HOSPITAL OF THE UNIVERSITY OF PENNSYLVANIA

A5308, Version 1.0, 09/13/12; LOA# 1, 2/19/13; LOA #2 4/11/14

A Prospective, Single-Arm, Open-Label Study to Evaluate the Effect of Fixed-Dose Emtricitabine/Rilpivirine/Tenofovir Disoproxil Fumarate on T-Cell Activation, Absolute CD4+ T-Cell Count, Inflammatory Biomarkers and Viral Reservoir in Treatment-Naïve HIV-1 Controllers

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

Your contacts for this study are:

Principal Investigator:	Pablo Tebas, MD	(215) 349-8092
Coordinator:	Joseph Quinn, RN, BSN	(215) 349-8092
Study Nurse:	Aleshia Thomas, RN, BSN	(215) 349-8092

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

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Introduction:

You are being asked to take part in this research study because you are infected with the human immunodeficiency virus (HIV-1), you do not show any symptoms of the virus, and your immune system has been able to control the virus without HIV medication. This study is sponsored by the National Institutes of Health (NIH). The doctor in charge of this study at this site is: Dr. Pablo Tebas. Before you decide if you want to be a part of this study, we want you to know about the study.

This is a consent form. It gives you information about this study. The study staff will talk with you about this information. You are free to ask questions about this study at any time. If you agree to take part in this study, you will be asked to sign this consent form. You will get a copy to keep.

Why Is This Study Being Done?

This study is being done with people who are infected with HIV, but do not show any signs of having HIV, and are doing well without taking HIV medication. The purpose of this study is to see if taking HIV medication (antiretroviral therapy [ART]) will reduce immune activation (your body's way of fighting disease) in people who have HIV, but do not show symptoms. Also this study will help determine how safe the drug is and how well your body reacts to the drug.

For this study, the following ART will be provided in the form of a single tablet that contains three different drugs: emtricitabine/rilpivirine/tenofovir disoproxil fumarate (FTC/RPV/TDF). These drugs are combined as one tablet which is approved by the Food and Drug Administration (FDA) as a single pill to treat HIV infection. The HIV medication provided is one of the recommended treatments for people with low viral loads (how much HIV you have in your body) who are taking HIV drugs for the first time. In people with low viral loads, this HIV medication works just as well as other HIV medications. The risks seen with this HIV medication are the same that you would encounter when taking these drugs outside of the study.

What Do I Have To Do If I Am In This Study?

Screening

If you would like to be in this study, after you have read and signed this informed consent form, you will come to the clinic for a screening visit to make sure you meet the requirements for joining the study. This visit will take about 1-2 hours. At this visit:

- Your HIV infection status will be confirmed. If there is no record available, another HIV test will be done. You may have to sign a separate consent form before this is done.

- The site staff will make sure that you do not show any resistance to the study medications (resistance means that the drugs are not likely to fight the HIV in your body). A blood test called a genotype which tests to see if the virus in your blood is resistant will be done before you can enter the study. If you have had this test before, you will not need to have it again. If you have not had this test before, you will need to have it before entering the study. The test will be provided by the study. Results must be available from testing any time in the past or from recent testing and must be reviewed by your study doctor. If the results of your resistance test show a "no result," you will be able to enroll in the study if you meet all other study requirements. There is, however, a small chance that your body has some resistance that doesn't show up in tests.

- You will be asked questions about your medical history and any medications you are taking or have taken within the last 24 months.

- You will have a complete physical exam, including your weight.

- You will have about 2 tablespoons (30 mL) of blood drawn to measure your viral load (the amount of HIV in your blood), to see if you are infected with the hepatitis B and/or C virus (an infection of the liver), and for routine lab tests for safety.

- If you are a woman able to become pregnant, you will be asked to give a urine sample or have an additional 1 teaspoon (5 mL) of blood drawn to see if you are pregnant. This test must show that you are not pregnant for you to enroll in the study.

<u>If you do not enroll into the study</u>

If you decide not to take part in this study or if you do not meet the eligibility requirements, we will still use some of your information. As part of this screening visit, some demographic (for example, age, gender, race), clinical (for example, disease condition, diagnosis), and laboratory (for example, CD4 cell count, viral load) information is being collected from you so that ACTG (AIDS Clinical Trials Group) researchers may help determine whether there are patterns or common reasons why people do not join a study.

<u>Entry</u>

If you are eligible for the study, you will come in for an entry visit. This visit will take about 1-2 hours. At this visit

- You will be asked what your lowest CD4+ cell count has ever been.

