UNIVERSITY OF PENNSYLVANIA HEALTH SYSTEM

HPTN 069 Version 2.0, April 9, 2012 (DAIDS Document ID: 11789):
A Phase II Randomized, Double-Blind, Study of the Safety and Tolerability of Maraviroc (MVC), Maraviroc + Emtricitabine (MVC+FTC), Maraviroc + Tenofovir disoproxil fumarate (MVC+TDF), or Tenofovir disoproxil fumarate + Emtricitabine (TDF+FTC) For Pre-Exposure Prophylaxis (PrEP) To Prevent HIV Transmission in At-Risk Men Who Have Sex with Men

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

Your contacts for this study are:

Principal Investigator:	Ian Frank, MD	(215) 662-7419
Coordinator:	Joseph Quinn, RN, BSN	(215) 349-8092
Study Nurse:	Randee Silverman, RN, BSN	(215) 349-8092

Office: 502 Johnson Pavilion
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 a research study. Joining this study is voluntary. You may refuse to join, or you may withdraw your consent to be in the study, for any reason. This research study is for men who may be a risk for getting Human Immunodeficiency Virus, or HIV. HIV is the virus that causes Acquired Immunodeficiency Syndrome, or AIDS. This study is sponsored by the Division of AIDS, U.S. National Institute of Allergy and Infectious Diseases, US National Institutes of Health. Study products are provided by Gilead Sciences, Inc. and Viiv Healthcare.

Before you decide whether to join the study, we would like to explain the purpose of the study, the risks and benefits to you, and what is expected of you.

A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by U.S.law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Your participation is voluntary which means you can choose whether or not you want to participate. If you choose not to participate, there will be no loss of benefits to which you are otherwise entitled. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. The research team is going to talk to you about the research study, and they will give you this consent form to read. You may also decide to discuss it with your family, friends, or family doctor. You may find some of the medical language difficult to understand. Please ask the study doctor and/or the research team about this form. If you decide to participate, you will be asked to sign this form. You will get a copy to keep.

If you decide not to take part in the study, you can still join another study at a later time if there is one available and you qualify.

You cannot join this study if you are taking part in another study of drugs or medical devices. You are asked to tell the study staff about any other studies you are taking part in or thinking of taking part in. This is very important for yor safety.

PURPOSE OF THE STUDY

This study will help us to understand the safety of the drugs being used in the study, as well as how well people who take them can handle them (meaning, do they make you feel sick, which is referred to as "tolerability"). This study is not being done to prevent HIV infection. The drugs used in this study are approved for treatment of people with HIV infection. We want to know if these same drugs are safe to take in people who are not HIV-infected. The study is being done in men who have sex with men who may be at risk for getting HIV infection through having sex. The drugs in this study are called maraviroc (also called Selzentry or MVC), emtricitabine (also called Emtriva or FTC), and tenofovir (also called Viread or TDF). These are all a type of drug called antiretrovirals.

Background
Other studies have been done or are being done to see if antiretrovirals can prevent HIV infection. We do not yet know the results of all of these studies.

On July 16, 2012, the U.S. Food and Drug Administration (FDA) approved Truvada (a fixed dose combination of emtricitibine [FTC] and tenofovir disoproxil fumarate [TDF]) "to be taken once daily and used in combination with safer sex practices to reduce the risk of sexually acquired HIV-1 infection in adults who do not have HIV but are at high risk of becoming infected." This is the first time that a drug known to be effective when used in combination with other antiretrovirals to treat HIV infection has also been approved to help someone who is not HIV-infected to reduce their risk of becoming infected.

The approval of Truvada for this use is based in part on a previous study in men who have sex with men, called iPrEX. The iPrEX trial enrolled close to 2,500 HIV-negative men or transgender women who have sex with men who were at higher risk for acquiring HIV infection, to see whether Truvada would lower their chances of becoming HIV-infected. As explained in the HPTN 069/ACTG 5305 study informed consent, the iPrEX study showed that FTC and TDF (Truvada) taken together daily might lower the risk of acquiring HIV in MSM. Some of the men given these drugs in the iPrEX study took the drugs more regularly; these men seemed to have been more likely to be protected against HIV than men who did not take the drugs regularly.

