Washington University in St. Louis

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INFORMED CONSENT DOCUMENT

Project Title: A5354: Effect of Antiretroviral Treatment Initiated During Acute HIV-1 Infection on Measures of HIV-1 Persistence and on HIV-1-Specific Immune Responses

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Research Team Contact: **DeMarco Shaw RN or Michael Royal RPh** [redacted]

This consent form describes the research study and helps you decide if you want to participate. It provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights and responsibilities as a research participant. By signing this form you are agreeing to participate in this study.

- You should read and understand the information in this document including the procedures, risks and potential benefits.
- If you have questions about anything in this form, you should ask the research team for more information before you agree to participate.
- You may also wish to talk to your family or friends about your participation in this study.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We invite you to participate in this research study because:

1. You are acutely infected with the human immunodeficiency virus type 1 (HIV-1, the virus that causes AIDS). Acutely infected means that you are newly infected with HIV.
2. You are willing and able to start taking antiretroviral therapy (ART, anti-HIV drugs) right away.

The purpose of this research study is to:

- start ART early in those recently or acutely infected with HIV-1
- see how starting ART as soon as the infection is found affects the amount of HIV-1 in your blood and how well your body fights the HIV-1 infection
- look at the amount of HIV-1 DNA (genetic material for HIV-1) seen in CD4+ T-cells (infection-fighting cells in your blood) after 48 weeks of ART
- see how early treatment for HIV affects the numbers of HIV-1 infection fighting cells (CD4+ and CD8+ T-cells) in your blood

WHAT WILL HAPPEN DURING THIS STUDY?

Screening visit

If you decide to join this study, you will first need to be screened for the study to make sure that you qualify to continue. After you have read and signed the consent form, the study staff will check your

medical records for available documentation of your HIV-1 diagnosis; for instance, whether you are recently or acutely infected with HIV-1 to make sure that you meet the requirement for continuing in the study. You will also be asked how to be contacted in case you miss a visit or there are problems with your tests, and whether you give the study team permission to contact you.

Entry Visit
If your records show that you are eligible to enter the study you may enter on the same day or within 7 days of this visit.

You will start taking ART at study entry. At study entry, a sample of your blood will be tested to confirm your HIV-1 infection. At the time of starting ART, an additional sample of your blood will be tested to see how far along you are with your HIV-1 infection; this is called Fiebig staging. In this study, there are three groups determined by Fiebig staging (Fiebig I/II, Fiebig III/IV and Fiebig V). Based on your medical records of HIV testing and the results from the day that you start the HIV medications, the study team will determine which study group you will be included in. Both you and your doctor will know which drugs you are taking. The study staff will work with you to make sure you are taking your medication correctly.

The study will provide a single tablet that contains 4 different drugs. Three of these drugs treat HIV, and one is a drug that increases the levels of one of the anti-HIV drugs. The names of these drugs, which will be provided as a single tablet regimen, are: elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide (EVG/COBI/FTC/TAF) and has been approved by the US Food and Drug Administration.

If you are not able to take the study-provided medicine, then you will be allowed to take the best ART available to you, as prescribed by your primary care doctor. These non-study-provided ART must be obtained locally.

The table below details what will happen at each visit.

Procedure	Entry	Wk 1	Wk 2	Wk 4	Wk 8	Wk 12	Wk 24	Wk 36	Wk 48	Wk 49	Wk 60	Wk 72	Special Visit	Leaving or Stopping the Study Early
HIV-1 infection confirmed and Fiebig stage testing	√													
Group assigned and ART started	√													
Physical exam	√	√		√		√	√	√	√	√	√	√		√
Blood collected	√			√		√	√		√	√	√	√	√	√
Pregnancy test	√	prn		prn		prn	prn	prn	prn	prn	prn	prn		√
Resistance test	√												√	
Urine collected	√													√
Telephone follow-up			√		√						√			
Adherence support	√	√		√		√	√	√	√		√	√	√	
Large volume blood draw	√										√			
Optional Leukapheresis											√ **14T***			
Optional Sigmoid gut biopsy											√			
Optional lumbar puncture											√			
Approximate amount of blood t=teaspoon **T=tablespoon**	**16T**	1 t		**5T**		**6T**	**6T**	3t	**16T**	**4T**	5t	5t	**2T**	2t
In mls	231	3	0	79	0	83	83	10	231	63	23*	23	20	9

prn = if suspected

NOTES:

- If your laboratory tests from entry show that you do not qualify to continue in the study, the study staff will tell you to stop all ART. You will be asked to complete the discontinuation evaluations, and your follow-up will end.
- After you enter the study, if your blood test shows that you have had HIV longer than expected at the time of entry, then your follow-up and HIV study treatment will end at week 24. Your doctor will tell you the results of the tests by week 12 so you will have time to pursue HIV treatment outside of the study.
- If you are eligible to join the study, you will enter the study and be placed into a group. At this visit, you will start taking ART. If you are unable or unwilling to take the study-provided drug, then you must have access to and can begin to take an alternative ART in order to enter the study.
- Large volume blood collection (200 mL, approximately 13.5 tablespoons, of blood) will be done at entry.

