

UNIVERSITY OF PENNSYLVANIA HEALTH SYSTEM

Gilead Sciences, Inc
GS-US-292-0104, Amendment 3, 18-DEC-2014

A Phase 3, Randomized, Double-Blind Study to Evaluate the Safety and Efficacy of
Elvitegravir/Cobicistat/Emtricitabine/ Tenofovir Alafenamide Versus Elvitegravir/Cobicistat/
Emtricitabine/Tenofovir Disoproxil Fumarate in HIV-1 Positive, 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

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. This new version of the consent form is updated to include the following new information: 1) the study has been extended from 96 weeks to 144 weeks (another 4 visits) at which time open label E/C/F/TAF will be offered; 2) the procedures section has been updated to note correct volume of blood from 12 mL (2 ½ teaspoons) to 24 mL (4 ½ teaspoons) required for genotype/phenotype testing and measuring the amount of HIV-1 in your blood if needed and some of the urine collected will be tested to check on kidneys and 3) the risk section of the consent has been updated to reflect new information from ongoing clinical trials of E/C/F/TAF.

INTRODUCTION

You have been asked to take part in a clinical research study involving an experimental drug named Elvitegravir/Cobicistat/Emtricitabine/Tenofovir Alafenamide Single Tablet Regimen (E/C/F/TAF STR). An experimental drug means that the FDA has not approved it for use by the general public. This drug will be compared to another drug called Elvitegravir/Cobicistat/Emtricitabine/Tenofovir Disoproxil Fumarate Single Tablet Regimen (E/C/F/TDF STR) that has recently been approved by the FDA in the United States for patients with HIV who have never been treated before.

YOUR RIGHTS

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 must understand the purpose of the study, how your participation may help you, any potential risks to you, and what is expected of you during the study.

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PURPOSE OF THE STUDY

The treatment of HIV infection requires the combination of several medications in order to decrease the amount of virus in the body, improve immune function and delay the progression of the disease. This has generally required patients to take a large number of pills each day. These drugs may stop working over time and may cause unacceptable side effects. Therefore, it is important to develop new drug regimens. In addition, the combination of drugs into a single tablet reduces the number of pills a patient has to take and makes it more convenient to stick to the prescribed drug regimen.

The purpose of this study is to evaluate safety and to determine whether E/C/F/TAF STR is effective against HIV-1 compared to E/C/F/TDF STR in subjects not currently receiving treatment for their chronic HIV-1 infection. Safety and tolerability will be determined on the basis of physical exams, laboratory tests, bone scans and questions about any problems you might experience during the study.

You have been asked to participate in this study because you have HIV and you are treatment-naïve, meaning you have never taken medications that fight HIV. 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.

This study will also include a pharmacokinetic portion. "Pharmacokinetics" is the study of the various actions a drug takes within the body including how it is absorbed by the body (such as through the mouth, stomach or intestine), how it moves throughout the body, how it is metabolized (processed, converted and used) by the body, and how it is removed from the body. As part of this study, levels of HIV-1 in the blood ("viral load") and drug levels of the study drugs will be determined at various times during the study.

DESIGN OF THE STUDY

If you participate, you will be one of 840 subjects recruited from about 250 study sites in North America, Europe and Asia Pacific regions. About 10 subjects are expected to enroll at the University of Pennsylvania.

This is a double-blinded study, which means neither you nor your Study Doctor will know what study drug you are assigned to receive.

This is a randomized study, which means you will be selected by chance (like a flip of a coin) to receive one of the two study treatments listed below:

Study Treatment Group 1: Single tablet regimen of E/C/F/TAF + placebo-to-match E/C/F/TDF once daily: 420 subjects

Study Treatment Group 2: Single tablet regimen of E/C/F/TDF + placebo-to-match E/C/F/TAF: 420 subjects

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.

The randomization for this study is in a 1:1 ratio, which means that your chance of being assigned to Study Treatment Group 1 is the same as your chance of being assigned to Study Treatment Group 2.