No new side effects were identified in the iPrEX study. The most common side effects reported with Truvada included diarrhea, nausea, abdominal pain, headache, and weight loss. Serious adverse events in general, as well as those specifically related to kidney or bone toxicity, were uncommon.

Two other studies also showed support for the use of antiretrovirals for HIV prevention. The CDC TDF-2 trial showed that daily TDF/FTC was safe and effective for prevention of HIV infection among African heterosexual men and women compared to placebo. The Partners PreP Study, which enrolled African heterosexual couples (one HIV positive and the other HIV negative), compared TDF once daily and TDF/FTC once daily regimens versus placebo. The TDF and TDF/FTC PrEP demonstrated a lower chance of getting HIV. Both studies showed that taking these drugs in this manner was safe and well-tolerated.

The approval of Truvada for use in people who are HIV-uninfected does not change the purpose of conducting HPTN 069/ACTG 5305. Despite the encouraging findings that led to Truvada's approval for use in HIV-uninfected adults to reduce their risk of sexually acquired HIV-1 infection, we still need to see if other drugs or combinations of drugs are safer, better tolerated, or might be better at preventing HIV infection. HPTN 069/ACTG 5305 is examining the first two of these research questions.

The three drugs used in this study have all been shown to be safe in people with HIV. Two of the drugs, FTC and TDF, also appear to be safe in people without HIV and to protect against HIV, but more research is needed to confirm this. The third drug, maraviroc, has not yet been studied very much in people without

HIV. In this study we will look at safety and tolerability when using different combinations of these three drugs in people without HIV. The results of this study will help us decide whether maraviroc could be used in a larger study to see if it prevents people from getting HIV.

HIV comes in 2 types, R5 virus and X4 virus. Almost all new HIV infections occur with R5 virus. Maraviroc is a drug that prevents R5 viruses from entering cells; however, it has no effect on X4 viruses. Other HIV drugs, including tenofovir and emtricitabine, work against both R5 and X4 viruses. It is possible that someone taking maraviroc (alone) could get infected with X4 virus. Adding tenofovir or emtricitabine to maraviroc could work against both R5 and X4 viruses. We do not know if having drugs that work against both kinds of HIV viruses is important in trying to prevent infection by using antiretrovirals.

The United States Food and Drug Administration (FDA) has been informed of this study and has permitted it to be conducted. The United States National Institutes of Health (NIH) is funding this study. About 400 men in the United States will be in this study. About 20-30 men will be in the study here at the University of Pennsylvania. The whole study will take about 2 years to finish. Each person will be in the study for about a year.

There may be no direct benefits for you if you participate in this study. There also may be some risks with taking part in the study. Before you can make an informed decision about whether to take part in this study, you should understand the possible risks and potential benefits of being in this study. This informed consent form gives information about the study that will be discussed with you. Once you understand the study, and if you agree to take part, you will be asked to sign your name on this form.

You will be offered a copy of this form to keep.

STUDY GROUPS

If you decide to take part in the study, you will be placed in 1 of 4 groups. Each group will have 100 people. Each group will get a combination of the study drug(s) and placebo pills. Each group contains one or more of the active ("real") study drugs. As mentioned above, placebo pills look and feel like the active or "real" drugs but they do not have the drugs or any other medicine in them. The groups will look like this:

One group will get maraviroc + placebo pill + placebo pill

One group will get maraviroc + FTC + placebo pill

One group will get maraviroc + TDF + placebo pill

One group will get TDF + FTC + placebo pill

All 4 groups will get 3 pills. The 3 pills are to be taken every day. The study staff and you will not know which group or drugs you are taking. This is because we do not want to have any influence on how the results of the study will come out. Within about 6 months after the study ends, you will be told which drugs you got. Until then, no one will be told.

