SUBJECT INFORMATION AND INFORMED CONSENT FORM AND AUTHORIZATION TO DISCLOSE HEALTH INFORMATION— STUDY EXTENSION

Sponsor / Study Title:	**Merck Sharp & Dohme Corp., (a subsidiary of Merck & Co. Inc.) / "A Phase III Multicenter,Double-Blind,Randomized,Active Comparator-Controlled Clinical Trial to Evaluate the Safety and Efficacy of MK-1439A Once-Daily Versus ATRIPLA™ Once-Daily in Treatment-Naïve HIV-1 Infected Subjects."**
Protocol Number:	**MK-1439A-021**
Principal Investigator: (Study Doctor)	**Pablo Tebas, MD**
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Address:	**Perelman Center for Advanced Medicine** **3400 Civic Center Blvd** **Philadelphia, PA 19104**

You are being invited to take part in the extension phase of protocol MK-1439A PN021 because you have completed approximately 96 weeks of treatment in the base study. This consent document has information regarding the study extension to help you decide if you want to continue to participate. Take your time, read this document carefully, and ask the study doctor or staff any questions you may have. You should not sign this document until you understand all of the information presented in the following pages and until all of your questions about the research have been answered to your satisfaction.

The study doctor [or institution] will be paid by the Sponsor, Merck Sharp & Dohme Corp., for conducting this study.

About This Study

The purpose of this study extension is to:

- evaluate the long-term effectiveness and safety of MK-1439A given up to 200 weeks in subjects who initially took MK-1439A or for up to 96 weeks in those who initially took **ATRIPLA™.**

This is a research study to test a drug that may be approved for sale in only some countries at this time.

There may be reasons why you are not allowed to take part in this study extension. The study doctor or staff will discuss these reasons and review with you why you may not be allowed to enter the study extension.

About 640 people will be in the study extension. You may be in the study extension about 96 weeks (approximately 2 years).

If commercial MK-1439A is not available at the time of your Week 192 visit and you wish to remain on MK-1439A, you may continue to receive study drug for up to 32 weeks or until commercial MK-1439A is locally available (whichever occurs first), and you will be discontinued as soon as possible after commercial MK-1439A is available. If you wish to remain on MK-1439A at the time of your Week 192 visit, you will come in for 2 additional visits (Week 208 and Week 224) unless discontinued.

What will I be asked to do?

If you take part in the study extension, you will need to do the following:

- Visit the study doctor as directed during treatment.
- Fast before coming to the doctor's office at certain visits.
- Keep a card with you that will let any doctor you see know that you are in a study, so they can find out what the study is about.
- MK-1439A is to be taken once daily. You will take MK-1439A by mouth daily with or without food at approximately the same time each day. Both you and the study doctor will know which dose of study drug you are receiving.
- Store study drug as instructed.
- Write down when you take your study drug on the Study Medication Diary given to you. Bring the diary and all study drug containers with you to each study visit.
- You will be asked to return about 14 days after the last dose of treatment for a follow up safety visit.

If your blood tests show that you have liver lab results that are not normal, the study doctor or staff will ask you to provide additional samples of blood for testing to find out why your liver lab results are not normal. If you do decide to provide the samples, the study staff will discuss with you the amount of the additional samples of blood that will be taken and the tests that will be performed on the blood.

The tests that may be performed include viral hepatitis tests to find out if hepatitis is the reason your liver lab results are not normal. Depending on the region where you live, you may need to sign another consent form to have these tests done.

The results of all of your blood tests, just like all other laboratory test results, will be provided to the Sponsor. Viral hepatitis test results may be reportable to local health authorities according to local laws.

It is your decision whether to provide the additional samples and have these tests performed. However, if you decide not to provide the additional samples and have the tests done, you may need to leave the study for your own safety (as the cause of your abnormal liver lab results may not be able to be determined without them).