All of your study drug will be supplied by Gilead Sciences, Inc. who is also the sponsor of this study. Your

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study doctor or study nurse will review the proper storage of all study drugs used in this study with you. **All study drugs must be taken once a day, at the same time every day, with food.** It is very important that you take your study drug every day as instructed by the study doctor. There is one visit (Week 16) for which you may have to take the study drug in the study center and all other days you will take it on your own at home. You must bring the study drug bottles including any unused study drug with you at each clinic visit.

DURATION OF THE STUDY

The screening period (the time between the Screening visit and Day 1 [baseline] visit) may last up to 30 days. Once you are confirmed to be eligible to participate in the study, and you state that you want to take part in the study, your participation in this study will last about 144 weeks, not including the screening visit. Following confirmation of your eligibility, you will be required to visit the study center at least 16 times (at weeks 2, 4, 8, 12, 16, 24 and then every 12 weeks through week 144).

Following your 144 weeks on-study, you will continue to take your study drugs and attend visits every 12 weeks until the study is unblinded ("unblinded" means that treatment arms are viewed by the doctor and study sponsor). After the study is unblinded, subjects who complete the required on-study treatment and who qualify will be offered the opportunity to receive open-label E/C/F/TAF. Open-label means you and your study doctor will know what study drugs you will be taking.

Subjects who choose to receive E/C/F/TAF will return for study visits every 12 weeks until E/C/F/TAF becomes commercially available or until Gilead Sciences chooses to terminate the study.

SUBJECT RESPONSIBILITIES

If you decide to be in this study, there are certain rules you must follow before, during, and after the study period. Some are listed below, but there could be others that the study doctor will discuss with you:

- It is very important not become pregnant or get someone pregnant during this study.
- It is very important that you tell your study doctors all of the information you know about your health and medications you may be taking throughout the study period. If you do not tell the study doctor everything you know, you may be putting your health at risk.
- It is very important to return all of the used and unused study drug and/or empty bottles to the clinic at each visit.
- It is very important to follow all instructions given to you while you are participating in this study. If you do not, you may be removed from the study. If you are unsure about what you are supposed to do, ask the Study Doctor.
- Some insurance companies require people who are renewing a policy or getting a new policy to tell them about participating in a clinical study. You should check with your insurer to determine if taking part in this study will affect your existing insurance policy.

STUDY PROCEDURES

Screening

To help the study doctor determine your eligibility to participate in this study and whether it is safe for you to do so, you need to be seen at the study center within 30 days before the study starts. After you sign the informed consent form and receive a copy of the informed consent form, you will have 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:

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- 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.
- A complete physical examination, vital signs, weight, and height.
- A 12-lead ECG (electrocardiogram) to check the functioning of your heart.
- 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 pregnancy test is positive, you will not be eligible to participate in the study.
- If you are a female that has stopped menstruating for ≥ 12 months but do not have documentation of ovarian hormonal failure, a blood test will be required to confirm your post-menopausal status.
- About 21 mLs (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 virus in your blood.
- About 12 mLs (about 3 teaspoons) 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, HIV-1 becomes "resistant" to that drug and possibly other similar drugs.

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-292-0111 study and you were not randomized into that study, some of these screening test results can be used for this study (GS-US-292-0104) 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-292-0111 study for this study. **If you have not had any screening tests done for the GS-US-292-0111 study, all of the screening assessments listed above for this study (GS-US-292-0104) will need to be completed to see if you are able to participate in this study.**

Baseline/Day 1

You will be asked to come back to the study center within 30 days after the Screening visit for the Day 1 (baseline) visit. You must not have anything to eat or drink, except water, for at least 8 hours before the visit. Eating or drinking may affect the results of your urine and blood testing. 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, vital signs and weight.
- Dual energy x-ray scan (called a DEXA scan) of your spine and hip (prior to taking study drug) will be done to measure the density of your bones.
- A urine sample will be collected for laboratory tests and a storage sample for possible future testing. Some of the urine collected will be tested to see if the study drugs have any effect on your kidneys.
- If you are a female able to become pregnant, a urine pregnancy test will be required. If the urine pregnancy test is positive, a blood pregnancy test will be done to confirm the result; if confirmed, you will not be able to participate in the study.