The study group that you will be in will be chosen randomly, like flipping a coin. You cannot choose your group, and the study staff cannot choose your group for you. You have an equal chance of being placed in each group.

No matter what group you are in, you must remember that we only know that TDF and FTC when taken together might lower the chances of getting HIV. And in this study, you will not know which group you are

in until the study is over. We also do not know if the other combination of study drugs we are using in this study will protect you from getting HIV. One of the best things you can do to protect yourself against getting HIV during sex is to use a condom every time you have sex.

STUDY PROCEDURES

If you decide to join the study, you will be asked to come to the Clinical and Translational Research Center on 1 Dulles at the Hospital of the University of Pennsylvania over the course of a year for approximately 10 times.

Screening Visits

Your first screening visit will happen after you read, discuss, understand, and sign this form. We will help you understand the form and answer your questions before you sign this form. The procedures done at these visits will take about 1-2 hours.

At Screen Visit 1, the study staff will:

- Ask you where you live and other questions about you, your medical health, your sexual practices, and whether you use alcohol or drugs.
- Talk with you about HIV and ways to protect yourself from getting it.
- Collect urine from you to check the health of your kidneys.
- Collect ~40 mL (about 8 teaspoons) of blood for HIV testing , hepatitis B testing, to check your general health and the health of your liver and kidneys,

At Screen Visit 2, the study staff will:

- Give you a brief physical exam to make sure you are healthy.
- Collect ~80 mL (about 6 tablespoons) of blood for very sensitive HIV testing, to check your general health and the health of your liver and kidneys, a vitamin D test, and for storage for study-related testing and long-term storage (if you provide consent).
- Give you condoms.

The results of the HIV test will be available in about 3-5 days. You will be contacted about the results of your other tests when they are available. A small amount of blood will be stored from this visit. No other samples collected at the time of screening will be kept or used for any other tests other than those listed above.

Confirmation of Eligibility:

Once all the results of the screening tests are known, the following will happen:

- You will be told your test results and what they mean.
- If you have a positive HIV test or a positive test for hepatitis B infection, you will not be eligible for the study, and you will be referred for the appropriate medical care.
- If you are negative for both HIV, hepatitis B infection, but the results from the other blood or urine tests show that you might have some health problems, you may not be eligible for the study. Study staff will refer you to available sources of medical care and other services you may need. Later, if these problems resolve, you can come back to find out if you are eligible at that time.
- Give you referrals for other health services if you need them.

Enrollment Visit

If you are eligible for this study and decide to take part in the study, you will be asked to return for the enrollment visit. This visit will last about 2-3 hours. During the visit, the study staff will:

Confirm where you live and how to contact you.

Ask you some questions about yourself, like your age, and your ethnic group.

Ask you to answer questions on a computer about your sexual practices, and how you feel about how your life is going. This survey will be done in another room in the hospital in order to have some privacy and to get the internet connection required.

Talk with you about HIV and ways to protect yourself from getting it.

Give you a complete physical exam, to include measuring your height, weight, temperature, blood pressure, and ask you about any other medicines you are taking.

Collect ~100 mL (about 7 tablespoons of blood) for HIV testing, anti-Hepatitis C virus (HCV) antibody, to check how much cholesterol is in your blood (a fatty substance in your blood), to check on a protein in your body called CCR5, and for storage for study-related testing and long-term storage (these tests are optional and will only be done if you provide consent (see page 17)). Information about the CCR5 testing is found later in this consent form. For the cholesterol test, you will be instructed to not eat or drink anything other than what the study staff tell you is acceptable for 8-12 hours before your blood is drawn. We will provide a snack for you once your blood is obtained.

Randomize you into one of the four study groups.

Give you your study pills, and explain how to take them, and any side effects they may cause. We will also give you an electronic pill box to put your pills in. The box sends an electronic message to our system when it is opened. We will explain to you how this pill box works and give you enough study drugs for 2 months.

