information included in the document, have your questions answered, and receive an explanation of anything you do not understand.
- To follow the procedures described in this document and the instructions of the research team to the best of your ability unless you choose to stop your participation in the research study.
- To give the research team accurate and complete information.
- To tell the research team promptly about any problems you have related to your participation, or if you are unable to continue and wish to stop participating in the research study.

Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a signed and dated copy of this form.

Do not sign this form if today’s date is after EXPIRATION DATE: 02/04/16.

(Signature of Participant)

(Date)

(Participant's name – printed)

Statement of Person Who Obtained Consent

The information in this document has been discussed with the participant or, where appropriate, with the participant's legally authorized representative. The participant has indicated that he or she understands the risks, benefits, and procedures involved with participation in this research study.

(Signature of Person who Obtained Consent)

(Date)

(Name of Person who Obtained Consent - printed)