- If you stop taking your ART for 7 or more days in a row, the last peripheral blood mononuclear cells (PBMC, cells separated from the blood taken from you) and plasma (the liquid part of blood taken from you) collection will be done at week 48.
- *Blood collection*-Blood will be collected from you for various tests during the study. These include: routine safety laboratory tests, HIV-1 viral load (a test that shows how much HIV-1 is in your blood), CD4+ T-cell count (a test that shows how many infection-fighting cells you have in your blood), and liver function tests. At entry and at the confirmatory visit to check whether your ART regimen has failed, a sample will be collected for resistance testing (a test that shows whether the ART is working for you). Routine PBMC and plasma storage will be done.
- *Human genetic testing*-Some of your blood will be tested to see whether the ART you are taking are making a difference by looking at your immune response (levels of infection fighting cells, CD4+ and CD8+ T-cells, in your blood) or whether development of resistance to ART is associated with different genes. Genes are a unique combination of molecules (called DNA) that we inherit from our parents. There are millions of tiny differences in our genes that determine things like our height or the color of our eyes. Some of these differences may make some people more or less likely to develop certain diseases or conditions or to have certain characteristics. You will not receive the results of these studies because they will be done in the future.
- *Pregnancy testing*-If you are a woman who is able to become pregnant, then you may be asked to give a small urine or blood sample for a pregnancy test.
- *HIV-1 resistance testing*-Your blood will be used to see which ART might work best for you. NOTE: If resistance testing was done as part of routine care, the study doctor may review these results to make sure that your current ART is still the best for you.
- *Urine collection*-You will be asked to provide a small amount of urine that will be used in safety tests.
- *Primary endpoint determination*-At week 48, you will be asked to give blood samples for testing to determine whether you met the main goal of the study by looking at the total amount of HIV genetic material in infection-fighting cells at study week 48 (also known as the primary endpoint).
- *Site follow-up with participants via telephone*-You will be asked about how you have been feeling and how well you are remembering to take your ART.
- *Adherence support*-Everyone will get some adherence support from the site staff. This means that study staff will explain to you in detail how to take the medications and help you find ways to take the medications correctly.

If you enter this study, you will need to come for study visits up to nine times in the first year, of which two of these visits (wks. 2, 4) will be done by telephone. If during these telephone visits, the study staff determines that you should be seen in person, you will be asked to go to the clinic.

In the next year, you will have up to two clinic visits (wks. 60, 72) that will include the study staff contacting you by telephone the day after completing the optional procedures (gut biopsy and/or lumbar puncture). You will be notified by the study staff of when to expect to receive these telephone calls before you are actually called. Most clinic visits will last about 1 hour. The study staff will tell you how long each visit will last.

You may need to come to the clinic for extra visits if you develop side effects or if you need to switch to non-study-provided ART or if the level of HIV in your blood increases after it has been undetectable.

During the study, you will receive results, when they are available, from any routine tests that are done during the study.

Optional procedures

These additional, optional procedures include leukapheresis or large volume blood collection, gut biopsy by flexible sigmoidoscopy, and lumbar puncture. These will be done at weeks 60 or 72. You will not receive the results of these procedures because they will be done in the future. No matter what you decide, it will not affect your participation in the study.

Leukapheresis or Large Volume Blood Collection

The leukapheresis procedure will be performed at the Barnes-Jewish Hospital Pheresis Center on the 4th floor of the Center for Advanced Medicine (CAM). We will take you over to the Pheresis Center for an assessment before we can schedule the procedure. This will be performed by Pheresis staff if we can continue we will schedule the procedure. The procedure will take between 1 and 3 hours and the full visit will last about four hours. You will have to remain in a semi-reclining or reclining position for the most of this time.

Leukapheresis involves taking some of your blood, processing it, and giving most of it back to you. This will be done by inserting a needle attached to sterile tubing in one arm, and first sending your blood through a machine. This machine spins your blood to separate the red blood cells (cells that carry oxygen), the white blood cells (cells that fight infection) and the platelets (cells that help form clots). The white blood cells will be kept for testing. All the rest of your blood will be returned to your body through another needle and tube in your other arm. Not all of your white blood cells are removed and your body will make more white cells within a few days. Losing the number of white blood cells that are collected does not pose a danger to you or to your health.