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- About 19 mLs (about 4 teaspoons) of blood will be taken for testing of chemistry, complete blood count, your bone health, thyroid function (thyroid is a gland that makes hormones which regulate metabolism), Cystatin C (to monitor kidney function), 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 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 given instructions on how to take your study drug (i.e. with food and at the same time each day).
- You will complete a questionnaire regarding your health.
- You will receive study drug and will be asked to begin taking your first dose within 24 hours after the clinic visit.

Week 2 to Week 48 Visits:

You will be asked to return to the clinic for study visits at Weeks 2, 4, 8, 12, 16, 24, 36 and 48.

At Weeks 2, 4, 12, 24, and 48, you must arrive in a fasting state for your visit. "Fasting" means that you will not eat or drink anything except water for at least 8 hours before your blood is drawn. Eating or drinking may affect the results of your urine and blood testing. If you have not fasted, you will be asked to return to the study center within 72 hours in a fasted state.

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.
- You will complete a questionnaire regarding your health at weeks 24 and 48.
- A physical examination, vital signs, and weight (a complete physical examination will be performed at Weeks 24 and 48; a symptom-directed physical examination will be performed at all other visits as needed).
- A urine sample for standard laboratory tests and storage sample for possible future testing. At weeks 2, 4, 12, 24, and 48, some of the urine will be tested to see if the study drugs have any effect on your kidneys; at these visits it is important that you arrive 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.
- 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, you will be discontinued from study drugs.
- About 19 mLs (about 4 teaspoons) of blood will be taken for testing of chemistry, complete blood count, your bone health (weeks 2, 4, 12, 24, and 48), thyroid function, CD4+ cell count, and to determine HIV-1 levels in your blood.
- Tests on blood being drawn at Weeks 24 and 48 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 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.

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- A 12-lead ECG (electrocardiogram) to check the functioning of your heart at Week 48.
- DEXA scan (x-ray) of your spine and hip will be performed at weeks 24 and 48.
- About 14 mL (about 3 teaspoons) of blood will be collected and stored to allow the possibility of conducting 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. 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 your study drugs.
- At the Week 16 visit only, the pharmacokinetic (PK) testing will be done 15 minutes to 4 hours after you have taken your study drug. For this test to be accurate, it is important that you take your dose of study medication as directed by the study doctor.
- If you do not appear to be responding properly to the study drugs, you may be required to return to the clinic for an unscheduled visit to confirm whether or not you are truly failing your study 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 study treatment regimen is required.
- You will receive a 4-week supply of study drugs at Weeks 4, 8, and 12. You will receive an 8-week supply of study drugs at Week 16. At Weeks 24, 36 and 48 you will receive a 12-week supply of study drugs. All study medication should be taken once a day at the same time every day with food. 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. The study drug (number of tablets) will be counted. You will be asked about any missed doses since your last visit.

Week 60 to Week 144 and every 12 weeks following Week 144 through the Unblinding Visit:

You will be asked to return to the clinic for study visits at Weeks 60, 72, 84, 96, 108, 120, 132, and 144 unless otherwise specified.

After the Week 144 visit you will be asked to continue coming in for study visits every 12 weeks until the study is unblinded. 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.
- You will complete a questionnaire regarding your health at weeks 72 and 96
- A physical examination, vital signs, and weight (a complete physical examination will be performed at Weeks 72, 96, 120, 144 and at the Unblinding Visit; a symptom-directed physical examination will be performed at all other visits as needed).
- A urine sample for standard laboratory tests and storage sample for possible future testing. Some of the urine will be tested to see if the study drugs have any effect on your kidneys; at these visits it is important that you arrive 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.

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- 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, you will be discontinued from study drugs.
- About 18 mL (about 4 teaspoons) of blood will be taken for testing of chemistry, complete blood count, thyroid function, CD4+ cell count, and to determine HIV-1 levels in your blood.
- Tests on blood being drawn at Weeks 72, 96, 122, 144 and every 24 weeks post Week 144, 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 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 Week 96 and at the Unblinding Visit.
- DEXA scan (x-ray) of your spine and hip will be performed at weeks 72, 96, 120, 144 and every 24 weeks post week 144. A DEXA scan will also be performed at the Unblinding Visit if the last scan was more than 12 weeks from the Unblinding Visit.
- About 14 mL (about 3 teaspoons) of blood will be collected and stored to allow the possibility of conducting tests at a later date (for example, to check whether the HIV in your blood can develop resistance to this anti-HIV drug).
- If you do not appear to be responding properly to the study drugs, you may be required to return to the clinic for an unscheduled visit to confirm whether or not you are truly failing your study treatment. Approximately 24 mL (about 4 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 study treatment regimen is required.
- At the Week 60 visit and every visit until the Unblinding Visit, you will receive a 12-week supply of study drugs until you become unblinded. All study medication should be taken once a day at the same time every day with food. 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. The study drug (number of tablets) 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 study treatment arm you are on. You will discontinue your blinded study drugs and will be given an option to receive open-label E/C/F/TAF STR.