If you choose to take part in the study extension, you will be given MK-1439A regardless of which treatment you had been receiving in the base study. You will be asked to take by mouth once daily about the same time each day.

What will happen during the study visits?

When you come in for your study visits, the study doctor or staff may do any or all of the following to measure if the drug is working and/or to monitor your health.

- Dispense study drug and instructions.
- Review Study Medication Diary.
- Perform a physical exam to check your weight and vital signs (including blood pressure, heart rate, temperature).
- Check to see what medications you are taking or any that you have taken recently.
- Check to see if you have any illnesses or other problems since your last study visit.
- Check if you have or have had any side effects.
- Confirm that you (or your partner) are using appropriate acceptable methods of birth control.
- Collect blood and urine samples:
    - to test the amount of virus that is in the body.
    - study related testing.
    - HIV testing.

  Your personal information may be given out if required by law. If you test positive for HIV, Hepatitis B or Hepatitis C, by law we have to report the infection to the City of Philadelphia Health Department/PA Department of Health. We would report your name, gender, racial/ethnic background, and the month and year you were born. 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. Please note that it is likely that this information has been already reported to the PA Health Department as the HIV test being done for this study is not the first test for you.

What effects could the tests have on me?

You may feel discomfort during some of these tests or may experience some inconveniences. Some may also have risks, which may include:

- Blood samples: drawing blood from your arm may cause pain, bruising, lightheadedness, and rarely, infection.
- Fasting for 8 hours could cause dizziness, headache, stomach discomfort or fainting.

About The Study Drug(s)

MK-1439A

MK-1439A is being studied by the Sponsor to treat HIV-1 infection. MK-1439A is a single tablet made from 3 different drugs. The drugs that are in MK-1439A are MK-1439 (doravirine), lamivudine and tenofovir disoproxil fumarate. Lamivudine and tenofovir disoproxil fumarate have been approved to treat HIV-1 infection, MK-1439 (doravirine) has been approved in the US.

MK-1439A is also known as DELSTRIGO™ and is available by prescription only in the US to treat HIV-1 infection.

MK-1439

MK-1439 (doravirine) is being studied by Merck & Co., Inc. to see if it has any effect in treating HIV-1.

MK-1439 has been given as:

- Multiple doses up to 200 mg once daily in combination with other approved HIV medications (combination therapy) to about 214 male and 18 female HIV-1 infected patients who have never taken HIV drugs before. This study is now complete and the longest period a patient has taken MK-1439 in this study is about 96 weeks.
- A dose of 100 mg once daily in combination with other approved HIV medications for up to 96 weeks in 318 HIV-1 infected men and 64 HIV-1 infected women.

MK-1439 is also known as PIFELTRO™ in the US and is available by prescription only in the US to treat HIV-1 infection.

Lamivudine

Lamivudine is an approved drug available by prescription. It is used to treat HIV-1.

Tenofovir

Tenofovir disoproxil fumarate is an approved drug available by prescription. It is used to treat HIV-1 and hepatitis B virus (HBV) infection.

What side effects could the study drug(s) cause?

MK-1439A

Treatment-naïve subjects:

The safety experience with MK-1439A in subjects not previously treated for their HIV-1 infection is based on data from one study. In this study, MK-1439A has been given to about 305 male and 59 female subjects as a single dose of 100 mg doravirine/300 mg lamivudine/300 mg tenofovir disoproxil fumarate. The study doctor believes that the following side effects could have been caused by MK-1439A and occurred in 2% or more of subjects in this study:

- Abnormal dreams
- Diarrhea
- Difficulty falling asleep/staying asleep
- Dizziness
- Headache
- Nausea
- Nightmare
- Sleepiness
- Tiredness

The majority of the side effects listed above were reported as mild or moderate in intensity except one report each of headache, nightmare and insomnia and two reports of tiredness that were considered severe.

