SUBJECT INFORMATION AND INFORMED CONSENT FORM
AND
AUTHORIZATION TO DISCLOSE HEALTH INFORMATION

Sponsor / Study Title:	**Merck Sharp & Dohme Corp., (a subsidiary of Merck & Co. Inc.) / "A Phase III Multicenter, Open-Label, Randomized Study to Evaluate a Switch to MK-1439A in HIV-1-Infected Subjects Virologically Suppressed on a Regimen of a Ritonavir-boosted Protease Inhibitor and Two Nucleoside Reverse Transcriptase Inhibitors (NRTIs)"**
Protocol Number:	**1439A-024-07 – Second Extension**
Principal Investigator: (Study Doctor)	**Pablo Tebas, MD**
Telephone:	**(215) 662-6059 - Immunodeficiency Program Doctor on call - 24-hour number** **(215) 349-8092 - office number**
Address:	**Perelman Center for Advanced Medicine** **3400 Civic Center Blvd** **Philadelphia, PA, 19104**

You are invited to take part in a second extension phase of this research study.

It is your choice if you want to be in this study. This form will help you decide.

If you agree to join, you can quit the study at any time.

If you agree to join, you also agree to let the sponsor of the study use and share your health data.

If you do not agree to join, your medical care will not change in any way.

Please take as much time as you need to make your choice and ask the study doctor or staff any questions.

Please sign this form after you understand all of the information

The study doctor [or institution] will be paid by the Sponsor, Merck Sharp & Dohme Corp., (a subsidiary of Merck & Co. Inc.) for conducting this study.

What is the purpose of this study?

The purpose of this second study extension is to provide continued access to MK-1439A if you have been benefiting from this treatment until MK-1439A is available locally in your country, or

for up to 96 weeks in this second study extension (whichever comes first) and to collect key safety information from participants who continue to take MK-1439A.

This is a study to test a drug that has not yet been approved for sale/may not be available.

What drug will I receive?

Everyone will receive MK1439A.

Who can join?

You may be able to join this study if you have participated and completed the base and extension 1 studies and your doctor has determined that you have been benefiting from this treatment.

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

About 660 people will be in the study.

How long will I be in the study?

You will be in the second study extension until MK-1439A becomes locally available or for up to 96 weeks in this second study extension (whichever comes first).

What happens at study visits?

The study doctor or staff may do any or all of the following:

- Visit the study doctor as directed.
- Take study drugs as instructed. MK-1439A is to be taken once daily without regard to food at approximately the same time each day.
- Check if you have or have had any serious side effects.
- Confirm if you (or your partner) are using appropriate acceptable methods of birth control.
- Collect urine and blood samples, if needed

What do I do on my own?

- Take study drug(s) as instructed.

- 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.

How could study tests make me feel?

There are no study tests unless your study doctor feels necessary for your safety. You may feel discomfort during some of these tests or you may experience some inconveniences. Some tests may also have risks, which may include:

- Blood samples: drawing blood from your arm may cause pain, bruising, lightheadedness, and rarely, infection.

What do I need to know about the study drug and side effects?

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 participants:

The safety experience with MK-1439A in participants 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 participants 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 participants in this study:

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

The majority of 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 participants:

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 participants 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 participants 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 participants with drug resistance to a class of drugs used for HIV-1 treatment:

The safety experience with MK-1439A in participants 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 participants 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
    - Dizziness
    - Difficulty falling and/or staying asleep
    - 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 medicines. 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, running 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 of 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

Tenofovir

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

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

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
- Lack of energy
- Sinus infection
- Upper respiratory tract infection
- Sweating
- Weight loss
- Changes in the location and amount of fat throughout the body

- Nerve changes that may result in numbness, pain or weakness
- Common cold
- Increased gas
- Anxiety
- Pneumonia
- Loss of desire to eat
- Upset stomach
- Increase in the amount of fat in the blood
- Changes in blood tests that may show muscle damage
- Changes in blood tests that may show liver damage
- Decrease in the number of cells in the body that fight infection
- Increase in blood sugar
- Excess sugar in the urine
- Excess blood in the urine
- 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?

There are other side effects that have been reported. 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 may not be in the study extension.

If you are able to have a baby and not willing to remain truly abstinent, you must use a reliable birth control method during the study extension and for a period of 14 days after your last dose of study drug. 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
  - contraceptive rod implanted into the skin

- Combination method (requires use of two of the following):
  - diaphragm with spermicide (cannot be used in conjunction 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

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 monitored.

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 and not willing to remain truly abstinent, you and your partner must use a reliable birth control method during the study extension and for a period of 14 days after your last dose of study drug. The following birth control methods are allowed during the study extension:

- Single method (one of the following is acceptable):
  - intrauterine device (IUD)
  - vasectomy
  - contraceptive rod implanted into the skin

- Combination method (requires use of two of the following):
  - diaphragm with spermicide (cannot be used in conjunction 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

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, you must notify the study doctor right away. You must also agree to not donate sperm starting at visit 1 through completion of the study extension.

Will I benefit from being in the study?

If the drug works, you may receive a health benefit. If the drug does not work, you may not receive a health benefit. Information learned from the study may help other people in the future.

What if new information comes out after I join the study?

You will be told in a timely manner about important new information that might affect your participation in the study.

What happens if I am injured in the study?

If you are injured as a direct result of the study drug or a properly performed study procedure the Sponsor will pay the reasonable costs of medical treatment for the injury. The Sponsor will not provide any other form of compensation. You are not being asked to release or waive any of your legal rights against the institution, the investigator or the Sponsor for liability for negligence.

Will I be paid?

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 $450. 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 I have to pay?

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. All study medication and study-related tests will be provided at no cost.

What are my other choices if I do not want to join?

If you decide not to join the study, or if you withdraw from this study, 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 other treatments and their potential benefits and risks, ask the study doctor for additional information. You do not need to join this study to be treated for your HIV infection.

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) and those working for or with the sponsor, which may include affiliates of the sponsor located in your country or other countries. An affiliate of the sponsor includes all companies directly or indirectly owned by Merck & Co., Inc. The sponsor is the company that supplies drugs for the study. Information regarding safety and adverse effects needs to be collected and monitored. The sponsor and those working for or with the sponsor, which may include affiliates of the sponsor, may use the health data sent to them to see if the study drug works and is safe; to compare the study drug to other drugs; to develop new tests; for other activities (such as development and regulatory) related to the study drug. For these uses, sponsor may share this health data with others involved in these activities as long as they agree to only use the health data as described here. The sponsor and those working for or with the sponsor, which may include affiliates of the sponsor may transfer health data about you from your country to other countries where privacy laws are not as strict.

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 oversite organizations

The Food and Drug Administration and regulatory and government agencies in other countries

The Office of Human Research Protections

The Study Monitoring Committee

Ethics committees that oversee the research

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 happens if I want to leave the study or stop taking study drug?

You should tell the study doctor if you are thinking about leaving. The study doctor can help you with your decision. If you decide to leave, you will not be penalized or lose any benefits that you had before starting the study.

If you decide to stop taking the study drug, please tell the study doctor or staff so this can be done safely. You can still stay in the study, even if you stop taking the study drug, by providing information or taking part in study procedures. The study doctor can discuss this with you.

Can I be taken out of the study?

There may be various reasons why you are taken out of the study. For example, you may need other treatment, you may have health issues that require you to leave the study, you are not able to follow study instructions, or the study may be stopped. Also, there may be a change in the study that could end your participation. The reason will be explained to you by the study doctor.

Will my privacy be protected?

The study doctor and research team will use health data about you (for example, name, address, medical history) to conduct this study, as described in this consent form. This health data may come from your family doctor or other health care workers.

By being in the study, this will allow study team to share health data about you with the following:

- government agencies throughout the world,
- ethics committees that oversee the research,
- the study Sponsor (wherever Sponsor is mentioned, this means those working for or with the Sponsor, which may include affiliates of the Sponsor located in your country or other countries).

It is the intent of the study doctor, study staff, and Sponsor that the health data (as described above) that is sent to the Sponsor will not identify you. Instead, it may include your initials, date of birth, and study visit dates.

You will not be identified by name in any published reports about this study or in any other scientific publication or presentation. If you think that you were harmed from being in the study, the study team may also share health data about you with the Sponsor's insurer to resolve your claim.

The Sponsor may use the health data sent to them:

- to see if the study drug works and is safe;
- to compare the study drug to other drugs;
- to develop new tests;
- for other activities (such as development and regulatory) related to the study drug;
- to allow outside researchers to use clinical data that does not identify you.

For these uses, the Sponsor may share this health data with others involved in these activities, as long as they agree to only use the health data as described here. The Sponsor may transfer health data about you from your country to other countries where the privacy laws may not as strict. Once the research team shares health data about you with others, it may no longer be protected by privacy laws.

There is a risk that if people other than the Sponsor may get your health data and genetic information they could misuse it for purposes other than those outlined in this consent. The Sponsor has strict privacy and confidentiality protection procedures in place to prevent this from occurring so the chance of this happening to you is extremely small.

Your permission to use and share health data about you will not end.

You may take away your permission to use and share health data about you at any time by contacting the study doctor. If you do this, you will not be able to stay in this study. No new health data that identifies you will be gathered after that date. However, health data about you that has already been gathered may still be used and given to others as described in this form.

You may not be able to review some of your records related to the study until after the study has been completed. When the study is over, you may contact the study doctor to see your health data from the study and to correct any errors. Results obtained from planned genetic and biomarker research will not be provided back to you or the study doctor.

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: Pro00025959.

By signing below, I agree that:

- I have read and understand this informed 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 voluntarily consent to take part in this research study.
- 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 do not give up any of my legal rights by signing this consent document.

I will receive a copy of this signed and dated 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