Explain and provide instructions about a text-message system we will be using in the study. This system will send you up to four text messages to your cell phone. The first message asks you to enter your chosen password (you will choose this password when you enter the study). You cannot get any messages from the sstem unless you enter your own password. The next two questions are about your sexual practices. The last text message is a reminder to delete the text messages to protect your privacy. The system is confidential and safe. We will ask you to use this system everyday for 7 days in a row during your first week on the study so that you can learn the system. After that, we will be using this system at approximately 12-13 different random times up to the end of the study. Each time you receive a text message, you will be asked the same two questions everyday for 7 days. You may receive up to approximately 392 text messages over the course of this study (up to 196 questions + up to 196 instruction texts).

Ask you to have a bone mineral density dual-energy x-ray absorptiometry (DXA) scan. A DXA scan is a special kind of x-ray using a small amount of radiation, allowing the doctor to see parts of the body better than a regular x-ray. During the DXA scan, you will lie very still on a table for about 15 minutes. The machine will then take the x-rays. This test will be done at this visit (Enrollment), and also at one visit toward the end of the study (Week 48).

Give you the results of your blood tests when they are available.

Give you condoms.

Week 2 Visit

This visit will last about 45 minutes –1 hour. During this visit, the study staff will**:**

Confirm where you live and how to contact you.

Give you a brief physical exam, ask you if you have experienced any side effects from the study drugs, and ask you about any other medicines you are taking.

Collect ~70 mL (about 5 tablespoons) of blood for HIV testing, to check your general health, the health of your liver and kidneys, and for storage for study-related testing and long-term storage (if you provide consent).

Talk with you about HIV and ways to protect yourself from getting it.

Ask you whether you have questions about taking your study pills.

Give you the results of your blood tests when they are available.

Remind you about how the SMS system works.

Give you condoms.

Week 4 Visit

This visit will last about 1 hour. During this visit, the study staff will**:**

Confirm where you live and how to contact you.

Give you a brief physical exam, ask you if you have experienced any side effects from the study drugs,and ask you about any other medicines you are taking.

Talk with you about HIV and ways to protect yourself from getting it.

Ask you whether you have questions about taking your study pills.

Ask you to answer questions on a computer about how you feel about this research study.

Collect ~70 mL (about 5 tablespoons) of blood for HIV testing, to check your general health and the health of your liver and kidneys, and for storage for study-related testing and long-term storage (if you provide consent).

Give you the results of your blood tests when they are available.

Remind you about how the SMS system works.

Give you condoms.

Week 8, 16, 32, and 40 Visits

These visits will last up to 2 hours. During these visits, the study staff will:

Confirm where you live and how to contact you.

Ask you to answer questions on a computer about your sexual practices, and your experiences taking your study pills.

Talk with you about HIV and ways to protect yourself from getting it.

Give you a brief physical exam, ask you if you have experienced any side effects from the study drugs, and ask you about any other medicines you are taking.

Collect urine from you to check the health of your kidneys (at the Week 8 visit only).

Collect ~70 mL (about tablespoons) of blood for HIV testing, to check your general health and the health of your liver and kidneys, and for storage for study-related testing and long-term storage (if you provide consent).

Give you your study pills, and ask you if you have any questions about taking them.

Give you the results of your tests when they are available.

Remind you about how the SMS system works.

Give you condoms.

Week 24 and 48 Visits

This visit will last about 2 – 3 hours. During these visits, the study staff will:

Confirm where you live and how to contact you.

Ask you to answer questions on a computer about your sexual practices, your experiences taking your study pills, and how you feel about how your life is going.

Talk with you about HIV and ways to protect yourself from getting it.

Give you a brief physical exam, ask you if you have experienced any side effects from the study drugs, and ask you about any other medicines you are taking.

Collect urine from you to check the health of your kidneys.

Collect ~100 mL (about 7 tablespoons) of blood for HIV testing, to check your general health and the health of your liver and kidneys, to check how much cholesterol is in your blood (a fatty substance in your blood), and for storage for study-related testing and long-term storage (if you provide consent). For the cholesterol test, you will be instructed to not eat or drink anything other than what the study staff tells you is acceptable for 8-12 hours before your blood is drawn.