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 and your urine is collected at Day 1 (baseline) visit, Weeks 2, 4, 12, 24, 48, 72, 96, 108, 120, 132, 144 and every 12 weeks post Week 144, and at the Unblinding Visit.

You cannot take any antacids that contain calcium, magnesium, or aluminum (for example, Tums®, Roloids® or Mylanta), 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 study drugs. You must check with the study doctor before taking any medication or health supplements for the length of the study.

Early Study Drugs Discontinuation (ESDD) Visit

If you stop taking the 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 stop taking the 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.
- You will complete a questionnaire regarding your health
- A complete physical examination, vital signs, and weight.
- A urine sample for standard laboratory tests and storage sample for possible future testing. Some of the urine may be tested to see if the study drugs have any effect on your kidneys if your last test occurred more than 12 weeks before the ESDD visit. For this test it is important that you arrive 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.
- 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+ (white blood cell that fights infection) cell count, thyroid function and to determine HIV-1 levels in your blood. Some of the blood may be tested for your bone health if your last test occurred more than 12 weeks before the ESDD visit. For this test it is important that you arrive 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.
- About 14 mL (about 3 teaspoons) of blood will be collected and stored to allow the possibility of conducting 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.
- DEXA scan (x-ray) will be performed if the last scan was more than 12 weeks from the ESDD visit.
- 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 stop taking your study drugs, and do not wish to continue attending regularly scheduled visits, you will be asked to return to the study center 30 days after the completion of the Early Study Drugs Discontinuation visit.
- If you continue on study drugs until the Unblinding Visit and decide not to receive open-label E/C/F/TAF, 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 standard laboratory tests and storage sample for possible future testing.
- 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+ (white blood cell that fights infection) cell count, thyroid function, and to determine HIV-1 levels in your blood.

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- About 8 mL (about 2 teaspoons) of blood will be collected and stored to allow the possibility of conducting tests at a later date.

RISKS

EVG/COBI/FTC/TAF (E/C/F/TAF)

E/C/F/TAF is a single-tablet regimen (STR, or "combination pill") containing four medications: elvitegravir (EVG), cobicistat (COBI), emtricitabine (FTC), and tenofovir alafenamide (TAF).

The following adverse reactions to treatment with E/C/F/TAF STR have been identified from two year-long clinical studies (GS-US-292-0104 and GS-US-292-0111) in which 866 treatment-naïve subjects received E/C/F/TAF STR:

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

- Headache
- diarrhea
- nausea

Common ($\geq 1\%$ and $< 10\%$):

- Vomiting
- abdominal pain
- dyspepsia (indigestion)
- flatulence (passing gas)
- rash
- fatigue

Tenofovir alafenamide is a new form of the anti-HIV drug, tenofovir. A study in dogs detected inflammation in the back portion of the eye (posterior uveitis) in some dogs when TAF was given at the highest doses. Across all Phase 2 and Phase 3 studies in which 2,394 subjects received E/C/F/TAF, eye disorders were uncommon, balanced between treatment arms, and most were considered by the investigator as unrelated to the study drugs. None were definitive for posterior uveitis, and none resulted in permanent discontinuation of study drugs. One subject in Study GS-US-292-0106 had an adverse reaction of intermediate uveitis (inflammation in the middle of the eye) that was considered related to study drug by the investigator but resolved while the subject continued on study drug without interruption. If you experience any visual disturbances or eye pain during this study, you should immediately report what you experienced to your doctor and be evaluated.