I agree to participate in optional leukapheresis or large volume blood collection

_____ Yes **_____ No**
Initials **Initials**

Gut Biopsy

The gut biopsy procedure will be performed at the Barnes Jewish Hospital Endoscopy Suite 8th floor of the Center for Advanced Medicine (CAM). The procedure will take about 1 hour and the full visit should last about 90 minutes.

A gut biopsy is a medical procedure that involves removing a sample of tissue taken from your gut to closely examine it. This will be performed following the local standards of care for this procedure. Just before the gut biopsy, you may have an enema (a salt water rinse that will flush out your lower bowel). Next, a lubricated flexible tube will be placed into your rectum. Using this instrument, the doctor will examine the inside of your intestine and will collect samples of tissue for testing.

You should not have anal sexual intercourse or insert anything into your rectum (including medications of any kind) for 3 days before and for 7 days after the procedure. The study or clinic staff will call you within 1 week after the procedure to check on how you are feeling.

I agree to participate in optional gut biopsy by flexible sigmoidoscopy

_____ Yes _____ No
Initials Initials

Lumbar puncture

You should drink plenty of fluids the day before the lumbar puncture procedure. The procedure will be performed at the AIDS Clinical Trials Unit (ACTU). On the day of the lumbar puncture, you will have a brief physical exam. Then you will be asked to lie down on your side or to sit 'backwards' in a chair (so that you are facing the back of the chair). An area of skin on your lower back will be sterilized with fluid. You will get an injection to numb the skin in the sterilized area. You may feel a burning sensation from the fluid that is injected. When the area is numb, the doctor will insert a thin needle between two of the bones in your spine. A small amount of fluid will be collected through the needle. The entire lumbar puncture procedure to this point will take about 30 minutes.

After the CSF (cerebrospinal fluid) collection, you may be asked to lie flat for up to 30 minutes to reduce the chance that you will get a headache. You should limit your physical activity for the remainder of the day.

I agree to participate to optional lumbar puncture

_____ Yes _____ No
Initials Initials

If you have to stop taking both study-provided and non-study-provided ART
During the study:
If you must stop taking ART for 7 or more days in a row while on study, you will be asked by the study staff to return to the clinic to have a repeat HIV-1 viral load test that will check whether your ART regimen is working. This test is called a virologic failure (VF) confirmatory test. If the confirmatory test results show that your ART regimen is working for you, then you will remain in the study for continued follow-up and no more PBMC and plasma collection will be done after week 48. If the test results show that your ART regimen has failed, then you will be asked to complete the discontinuation evaluations before having to stop the study medication and being taken off the study. The study staff will discuss other options that may be available to you.

After the study:
After you have completed the study, the study will not provide you with study drugs. The study staff will talk with you about your choices. You and your doctor will decide what treatment you should have, and the study staff will discuss with you how you may be able to obtain ART after the study ends.

If you do not enroll into the study

After signing this consent form, if you decide not to take part in this study or if you do not meet the eligibility requirements, the study team 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, HIV-related blood test results) information is being collected from you so that the AIDS Clinical Trials Group (ACTG) researchers may help determine whether there are patterns or common reasons why people do not join a study.

Will you save my samples or research data to use in future research studies?

As part of this study, we are obtaining blood samples from you. We would like to use these blood samples for studies going on right now as well as studies that are conducted in the future. These studies may provide additional information that will be helpful in understanding HIV, or other diseases or conditions, including research to develop investigational tests, treatments, drugs or devices that are not yet approved by the U.S. Food and Drug Administration. It is unlikely that what we learn from these studies will have a direct benefit to you. There are no plans to provide financial compensation to you should this occur. By allowing us to use your blood samples you give up any property rights you may have in the blood samples.

If you agree, some of your blood will be saved (with protectors of identity) and tested in the future to see how your own genes can help to show how your immune system and/or virus will respond to the ART, either successfully or unsuccessfully. You will not receive the results of these studies because they will be done in the future. This future research may focus on one or more genes to study the differences in specific genes or small groups of genes in people who have HIV when compared to people who do not have HIV. Future research with your blood may also attempt to sequence large parts of your genome or even your entire genome. These types of sequencing provide detailed descriptions of your DNA and result in the creation of information that is as unique to you as your fingerprint.