Virologically suppressed subjects:

The safety experience with MK-1439A in virologically suppressed participants is based on data from one study. In this study, MK-1439A has been given to about 554 male and 102 female subjects as a single dose of 100 mg doravirine/300 mg lamivudine/300 mg tenofovir disoproxil fumarate. The study doctor believes that the following side effects could have been caused by MK-1439A and occurred in 2% or more of subjects in this study.

- Changes in blood test that may show liver damage.

All of these side effects were reported as mild or moderate in intensity.

Treatment naïve subjects with drug resistance to a class of drugs used for HIV-1 treatment:

The safety experience with MK-1439A in subjects not previously treated for their HIV-1 infection and with drug resistance to a class of drugs used for HIV-1 treatment is based on data from one study. In this study, MK-1439A has been given to 8 male and 2 female subjects as a single dose of 100 mg doravirine/300 mg lamivudine/300 mg tenofovir disoproxil fumarate. The study doctor believes that the following side effects could have been caused by MK-1439A and occurred in 2% or more of subjects participating in this study:

- Abdominal discomfort
- Abdominal pain
- Back pain
- Diarrhea
- Difficulty falling asleep/staying asleep
- Distortion of taste
- Dizziness
- Dry mouth
- Nausea
- Tiredness
- Vomiting

All side effects listed above were reported as mild or moderate in intensity.

MK-1439

The study doctor believes that the following side effects could have been caused by MK-1439 and occurred in 2% or more of subjects when MK-1439 was given as:

- Doses ranging from 25 mg to 200 mg once daily in combination with other approved HIV medications for up to 96 continuous weeks in 214 HIV-1 infected men and 18 HIV-1 infected women.
- A dose of 100 mg once daily in combination with other approved HIV medications for up to 96 continuous weeks in 318 HIV-1 infected men and 64 HIV-1 infected women.

- Abnormal dreams
- Diarrhea/loose stools
- Difficulty falling asleep and/or staying asleep
- Dizziness
- Headache
- Nausea
- Sleep disorder
- Tiredness

Most of these side effects were mild or moderate in intensity and short lived except for one report each of difficulty falling asleep, nausea and tiredness that were considered severe.

Lamivudine

The following serious side effects have been reported in some patients that were given lamivudine:

- Inflammation of the pancreas
- Increased acid in the blood: symptoms may include feeling very weak or tired, unusual muscle pain, trouble breathing, stomach pain with nausea or vomiting, feeling cold (especially in your arms and legs), feeling dizzy or lightheaded, and having a fast or irregular heartbeat
- Worsening of hepatitis B (for patients that already have hepatitis B) if you stop taking Lamivudine
- Enlarged liver with changes in fat distribution in liver cells

- Changes in your immune system (Immune Reconstitution Syndrome) can happen when you start taking HIV medications. Your immune system may get stronger and begin to fight infections that have been hidden in your body for a long time
- Bone problems, which may include bone pain or softening or thinning of bones (which may lead to fractures)

The following common side effects have been seen in people who have taken Lamivudine:

- Cough
- Diarrhea
- Difficulty falling and/or staying asleep
- Fever
- General feeling of being unwell
- Hair Loss
- Headache
- Lack of energy
- Muscle and joint aches and pain
- Nasal symptoms including irritation, runny nose and congestion
- Nausea
- Rash
- Stomach pain / cramps
- Vomiting

The following less common side effects have been seen in people who have taken Lamivudine:

- Body produces insulin (a hormone that lowers the level of sugar in your blood) but does not use it effectively
- Breakdown of muscle cells that cause kidney problems
- Chills
- Decrease in the number of cells in the blood that fight infection
- Decrease in the number of cells involved in blood clotting
- Depression
- Dizziness
- Failure to produce or decrease in the number of cells in the blood that carry oxygen
- Hepatitis