EVG/COBI/FTC/TDF (E/C/F/TDF)

Stribild™ is a combination medication containing four medications: elvitegravir (EVG), cobicistat (COBI), Emtriva® (FTC), and Viread® (TDF) in a single tablet form.

The following adverse reactions to treatment with Stribild have been identified.

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

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

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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)

In addition, side effects on the individual components of E/C/F/TDF STRs are described below:

Elvitegravir (EVG)

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 E/C/F/TDF STR.

Cobicistat (COBI)

COBI is associated with mild decreases in estimated kidney function, but does not affect actual kidney function. 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 COBI have been observed in clinical studies of COBI as an individual agent in addition to those listed above for E/C/F/TDF STR.

Tenofovir DF (TDF, Viread®)

Tenofovir DF has been studied in approximately 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.

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).

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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, was seen in animals following treatment with tenofovir DF. Decreases in bone mineral density have been seen in humans. The risk of bone fractures associated with these types of changes is unknown. One of the purposes of this study is to evaluate bone health using DEXA scans. Because reports of bone fractures have not been collected systematically, it is not possible to determine the rates at which these events happen.

If you are infected with hepatitis B virus (HBV), there is a possibility of an unexpected worsening of hepatitis B if you stop taking tenofovir DF.

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

Emtricitabine (FTC, Emtriva®)

The most common adverse reactions seen in at least than 10% of patients treated with FTC include headache, diarrhea, nausea, fatigue, dizziness, depression, trouble sleeping, abnormal dreams, rash, abdominal pain, weakness, increased cough and runny nose. The most common side effects seen in more than 10% of patients treated with FTC in combination with other anti-HIV drugs are headache, diarrhea, nausea, and rash.

Other common side effects seen more than 1% and less than 10% with emtricitabine include: vomiting, indigestion, changes in skin color primarily on the palms and/or soles, increased triglycerides (a type of fat in the blood), increased bilirubin in the blood (an indication of possible liver damage), increased sugar in the blood, allergic reaction, increased liver enzymes in the blood (an indication of possible liver damage), increased pancreatic enzymes in the blood (an indication of possible damage to the pancreas) and low white blood cell count. A reduction in your white blood cell count can make you more prone to infection. You may also experience muscle pain and increased muscle enzymes in the blood (an indication of possible muscle damage).

A serious condition called lactic acidosis (high levels of lactic acid in the blood), liver problems with enlargement of the liver and fat in the liver, including deaths were reported in HIV-infected patients

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treated with anti-HIV medications similar to emtricitabine. Symptoms of liver problems include yellowing of the skin or whites of the eyes, dark urine, light-colored bowel movements, and loss of appetite, nausea and lower stomach pain. If you notice any of these symptoms, you must immediately report them to the study doctor or staff.

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.

Autoimmune disorders such as Graves' disease (a disease in which the thyroid produces excessive thyroid hormones), polymyositis (a disease 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. Call your study doctor right away if you notice any signs or symptoms of an infection after starting study medication.

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

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.

DEXA

Decreases in bone mineral density have been observed in HIV-infected patients. An X-Ray called dual energy X-ray absorptiometry, or a DEXA scan, will be performed on your spine and hip to measure changes in bone mineral density.

DEXA scan will be performed at the Day 1 (baseline) visit, Weeks 24, 48, 72, 96, 120, 144 and then every

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24 weeks post Week 144 until the unblinding visit. It is possible that you will be asked to have a repeat DEXA scan in the case that the initial scan cannot be read.

DEXA scans involve exposure to radiation. Therefore, you will receive a radiation dose. This radiation dose is not necessary for your medical care and will occur only as a result of your participation in the study. At doses much higher than you will receive, radiation is known to increase the risk of developing cancer after many years. At the doses you will receive, it is very likely that you will see no effects at all.

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 will be reported to the PA Department of Health. You will be told, face-to-face, the results of these tests. Counseling will be available to you if necessary.

UNKNOWN/UNEXPECTED RISKS AND DISCOMFORTS

In addition to the risks listed above, there are risks that are not known or do not happen often when subjects take these study drugs, including severe or life-threatening allergic reactions, interactions between study drugs or interactions with another medication. You will be informed in a timely manner, both verbally and in writing of any new information, findings or changes to the way the research will be done that might influence your willingness to continue to take part in this study.