We will share your blood with other researchers. They may be doing research in areas similar to this research or in other unrelated areas. These researchers may be at Washington University, at other research centers and institutions, or industry sponsors of research. We may also share your research data with large data repositories (a repository is a database of information) for broad sharing with the research community. If your individual research data is placed in one of these repositories only qualified researchers, who have received prior approval from individuals that monitor the use of the data, will be able to look at your information.

If you change your mind and do not want us to store and use your blood samples for future research you should contact the research team member identified at the top of this document. The blood samples will no longer be used for research purposes. However, if some research with your blood samples has already been completed, the information from that research may still be used. Also, if the blood samples has been shared with other researchers it might not be possible to withdraw the blood samples to the extent it has been shared.

My blood samples may be stored and used for future research as described above.

_____ Yes **_____ No**
Initials **Initials**

My blood samples may be shared with other researchers and used by these researchers for the future research as described above.

_____ Yes **_____ No**
Initials **Initials**

My blood samples may be stored and used for genetic testing as described above.

_____ Yes **_____ No**
Initials **Initials**

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 6 people will take part in this study conducted by investigators at Washington University. About 150 people (men and women age 18 years and older) who have acute HIV-1 infection will take part in this study nationwide.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement is dependent on your Fiebig score. If you are determined to be in Fiebeig 1-V you will be seen at will be seen at 1 week, 4 weeks, 12 weeks, and 24 weeks after entering the study and then at 48 weeks and thereafter at weeks 60 and 72. If you are determined to be Fiebig VI you will be seen at 1 week, 4 weeks, 12 weeks, and your final visit will be at week 24.

WHAT ARE THE RISKS OF THIS STUDY?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

Some risks described in this consent document, if severe, may cause death.

Risks of Social Harm
Although the study site will make every effort to protect your privacy and confidentiality, it is possible that other people could find out that you are in a study and this could cause problems for you. For example, other people might figure out that you are infected with HIV-1. If this happens, you could be treated unfairly or you could have problems being accepted by other family members, friends, and/or the community.

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

Risks Related to Pregnancy
The ART in this study may be unsafe for unborn babies. If you are having sex that could lead to pregnancy, you must agree not to become pregnant or to attempt to make a woman pregnant.

Because of the risk involved, you and your partner must use at least one effective method of birth control. You must continue to use birth control while receiving study drugs.

Remember: If you are having sex, you need to use condoms to prevent transmitting your HIV-1 infection to others.

Approved methods of birth control are listed below. The study staff will talk with you about your choices.
- 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

If you can become pregnant, you must have a pregnancy test, and the test result must be available before you can start ART. If you think you may be pregnant at any time during the study, you must tell the study staff right away. If you become pregnant during the study, you will no longer be able to participate. However, the study staff may contact you to ask you if you agree to allow us to collect information on your pregnancy and outcome. You will be asked to sign a separate consent form for this. The study staff will talk to you about your choices.

Risks of ART
All ART medications can have side effects. The drug regimen provided in this study may have side effects. Listed below are the more serious or common side effects that may be related to the study-provided drugs. Please note that these lists do not include all the side effects seen with the study-provided drugs. The staff will be able to tell you which are the most serious side effects. They will also be able to tell you what to do if you have any of these side effects. If you have questions concerning the additional study-provided drug side effects, please ask the medical staff at your site.

<u>Emtricitabine (FTC)</u>
The following side effects have been associated with the use of FTC:
Less Likely
- Headache
- Dizziness
- Tiredness
- Inability to sleep, unusual dreams
- Loose or watery stools
- Nausea or vomiting
- Abdominal pain
- Rash, itching, which sometimes can be a sign of an allergic reaction
- Darkening of the skin on the palms of the hands and/or soles of the feet
- Increased cough

- Runny nose
- Abnormal liver function tests, which could mean liver damage, and can cause symptoms such as fatigue and yellowing of the eyes and skin
- Increases in pancreatic enzyme (a substance in the blood), which could mean a problem with the pancreas
- Increased triglycerides (a type of fat found in the blood)
- Increased creatine phosphokinase (a substance found in the blood), which could mean muscle damage

NOTE: If you are infected with both hepatitis B and HIV-1, your liver function tests may increase and symptoms caused by hepatitis may get worse if you stop FTC.

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, such as FTC, when used 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.

Some side effects of FTC may not need any medical attention. As your body gets used to the medicine, these side effects may disappear.