Ask you to have a DXA scan (x-ray) (Week 48 only).

Give you your study pills, and ask you if you have any questions about taking them (Week 24 only)

Give you the results of your tests when they are available.

Remind you about how the SMS system works (Week 24 only).

Give you condoms.

Week 49 Visit

This visit will last about 1 hour. During this visit, the study staff will:

Talk with you about the end of the study, and when you will know what drugs you were taking, and when the results of the study will be available.

Give you a brief physical exam, ask you if you have experienced any side effects from the study drugs, and ask you about any other medicines you are taking.

Collect urine from you to check the health of your kidneys.

Collect ~70 mL (about 5 tablespoons) of blood for HIV testing, to check your general health and the health of your liver and kidneys, and for storage for study-related testing and long-term storage (if you provide consent).

Give you the results of your tests when they are available.

Give you condoms.

If you permanently stop taking your medications

If you permanently stop taking the study drugs during the study for any reason, we will ask you to continue to come for your regular study visits, but you will no longer have to undergo certain procedures, like answering questions about taking the study pills, talking to us about taking the study pills, etc. We will fully explain to you what will happen if you permanently stop taking your study drugs.

POSSIBLE FUTURE TESTS

Some of the blood that you give during this study may be left over after all of the study tests are completed. We would like to keep this blood for an indefinite amount of time for future testing that may be unrelated to this study, but still related to HIV. You will be asked to sign at the end of this consent form to give permission for this. Even if you do not give permission to store your blood after the study, you can still be in this study. You may also withdraw your consent for specimen storage at any time.

RISKS AND/OR DISCOMFORTS

Blood Draws

Taking blood samples may cause some pain, bruise your arm, or make you feel lightheaded. In rare cases you may faint. There is also a slight chance of infection when blood is drawn. You may be nervous while you are waiting for your HIV test result. If the tests show that you have HIV, you may worry about your health and future. You will receive counseling before and after the test to help address your concerns. We will make every effort to protect your confidentiality during the study. However, it is possible that others may learn that you are part of this study and they may think that you are infected with HIV or are at high risk for infection with HIV. Because of this you could have trouble finding or keeping a job. You could also have problems with your family, friends and community.

Sensitive Questions

The questions we will ask you about your sexual behavior may make you feel uneasy. However, you do not have to answer any question that you do not want to and you can stop answering the questions at any time.

DXA Scan

This research study involves exposure to radiation from the DXA scans. 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.

CCR5 Testing

We want to test to see if your body makes the CCR5 protein. This is done by testing your DNA (your genes). Genes, called DNA, tell us about the way your body is programmed to work. For instance a person that is very tall probably has different genes than a person who is very short. HIV uses the CCR5 protein to attach to cells. Some strains of HIV use another protein to attach to cells. One of the drugs we are using in this study, maraviroc, works by blocking the ability of HIV to attach to the CCR5 protein. Since maraviroc blocks the way the CCR5 protein works, it might interfere with the normal function of CCR5 in your body and may increase your risk of infections or cancer. The results of your CCR5 testing will not be shared with you.

Study Medications

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. It should be noted that these are the risks that are seen in HIV positive people taking these medications. It is not known if these side effects will occur as often and it could be that some of these side effects might be more or less serious HIV negative people.

The three drugs being used in this study have all been shown to be safe in people with HIV. Two of the drugs, FTC and TDF, also appear to be safe in people without HIV and to protect against HIV, but more research is needed to confirm this. The third drug, maraviroc, has not yet been studied very much in people without HIV. In this study we will look at safety and tolerability when using different combinations of these three drugs in people without HIV. The results of this study will help us decide whether maraviroc could be used in a larger study to see if it prevents people from getting HIV.

Maraviroc (MVC, Selzentry®)

The following serious side effects have been associated with the use of maraviroc:

Liver problems (liver toxicity) have occurred in people who took maraviroc. An allergic reaction may happen before liver problems occur, and includes a rash on your body (allergic reaction), yellowing of the skin or whites of your eyes, dark urine, vomiting, stomach pain, or elevated liver related function tests. People who have hepatitis B or C might be at higher risk of having liver problems.