- You will have a brief physical exam, including your temperature, pulse, respiration rate, blood pressure, height, and weight.

- You will be asked questions about your medical history and any medications you are taking or have taken within the last 24 months.

- You will have about 11 and a half tablespoons (170 mL) of blood drawn to measure the amount of HIV in your blood, to measure your CD4+ and CD8+ cell counts, for immunologic studies, for viral reservoir testing (where HIV is hidden in your body), and for routine lab tests for safety. You will also have a blood test which may help us to understand your immune responses (how well your body fights infection). Some of these tests will be performed after the study ends, and some of the blood that you provide may be sotred for future protocol-required testing.

- If you are a woman and think you might be pregnant, you will have a pregnancy test. This test must show that you are not pregnant for you to enroll in the study.

- You will be asked to complete a questionnaire about your quality of life

Study Visits

After your entry visit, you will come to the clinic at weeks 4, 12, 16, 24, 36, 48, and 60. These study visits will last about 30 minutes.

During Most Study Visits

- You will be asked about your health and any changes in your medicines since your last visit.

- You will have a brief physical exam at weeks 12, 24, 48, and 60, including your temperature, pulse, respiration rate, blood pressure, and weight.

- You will have about 3 tablespoons (50 mL) of blood drawn for routine safety tests, to measure the amount of HIV in your blood, to measure your CD4+ and CD8+ cell counts, and for viral reservoir testing. Some of these tests will be performed after the study ends.You will not have blood taken to measure the amount of HIV in your blood at week 4 and you will not have blood taken to measure your CD4+ and CD8+ cell count at week 4 and week 16.

- You will be told the results of HIV viral load tests, CD4+ and CD8+ cell counts, pregnancy tests, and routine blood tests done on this study. You will not be told the result of your viral reservoir test. If at any time during the study your CD4+ count drops too low (below 350 cells/mm^3), you may need to start taking HIV medication if you are not already taking it.

- You will have about 5 tablespoons (75 mL) of blood drawn to for immunologic studies at weeks 12, 16, 36, and 60. At week 12 you will have only about 2 tablespoons (35 ml) of blood drawn for these immunologic studies.

- You will have about 3 tablespoons (50 mL) of blood drawn and stored for future protocol required testing. You will not have blood taken for this purpose at your week 16 visit.

- For all study visits up until week 60, you will only have a pregnancy test if you think you might be pregnant.

- You will be asked to complete a questionnaire about how well you are taking your HIV drugs.

- You will be asked to complete a questionnaire about your quality of life at weeks 12, 16, 36, and 60.

Week 12

- You will receive and begin to take FTC/RPV/TDF.

- If you are a woman able to become pregnant, you will have a pregnancy test at your week 12 visit before beginning study medication (FTC/RPV/TDF).

Week 60 Visit

After completing the week 60 evaluations, your study doctor or nurse will discuss with you your options for continuing on the study or not. Continuing on the study is completely optional. You will not be penalized if you decide not to continue the study and your study doctor or nurse will discuss other treatment options with you.

If you decide to continue the study, you will be asked whether or not you would like to continue to receive the study medication. Your decision of whether or not to continue to take study medication will not affect your ability to continue on the study. At any time, you may choose to begin non-study medication, but it will not be provided by the study. If you decide to take non-study medication or receive no study medication, you will not be able to switch to study medication later on. If you decide to continue to take study medication at week 60, you will continue to receive FTC/RPV/TDF.

Continued Study Visits

If you decide to continue the study, you will come to the clinic at weeks 72, 84, and 108. These study visits will last about 30 minutes.

Week 72 Visit

- You will be asked about your health and any changes in your medicines since your last visit.

- You will have your weight measured.

- You will have about 6 and a half tablespoons (100 mL) of blood drawn, for routine blood safety tests, to measure the amount of HIV in your blood, to measure your CD4+ and CD8+ cell counts, and for viral reservoir testing. Some of these tests will be performed after the study ends and some of the blood that you provide may be stored for future protocol-required testing.

- If you are a woman and think you might be pregnant, you will have a pregnancy test.

- You will be asked to complete a questionnaire about how well you are taking your HIV drugs.

Week 84 and 108 Visits

- You will be asked about your health and any changes in your medicines since your last visit.

- You will have a brief physical exam at your week 108 visit, including your temperature, pulse, respiration rate, blood pressure, and weight.

- If you are a woman and you think you might be pregnant, you will have a pregnancy test.