<u>Tenofovir Alafenamide (TAF)</u>
The following side effects have been associated with the use of TAF:
Less Likely
- Nausea, vomiting, gas, loose or watery stools
- Generalized weakness
- Dizziness
- Depression
- Headache
- Abdominal pain
- Worsening or new kidney damage or failure, which can cause fatigue, nausea, and loss of appetite
- Inflammation or swelling and possible damage to the pancreas (which can cause pain in the upper abdomen) and liver (which can cause a loss of appetite, fever, tiredness, and muscle and joint aches)
- Shortness of breath
- Rash
- Allergic reaction: symptoms may include fever, rash, nausea, 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
- Sleeping problems

NOTES:
- If you are infected with both hepatitis B and HIV-1, your liver function tests may increase and symptoms caused by hepatitis may get worse if you stop TAF.
- Because there is only a small amount of information on TAF in pregnant and breastfeeding women, you should not use TAF during pregnancy or if breastfeeding.

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, such as FTC, when used 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.

Some side effects of TAF may not need any medical attention. As your body gets used to the medicine, these side effects may disappear.

Cobicistat (COBI)
The following side effects have been associated with the use of COBI:
Less likely
- Abdominal or stomach pain
- Bloody urine
- Chills
- Clay-colored stools
- Dark urine
- Decreased frequency or amount of urine
- Dizziness
- Fast heartbeat
- Fever
- Headache
- Hives or welts, itching, or rash
- Hoarseness
- Increased thirst
- Irritation
- Joint pain, stiffness, or swelling
- Loss of appetite
- Lower back or side pain
- Nausea and vomiting
- Pain in the groin or genitals
- Redness of the skin
- Sharp back pain just below the ribs
- Swelling of the eyelids, face, lips, hands, lower legs, or feet
- Tightness in the chest
- Troubled breathing or swallowing

- Unpleasant breath odor
- Unusual tiredness or weakness
- Vomiting of blood
- Weight gain
- Yellow eyes or skin
- Dark-colored urine
- Muscle cramps or spasms
- Muscle pain or stiffness
- Diarrhea
- Discouragement
- Feeling sad or empty
- Irritability
- Loss of interest or pleasure
- Trouble concentrating
- Trouble sleeping
- Upper abdominal or stomach pain

Some side effects of COBI may not need medical attention. As your body gets used to the medicine, these side effects may disappear.

Elvitegravir (EVG)
Less Likely
The following side effects have been associated with the use of EVG:

- Diarrhea
- Headache
- Nausea
- Discouragement
- Feeling sad or empty
- Heartburn
- Indigestion
- Irritability
- Lack of appetite
- Loss of interest or pleasure
- Rash
- Stomach discomfort, upset, or pain
- Thoughts or attempts at killing oneself
- Trouble concentrating
- Trouble sleeping
- Unusual tiredness or weakness
- Vomiting

Some unwanted effects may be caused by EVG. In the event that any of these side effects do occur, they may require medical attention. Some of the side effects that can occur with EVG may not need medical attention. As your body adjusts to the medicine during treatment, these side effects may go away. Your

health care professional may also be able to tell you about ways to reduce or prevent some of these side effects. If any of the aforementioned side effects continue, are bothersome, or if you have any questions about them, check with your health care professional.

Use of Combination Antiretroviral (ARV) Drugs
In some people with advanced HIV-1 infection, symptoms from other infections or certain diseases may occur soon after starting combination ART 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 ART, tell your health care provider right away.

The use of potent ARV 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

There is a risk of serious and/or life-threatening side effects when non-study-provided medications are taken with the study-provided drugs. For your safety, you must tell the study doctor or nurse about all medications you are taking before you start the study. It is also important that you do not start any new medications while on the study before discussing it with the study doctor or nurse. Also, you must tell the study doctor or nurse before enrolling in any other clinical trials while on this study.

Risks of Optional Procedures

Leukapheresis

Likely

- Fatigue

Less Likely

- Nausea
- Vomiting
- Fainting or dizziness
- Bruising or swelling where the needles are put in
- Low blood pressure, which can cause dizziness, lightheadedness, of fainting
- Increased pulse rate
- Seizures
- Blood loss
- Infection

Rare:

- Allergic reaction to some of the material used during the leukapheresis.
- The procedure might have to be stopped early, before it is finished, and could result in the loss of as much as 1/2 pint of blood if it is not possible to complete the return of blood to the participant.

During the procedure, you will receive a compound called ACD-A (citrate), which prevents blood from clotting. Citrate is approved by the U.S. Food and Drug Administration for use in this procedure. Citrate leaves the body within 15-30 minutes after the procedure is complete. If you notice any symptoms while undergoing leukapheresis please let the nurse know immediately since the symptoms can usually be treated.