PREGNANCY AND BREAST-FEEDING

The effects of TAF and TDF have not been fully evaluated on the developing fetus in humans. Animal studies do not indicate direct or indirect harmful effects of TAF and TDF with respect to pregnancy. Because the effects of TAF and TDF 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, 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. Not having sex is the only certain way to prevent pregnancy.

If you are a sexually active male or female, it is required that you use a protocol recommended method of birth control from the screening visit throughout the study and for 30 days 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 (without spermicide); 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. If you are female and use hormonal contraceptives as one of your birth control methods you must have used the same method for at least 3 months before study drug dosing. Since the effect of the study drugs on hormonal contraceptives is unknown, if you are on hormonal contraceptives you must agree to a barrier method in addition to continuing your current hormonal contraceptives. Acceptable

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barrier methods include: diaphragm, cervical cap, and the male condom (without spermicide). If you are female, you must use either a hormonal method or a barrier method if the partner has a vasectomy.

Protocol-Recommended Contraceptive Methods

Methods to Use by Themselves	Combination Methods	
	Hormone Methods (choose one and use with a barrier method)	Barrier Methods (use both OR choose one and use with a hormone method)
Intra-uterine devices (IUDs) <ul style="list-style-type: none"> • Copper T 380A IUD • LNG 20 IUD 	Estrogen and Progesterone <ul style="list-style-type: none"> • Oral contraceptives • Transdermal patch • Vaginal ring 	<ul style="list-style-type: none"> • Diaphragm OR Cervical cap
Tubal sterilization	Progesterone <ul style="list-style-type: none"> • Injection • Implant 	<ul style="list-style-type: none"> • Male condom (without spermicide)
Partner's vasectomy must be used along with a hormone or barrier method.		

If you are a female who is sexually active and able to become pregnant, please speak with your study doctor to determine the best method of birth control for you to use during this study. Hormone-based contraceptives may not be effective at preventing pregnancy when they are used with study drug.

Even if you use a protocol recommended birth control method, 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 (problems during pregnancy, health of the baby at delivery, ie. Weight, APGAR scores) to Gilead. This information will be obtained by asking you about your pregnancy and its outcome; if you cannot recall the information, we may ask you to sign a release form so that the information can be obtained from your hospital records or from your obstetrician.

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 (except for lambskin) be used for all sexual activity to include oral, vaginal, and anal sexual contact. Condom use is

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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. Male subjects must agree to use condoms during heterosexual intercourse and avoid sperm donations while enrolled in the study and for 30 days after administration of the last dose of study drug.

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 taking part in this study, you and the Sponsor, Gilead Sciences, Inc., may benefit if E/C/F/TAF is effective in treating 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.

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.

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 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 study drug 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.

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PAYMENT FOR PARTICIPATION

You will be paid \$25.00 for your screening visit. For visits thereafter, Baseline and 12 visits through wk 144 (2, 4, 8, 12, 16, 24, 36, 48, 60, 72, 84, 96, 108, 120, 132 and 144 and for any additional study visits beyond week 144), you will be paid \$40 for every visit you attend. An additional payment of \$10 will be made at these visits if you bring back the study medication bottles dispensed at the last visit (empty or with any unused study drugs). An additional compensation of \$25 will be provided for regular study visits that require a DEXA scan; there are 7 DEXA scans required (Baseline and one every 24 wks to week 144). Please note that if a separate visit is required to complete the DEXA scan, \$46 will be provided as compensation. Thus if you attend all required visits, complete the 7 DEXA scans and return your medication bottles for the study through wk 144, the maximum payment you can receive is \$1050. If you stop taking study drugs early and complete the Early Study Drug Discontinuation Visit and return the study medication bottles, you will be compensated \$50. If a DEXA scan is needed at this visit, additional compensation of \$25 will also be provided. You will be compensated \$50 for the 30-Day Follow-Up Visit after the Early Study Drugs Discontinuation Visit. You will be compensated \$10 for any unscheduled visit that is requested by the study staff. The total payment 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 become sick or injured as a direct result of taking the study drug and/or following the study procedures, the University of Pennsylvania will provide you with medical treatment. The Sponsor, Gilead Sciences, Inc., will reimburse you or the University of Pennsylvania for the reasonable and necessary costs of such medical treatment. No other form of reimbursement for study-related injury or illness is offered by the Sponsor. You do not give up any legal rights by signing this form. You should immediately contact your Study Doctor at the contact information on page 1 of this form 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.