Heart problems, including heart attack.

Low blood pressure when standing up, which can cause dizziness or fainting. People who have serious kidney problems may be at increased risk.

In addition to the serious side effects listed above, additional side effects include:

Colds
Cough
Fever
Rash
Dizziness
Diarrhea
Swelling of parts of the body
Flu and flu-like symptoms
Muscle aches, spasms and pain
Stomach pain and bloating
Sleeping problems
Runny, congested nose
Problems with urination
Low amounts of white blood cell counts (neutropenia)

NOTE: Because of how the drug works in your body, there is a possible increased risk for getting other infections or cancer, although there is no evidence from other studies of an increase in serious infections or cancer.

Maraviroc contains soy lecithin. If you have a medical history of allergy to soy (soya or soybeans) or peanuts, you may develop an allergic reaction to maraviroc. Before starting maraviroc, you should inform your health care provider if you are allergic to soy or peanuts.

Nucleoside Analogue (this applies only to Emtriva and Viread)

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 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.

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

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 increase, and symptoms associated with hepatitis (an acute inflammation of the liver) may worsen if tenofovir is stopped. You could have these side effects or other side effects that we do not know about.

Other Possible Risks

We do not know if there are other risks if you use herbal treatments or supplements while you are using the tablets. Please tell study staff if you are using any herbal treatments or supplements.

We will perform an HIV test, which is routinely done before HIV drugs are tested in non-HIV subjects. You will be counseled before and after this test is done.

In addition, there may be uncommon or previously unknown risks that might occur. You should report any problems to the researchers immediately.

There may also be some social risks to participating in this study. You may feel embarrassed or uncomfortable with some of the questions you will be asked, some of the procedures that will be done, or some of the test results that you will receive. You may also experience stigma as a result of being involved in a study about HIV because people may assume that you are HIV-infected.

If you test positive for HIV during the study

If you test positive for HIV during the study you will be asked to stop taking your study medication. If you continue to take the study medication after HIV infection has occurred, there is a chance that drug resistance may occur.

BENEFITS

We will test you for HIV infection throughout this study. The counseling you get during this study may help you to avoid HIV and other sexually-transmitted infections. If you have or become infected with HIV, this counseling may help you to learn how to better care for yourself and avoid passing HIV to your sexual partners. If you become HIV infected, we will refer you for care and/or treatment. At the screening visit we will also check if you have hepatitis B infection. If needed, we will refer you for hepatitis B vaccination. During the study you will have tests to check on the health of your blood, liver, and kidneys. If any health problems are found, you will be referred for care. At every visit you will receive condoms free of charge.

You may not receive any other direct benefit from being in this study; however, you or others in your community may benefit from this study later. The information gathered during this study may help to prevent HIV and other infections. This may be beneficial to you and your community.

NEW INFORMATION

You will be told any new information learned during this study that might affect your willingness to stay in the study. For example, if information becomes available that shows that the medication may be causing bad effects, you will be told about this. You will also be told when the results of the study may be available, and how to learn about them.

WHY YOU MAY BE WITHDRAWN FROM THE STUDY WITHOUT YOUR CONSENT

You may be withdrawn from the study without your consent if any of the following occur:

You are unable or unwilling to follow all of the study procedures or instructions.

You could be harmed by continuing to take tablets.

The study is stopped or canceled.

The study staff feels that staying in the study would be harmful to you.

You are not able to attend clinic visits or complete all of the study procedures.

Other reasons, as decided by the study staff.

ALTERNATIVES TO PARTICIPATION

There may be other studies going on here or in the community that you may be eligible for. If you wish, we will tell you about other studies that we know about. There also may be other places where you can go for HIV counseling and testing. We will tell you about those places if you wish. In addition, maraviroc, emtricitabine, tenofovir, and/or the combination pill, Truvada (TDF+FTC), are all available by prescription from your healthcare provider to treat HIV infection.