Likely
- Muscle cramping
- Numbness or tingling of the lips and/or fingers
- Chills
- Feeling that the body is vibrating
- Feelings of anxiety

Rare
- Seizures

Gut Biopsy/Rectal biopsy

Likely
- Discomfort during the collection of tissue sample.
- Urge to have a bowel movement
- Cramping as the instrument is placed into the rectal area
- Feeling of a "bloated stomach"

Rare:
- Pain
- Infection
- Bleeding or perforation (a cut or a hole) of the gastrointestinal tract (this occurs about once out of every 1000 procedures and may require hospitalization and surgical management)

Lumbar puncture

Less Likely
- Headache, sometimes severe
- Back pain, slight
- Bruising, soreness at collection site
- Dizziness, nausea
- Fever
- Numbness

Extremely Rare
- Paralysis

There is a federal law called the Genetic Information Nondiscrimination Act (GINA). In general, this law makes it illegal for health insurance companies, group health plans and employers with greater than 15 employees to discriminate against you based on your genetic information. However, it does not protect you against discrimination by companies that sell life insurance, disability insurance or long term-care insurance.

Breach of Confidentiality
One risk of participating in this study is that confidential information about you may be accidentally disclosed. We will use our best efforts to keep the information about you secure. Please see the section in this consent form titled *"How will you keep my information confidential?"* for more information.

WHAT ARE THE BENEFITS OF THIS STUDY?

You may not benefit from being in this study.

However, we hope that, in the future, other people might benefit from this study because this study will provide information that may help others with HIV-1 infection.

WHAT OTHER TREATMENT OPTIONS ARE THERE?

Before you decide whether or not to be in this study, your doctor will discuss the other options that are available to you. Instead of being in this study, you have the choice of:

- treatment with the anti-HIV drugs available to you locally
- treatment with investigational drugs, if there is a study available locally for which you qualify
- no treatment

Each of these options has risks and benefits. There are several drug regimens that you and you provider could elect to begin. These have the prospect of controlling HIV infections but all have potential side effects much like those listed of the study drug. Investigational treatment options also may result in control of HIV infections but all involve risks, many of which are unknown. Finally, not treating your HIV infection avoids the risks of medications but may risk progression of the disease.

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

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

The sponsor is providing the study drug (EVG/COBI/FTC/TAF) at no cost to you.
You will not have any additional costs for being in this research study.
You and/or your medical/hospital insurance provider will remain responsible for your regular medical care expenses.

WILL I BE PAID FOR PARTICIPATING?

You will be paid for being in this research study. You will need to provide your social security number (SSN) in order for us to pay you. You may choose to participate without being paid if you do not wish to provide your social security number (SSN) for this purpose. You may also need to provide your address if a check will be mailed to you. Checks arrive to the address you give us within about ten business days of a visit. If your social security number is obtained for payment purposes only, it will not be retained for research purposes.

You will receive payments beginning at study screening at the rate of [redacted] per visit. There are 10

possible visits for a total over the life of the study of [redacted]

If you complete the optional procedures, you will be paid [redacted] per procedure. If you complete all 3 optional procedures, you will receive a total of [redacted] for the optional procedures.

If you do not complete all visits, you will be paid for the visits you do complete.

WHO IS FUNDING THIS STUDY?

The National Institutes of Health (NIH) is funding this research study. This means that Washington University is receiving payments from the NIH to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from the NIH for conducting this study.

WHAT IF I AM INJURED AS A RESULT OF THIS STUDY?

Washington University investigators and staff will try to reduce, control, and treat any complications from this research. If you feel you are injured because of the study, please contact the investigator at [redacted] and/or the Human Research Protection Office at [redacted].

Decisions about whether payment for medical treatment for injuries relating to your participation in research will be made by Washington University. There is no program for compensation through the National Institutes of Health. If you need to seek medical care for a research-related injury, please notify the investigator as soon as possible.

HOW WILL YOU KEEP MY INFORMATION CONFIDENTIAL?

It is possible that other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

- Government representatives, (including the Office for Human Research Protections) to complete federal or state responsibilities
- The U.S. Food and Drug Administration (FDA)
- The National Institutes of Health (NIH)
- The ACTG
- Gilead Sciences, Inc., providing the study drug
- Your primary care physician if a medical condition that needs urgent attention is discovered
- Hospital or University representatives, to complete Hospital or University responsibilities
- Information about your participation in this study may be documented in your health care records and be available to your health care providers who are not part of the research team.
- The last four digits of your social security number may be used in hospital or University systems to track billing information for research procedures
- Washington University's Institutional Review Board (a committee that oversees the conduct of research involving human participants) and the Human Research Protection Office. The Institutional Review Board has reviewed and approved this study.