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. Your personal information may be given out if required by law. If you test positive for HIV, Hepatitis B or Hepatitis C, by law we have to report the infection to the City of Philadelphia Health Department/PA Department of Health. We would report your name, gender, racial/ethnic background, and the month and year you were born. This is to keep track of how many people in the U.S. have HIV infection. It is also to make sure that states get enough money from the federal government to support the medical care of people living with HIV. The Health Department does not share the names of HIV infected people with anyone else. It removes all personal identifiers, such as your name, before giving information on the number of HIV infections to the federal

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government. Please note that it is likely that this information has been already reported to the PA Health Department as the HIV test being done for this study is not the first test for you. 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 E/C/F/TAF (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 or placebo 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
- 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

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- 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 and regulatory agencies in other countries
- 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 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?

Since this is an open-label study, 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.

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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).

WHO CAN I CALL WITH QUESTIONS, COMPLAINTS OR IF I'M CONCERNED ABOUT MY RIGHTS AS A RESEARCH SUBJECT?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on page one of this form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Office of Regulatory Affairs with any question, concerns or complaints at the University of Pennsylvania by calling (215) 898-2614.

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.

STORAGE AND USE OF URINE SAMPLES

A portion of the urine samples taken at each visit, except screening, will be frozen and stored. The stored urine samples may be used by the Sponsor or its research partners for possible additional clinical analyses. At the conclusion of this study, these samples may be retained in storage by Gilead Sciences, Inc. for a period of up to 10 years.

STORAGE AND USE OF BLOOD SAMPLES

A portion of your blood sample drawn at each visit, except screening, will be frozen and stored. These stored blood samples and the information collected about you during the study may be used by the Study Sponsor or its research partners for HIV-1 genotyping/phenotyping assays 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 whether a mutation in an HIV-1 gene changes how anti-HIV drugs affect the HIV-1 virus. 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.

Blood Sample Storage for Future Research

As an optional part of this study, you are also being asked to allow the Study Sponsor to store your blood samples for future testing to learn more about how the study drug(s) has worked against HIV-1. From these samples, it might also be possible to learn more about what causes HIV-1, how to prevent HIV, or how to better treat HIV. These samples may be also be used for purposes that are not yet known.

If you choose to allow your samples to be banked for future research, about 14 mL (about 3 teaspoons) of blood will be drawn at all study visits (starting at Day 1) to be frozen and stored. If you do not agree to banking of your samples, you can still take part in the main research study.

You should also know that the Sponsor and other researchers who may study your blood samples have an economic interest in developing new drugs and medical tests. The results of this research may lead to a commercial product for the diagnosis, cure, mitigation, treatment, or prevention of disease. You understand and agree that by consenting to the storage of your samples for possible future research, you authorize the use of your sample, the by-products of the sample, and any products developed from the sample as described by this form. The Sponsor or other researchers or research companies may patent or sell discoveries that result from this research. Neither the Sponsor nor the Study Doctor has any plans to compensate you if this happens.

Withdrawing consent to the storage and future testing of your sample will result in destruction of your sample. However, if you withdraw your consent after the sample has been tested, the test results and research study/sample-related information must remain in any database(s) that were created for the research study. The reason for this is to comply with regulations that require the Sponsor to make data available for review by the United States Food and Drug Administration (FDA) or other appropriate regulatory authorities, or if this research is used to support an application for FDA approval to market the study drug.

If you withdraw consent for participation in the main study or are discontinued from the main study, the blood sample you provided will continue to be available for storage and future testing unless you also withdraw your consent for this purpose as stated above.

Please initial next to one of the statements below to indicate whether or not you agree to allow storage of your samples for possible future research outside of the main research study.

Yes_____ No_____ I agree to allow my blood samples to be stored for future research outside of the main research study.