- High blood sugar levels
- Increase in liver tests which may be a sign of liver problems
- Increase in the amount of fat in the blood
- Increased cholesterol
- Indigestion
- Inflammation of the pancreas, which could result in abdominal pain and discomfort and could require hospitalization and intravenous treatment
- Lack or decreased appetite
- Nerve changes that may result in numbness, pain or weakness. Tingling or numbness of the arms, legs, hands and feet.
- Serious, potentially life threatening allergic reaction
- Swollen skin

The following side effects have been seen in people who have taken Lamivudine but who were not in studies:

- Hives
- Itching
- Weakness

<u>Tenofovir</u>

The most common side effects seen in people who have taken tenofovir include:

- Rash
- Diarrhea
- Headache
- Itchy skin
- Stomach pain
- Depression
- Pain
- Vomiting
- Weakness
- Dizziness
- Nausea
- Difficulty falling and/or staying asleep
- Stomach Bloating
- Fever

Serious side effects that may be life threatening that have been seen in some patients taking tenofovir include:

- Liver problems: symptoms may include your skin or the white parts of your eyes turning yellow, dark urine, light colored stool, loss of appetite for several days or

longer, nausea and stomach pain.
- Increased acid in the blood: symptoms may include feeling very weak or tired, unusual muscle pain, trouble breathing, stomach pain with nausea or vomiting, feeling cold (especially in your arms and legs), feeling dizzy or lightheaded, and having a fast or irregular heartbeat.
- New or worsened kidney problems, including kidney failure.
- Bone problems, which may include bone pain or softening or thinning of bones (which may lead to fractures).
- Changes in your body's ability to fight infection.

Less common side effects seen in patients taking tenofovir include:

- Back or chest pain
- Joint pain
- Muscle aches
- Nerve changes that may result in numbness, pain or weakness
- Anxiety
- Upset stomach
- Changes in blood tests that may show liver damage
- Excess sugar in the urine
- Lack of energy
- Sinus infection
- Upper respiratory tract infection
- Common cold
- Pneumonia
- Increase in the amount of fat in the blood
- Decrease in the number of cells in the body that fight infection
- Excess blood in the urine
- Sweating
- Weight loss
- Changes in the location and amount of fat throughout the body
- Increased gas
- Loss of desire to eat
- Changes in blood tests that may show muscle damage
- Increase in blood sugar
- Swollen skin

The following additional side effects have been seen in people who have taken tenofovir but were not in studies:

- Low levels of potassium in the blood, which can cause muscle cramps or an irregular heart beat
- Allergic reaction (may include rash, hives, swelling, trouble breathing)
- Breakdown of muscle cells that cause kidney problems
- Low phosphate levels, which may cause muscle weakness or breakdown, bone pain and confusion
- Muscle weakness
- Abnormal kidney function causing a loss of fluids
- Inflammation of the pancreas, a gland in the abdomen that produces insulin and substances that help food be digested
- Shortness of breath
- Excess protein in the urine
- Changes in blood test that may show damage to the pancreas, a gland in the abdomen that produces insulin and substances that help food be digested
- Increased urination

Are there any other risks?

Other less common side effects have been reported with the use of the drugs in this study extension. The study doctor or staff can discuss these with you.

There may be other side effects or risks that are not known at this time.

Are there pregnancy risks?

It is not known if the study drug(s) may affect an unborn or nursing baby. If you are pregnant, trying to become pregnant or breast-feeding, you cannot be in the study extension. The study doctor will perform a urine pregnancy test at each visit of the study extension, if you are able to have a baby.

If you are able to have a baby, and not willing to remain truly abstinent (no sexual intercourse) you must use reliable birth control for 12 weeks after completion of the base study and for 14 days after the last dose of MK-1439A in the study extension. You must also agree to not donate eggs for 12 weeks after completion of the base study and for 14 days after the last dose of MK-1439A in the study extension.

The following birth control methods are allowed during the study extension:

Single method (one of the following is acceptable):
- intrauterine device (IUD).
- vasectomy of a female subject's male partner.