- You will have about 12 tablespoons (180 mL) of blood drawn to measure the amount of HIV in your blood, to measure your CD4+ and CD8+ cell counts, for routine safety tests, for immunologic studies, and for viral reservoir testing. You will also have a blood test which may help us to

understand your immune responses. Some of these tests will be performed after the study ends and some of the blood that you provide may be stored for future protocol-required testing.

- You will be asked to complete a questionnaire about how well you are taking your HIV drugs.

Confirmation of Virologic Failure
At or after week 24, if the result of your viral load test shows that your HIV drugs may not be fighting your HIV infection well, you will be asked to return to the clinic.

- You will have about 1 tablespoon (15 mL) of blood drawn to measure the amount of HIV in your blood and for an HIV resistance test.

- If you are a woman and think you might be pregnant, you will have a pregnancy test.

Even if your HIV medicine is not fighting your infection well, we will ask you to continue your study visits. You and your doctor may decide to stop your study medication and switch to an HIV treatment that is not provided by the study if your doctor thinks it might work better for you.

Viral Decay Component
A small group of people (about 30) enrolled in A5308 will have the opportunity to participate in a viral decay component of the study. This component will help determine how quickly your HIV-1 virus is eliminated from your blood after starting ART. If you agree to participate in this component of the study, you will have an additional 30 mL of blood drawn (about 2 tablespoons) at each viral decay study visit. Some of your blood will also be stored for protocol-required tests to be done after the study ends.

You will be asked to come in to the clinic for 6 extra study visits between study weeks 13 through 20. These visits will take no longer than 30 minutes. You will also be asked to keep a medication diary for the first 2 weeks of the viral decay component of the study to help track when you take your medication. If you miss any dose of the study medication in the first 14 days, you will be taken off the viral decay component of the study. This will not affect your participation in the main study.
Please write your initials in one of the spaces below. You will be treated the same in the study no matter which you choose.

_____YES, I agree to participate in the viral decay component of the study.

_____NO, I do not want to participate in the viral decay component of the study.

If You Have to Stop Taking the Study Drugs Early or You Have to Stop the Study Early

If you stop taking the study drugs or leave the study early, you will be asked to come to the clinic for an additional study visit. At this visit:

- You will have a brief physical exam, including your temperature, pulse, respiration rate, blood pressure, and weight.

- You will be asked about your health and any changes in your medicines since your last visit.

- You will have about 12 and a half tablespoons (182 mL) of blood drawn to measure the amount of HIV in your blood, for resistance testing, to measure your CD4+ and CD8+ cell counts, for routine

safety tests, for immunologic studies, and for viral reservoir testing. If you are in Step 2 and you have to stop the study early, you will only have about 9 and half tablespoons (142 ml) of blood drawn. Some of these tests will be performed after the study ends and some of the blood that you provide may be stored for future protocol-required testing.

- If you are a woman and think you might be pregnant, you will have a pregnancy test.
- You will be asked to complete a questionnaire about how well you are taking your anti-HIV drugs.
- You will be asked to complete a questionnaire about your quality of life (this questionnaire will not be given to you in the second part of the study).
- Your study doctor or nurse will discuss other treatment options which will not be provided by the study.

Other
Some of your blood that is leftover after all required study testing is done may be stored (with usual steps taken to protect your confidentiality) and used for ACTG-approved HIV-related research, separate from this study (non-A5308 research). These samples may be held for an indefinite length of time. Storage of leftover blood is not a requirement to participate in the study and you may withdraw your approval for the storage of your leftover blood at any time. We cannot ensure that you will be told of the results of the research done on these samples. *Please indicate with your initials below whether you agree to have your leftover blood samples stored.*

_____ YES _____ NO

How Many People Will Take Part in This Study?
57 people will take part in this study. Only 1-3 people are expected to enroll at the University of Pennsylvania.

How Long Will I Be In This Study?
You will be in this study for up to 108 weeks (about 2 years and 3 months). The first part of the study is 60 weeks (about 1 year and 3 months) and the second part of the study is an optional 48 weeks (about 1 year). You do not have to participate in the second part of the study.

Why Would The Doctor Take Me Off This Study Early?
The study doctor may need to take you off the study early without your permission if:
- the study is cancelled
- you are not able to attend the study visits as required by the study
- your primary care physician no longer thinks that participating in the study is in your best interest

The study doctor may also need to take you off the study drug without your permission if:
- continuing the study drug may be harmful to you
- you need a treatment that you may not take while on the study
- you are not able to take the study drug as required by the study
- you become pregnant or begin breastfeeding

If you must stop taking the study drug before the study is over, the study doctor may ask you to continue to be part of the study and return for some study visits and procedures.