If you would like to choose to take Truvada by prescription to reduce your chances of becoming infected with HIV, we will refer you to local physicians who may prescribe it to you. If you are not already enrolled in the study and would like to take Truvada, you will not be eligible to be in the study. If you are already in the study and want to take Truvada, we we will stop giving you your study-provided drugs, and refer you to where you can get a prescription. We would like you to still come to the clinic for your study visits if you choose to do so.

COSTS TO YOU

There will be no cost to you for study related visits, study products, physical examinations, laboratory tests, or other procedures

REIMBURSEMENT

You will receive $35 and two SEPTA tokens for each screening visit, then $50 and two SEPTA tokens for each of the study required visits (7) and an additional $25 at visits where a Dexa scan(2) is completed. Each participant will receive $2.00 per day (for completing all of the questions for that singe day) for 7 days, and an $11.00 bonus for fully completing and answering all questions for all 7 days, for a total of $25.00]. Payments will be given as cash at the completion of the visit. The total amount of compensation for the study is $470 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 or have a repeat fasting lab test), you will be compensated $25 and two SEPTA tokens for every visit. If you travel a long distance to the clinic, we can provide some financial assistance if you provide us with receipts.

CONFIDENTIALITY

We will do our best to protect your private information. Your study records are kept in locked files at the clinic. On most records, we use a participant identification number, not your name. *We cannot guarantee absolute privacy.* At this clinic, we have to report the following information**:**

If you become infected with HIV or Hepatitis, by law we have to report the infection to the City of Philadelphia Health Department. 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.

If you receive $600 or more in a calendar year from the University of Pennsylvania, federal law requires us to submit a 1099 form to the IRS stating the amount of money that you received.

Any publication of this study will not use your name or identify you personally. However, your records may be reviewed, under guidelines of the United States Federal Privacy Act, by the United States Food and Drug Administration (FDA); the sponsor of the study (United States National Institutes of Health [NIH]), the University of Pennsylvania Institutional Review Board (IRB), study staff, study monitors, and the companies that make the drugs used in this study.

In addition to the efforts made by the study staff to help keep your personal information confidential, we have obtained a Certificate of Confidentiality from the U.S. Federal Government. This Certificate protects researchers from being forced to tell people who are not connected with this study, such as the court system, about your participation. The Certificate of Confidentiality does not prevent you from releasing information about yourself and your participation in the study. The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). Even with the Certificate of Confidentiality, if the study staff learns of possible child abuse and/or neglect or a risk of harm to you or others, we will tell the proper authorities.

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

All of the groups who watch over this study may review your study records. Your study records may also be reviewed by clinic staff. Reviewers will keep your records private.

a. The following personal health information is collected and used in this study and might be made known to others.

- Name, address, telephone number, & other personal contact information
- Date of birth
- Social Security number
- Personal and family medical history
- Current and past medications or therapies
- Current and past HIV risk behaviors
- Current and past drug & alcohol use
- Information from a physical exam that will include blood pressure reading, heart rate, breathing rate and temperature
- Results of tests, including HIV testing, and procedures you will undergo during this research study as described in the informed consent form
- Health information received from your doctor or other health workers with your consent

b. There are reasons for asking you for your personal contact and health information.
The research study staff needs your personal contact information to find and contact you during the study. The staff collects your personal health information and results of tests and procedures as part of this research study. Your personal health information may also be used to help guide your medical care.

c. These members of our staff may use or make your personal health information known to others:

- The Principal Investigator and the Investigator's study staff
- Authorized members of the staff of the UPHS and the School of Medicine and University of Pennsylvania office staff who may need to know your information to perform their jobs (for example, to manage study payment records, etc.)
- The University of Pennsylvania Institutional Review Board, the University of Pennsylvania Office of Regulatory Affairs, and the University of Pennsylvania Office of Human Research (groups at the University that make sure your rights are protected while you are in the study).

d. The following groups outside of UPHS and the School of Medicine might receive your personal health information.