Combination method (requires use of two of the following):
- diaphragm with spermicide (cannot be used with cervical cap/spermicide).
- cervical cap with spermicide (only for females that have not birthed a child).
- contraceptive sponge (only for females that have not birthed a child).
- male condom or female condom (cannot be used together).
- hormonal contraceptive: oral contraceptive pill (estrogen/progestin pill or progestin-only pill), contraceptive skin patch, vaginal contraceptive ring, contraceptive rod implanted into the skin or subcutaneous contraceptive injection.

Use of barrier methods of contraception is strongly encouraged to reduce the risk of HIV-1 transmission during sexual contact.

If you become pregnant during the study extension you must notify the study doctor right away. The study drug will be stopped and your pregnancy will be followed to completion.

There may be risks if you are male and your partner is pregnant or trying to become pregnant. If you are male and your partner is able to have a baby, you and your partner must use reliable birth control for 12 weeks after completion of the base study and for 14 days after the last dose of MK-1439A in the study extension.

The following birth control methods are allowed during the study extension:

Single method (one of the following is acceptable):
- intrauterine device (IUD).
- vasectomy.

Combination method (requires use of two of the following):
- diaphragm with spermicide (cannot be used with cervical cap/spermicide).
- cervical cap with spermicide (only for females that have not birthed a child)
- contraceptive sponge (only for females that have not birthed a child).
- male condom or female condom (cannot be used together).

- hormonal contraceptive: oral contraceptive pill (estrogen/progestin pill or progestin-only pill), contraceptive skin patch, vaginal contraceptive ring, or subcutaneous contraceptive injection, contraceptive rod implanted into the skin.

Use of barrier methods of contraception is strongly encouraged to reduce the risk of HIV-1 transmission during sexual contact.

If your partner becomes pregnant during the study extension you must notify the study doctor right away. You must also agree to not donate sperm for 12 weeks after completion of the base study and for 14 days after the last dose of MK-1439A in the study extension.

Additional Information You Need to Know

You will be told in a timely manner about significant new information that might affect your decision to stay in the study extension.

If I am injured from the study drug, who will pay the doctor and hospital bills?

If you are injured as a direct result of the study drug or a procedure required by the study plan, the study sponsor will pay the reasonable (customary treatment) costs of medical treatment.

The sponsor will determine if the injury is caused by the study drug and the reasonableness of the expenses taking into consideration the study doctor's evaluation, other physicians' evaluations of the subject, sponsor's experience with the study drug and other relevant factors.

The study sponsor or the University of Pennsylvania has no plans to provide any other form of compensation. You will not lose any of your legal rights or release the Sponsor, the study doctor, the study staff, or study site from liability for mistakes or intentional misconduct by signing this consent document.

If you are injured during this study, your study doctor will discuss with you the available medical treatment options.

What benefits could there be from taking part in the study?

If the drug works, you may have some benefit. If the drug does not work, you may not benefit. Information learned from the study may help other people in the future. The Sponsor does not intend to provide you with ownership or financial benefits that may result from this study.

Will I receive a fixed payment per visit to cover any out of pocket expenses?

You will receive a payment of $50 dollars per visit to help cover the cost of travel and expenses (which may include such things as parking, baby-sitting, time off from work, meals, etc.). If all study required visits are completed, the total compensation for the study would be $350. As part of this study you will be given the option to receive a ClinCard (similar to a debit card). If you choose to receive the ClinCard, you will be given a separate consent to describe this program.

Please note that if you receive more than $600.00 compensation in one calendar year for participation in research studies at the University of Pennsylvania, you must provide an Individual Tax Identification Number or Social Security Number for tax purposes.

As part of this study you will be provided with a Study Supply Carry All Bag. You may retain the items regardless if you complete the entire study.

Will there be any charge for me to be in this study?

Some of the tests or treatments used in this study may be part of standard care used to maintain your health even if you did not take part in this study. You or your insurance company may be responsible for the cost of this standard care. All trial medication and trial-related tests will be provided at no cost to you.