The research team will send study results to the National Institutes of Health (NIH). Information sent to the National Institutes of Health (NIH) is given a code number and does not identify you for the purposes of conducting this study. The National Institutes of Health (NIH) will use this information to study the safety and effectiveness of the drug. In the future, the National Institutes of Health (NIH) may continue to use your health information that is collected as part of this study. For example, the National Institutes of Health (NIH) may combine information from this study with the results of other studies to re-analyze the safety and effectiveness of the study drug, to evaluate other products or therapies, to develop a better understanding of a disease, or to improve the design of future research studies. The National Institutes of Health (NIH) may also share information from the study with regulatory agencies in foreign countries.

If you receive Medicare benefits, are injured as part of your participation in this research study and medical treatment relating to this injury is paid by anyone other than you or your insurance company, that payer will need to collect personal information about you. This information includes your name, date of birth, gender, social security number, Medicare identification number and information related to this research study. The payer will report this information to the Centers for Medicare & Medicaid Services (CMS), the federal agency that oversees the Medicare program, during your participation in the study and for as long as the payer is required by CMS to report this information. If you do not want to release your personal or treatment related information you have the right to refuse reimbursement by the payer for any research injury. The payer will not use this information for any other purpose.

Research monitors, auditors, the study sponsor, the Institutional Review Board, and other regulatory authorities will be granted directed access to your original health care record to verify the conduct of the clinical trial procedures and/or data. This access will be permitted to the extent permitted by the applicable laws and regulations without violating the confidentiality of your information. By signing this form you are authorizing such access.

To help protect your confidentiality, we will assign the information you give us a code number. We will protect your information, but there is a chance somebody might see it.

- Electronic records - Any computer data is accessible only by passwords which are changed every 90 days.
- Blood, urine, CSF, and tissue samples – Initially labeled only with ID number, gender, date of birth, and date and time of collection, then barcode that has no identifying information on it.
- Paper/hard copy records - Patient information is given a code number. A master list linking the code number and subject identity will be kept separate from the research data. Only the principal investigator and people helping him/her will be able to see the list.
- Kept in locked, security controlled environment.

If we write a report or article about this study or share the study data set with others, we will do so in such a way that you cannot be directly identified

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

To further protect your privacy, the investigator has obtained a Certificate of Confidentiality from the Department of Health and Human Services (DHHS). This Certificate may prevent the investigator from being forced (for example by court subpoena) to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceeding. However, a Certificate of Confidentiality does not prohibit the investigator from disclosing information about you or your involvement in this research that you have agreed to disclose or make available. For example, if you request in writing that information about you or your participation in the research be released to an insurance company, the investigator may not use the Certificate of Confidentiality to withhold this information. This means that you and your family should actively protect your own privacy. Finally, the investigator is not prevented from disclosing, including reporting to appropriate authorities, information concerning abuse, neglect or harm to others or yourself.

Are there additional protections for my health information?

Protected Health Information (PHI) is health information that identifies you. PHI is protected by federal law under HIPAA (the Health Insurance Portability and Accountability Act). To take part in this research, you must give the research team permission to use and disclose (share) your PHI for the study as explained in this consent form. The research team will follow state and federal laws and may share your health information with the agencies and people listed under the previous section titled, "How will you keep my information confidential?"

Once your health information is shared with someone outside of the research team, it may no longer be protected by HIPAA.

The research team will only use and share your information as talked about in this form or as permitted or required by law. When possible, the research team will make sure information cannot be linked to you (de-identified). Once information is de-identified, it may be used and shared for other purposes not discussed in this consent form. If you have questions or concerns about your privacy and the use of your PHI, please contact the University's Privacy Officer at [redacted].

Although you will not be allowed to see the study information, you may be given access to your health care records by contacting your health care provider.

If you decide not to sign this form, it will not affect

- your treatment or the care given by your health provider.
- your insurance payment or enrollment in any health plans.
- any benefits to which you are entitled.

However, it will not be possible for you to take part in the study.

If you sign this form:

- You authorize the use of your PHI for this research
- This authorization does not expire.

- You may later change your mind and not let the research team use or share your information (you may revoke your authorization).
  - To revoke your authorization, complete the withdrawal letter, found in the Participant section of the Human Research Protection Office website at http://hrpo.wustl.edu/participants//withdrawing-from-a-study/ or you may request that the investigator send you a copy of the letter.
    - **If you revoke your authorization:**
      - The research team may only use and share information already collected for the study.
      - Your information may still be used and shared as necessary to maintain the integrity of the research, for example, to account for a participant's withdrawal from the research study or for safety reasons.
      - You will not be allowed to continue to participate in the study.