If I have to permanently stop taking study-provided FTC/RPV/TDF or once I leave the study, how would FTC/RPV/TDF be provided?

During the study:
If you must permanently stop taking study-provided FTC/RPV/TDF before your study participation is over, the study staff will discuss other options that may be of benefit to you.

After the study:
After you have completed your study participation, the study will not be able to continue to provide you with FTC/RPV/TDF you received on the study. If continuing to take these or similar drugs/agents would be of benefit to you, the study staff will discuss how you may be able to obtain them.

What Are The Risks Of The Study?
Any time HIV-infected people take therapy to treat their HIV infection, there is a risk that their virus may mutate (change) to become less sensitive to the medications they are taking and to other closely-related medications. This means that the medication might not work as well to fight their HIV. To reduce this risk, we encourage you to take the medications as prescribed by your doctor, to not miss doses, and to stop all the study medications at the same time if they need to stop. If you stop study drugs or meet the protocol definition of virologic failure while taking HIV drugs, blood will be drawn for test to see if your virus has become resistant. The site staff will share the results of the test with you and provide more information about your choices at that time.

It is not known for how long the immune system can control the amount of HIV in your blood stream and over time, the amount of virus in your blood might change. It is also unknown what effect the HIV drugs will have on your immune system's ability to respond to the virus. Although, in theory, there is a risk of changing your immune system with HIV drugs, in most individuals who take HIV drugs for a short period of time, including pregnant women, the immune system goes back to the way it was before and the amount of HIV virus in the blood remains the same as it was before they started taking study drugs.

Risks of Drawing Blood
Having blood drawn may cause some discomfort, lightheadedness, bleeding, swelling, or bruising where the needle enters the body, and in rare cases, fainting, or infection.

Risks of HIV Drugs
The drugs used in this study may have side effects, some of which are listed below. Please note that these lists do not include all the side effects seen with these drugs. These lists include the more serious or common side effects with a known or possible relationship. If you have questions concerning the additional study drug side effects please ask the medical staff at your site.

There is a risk of serious and/or life-threatening side effects when non-study medications are taken with the study drugs. For your safety, you must tell the study doctor or nurse about all medications you are taking before you start the study and also before starting any new medications while on the study. Also, you must tell the study doctor or nurse before enrolling in any other clinical trials while on this study

Use of Combination Antiretroviral Drugs
Immune Reconstitution Syndrome:
In some people with advanced HIV infection, symptoms from other infections or certain diseases may occur soon after starting combination anti-HIV treatment but can also occur later. Some of these symptoms may be life threatening. If you start having new symptoms, or notice that existing symptoms are getting worse after starting your antiretroviral therapy, tell your healthcare provider right away.

The use of potent antiretroviral drug combinations may be associated with an abnormal placement of body fat and wasting. Some of the body changes include:

- Increase in fat around the waist and stomach area
- Increase in fat on the back of the neck
- Thinning of the face, legs and arms
- Breast enlargement

Use of Nucleoside Analogues (NRTIs)
Lactic acidosis (elevated lactic acid levels in the blood) and severe hepatomegaly (enlarged liver) with steatosis (fatty liver) that may result in liver failure, other complications or death have been reported with the use of antiretroviral nucleoside analogues alone or in combination. The liver complications and death have been seen more often in women who are on these drug regimens. Some nonspecific symptoms that might indicate lactic acidosis include: unexplained weight loss, stomach discomfort, nausea, vomiting, fatigue, cramps, muscle pain, weakness, dizziness and shortness of breath.

Risks of Emtricitabine (FTC, Emtriva)
The following side effects have been associated with the use of emtricitabine:

- Headache
- Dizziness
- Tiredness
- Inability to sleep, unusual dreams
- Loose or watery stools
- Upset stomach (nausea) or vomiting
- Abdominal pain
- Rash, itching, which sometimes can be a sign of an allergic reaction
- Skin darkening of the palms and/or soles
- Increased cough
- Runny nose
- Abnormal liver function tests, which could mean liver damage
- Increases in pancreatic enzyme (substances in the blood), which could mean a problem with the pancreas
- Increased triglycerides
- Increased creatine phosphokinase (CPK), which could mean muscle damage