As part of the study, the Principal Investigator, the study staff and others listed above, may make known your personal health information, including the results of the research study tests and procedures. This information may be made known to the following people:

Individuals or organizations responsible for helping with the study work and monitoring the study:

- Staff of the study sponsor, the Division of AIDS (DAIDS), a Division of the National Institute of Allergies and Infectious Diseases (NIAID) of the U.S. National Institutes of Health (NIH), (a government agency in Bethesda, MD) and people or companies working for the sponsor, who will send the study results to the U.S. Food and Drug Administration (FDA), a government agency that oversees the safety and effectiveness of this research
- Staff of the HIV Prevention Trials Network (HPTN) and people or companies working for the HPTN, an organization running this study for DAIDS here and at some other sites in the US and other countries, who manage the study and study data and report the study results
- Labs handling specimens: University of Pennsylvania and other labs hired by the study sponsor to do lab tests and analyze results for the study
- Staff of Pharmaceutical Product Development, Inc. (PPD), an agency hired by the sponsor to review study procedures and data and correct any mistakes before the results are given to the study sponsor and government agencies funding and/or monitoring study safety.
- Staff of the following U.S. government agencies, and/or people they hire, that watch over this study to see that your rights are protected and make sure that staff here are following the study plan: The NIH (U.S. National Institutes of Health), the U.S. Office of Human Research Protections (OHRP) and the HVTN Statistical and Data Management Center (SDMC).

Once your personal health information is given to others outside of the University of Pennsylvania Health System (UPHS) or School of Medicine, it may no longer be covered by federal privacy protection regulations. However, anytime that we give your information to outside groups or agencies:

- it will not include your name, social security number, address, telephone number, other contact information or any other personal identifying information unless it is required by law
- it will be assigned a unique code number. The Principal Investigator and his staff will keep the information that links your name to the code in a locked file cabinet and in a password-protected computer file

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

e. Your authorization for use of your personal health information for this study does not expire or end.

We may hold your information in a research storage file or database. However, UPHS and the School of Medicine may not re-use or make known information collected in this study for a purpose other than this study unless:

- You have given written permission to do so
- The University of Pennsylvania's Institutional Review Board allows it after making sure that the proper privacy safeguards are in place
- As permitted by law.

f. You may not be able to access some of your records.

While you take part in this study, you might not be able to see or get some of your research medical exam or test results. This is because by knowing your study results, you could affect the reliability of the study. You will be able to get this medical record information when the study is over, or earlier, if possible. The Principal Investigator is not required to release research information to you that is not part of your medical record.

You can change your mind.

At any time you may decide that you do not want us to use and make known your personal health information as described here. You must do so by writing to the Principal Investigator at the address on the first page. However, any personal health information that was collected before we received your written request may still be used and made known to others as needed for the study. If you decide to no longer allow us to use your personal health information, you will not be able to stay in the research study.

You will be given a copy of this consent form that tells you about 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 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.

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

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 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 Do I Do If I Have Questions Or Problems?

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

- Ian Frank, MD (215-662-7419)
- Joseph Quinn (215 349-8092)

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

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

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.

If you have read this consent form, or had it read and explained to you, and you understand the information, and you voluntarily agree to join the study, please sign your name or make your mark below. Also, please indicate by providing your initials in the spaces below the additional sample collection, genetic testing, or long-term storage that you agree to.

_____ I agree to take part in this study.
_____ I agree to take part in the Drug Interaction Subset, where I will have an additional blood draw at the Week 2 visit. or N/A if the slots for the Drug Interaction Subset are filled.
_____ I agree to have samples of my blood stored and used for future testing related to HIV infection.
_____ I do not agree to have samples of my blood stored and used for future testing related to HIV infection.
_____ I agree to allow my blood to be tested to see if my genes make the CCR5 protein
_____ I do not agree to allow my blood to be tested to see if my genes make the CCR5 protein

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_____ _____
Participant Name (print) Participant Signature and Date

_____ _____
Study Staff Conducting Consent Discussion (print) Study Staff Signature and Date