What are my options if I am not in the study?

If you should decide not to participate in, or if you withdraw from this study extension, the study doctor can recommend other treatments.

Alternative treatments for HIV infection include combinations of several medications given either as separate pills or in combination tablets. Typical treatments include 2 drugs from the nucleoside/nucleotide reverse transcriptase inhibitors (NRTI) class and a drug from the non-nucleoside reverse transcriptase inhibitor (NNRTI), the protease inhibitor (PI) or the integrase inhibitor (InSTI) class. Your doctor will prescribe the best option according to the medications that are available in your country, taking into account your personal condition and the treatment recommendations in your country.

If you have questions about alternate treatments and their potential benefits and risks, ask the study doctor for additional information. You do not need to participate in this study extension to be treated for your HIV infection.

Who will be able to see my records and know that I am in the study?

Information from this study will be given to the sponsor. It will also be given to the U.S. Food and Drug Administration (FDA). Unless otherwise required by law, medical records which identify you and the consent document signed by you may be looked at and/or copied for research or regulatory purposes by:

- the study doctor and staff;
- the study sponsor;
- those working for or with the sponsor;
- the institutional review board; and
- government agencies in other countries where the study drug may be considered for approval

Because of the need to release information, complete confidentiality cannot be promised. The study results may be published in medical journals or presented at medical meetings, but your identity will not be revealed.

A more detailed explanation of how health information about you will be used and shared is included in a separate document called an Authorization**.** If you decide not to sign the Authorization you will not be permitted to participate in the study.

The authorization part of the consent gives more detailed information about how your personal health information may be used and disclosed by the University of Pennsylvania Health System (UPHS), the School of Medicine and the individual Principal Investigator, subject to University of Pennsylvania procedures.

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

The following personal health information will be collected, used for research, and may be disclosed during your involvement with this research study:

- Name, address, telephone number, date of birth
- Social Security Number (if you receive more than $600 for participating in studies at PENN, we will need your SSN for the W-9)
- Personal and family medical history
- Current and past medications or therapies
- Results of physical exams, laboratory tests and procedures you will undergo during this research study

Why is your personal contact and health information being used?

Your personal contact information is important for the research team to contact you during the study. Your personal health information and results of tests and procedures are being collected as part of this research study. In some situations, your personal health information might be used to help guide your medical treatment.

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

The following individuals may use or disclose your personal health information for this research study:

The Principal Investigator and the Investigator's study team

Authorized members of the workforce of the UPHS and the School of Medicine, and University of Pennsylvania support offices, who may need to access your information in the performance of their duties (for example: for research oversight and monitoring, to provide treatment, to manage accounting or billing matters, etc.).

Who, outside of UPHS and the School of Medicine, might receive your personal health information?

As part of the study, the Principal Investigator, the study team and others listed above, may disclose your personal health information, including the results of the research study tests and procedures. This information may be disclosed to those listed below:

Individuals or organizations responsible for administering the study:

- Pharmaceutical sponsor (Merck Sharp & Dohme Corp): This is the company that supplies drugs for the study. Information regarding safety and adverse effects needs to be collected and monitored.

- Contract Research Organization: Monitors will visit the site on a regular basis to review data and assure accuracy and completeness of information before the data are analyzed.

Regulatory and safety oversight organizations

The Food and Drug Administration and regulatory agencies in other countries

The Office of Human Research Protections

The Study Monitoring Committee

Schulman Institutional Review Board

Once your personal health information is disclosed to others outside of UPHS or the School of Medicine, it may no longer be covered by federal privacy protection regulations. Data are reported to the sponsor on Case Report Forms that identify you by your unique study number and not your name or medical record number. Information regarding your health, such as side effects of the study medications you experience will be reported only by code number. All samples collected for analysis will be labeled with your study number, visit number and date of your visit.