NOTE: If you are infected with both hepatitis B and HIV, you should be aware that your liver function tests may increase, and symptoms associated with hepatitis (an acute inflammation of the liver) may worsen if emtricitabine is stopped

Risks of Tenofovir Disoproxil Fumarate (Tenofovir DF, TDF, VIREAD)
The following side effects have been associated with the use of tenofovir:

- Upset stomach, vomiting, gas, loose or watery stools
- Generalized weakness
- Dizziness
- Depression
- Headache
- Abdominal pain
- Worsening or new kidney damage or failure
- Inflammation or swelling and possible damage to the pancreas and liver
- Shortness of breath
- Rash
- Allergic reaction: symptoms may include fever, rash, upset stomach, vomiting, loose or watery stools, abdominal pain, achiness, shortness of breath, a general feeling of illness or a potentially serious swelling of the face, lips, and/or tongue
- Bone pain and bone changes such as thinning and softening which may increase the risk of breakage
- Muscle pain and muscle weakness

NOTE: If you are infected with both hepatitis B and HIV, you should be aware that your liver function tests may be abnormal, and symptoms associated with hepatitis (an acute inflammation of the liver) may worsen if tenofovir is stopped.

Risks of Rilpivirine (RPV, Edurant)
The following serious side effects have been associated with the use of rilpivirine:

- Depression or mood changes. Be sure to contact your health care provider immediately if you are feeling sad or hopeless, feeling anxious or restless, or have thoughts of hurting yourself (suicide) or have tried to hurt yourself.

Additional side effects include:

- Trouble sleeping
- Headache
- Rash

Are There Risks Related To Pregnancy?
It is not known whether the drug or drug combination in this study harm unborn babies.
If you are having sex that could lead to pregnancy, you must agree not to become pregnant or make a woman pregnant.

If you are a woman and you can become pregnant you must agree to use at least one reliable form of birth control. You must continue to use birth control until 6 weeks after stopping study drug.

Reliable methods of birth control are:

- Birth control medications that prevent pregnancy given as pills, shots, or placed on or under the skin
- Male or female condoms with or without a cream or gel that kills sperm
- Diaphragm or cervical cap with a cream or gel that kills sperm
- Intrauterine device (IUD)
- NuvaRing

Some of the birth control methods listed above may not prevent spreading HIV and some may increase the risk of getting HIV and giving it to others.

If you can become pregnant, you must have a pregnancy test before you enter this study. The test must show that you are not pregnant. If you think you may be pregnant at any time during the study, tell your study staff right away. You will be taken off of study drug and you will be asked to come back to the clinic for your remaining study visits. The study staff will talk to you about your choices.

This study will not provide care related to your pregnancy, the delivery of your baby or the care of your baby. You must arrange for your care and your baby's care outside of this study.

If you become pregnant while you are on the study, your doctor will contact you about your birth outcome. With your permission, you will be asked questions about the birth outcome (length of pregnancy, type of delivery, APGAR scores). If you are unable to recall the information, you may be asked to sign a medical release for information, so that the research staff can request your records from the delivery center or your obstetrician. The information that you provide will be reported to the Antiretroviral Pregnancy Registry.

Breastfeeding
It is unknown whether the study drug or study drug combinations pass through the breast milk and may cause harm to your infant.

Are There Benefits to Taking Part in This Study?

If you take part in this study, there may be a direct benefit to you in terms of a reduction in viral load and/or an increase in your CD4+ cell count, but no guarantee can be made. It is also possible that you may receive no benefit from being in this study. Information learned from this study may help others who have HIV.

What Other Choices Do I Have Besides This Study?

Instead of being in this study you have the choice of:

- treatment with prescription drugs available to you.
- treatment with experimental drugs, if you qualify.
- no treatment.

Please talk to your doctor about these and other choices available to you. Your doctor will explain the risks and benefits of these choices.

What About Confidentiality?

We will do everything we can to protect your privacy. In addition to the efforts of the study staff to help keep your personal information private, we have obtained a Certificate of Confidentiality from the U.S. Federal Government. This certificate means that researchers cannot be forced to tell people who are not connected with this study, such as the court system, about your participation. Also, any publication of this study will not use your name or identify you personally.

People who may review your records include the University of Pennsylvania institutional review board (IRB), National Institutes of Health (NIH), Office for Human Research Protections (OHRP), AIDS Clinical Trials Group (ACTG), pharmaceutical supporters or designees, study staff, and study

monitors. Having a Certificate of Confidentiality does not prevent you from releasing information about yourself and your participation in the study.