Can we contact you by email?
We would like to contact you by email for the purposes listed below. Some of these emails may contain health information that identifies you.

- Appointment scheduling and confirming
- Questions you may have
- Lab results if you desire

Only the research team will have access to your e-mail communications. We will only communicate by email to send you the information listed above. If you have any questions or need to contact us for an urgent or emergent situation, please contact the research team member identified at the top of this document.

You should be aware that there are risks associated with sending your health information via e-mail.

- There is always a risk that the message could be intercepted or sent to the wrong e-mail address. To avoid sending messages to the wrong e-mail address, the first e-mail we send you will be a test message to ensure we have the correct e-mail address.
- When using any computer you should be careful to protect your username and password. Make sure you log-out before getting up from the computer.
- If you share a home computer with other family members, and do not want them to know you are participating in this study make sure you provide an e-mail address that only you can access.
- Your employer will have access to any e-mail communications sent or received on any electronic devices for work or through a work server.

Do you agree to allow us to send you protected health information via e-mail?

_____ Yes **_____ No**
Initials **Initials**

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. Any data that was collected as part of your participation in the study will remain as part of the study records and cannot be removed.

If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

What if I decide to withdraw from the study?

You may withdraw by telling the study team you are no longer interested in participating in the study or you may send in a withdrawal letter. A sample withdrawal letter can be found at http://hrpo.wustl.edu/participants/ under Withdrawing from a Research Study.

If you decide to leave the study early, or must stop taking ART before the study is over, then the study staff will ask you to return to the clinic for a final visit.

Will I receive new information about the study while participating?

If we obtain any new information during this study that might affect your willingness to continue participating in the study, we'll promptly provide you with that information.

Can someone else end my participation in this study?

Under certain circumstances, the investigator or the study sponsor might decide to end your participation in this research study earlier than planned. This might happen for no reason or because

- You never started ART (study-provided or non-study-provided drugs) or started ART later than 48 hours after joining the study.
- An HIV-1 test shows that you are not infected with HIV or you have had HIV infection for a longer period of time than expected or your laboratory tests from entry show that you do not qualify for the study.
- You miss 3 study visits in a row.
- Your viral loads show that the HIV medications you are taking are no longer working well for you; this is known as having VF.
- Your study doctor believes that remaining on the study is no longer what is best for you.
- You are unable to follow the requirements of the study or at the recommendation of the IRB/EC, NIAID, OHRP, other government agencies as part of their duties, or industry supporter.
- A Study Monitoring Committee (SMC), an outside group of experts that monitors the study, recommends that the study be stopped early or canceled.

The study doctor may also need to take you off the study-provided drugs without your permission if:

- Continuing the study-provided drugs may be harmful to you, for example, if the study drugs are making you sick.
- You need a treatment that you may not take while on the study-provided drugs.
- You become pregnant and/or start breastfeeding.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: Rachel Presti, MD at Telephone: [redacted]. If you experience a research-related injury, please contact: Rachel Presti, MD at [redacted].

If you have questions, concerns, or complaints about your rights as a research participant, please contact the [redacted] General information about being a research participant can be found on the Human Research Protection Office web site, http://hrpo.wustl.edu. To offer input about your experiences as a research participant or to speak to someone other than the research staff, call the Human Research Protection Office at the number above.

This consent form is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by agreeing to participate in this study. As a participant you have rights and responsibilities as described in this document and including:

- To be given enough time before signing below to weigh the risks and potential benefits and decide if you want to participate without any pressure from the research team or others.
- To understand all of the information included in the document, have your questions answered, and receive an explanation of anything you do not understand.
- To follow the procedures described in this document and the instructions of the research team to the best of your ability unless you choose to stop your participation in the research study.
- To give the research team accurate and complete information.
- To tell the research team promptly about any problems you have related to your participation, or if you are unable to continue and wish to stop participating in the research study.

Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a signed and dated copy of this form.

Do not sign this form if today's date is after EXPIRATION DATE: 06/08/17.

_____ _____
(Signature of Participant) (Date)

_____
(Participant's name – printed)

Statement of Person Who Obtained Consent

The information in this document has been discussed with the participant or, where appropriate, with the participant's legally authorized representative. The participant has indicated that he or she understands the risks, benefits, and procedures involved with participation in this research study.

_____ _____

(Signature of Person who Obtained Consent) (Date)

_____

(Name of Person who Obtained Consent - printed)