The Principal Investigator or study staff will inform you if there are any additions to the list above during your active participation in the trial. Any additions will be subject to University of Pennsylvania procedures developed to protect your privacy.

How long may UPHS and the School of Medicine be able to use or disclose your personal health information?

Your authorization for use of your personal health information for this specific study does not expire.

Your information may be held in a research repository (database). However, UPHS and 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 to do so
- The University of Pennsylvania's Institutional Review Board grants permission after ensuring that appropriate privacy safeguards are in place
- As permitted by law

Will you be able to access your records?

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.

Can you change your mind?

Yes, at any time you may withdraw your approval to allow the use and disclosure of your personal health information as described here. You must do so in writing to the Principal Investigator at the address on the first page. 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 to use your personal health information, you will also be withdrawn from the research study.

If you withdraw your permission to use any blood or tissue obtained for the study, the Sponsor may need to retain and use any samples that have already been collected to comply with its legal obligations and to maintain the scientific integrity of the 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.

If you have never received care within UPHS and are participating in a University of Pennsylvania research study that uses UPHS services, an EMR will be created for you for the purpose of maintaining any results of procedures performed as part of this research study. The creation of this EMR is required for your participation in this study. In order to create your EMR, the study team will need to obtain basic information about you that would be similar to the information you would provide the first time you visit a hospital or medical facility (i.e. your name, the name of your primary doctor, the type of insurance you have). Results of research procedures performed as part of your participation in the study (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in this EMR.

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 I choose to withdraw from the study?

Your decision to participate in this study extension is voluntary. You can choose at any time to withdraw from the study extension by telling the study doctor without any penalty or loss of benefits to which you are entitled. If you choose to stop taking the study drug, please tell the study doctor/staff so this can be done safely. If at some point you consider withdrawing from the study extension, you can decide if you are willing to continue to provide information or not. This would be helpful for the purposes of the study. To help you decide, the study doctor/staff can tell you which study procedures and information collection would still apply if you stop taking the study drug but choose to remain in the study extension.

Will information about this trial be included in a Registry Databank?

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.

Whom to contact about this study

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study, please contact the Investigator at the telephone number listed on the first page of this consent document. If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, contact:

- By mail:
  Study Subject Adviser
  Advarra IRB
  6940 Columbia Gateway Drive, Suite 110
  Columbia, MD 21046
- or call toll free: 877-992-4724
- or by email: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00025957.

All other elements of the original consent document still apply.

By signing below, I agree that:

- I have read this consent document.
- I have had the chance to ask questions and they have been answered.
- I understand that taking part in this study is voluntary.
- I give permission to use and share my health data as described in this document.
- I may choose not to be in the study or to leave the study at any time by telling the study doctor. I will not be penalized or lose any benefits to which I am otherwise entitled.
- I may have to leave the study without my consent if I need other treatment, do not follow the study plan, have a study-related injury, or for any other reason.
- If I leave the study for any reason, the study doctor may ask me to have some end-of-study tests.

I will receive a signed and dated copy of this consent document.

_____	_____	_____
Printed Name of Subject	Signature of Subject	Date (MM/DD/YYYY)
_____	_____	_____
Printed Name of Person Conducting Consent Discussion	Signature of Person Conducting Consent Discussion	Date (MM/DD/YYYY)

CONSENT FOR SUBJECTS WHO CANNOT READ

The study subject has indicated that he/she is unable to read. The consent document has been read to the subject by a member of the study staff, discussed with the subject by a member of the study staff, and the subject has been given an opportunity to ask questions of the study staff.

_____
Printed Name of Impartial Witness

_____ _____
Signature of Impartial Witness* Date

*Impartial Witness: A person, who is independent of the trial, who cannot be unfairly influenced by people involved with the trial, who attends the informed consent process if the subject or the subject's legally acceptable representative cannot read, and who reads the informed consent and any other written information supplied to the subject. **Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance**