UNIVERSITY OF PENNSYLVANIA HEALTH SYSTEM

Gilead Sciences, Inc
GS-US-236-0102, Amendment 2, 19-JAN-2012

A Phase 3, Randomized, Double-Blind Study to Evaluate the Safety and Efficacy of Elvitegravir/Emtricitabine/Tenofovir Disoproxil Fumarate/GS-9350 Versus Efavirenz/Emtricitabine/ Tenofovir Disoproxil Fumarate in HIV-1 Infected, Antiretroviral Treatment-Naïve Adults

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

Your contacts for this study at the Hospital of the University of Pennsylvania [HUP] are:

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24 Hour Emergency Number (215) 662-6059 Ask for the Immunodeficiency Program Doctor on call

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NEW INFORMATION

In the Informed Consent Form you signed when you agreed to take part in this research study, you were told that you would be informed if there was new or updated information related to the study. We are providing information about a change in the frequency of the side effects of EVG/COBI/FTC/TDF (Stribild™).

The frequency of suicidal ideation and suicide attempt in patients with a pre-existing history of depression or psychiatric illness has been changed from uncommon (occurred in more than or equal to 0.1% and less than 1% of patients) to common (occurring more than or equal to 1% and less than 10% of patients)

INTRODUCTION

The Informed Consent Form that you signed at the beginning of this study stated that the study involved an experimental combination medication: one pill containing two experimental medications [elvitegravir (EVG) and GS-9350 (cobicistat)] and two medications that are approved by the United States Food and Drug Administration (FDA) for the treatment of HIV-1 infection or EVG/FTC/TDF/GS-9350. On August 27, 2012 the United States Food and Drug Administration (FDA) approved the elvitegravir (EVG)/emtricitabine (FTC)/tenofovir disoproxil fumarate (TDF)/GS-9350 single tablet regimen (STR) under the brand name of Stribild™ for use in the United States by patients with HIV-1 who have never taken HIV therapies, and are starting HIV therapy for the first time. As a result of the recent FDA approval, there are no longer any experimental medications used in this study.

This consent form may contain words you do not understand. Please ask the study doctor or study staff to explain any words or information you do not clearly understand before agreeing to volunteer for this clinical research study.

YOUR RIGHTS

GS 0102: EVG/FTC/TDF/GS-9350 Versus EFV/FTC/TDF in Naïve HIV+ Subjects

This consent form tells you about the study. Your study doctor or study staff will go over this with you and answer any questions you may have regarding this study. If you agree to volunteer, you will be asked to sign and date this consent form. You will be given a copy of the signed and dated consent form to keep.

No one can force you to take part in this study. Even if you agree to participate now, you are free to change your mind. You may stop at any time without penalty or loss of benefits which you would otherwise have.

Before you agree to volunteer, you will need to know the purpose of the study, the potential risks and benefits to you, and what is expected of you during the study.

PURPOSE OF THE STUDY

The purpose of this study is to see if EVG/FTC/TDF/GS-9350 is safe and effective in reducing levels of HIV-1 in the blood of subjects who are treatment-naïve (those who have not received any antiretroviral medication). You have been asked to participate in this study because you have HIV and you are treatment-naïve. If you have previously (ever) taken, or are currently taking any antiretroviral medication (medications that fight retroviruses like HIV or hepatitis), you will not be allowed in the study.

The safety and effectiveness of EVG/FTC/TDF/GS-9350 will be compared with that of Atripla® (control arm). Atripla® is a combination medication containing efavirenz (also known as Sustiva®), FTC and TDF. Atripla® has been approved by the FDA for the treatment of HIV and is being used in this study because it is currently the only preferred regimen that is one tablet. The approved dose of Atripla® is being used in this study.

The safety and how well these drug combinations are tolerated will be determined based on physical exams, laboratory tests and questions about any problems you might experience during the study. As part of this study, levels of HIV-1 in the blood and drug levels of GS-9350 and EVG (and possibly FTC and TDF) will be measured at various times during the study.

DESIGN OF THE STUDY

If you agree to participate, you will be one of 700 subjects recruited from about 130 study sites in the United States and Puerto Rico.

This is a double-blind study, which means that neither you nor your study doctor will know whether you are receiving EVG/FTC/TDF/GS-9350 or Atripla. This is a randomized (by chance, like a flip of a coin) study and you will be selected to receive one of the two treatments listed below:

Treatment Arm 1: EVG/FTC/TDF/GS-9350 active + Atripla placebo

Treatment Arm 2: Atripla active + EVG/FTC/TDF/GS-9350 placebo

The randomization for this study is in a 1:1 ratio, which means that your chance of being assigned to Treatment Arm 1 or to Treatment Arm 2 is equal. Your treatment arm assignment will not be known to you or your study doctor.

You will receive study drug bottles from your doctor during study visits. You will need to take two tablets of study drugs per day. Of these two tablets, one of the tablets will be active EVG/FTC/TDF/GS-9350 or active Atripla, and one of the tablets will be a placebo (EVG/FTC/TDF/GS-9350 placebo or Atripla placebo). "Active" means that the tablet works to stop HIV from replicating. "Placebo" means the tablet contains material that does not stop HIV from replicating but looks like the active study drug. EVG/FTC/TDF/GS-9350 or placebo should be taken once a day at the same time every day with food. Atripla or placebo should be taken once every day on an empty stomach and preferably at bedtime.

Once you are confirmed to be eligible to participate in the study, and you state that you want to take part in the study, you will be assigned a subject number.

All of your study drugs will be supplied by Gilead Sciences, Inc., the Sponsor of this study. Your study drugs must be stored at room temperature. Your study doctor or study nurse will review the proper storage of all study drugs used in this study with you. It is very important that you take your study drugs every day as instructed by the study doctor.

DURATION OF THE STUDY

The screening period (the time between the Screening visit and Baseline visit) may last up to 35 days. The screening period may be extended to up to 42 days after the Screening Visit if a certain screening test called a genotype needs to be repeated. You will be treated with the study drug(s) for a minimum of 192 weeks (44 months). During this time, you will be required to visit the clinic at least 23 times. Following your 192 weeks on-study, you will continue to take your study drugs and attend visits every 12 weeks thereafter until the study is unblinded ("unblinded" means that you and your study doctor will be told which treatment arm you received). Subjects who complete the required on-study treatment and who qualify will be offered the opportunity to receive EVG/FTC/TDF/GS-9350 as part of a separate, open-label roll-over study. "Open-label" means you and your doctor will know what study drugs you will be taking.

Subjects who choose to participate in the open-label rollover study will receive EVG/FTC/TDF/GS-9350 until it becomes commercially available or until Gilead Sciences chooses to stop the development of the EVG/FTC/TDF/GS-9350 single-tablet regimen (STR).

STUDY PROCEDURES

During this study you will have laboratory evaluations performed, including chemistries to look at your liver and kidney functions, hematology to monitor for anemia, CD4 cell counts, HIV viral loads to see if the virus is detected in your blood, resistance tests to see if the drugs you are taking are still effective against the virus, pregnancy tests, tests to see if you are infected with Hepatitis and urinalyses. All of these tests would be conducted routinely to manage HIV treatment and care regardless of if you are in a study. The only difference is that when you are in this study, some of these tests are performed more frequently. The only tests that are done specifically for this research study are 1) blood samples to measure the amount of study drug in your blood and 2) electrocardiograms to monitor any changes in your heart rhythm.

Screening

To help the study doctor determine your eligibility and safety to participate in this study, you need to be seen at the study center within 35 days before the study starts. After you sign the informed consent form and receive a copy of the informed consent form, you will have several screening

procedures done. Note that all of the procedures listed below may not be performed if at any point during the evaluation you fail eligibility. These procedures will include:

- An interview about your medical history, including any illnesses or health problems, your history of HIV-1 disease-related events, and prior medications within 30 days. If you have previously (ever) taken, or are currently taking any HIV medications, you will not be allowed in the study.
- A complete physical examination, weight, and height.
- A urine sample for laboratory tests.
- If you are a female able to become pregnant, a blood pregnancy test will be required. If the blood test is positive, you will not be eligible to participate in the study.
- If you are a female and are post-menopausal, a blood test will be required to confirm your post-menopausal status.
- About 21 mL (about 4 teaspoons) (5 mL = 1 teaspoon) of blood will be taken for general health screening tests and tests related to your HIV, such as chemistry, complete blood count, CD4+ (white blood cell that fights infection) cell count, tests for hepatitis B virus, hepatitis C virus, and to measure the amount of HIV-1 in your blood.
- About 6 mL (about 1 teaspoon) of blood will be drawn for an HIV-1 genotype test. Genotype testing is a technique that finds changes or "mutations" in certain regions of the HIV-1 gene. Some mutations can prevent certain anti-HIV drugs or drug regimens from reducing the level of HIV-1 in your blood. When this occurs, the HIV-1 has become "resistant" to that drug and possibly other similar drugs. Therefore this test is being done to see if the HIV that infects you is resistant to one of the medications used in the study. This can happen because resistant virus can be transmitted from one person to another. In other words you may have become infected with resistant virus. Your screening time may be extended from 42 days if your study doctor requires you to repeat the genotype test.
- A 12-lead ECG (electrocardiogram) to check the functioning of your heart.

The study doctor will review all of your medical information and findings from your Screening visit (including medical history, medications, clinical laboratory results, physical exam, etc.) and other entry criteria, as required by the study protocol, to determine if you are eligible to participate in this study.

If some tests were done to see if you were eligible for the GS-US-216-0114 study, and you were not randomized into that study, some of these screening test results can be used for this study (GS-US-236-0102) and will not need to be re-done. By signing this consent form, you agree to allow the sponsor to use screening information from the GS-US-216-0114 study for this study. If you have not had any screening tests done for the GS-US-216-0114 study, all of the screening assessments listed above for this study (GS-US-236-0102) will need to be completed to see if you are able to participate in this study.

Restrictions During the Study

You will be told not to eat or drink anything except water for at least 8 hours before your blood is drawn at the Baseline Visit, at the Weeks 24, 48, 72, 96, 120, 144, 168 and 192 visits, at some visits that you attend after the Week 192 visit, and at the Unblinding Visit.

You cannot take any antacids that contain calcium, magnesium, or aluminum (for example, Tums® or Rolaids®), Carafate® (an ulcer medicine), or vitamins/mineral supplements that contain calcium, iron or zinc for a minimum of 2 hours before and 2 hours after any dose of EVG/FTC/TDF/GS-9350 or

placebo. You must check with the study doctor before taking any medication or health supplements for the length of the study.

Baseline/Day 1

You will be asked to come back to the study center within 35 days after the Screening visit for the "Baseline" (Day 1) visit. The following procedures will occur during this visit:

- You will be asked whether there has been any change in your health (illness or health problems) and whether you have taken any new medications since your last visit.
- A complete physical examination and weight.
- A urine sample for laboratory tests. Some of this urine will be stored to conduct possible clinical testing in the future.
- If you are a female able to become pregnant, a urine pregnancy test will be required. If the urine pregnancy test is positive, you will not be dispensed drug at this visit. You will have a blood pregnancy test to confirm the result of the urine pregnancy test. If the blood test is positive, you will not be allowed to participate in this study.
- About 21 mL (about 4 teaspoons) of blood will be taken for testing of chemistry, complete blood count, CD4+ cell count and to determine HIV-1 levels in your blood.
- Tests on blood being drawn at this visit will be used to measure changes in the amount of sugar and fats in your blood. About 4 mL (about 1 teaspoon) of blood will be taken for this test. It is important that your blood is drawn for this sample in the morning prior to eating (in a fasting state). If you have not fasted, you will be asked to return to the study center within 72 hours in a fasted state. "Fasting" means that you will not eat or drink anything except water for at least 8 hours before your blood is drawn.
- About 14 mL (about 3 teaspoons) of blood will be collected and stored to allow the possibility of conducting clinical tests at a later date (for example, to check whether the HIV in your blood can develop resistance to this anti-HIV drug).
- You will be counseled regarding the importance of taking all study medications.
- You will receive a 4-week supply of study drug at this visit.

Week 2 to Week 192 and every 12 weeks following Week 192 through the Unblinding Visit

You will be asked to return to the clinic for study visits at Weeks 2, 4, 8, 12, 16, 24, 32, 40, 48, 60, 72, 84, 96, 108, 120, 132, 144, 156, 168, 180 and 192. After the Week 192 visit you will be asked to continue coming in for study visits every 12 weeks until the study is unblinded. **The study will be unblinded once the last subject in the study completes the Week 192 visit and the Sponsor has reviewed the study data**. Once the study is unblinded, you will be asked to return to the clinic for an Unblinding Visit.

The following procedures will occur during these visits:

- You will be asked whether there has been any change in your health (illness or health problems) and whether you have taken any new medications since your last visit.
- A physical examination and weight (a complete physical examination will be performed at Weeks 24, 48, 72, 96, 120, 144, 168, 192 and at the Unblinding Visit; a symptom-directed physical examination may be performed at all other visits as needed).
- A urine sample for laboratory tests. Some of this urine will be stored at all visits to conduct possible clinical testing in the future.

- If you are a female able to become pregnant, a urine pregnancy test will be required. If the urine pregnancy test is positive, you will have a blood pregnancy test to confirm the result. If the blood test is positive, your study drug treatment will be discontinued.
- About 18 mL (about 4 teaspoons) of blood will be taken for testing of chemistry, complete blood count, CD4+ cell count, and to determine HIV-1 levels in your blood.
- Tests on blood being drawn at Weeks 24, 48, 72, 96, 120, 144, 168, 192 and some visits that you attend after the Week 192 visit, and at the Unblinding Visit will be used to measure changes in the amount of sugar and fats in your blood. About 4 mL (about 1 teaspoon) of blood will be taken for this test. It is important that your blood is drawn for this sample in the morning prior to eating (in a fasting state). If you have not fasted, you will be asked to return to the study center within 72 hours in a fasted state.
- A 12-lead ECG (electrocardiogram) to check the functioning of your heart at Weeks 48, 96, 144, 192 and at the Unblinding Visit.
- About 14 mL (about 3 teaspoons) of blood will be collected and stored to allow the possibility of conducting clinical tests at a later date (for example, to check whether the HIV in your blood can develop resistance to this anti-HIV drug).
- About 6 mL (about 1 teaspoon) of blood will be taken to measure the amount of study drugs in your blood at Weeks 2, 4, 8, 12, 16, 24, 32, 40, and 48. This type of testing is called pharmacokinetics (PK) and measures the amount of the study drug in your blood. It tells the researchers how much time it takes for the study drug to be absorbed into your body and how long it stays in your body after it has been absorbed. On these visit days you will be asked the time and date that you took your last dose of EVG/FTC/TDF/GS-9350 or placebo.
- If you do not appear to be responding properly to the study drugs, you will be required to return to the clinic for an unscheduled or scheduled visit to confirm whether or not you are truly failing your treatment. Approximately 12 mL (about 2 ½ teaspoons) of blood will be drawn during this visit to measure the amount of HIV-1 in your blood and for genotype/phenotype testing. Phenotype testing is a technique used to determine whether a mutation in the HIV-1 gene changes how anti-HIV drugs affect the HIV-1 virus. The study doctor will then decide whether or not a change to your treatment regimen is required.
- You will receive a 4-week supply of study drugs at Weeks 4, 8 and 12 visits. You will receive an 8-week supply of study drugs beginning at the Week 16 visit and continuing every 8 weeks until the Week 48 visit. At the Week 48 visit and every visit until the Unblinding Visit, you will receive a 12-week supply of study drugs until you become unblinded. EVG/FTC/TDF/GS-9350 or placebo should be taken once a day at the same time every day <u>with food</u>. Atripla or placebo should be taken once every day <u>on an empty stomach preferably at bedtime</u>. You will be counseled regarding the importance of taking all study drugs.
- **You will be required to bring your used and unused study drug bottles back to the clinic at each visit (with the exception of your Week 2 visit). The study drug (number of tablets and/or capsules) will be counted. You will be asked about any missed doses since your last visit.**
- At the Unblinding Visit the study doctor will tell you which treatment arm you are on. You will discontinue your blinded study drugs and will be given an option to take part in the open-label rollover study and receive EVG/FTC/TDF/GS-9350.

<u>Early Study Drugs Discontinuation Visit</u>

If you discontinue study drugs at any time before the study is complete, you will be asked to return to the study center within 72 hours of stopping study drugs. If you discontinue study drugs before

the study is unblinded, for safety purposes, you will be asked to continue to come to the scheduled study visits until the study is unblinded. Procedures at this visit will include:

- You will be asked whether there has been any change in your health (illness or health problems) and whether you have taken any new medications since your last visit.
- A complete physical examination and weight.
- A urine sample for laboratory tests. Some of this urine will be stored to conduct possible clinical testing in the future.
- If you are a female able to become pregnant, a urine pregnancy test will be required. If the urine pregnancy test is positive, you will have a blood pregnancy test to confirm the result.
- About 18 mL (about 4 teaspoons) of blood will be taken for testing of chemistry, complete blood count, CD4+ cell count, and to determine HIV-1 levels in your blood.
- About 14 mL (about 3 teaspoons) of blood will be collected and stored to allow the possibility of conducting clinical tests at a later date (for example, to check whether the HIV in your blood can develop resistance to this anti-HIV drug).
- About 12 mL (about 2 ½ teaspoons) of blood may be drawn for genotype/phenotype testing.
- A 12-lead ECG (electrocardiogram) to check the functioning of your heart
- You will be required to bring your used and unused study drug bottles back to the clinic.

30-Day Follow-Up

You will be asked to attend a 30-Day Follow-Up visit in the following cases:

- If you discontinue your study drugs, you will be asked to return to the study center 30 days after the completion of the Early Study Drugs Discontinuation visit. (After discontinuing study drugs if you have continued to attend regularly scheduled visits, you will not be required to come in for a 30-Day Follow-up visit.)
- If you continue on study drugs until the Unblinding Visit and decide not to take part in the optional open-label roll-over study, you will be asked to return to the study center 30 days after completion of study drugs.

Procedures at this visit will include:

- You will be asked whether there has been any change in your health (illness or health problems) and whether you have taken any new medications since your last visit.
- A symptom-directed physical examination and weight.
- A urine sample for laboratory tests. Some of this urine will be stored to conduct possible clinical testing in the future.
- If you are a female able to become pregnant, a urine pregnancy test will be required. If the urine pregnancy test is positive, you will have a blood pregnancy test to confirm the result.
- About 18 mL (about 4 teaspoons) of blood will be taken for chemistry, complete blood count, CD4+ cell count, and to determine HIV-1 levels in your blood.
- About 8 mL (about 1 ½ teaspoons) of blood will be collected and stored to allow the possibility of conducting other clinical tests at a later date.

STORAGE OF BLOOD SAMPLES

A portion of your blood sample drawn at each visit will be frozen and stored. These stored blood samples may be used by the Sponsor or its research partners for HIV-1 genotyping/phenotyping resistance tests or their development, for retesting the amount of HIV-1 in your blood, for measurement of antiviral drug levels in the blood, for future testing to learn more about how the study drug has worked against HIV-1 or clinical laboratory testing to provide additional clinical data.

At the conclusion of this study, these samples may be retained in storage by Gilead Sciences, Inc. for a period up to 10 years.

Genotype testing detects changes or "mutations" in certain genetic regions of the HIV-1 virus. Phenotype testing is used to determine how much drug is needed to stop the virus from replicating. Some mutations can prevent certain anti-HIV drugs or drug regimens from reducing the level of HIV-1 in your blood. When this occurs, the HIV-1 has become "resistant" to that drug and possibly other similar drugs. Genotype and phenotype tests may be experimental; that is, these tests may not have been approved by the FDA. The results of such tests are for research use only, and the interpretation of the test results may not have direct benefit to you. At the conclusion of this study, these samples may be retained in storage by Gilead Sciences, Inc. for a period up to 10 years.

No human genetic testing will be performed without your expressed consent. At the present time, no genetic testing is planned. However, if the sponsor decides to perform genetic testing in the future, participants will be contacted and written informed consent obtained before any tests are done.

STORAGE OF URINE SAMPLES

A portion of the urine samples taken at each visit, except screening, will be frozen and stored. These stored urine samples may be used by the Sponsor or its research partners for possible additional clinical analyses to assess the function of your kidneys.

RISKS AND BENEFITS

EVG/FTC/TDF/GS-9350

EVG/FTC/TDF/GS-9350 is a combination medication containing four medications: elvitegravir (EVG), Emtriva® (FTC), Viread® (TDF), and GS-9350.

A total of 194 healthy subjects have been dosed with the EVG/FTC/TDF/GS-9350 single tablet regimen (STR) as part of five phase 1 clinical studies and in 48 HIV-infected ARV treatment naïve subjects in a blinded Phase 2 study that is still ongoing. As of 10April2012, 916 HIV-infected subjects, both treatment naïve and ARV treatment experienced had been dosed with the EVG/FTC/TDF/GS-9350 STR while participating in ongoing Phase 3 studies. The following adverse reactions to treatment have been identified:

Very common (more than or equal to 10%):

- diarrhea
- nausea
- fatigue
- headache
- depression
- difficulty sleeping (insomnia)

Common (more than or equal to 1% and less than 10%):

- stomach pain (abdominal pain)
- indigestion (dyspepsia)
- gas (flatulence)
- vomiting
- dizziness

- abnormal dreams
- rash
- abnormal kidney function test (increased blood creatinine)
- kidney failure (renal failure)
- Suicidal ideation and suicide attempt in patients with a pre-existing history of depression or psychiatric illness

Uncommon (more than or equal to 0.1% and less than 1%):

- a certain type of kidney disease (Fanconi syndrome)

Side effects on the individual components of EVG/FTC/TDF/GS-9350 are described below:

EVG; ELVITEGRAVIR SIDE EFFECTS

As of 30 June 2011, a total of 390 HIV-infected subjects and 960 healthy subjects have been dosed with EVG as an individual agent as part of Phase 1 and 2 clinical studies. In addition, approximately 358 HIV-1 infected treatment experienced subjects have been dosed in an on-going blinded Phase 3 study. Additionally, 462 healthy subjects and 48 HIV-infected ARV-naïve subjects have been dosed with EVG in a single tablet regimen containing elvitegravir (EVG), emtricitabine (FTC), tenofovir disoproxil fumarate (TDF) and GS-9350 (cobicistat) as part of Phase 1 and 2 clinical studies. As of 10 April 2012, 916 HIV-1 infected subjects, both ARV treatment-naïve and ARV treatment-experienced, had also received elvitegravir as part of the EVG/FTC/TDF/GS-9350 STR in ongoing Phase 3 studies.

No additional side effects for EVG have been observed in clinical studies of EVG as an individual agent in addition to those listed above for EVG/FTC/TDF/GS-9350.

FTC; Emtriva® SIDE EFFECTS
(Emtricitabine)

The most common side effects seen in patients treated with emtricitabine in combination with other anti-HIV drugs are: headache, diarrhea, nausea, and rash, which were generally mild. Other common side effects with emtricitabine include dizziness, changes in skin color primarily on the palms and/or soles, weakness, difficulty sleeping, abnormal dreams, pain, vomiting, stomach pain, problems with digestion resulting in gastrointestinal discomfort after meals, increased triglycerides (fatty acid), increased bilirubin in the blood, increased glucose in the blood, allergic reaction, hives, adverse effects on the function of the liver and pancreas, and low white blood cell count. A reduction in your white blood cell count can increase your risk for infection. You may also experience increased creatinine kinase in the blood. If creatine kinase is increased, you may experience muscle pain and weakness.

Additionally, cases of lactic acidosis (high levels of lactic acid in the blood), and liver problems with enlargement of the liver and fat in the liver, including fatal cases, were reported in HIV-infected patients treated with anti-HIV agents similar to emtricitabine. The symptoms of lactic acidosis include: weakness, unexpected and uncommon abdominal pain, nausea and vomiting. Symptoms of liver problems include; yellowing of the skin or whites of the eyes, dark urine, light-colored bowel movements, loss of appetite, nausea and lower abdominal pain. If you notice any of these symptoms, please request medical assistance immediately.

Please talk to your study doctor for more details on side effects or refer to the emtricitabine package insert for additional information.

TDF; Viread® SIDE EFFECTS
(Tenofovir DF)

Tenofovir DF has been studied in more than 12,000 HIV-infected adults for as long as 480 weeks in some patients. Common potential side effects identified in patients who received at least one dose of tenofovir DF 300 mg include diarrhea, nausea, vomiting, flatulence (intestinal gas), and dizziness. Those side effects were often mild or moderate in severity, and did not lead to discontinuation of tenofovir DF. Of these events, only vomiting and flatulence (intestinal gas) were more common for patients taking tenofovir DF than those taking placebo (sugar pill).

In addition to side effects reported from clinical trials the following side effects have also been identified after tenofovir DF was approved in HIV-infected patients treated with combination therapy that has included tenofovir DF and other anti-HIV drugs: weakness, abdominal pain, allergic reaction including potentially serious swelling of the face, lips, and/or tongue, with or without rash, pancreatitis (inflammation of the pancreas), high levels of amylase in the blood, shortness of breath, rash, abnormalities of tests that measure hepatic (liver) function and hepatitis (inflammation of liver).

Cases of lactic acidosis (high levels of lactic acid in the blood), liver problems with enlargement of the liver and fat in the liver, including fatal cases, were reported in HIV-infected patients treated with anti-retroviral agents similar to tenofovir DF. The symptoms of lactic acidosis include: weakness, unexpected and uncommon abdominal pain, nausea and vomiting. Symptoms of liver problems include yellowing of the skin or whites of the eyes, dark urine, light colored bowel movements, loss of appetite, nausea and lower abdominal pain. If you notice any of these symptoms, please request medical assistance immediately.

Cases of kidney damage have been reported in patients taking tenofovir DF who already have circulatory disease or specific kidney disease, and patients who, while receiving tenofovir DF, were also taking medications that may cause damage to the kidneys. Kidney damage has also been reported in patients without any of these factors. For example, some patients have had damage to the structure and function of the kidneys, which may lead to muscle abnormalities, muscular weakness, destruction of muscle tissue, bone pain and fractures due to softening of bones, and low potassium and phosphate in the blood. In addition, death of kidney tissue, continuous or sudden kidney failure, abnormal kidney function, inflammation of the kidneys, protein in the urine, excessive urination, nephrogenic diabetes insipidus (excretion of urine resulting in dehydration and thirst), and increased creatinine in the blood have also been reported in patients taking tenofovir DF.

Bone toxicity, including a decrease in bone mineral density, can be seen in patients taking TDF. The risk of bone fractures associated with these types of changes is unknown.

Because these events have been reported voluntarily from a population of unknown size, estimates of frequency cannot be made.

TDF and FTC are active against hepatitis B. If you are infected with hepatitis B virus (HBV), there is a possibility of an unexpected worsening of hepatitis B if you stop taking TDF or FTC.

Please talk to your study doctor for more details on side effects or refer to the tenofovir DF package insert for additional information.

GS-9350; SIDE EFFECTS

As of 30 June 2011, 561 healthy subjects have been dosed with GS-9350 as an individual agent as part of 17 Phase 1 studies and in 50 HIV-infected ARV treatment naïve subjects in a blinded Phase 2 study that is currently ongoing. Approximately 350 HIV-infected ARV-naïve subjects have received GS-9350 as an individual agent in an ongoing, blinded Phase 3 study. Additionally, 194 healthy subjects have been dosed with the EVG/FTC/TDF/GS-9350 single tablet regimen (STR)as part of five Phase 1 clinical studies and in 48 HIV-infected ARV naïve subjects in a blinded Phase 2 study that is currently ongoing. As of 10 April 2012, 916 HIV-1 infected subjects, both ARV treatment-naïve and ARV treatment-experienced, had also received GS-9350 as part of the EVG/FTC/TDF/GS-9350 STR in ongoing Phase 3 studies.

No significant changes in serum immunoglobulins (antibodies), ECG, thyroid hormone levels or urine characteristics have been seen in clinical studies to date. In two ongoing studies in which approximately 100 HIV-positive subjects are receiving GS-9350, mild decreases in estimated kidney function were observed. A follow-up study in healthy subjects showed that actual kidney function does not change. This phenomenon is seen with two other commonly used FDA-approved drugs, trimethoprim (an antibiotic) and cimetidine (an antacid). Your kidney function will be closely monitored throughout your participation in this study with blood and urine tests.

No additional side effects for GS-9350 have been observed in clinical studies of GS-9350 as an individual agent in addition to those listed above for EVG/FTC/TDF/GS-9350.

EFV/FTC/TDF; Atripla® SIDE EFFECTS
(Efavirenz/Emtricitabine/Tenofovir DF)

Please refer to the Emtriva® and Viread® side effects described above for side effects associated with Atripla®, a combination medication containing Emtriva® and Viread®.

Efavirenz

A common side effect reported in clinical trials of efavirenz was rash. Rashes usually go away without any change in treatment. In a small number of patients, rash may be serious. If you develop a rash, call your study doctor right away. Other side effects including insomnia, abnormal dreams, trouble concentrating, dizziness, headache, and drowsiness, and are commonly reported during the first weeks of therapy with efavirenz. Dosing at bedtime may improve the tolerability of these symptoms, which are likely to improve with continued therapy. Tell your study doctor right away if any of these side effects continue or if they bother you. It is possible that these symptoms may be more severe if efavirenz is used with alcohol or mood altering (street) drugs. If you are dizzy, have trouble concentrating, or are drowsy, avoid activities that may be dangerous, such as driving or operating machinery. Other common side effects include anxiety, depression, diarrhea, nausea, vomiting, tiredness, stupor, and changes in thinking.

A small number of patients may experience strange thoughts or angry behavior while taking efavirenz. Some patients have thoughts of suicide, and a few have actually committed suicide. These problems may occur more often in patients who have had mental illness. Other uncommon side effects include hypersensitivity (allergic reaction), emotional lability (mood swings), sense of elation, hallucination, manic reactions, paranoid reactions, confusion, agitation, amnesia (memory

loss), ataxia (unsteadiness when walking), abnormal coordination, vertigo (sensation of spinning), and hepatitis.

In addition to side effects from clinical trials, the following have been reported during post-approval use of efavirenz including suicide, psychosis (mental illness), delusion (false beliefs), neurosis (anxiety, fear of objects, places or people), tremor (involuntary muscle movements), convulsions, blurred vision, tinnitus (buzzing in ears), inflammation of the pancreas, abdominal pain, liver failure progressing in some cases to liver transplantation or death, photosensitivity (increased sensitivity of the skin to the sun), itchiness, flushing, and gynecomastia (development of breast tissue in males).

There is a very small risk of Stevens-Johnson Syndrome which is an uncommon, potentially fatal condition that may begin with flu-like symptoms, such as headache, fever, cough, and body aches, and then progress to a more serious condition with rash, blistering and sloughing of the outermost layer of skin, burning eyes, visual impairment and blindness. Tell the study doctor right away if you experience any of these symptoms.

Because of possible serious and life-threatening side effects when taking Atripla® with other medications, including those you take without a prescription, tell your study doctor about all the medications you are taking or planning to take, including any herbal supplements such as St. John's Wort.

Please talk to your study doctor for more details on side effects or refer to the Atripla package insert for additional information.

Immune Reconstitution Syndrome

A condition called immune reconstitution syndrome can happen in some patients with advanced HIV infection (AIDS) when combination anti-HIV treatment is started. Signs and symptoms of inflammation from opportunistic infection that a person has or had may occur as the medicines work to control the HIV infection and strengthen immune system. Call your study doctor right away if you notice any signs or symptoms of an infection after starting study medication.

Autoimmune disorders such as Graves'disease (a disease in which the thyroid produces excessive thyroid hormones), polymyositis (a disease of caused by inflammation leading to weakness of the muscles), and Guillain-Barre syndrome (a disease that occurs when the body's immune system attacks part of the nervous system, leading to nerve inflammation that causes muscle weakness), have also been reported to occur in the setting of immune reconstitution, however, the time to onset is variable and can occur many months after starting treatment.

Allergic Reaction Risks

As with taking any drug, there is a risk of allergic reaction. If you have a very serious allergic reaction, you may be at risk of death. Some symptoms of allergic reactions are:

- Rash.
- Difficulty breathing.
- Wheezing.
- Sudden drop in blood pressure.
- Swelling around the mouth, throat or eyes.
- A fast pulse.
- Sweating.

Please seek treatment and alert the study doctor and study staff immediately if you have any of these symptoms, or any other side effects, during the study.

Blood Draws
In addition to risks associated with the study drug, drawing blood from a vein may cause local pain, bruising, occasional lightheadedness, fainting, and very rarely, infection at the site of the blood draw.

ECG
After you have an ECG, you may have mild irritation, slight redness, and itching at the places on your skin where the recording patches are placed. You may have to have your chest shaved for this procedure.

Hepatitis B and C Testing Risks
At the Screening visit, you will be tested for hepatitis B and C, and the results of these tests may be reported to your local health authority. You will be told, face-to-face, the results of these tests. Counseling will be available to you if necessary.

Other
As with all drugs, unexpected or yet unknown side effects may occur. Any new information that becomes known during the study and that may affect your participation will be shared with you by your study doctor.

Viruses, which are resistant to the study drugs, may develop during the course of treatment. This may reduce your treatment options in the future. Throughout the study, your study doctor will monitor your HIV-1 levels for viral rebound (increases in HIV-1 levels after having previous results of lowered HIV-1 levels). Resistant mutations develop most rapidly in people who do not take all of their HIV-1 drugs. Therefore, it is important to take all your study drugs as prescribed by your study doctor.

You may have a side effect that requires your study doctor to end your participation in the study. You should contact your study doctor immediately if you feel that you cannot tolerate your drug regimen.

Possible Benefits of the Study
There is no guarantee that you will receive personal benefit from participating in this study. The study drugs are not expected to cure you of HIV. However, clinical research studies such as this are a way for doctors to determine if a drug is useful in fighting a disease. By participating in this study, you and the Sponsor, Gilead Sciences, Inc., may benefit if EVG/FTC/TDF/GS-9350 is effective in treating your HIV-1 infection. Your participation in this study may benefit the community, scientists and doctors who work with HIV by providing increased knowledge and information about the treatment of your disease. In addition, during your participation you will have close medical monitoring of your health condition by blood tests and other evaluations during clinic visits.

PREGNANCY AND BREAST FEEDING
The effects of EVG/FTC/TDF/GS-9350 and Atripla® have not been fully evaluated on the developing fetus in humans. Animal studies do not indicate direct or indirect harmful effects of EVG, FTC, TDF, and GS-9350 with respect to pregnancy. The effects of some anti-HIV medications (including the drug efavirenz, which is one of the drugs found in Atripla®) may be harmful to unborn babies.

Changes have been seen in animals, and a small number of reports of neural tube defects (a problem with development of the spine and/or brain) in babies of women who were taking efavirenz in the early part of their pregnancy have been reported, but it is not certain that efavirenz was the cause. Because the effects of EVG/FTC/TDF/GS-9350 and Atripla® on a developing fetus as well as on exposed infants are unknown, any female able to become pregnant (i.e., a female subject of childbearing potential is a nonmenopausal female who has not had a hysterectomy, bilateral oophorectomy (surgery to remove the ovaries), or medically documented ovarian failure [this definition includes a young woman who has not yet started menstruating]) must have a negative blood pregnancy test to enroll; females who are breast-feeding will not be enrolled in this study.

It is very important while you are in this study that you do not become pregnant if you are a female, or do not cause others to become pregnant if you are a male. You are aware that not having sex is the only certain way to prevent pregnancy.

If you are a sexually active male or female, you must agree to use protocol-recommended methods of birth control from the screening/enrollment visit throughout the study and for 12 weeks following the last dose of study drug

Protocol-recommended contraceptive methods are: (1) a combination of one hormonal method and one barrier method; (2) two barrier methods where one method is the male condom; or (3) use of an IUD or tubal sterilization (see table below). Acceptable hormonal methods include: injectable progesterone, progesterone implants, combination oral contraceptives, transdermal patch and vaginal ring. Acceptable barrier methods include: diaphragm (without spermicide), cervical cap (without spermicide) and the male condom. If you are a female subject you must use either a hormonal method or a barrier method if your partner has a vasectomy. If you have undergone tubal sterilization or had a Copper T 380A IUD or LNg 20 IUD inserted, no other contraception is needed.

If you utilize hormonal contraception as one of your birth control methods, you must have used the same method for at least 3 months prior to starting the study drug. It is recommended that an oral contraceptive contains 30 µg of ethinyl estradiol (EE) if you are taking it with the study drug.
If your tubal sterilization was performed via the Essure procedure, your doctor will need to perform a hysterosalpingogram (HSP) about 3 months after the procedure has been completed in order to verify tubal blockage and confirm that this is a reliable form of contraception for you.

Protocol-Recommended Contraceptive Methods

<table>
<tr><th rowspan="2">Methods to Use by Themselves</th><th colspan="2">Combination Methods</th></tr>
<tr><th>Hormone Methods
(choose one and use with a barrier method)</th><th>Barrier Methods
(use both OR choose one and use with a hormone method)</th></tr>
<tr><td rowspan="2">Intra-uterine devices (IUDs)
• Copper T 380A IUD
• LNg 20 IUD

Tubal sterilization</td><td>Estrogen and Progesterone
• Oral contraceptives
• Transdermal patch
• Vaginal ring
Progesterone
• Injection
• Implant</td><td>• Diaphragm without spermicide
OR
Cervical cap
• Male condom</td></tr>
<tr><td colspan="2">Partner’s vasectomy must be used along with a hormone or barrier method.</td></tr>
</table>

*It is recommended that an oral contraceptive contain 30 µg of EE if administered with study drug

All subjects must undergo appropriate contraceptive counseling. Your study doctor will counsel you onthe most effective method(s) for avoiding pregnancy during the study.

Even if you use highly effective birth control methods, you could still become pregnant. There is a slight chance that a pregnancy test could be wrong. If the pregnancy test is wrong, and you receive the study drug while pregnant, the study drug may harm an unborn baby.

If you are female and become pregnant or suspect that you have become pregnant while in the study and within 30 days of last dose of study drug, you will be required to stop taking all the study drugs and to notify your study doctor immediately. You will be discontinued from the study. The study doctor will request to track your pregnancy and will report the pregnancy and outcome to Gilead.

Other not yet identified side effects could occur to you, your embryo or fetus should you become pregnant during the time you participate in the study or after you have completed the study.

CONDOM USE

It has been proven that condom use decreases the risk of spreading HIV and hepatitis B between sexually active individuals. To decrease your risk of transmitting the virus to another individual and to decrease the risk of being infected with a different strain of HIV, we recommend that condoms be used for all sexual activity to include oral, vaginal, and anal sexual contact. Condom use is recommended in addition to your current form of birth control. The use of spermicide is not recommended if you or your partner is HIV-infected.

TREATMENT OPTIONS

You have the option to discuss with your study doctor not to have treatment or to choose other anti-HIV drugs to treat your disease. These medicines include commercially available medicines. Your study doctor will discuss appropriate alternative treatment options with you. You will be made aware

of any new findings that become available during the course of the study that may affect your willingness to participate in this study.

STATEMENT ABOUT PRIVACY

Records identifying you will be kept confidential and, to the extent permitted by applicable laws and/or regulations, will not be made publicly available. In the event of any publication regarding this study, your identity will remain confidential.

Representatives from government agencies, including the U.S. Food and Drug Administration ("FDA"), institutional review boards, the Sponsor and/or the Sponsor's authorized representatives may need access to your original medical records and study records for the purpose of checking data collected for the study. By signing this consent form, you authorize this access.

Your coded study information and samples may also be used for additional unanticipated medical and/or scientific research projects in the future relating to HIV-1 or the development of the EVG/FTC/TDF/GS-9350 (but at all times in compliance with applicable law and regulation).

As explained in this consent form, treatment in this study is randomized and neither you nor your Study Doctor will know whether you have received the study drug until the study is over. While this is the case, the study is referred to as being "blinded." The study needs to be blinded to ensure its scientific integrity, so it is important that it remains this way until the study is over. By signing this consent form you agree that you will not be able to have access to information about your participation in the study until the study is over. After that, you can obtain access to your information through your Study Doctor.

AUTHORIZATION TO USE AND DISCLOSE RECORDS

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
- 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 (Gilead Sciences): 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
- The Office of Human Research Protections
- The Study Monitoring Committee

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, date of birth 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?
During your participation in this study, you might not be able to access some or all of your medical records. For example, access to portions of your medical records may be denied in studies where your knowledge of study results included in such records could affect the reliability of the study. You will have access to your medical record information when the study is over or earlier, if possible. 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.

RESEARCH STUDY REGISTRY
A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Website will not include information that can identify you. At most, the Website will include a summary of the results. You can search this Website at anytime.

WITHDRAWAL FROM STUDY AND REFUSAL TO PARTICIPATE
Special care will need to be taken when determining if you need to stop the study drug. Your study doctor will supervise any discontinuation of the study drug with your health as the first priority. Your participation in this study may be stopped at any time by a) your study doctor, b) Gilead Sciences, Inc., c) the FDA, d) the Institutional Review Board (a review group that gives approval to your study doctor to conduct this study), and (e) other appropriate regulatory agencies.

Your participation in this clinical research study is voluntary, and you can refuse to participate or stop at any time without stating a reason. Your withdrawal will not affect your access to other medical care.

Your study doctor may withdraw you from the study if it is considered important for your medical safety. If it is learned that you did not give an accurate medical history or did not follow the instructions for the study given by your study doctor and/or study nurse, you may be taken off the study at any time. If you are taken off the study, you will no longer receive the study drugs.

COST OF TREATMENT
The EVG/FTC/TDF/GS-9350 and Atripla® used in this study will be given to you free of charge. All clinic, professional, diagnostic, and laboratory fees for tests and procedures that are part of this

study will be provided at no cost to you. You or your usual health care payer will be responsible for any other health care costs.

PAYMENT FOR PARTICIPATION

You will be compensated $25.00 for your screening visit. For visits thereafter, Baseline, 9 visits for year 1; 4 visits on year 2 and 3 visits every year thereafter, you will be compensated $50 for every visit you attend. If you need to come in for an unscheduled visit that is requested by the study staff, you also will be compensated $50 for that visit. The total compensation you will receive for the study depends on how long you participate.

Please note that if you receive more than $600.00 compensation in one 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.

COMPENSATION FOR STUDY-RELATED INJURY

If you are injured or become sick as a direct result of taking the study drug and/or following the study procedures, medical treatment will be offered to you by the University of Pennsylvania. The Sponsor, Gilead Sciences, Inc., will reimburse you or the University of Pennsylvania for the reasonable and necessary costs of such medical treatment provided that you have followed the instructions of the study doctors. Other than reimbursement of medical treatment expenses, the Sponsor and the University of Pennsylvania has no plans to provide any other form of compensation for study-related injury or illness. You do not give up any legal rights by signing this form. You should immediately contact your Study Doctor at the contact information shown below in the event you experience any study-related illness or injury.

If you receive Medicare benefits, the Sponsor, Gilead Sciences, Inc., is required by law to report payments made to you for treatment, complications, and injuries that arise from this study. Information that you are taking part in the study, medical treatments received, Medicare claims, and other personal information about you such as your name, social security number, and date of birth, will be provided to the Centers of Medicare and Medicaid Services and its agents and/or contractors for this purpose.

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

What 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).

SOURCE FOR ADDITIONAL INFORMATION

For questions about this study or a research-related injury, contact:

- Pablo Tebas, MD (215-349-8092)
- Clinical Trials Unit (215 349-8092)

For questions about your rights as a research subject, contact:

- Director of Regulatory Affairs at the University of Pennsylvania by phoning (215) 898-2614

AGREEMENT TO BE IN THE STUDY

This Subject Information and Informed Consent Form contains important information to help you decide if you want to be in this study. If you have questions that are not answered in this form, please ask one of the study staff. Please answer the following questions by placing your initials in the line for "Yes" or "No".

1. Have you read this form?	___ Yes ___ No
2. Have you had the opportunity to ask questions and discuss the study?	___ Yes ___ No
3. Have you received answers you find acceptable to all of your questions?	___ Yes ___ No
4. Have you received enough information about the study to make an informed decision?	___ Yes ___ No
5. Have you been told that you are free to stop the study at any time without having to give a reason and without affecting your medical care?	___ Yes ___ No
6. Have you been told that you understand your medical records may be reviewed and how the information will be used?	___ Yes ___ No
7. Do you agree to have your personal information collected during this study and blood and urine samples stored for future commercial research related to the treatment, prevention or diagnosis of HIV-1?	___ Yes ___ No
8. Have you been told that you will not have any rights to any discovery or inventions which result from future research, and you will not receive any financial compensation in connection with any future research?	___ Yes ___ No

If you answered NO to any of the eight questions listed above you should not sign this form. If you have had all your questions answered and you are comfortable participating in this study, please sign below.

By signing and dating this form you agree that you are volunteering to be in this study.

CONSENT

When you sign this form, you are agreeing to take part in this research study. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer. Your signature also means that you are permitting the University of Pennsylvania Health System and the School of Medicine to use your personal health information collected about you for research purposes within our institution. You are also allowing the University of Pennsylvania Health System and the School of Medicine to disclose that personal health information to outside organizations or people involved with the operations of this study.

I have read this form and its contents were explained to me. I agree to be in this research study for the purposes listed above. All of my questions were answered to my satisfaction. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing this form.

_____ ____/____/____
Signature of Research Subject Date

_____
Printed Name of Research Subject

STATEMENT OF PERSON EXPLAINING CONSENT

I have carefully explained to the subject the nature and purpose of the above study. There has been an opportunity for the subject to ask questions about this research study. I have been available to answer any questions that the subject has about this study.

_____ ____/____/____
Signature of Person Explaining Consent Date

_____
Printed Name and Title of Person Explaining Consent