Even with the Certificate of Confidentiality, if the study staff learns of possible child abuse and/or neglect or a risk of harm to yourself or others, we will be required to tell the proper authorities.

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

HIPAA AUTHORIZATION
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
- Information from questionnaires administered in the study
- Results of tests and procedures you will undergo during this research study
- Social Security Number

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 Companies: Gilead Sciences who supplies drug for the study.
- ACTG Data Coordinatin g Center, Frontier Science Technology Research Foundation (FSTRF): Data for this study will be recorded on case report forms, keyed into a central database and electronically submitted to the Data Coordinating Center. The data will be cleaned and stored at this facility until it is ready to be analyzed.
- Statistical Data Analysis Center (SDAC): Approved data will be downloaded from FSTRF to the statistical data center for the AACTG at the Harvard School of Public Health. Specific study reports will be periodically provided to the study team and data safety review board to monitor if the trial is safe.
- Contract Research Organization (PPD, Inc): Monitors from PPD will visit the AACTG on a quarterly basis to review data and correct mistakes before the data are sent to SDAC for analysis.
- Government Agencies: Data from this study will be made available to the Food and Drug Administration and to the National Institutes of Health/Division of AIDS (DAIDS)/National Institute for Allergy and Infectious Disease (NIAID), for them to evaluate the safety and efficacy of the treatments being used in this study.

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 drug 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 database. However, 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

- The University of Pennsylvania's Institutional Review Board grants permission
- As permitted by law

Can I change my mind about giving permission for use of my information?
Yes. You may withdraw or take away your permission to use and disclose your health information at any time. 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, you will not be able to stay in this study.

What if I decide not to give permission to use and give out my health information?
Then you will not be able to be in this research study.

You will be given a copy of this Research Subject HIPAA Authorization describing your confidentiality and privacy rights for this study. You will also be given the UPHS and School of Medicine's Notice of Privacy Practices that contains more information about the privacy of your personal health information.

What is an Electronic Medical Record?
An Electronic Medical Record (EMR) is an electronic version of the record of your care within a health system. An EMR is simply a computerized version of a paper medical record.

If you are receiving care or have received care within the University of Pennsylvania Health System (UPHS) (outpatient or inpatient) and are participating in a University of Pennsylvania research study, results of research-related procedures (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in your existing EMR maintained by UPHS.

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

Once placed in your EMR, these results are accessible to appropriate UPHS workforce members that are not part of the research team. Information within your EMR may also be shared with others who are determined by UPHS to be appropriate to have access to your EMR (e.g. health insurance company, disability provider, etc).

What Are the Costs To Me?
Taking part in this study may lead to added costs to you and your insurance company. In some cases it is possible that your insurance company will not pay for these costs because you are taking part in a research study. Study drugs other than FDC (FTC/RPV/TDF) will not be provided by the study. Study drug will not be provided after you complete the study.

Will I Receive Any Payment?

You will be compensated $20 for the screening visit, then $50 for each of the study required visits (8 for Part I and 3 for Part II). Compensation will be given as cash. The total amount of compensation for the study is $550 if all visits are attended. If you are required by the study staff to come in for any additional unscheduled visits (usually to check a lab value), you will be compensated $25 for every visit. There is no other form of compensation available such as reimbursements for parking, tokens or child care.

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 a Individual Tax Identification number or Social Security Number for tax purposes.

What Happens If I Am Injured?

If you are injured as a result of being in this study, you will be given immediate treatment for your injuries. The cost for this treatment will be charged to you or your insurance company. There is no program for compensation either through this institution or the NIH. You will not be giving up any of your legal rights by signing this consent form.

What Are My Rights As a Research Subject?

Taking part in this study is completely voluntary. You may choose not to take part in this study or leave this study at any time. Your healthcare provider will treat you the same no matter what you decide.

We will tell you about new information from this or other studies that may affect your health, welfare, or willingness to stay in this study. If you want the results of the study, let the study staff know.

What Do I Do If I Have Questions Or Problems?

If you have questions about this study or a research-related injury, please contact the research team listed on page 1 of this consent form.

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

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

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.

A copy of this consent form will be given to you. You will also be given the University of Pennsylvania Health System and School of Medicine's Notice of Privacy Practices that contains more information about the privacy of your health information.

Name of Subject (Please Print)	Signature of Subject	Date
Name of Person Obtaining Consent (Please Print)	Signature	Date
Witness's Name (print) (As appropriate)	Witness's Signature and Date	