HOSPITAL OF THE UNIVERSITY OF PENNSYLVANIA

CONSENT FOR OPTIONAL PROCEDURES AND SAMPLES COLLECTION AFTER WEEK 48

Protocol Title:	**A5354 Version 1.0, dated 4/19/16, Letter of Amendment #1, 12/13/16, Letter of Amendment #2, 11/7/17** **Effect of Antiretroviral Treatment Initiated During Acute HIV-1 Infection on Measures of HIV-1 Persistence and on HIV-1-Specific Immune Responses A Limited-Center Trial of the AIDS Clinical Trials Group (ACTG)**
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Introduction:

If you met the main goal of the study (ie, to look at the total amount of HIV genetic material in infection fighting cells at week 48), you may be asked and consented to take part in the optional procedures and samples collection that will be done between weeks 60 and 72. The optional procedures and samples collection (as described below) will advance the scientific goals of this study but will offer no direct benefit to participants. Neither you nor your doctor will receive any results from these procedures because these tests are for research purposes only. If you choose not to participate in the optional procedures, it will not affect your ability to take part in this study.

NOTE: If you are pregnant, these optional procedures and samples collection will not be done.

A. Explanation of Optional Procedures and Samples Collection

- Leukapheresis

  The leukapheresis procedure may be performed at the transfusion medicine center located at 3 Ravdin. The procedure will take about 3 hours and the full visit will last about 4 hours. You will have to remain in a semi-reclining or reclining position for most of this time.

  Leukapheresis is a medical procedure that involves removing whole blood from an individual/donor and separating the blood into individual components so that leukocytes (white blood cells) can be removed. The remaining blood components are then put back into the bloodstream of the individual/donor. 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. 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 your health.

IRB APPROVAL FROM: 12/19/2017 TO: 04/19/2018

- Large volume blood collection (in place of leukapheresis)

  If leukapheresis is not done, then a large volume blood draw (about 320 mL) will be collected.

- Gut biopsy

  The gut biopsy procedure will be performed at the Gastroenterology offices located in the Perelman Center for Advanced Medicine. The procedure will take about 1 hour, and the full visit should last about 3 hours.

  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 for 3 days before and for 7 days after the procedure. The study or clinic staff will call you the day after the procedure to check on how you are feeling.

- Lumbar puncture

  A lumbar puncture is a medical procedure that involves removing a small amount of cerebrospinal fluid (CSF) from your spine. You should drink plenty of fluids the day before the lumbar puncture procedure. The procedure will be performed at the Center for Human Phenomic Science (CHPS) in the Perelman Center for Advanced Medicine. 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 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. The study or clinic staff will call you the day after the procedure to check on how you are feeling.

B. Risks Associated with Optional Procedures and Samples Collection

- <u>Leukapheresis</u>
  Leukapheresis has been shown to be safe in HIV-infected donors and does not affect CD4+ T-cell count or immune status of short-term donors. The needle used is larger than normal blood draw and may be uncomfortable. Taking blood may cause some discomfort, lightheadedness, bleeding, swelling, or bruising where the needle enters the body, and in rare cases, fainting or infection. Rarely, a participant may feel faint during or after leukapheresis. This sort of reaction can be handled by changing the participant’s position or administering intravenous fluids. You may experience chills, nausea, and heartburn caused by the citrate anticoagulant that is used

during the procedure to keep the collected cells from clumping together in the bag. This chemical may use up some of the calcium in your blood stream, and tingling in the face, lips, or hands may be noted. If this happens, study staff may slow the rate of infusion of this chemical and may offer you one or two calcium carbonate tablets to correct the calcium loss. Participants will be observed closely by an experienced blood bank technician during the procedure.

- Large volume blood collection (in place of leukapheresis)
  Taking blood may cause some discomfort, lightheadedness, bleeding, swelling, or bruising where the needle enters the body, and in rare cases, fainting or infection.

- Gut biopsy
  The preparation before the procedure may include taking laxatives or enema, which may be uncomfortable and may make participants feel weak from diarrhea. You may feel pressure or discomfort as the instrument (a lubricated flexible tube called a sigmoidoscope) is placed into your rectum as it passes through the curves of your colon during the procedure. You may receive medication throughout the procedure to reduce any discomfort. The doctor will put air into your colon in order to see the lining, and you may have some bloating or abdominal discomfort from the air. You may feel as though you need to have a bowel movement. You can pass the air if you feel the need. The doctor will remove as much air as possible after the procedure.

  There is a small risk (about 1/3,600) for bowel perforation which is a tear through the wall of the bowel that may allow leakage of bowel fluids. Perforations are generally treated with hospitalization, antibiotics, and possibly surgery. Bleeding can occur but usually will stop without treatment or can be controlled at the time of the procedure. Rarely, blood transfusions or other treatments may be required to stop the bleeding.

  After the procedure, you may feel dizzy or sleepy from the sleep and pain medicines. You should have someone come with you to accompany you home. You should not drive a car or a motorcycle. There is a small risk (less than 1/10,000) for a more severe allergic reaction to the sleeping medicine.

- Lumbar puncture
  The risks of lumbar puncture include local soreness at the site of needle entry and pain and possible allergic reaction associated with local anesthesia. There is a small risk of headache or decreased blood pressure from removing the small amount of fluid or leaking of CSF after the procedure. There is a small risk of infection and a very small risk of damage to nerves in the lumbar spinal roots after the procedure, which could cause pain, numbness, or loss of sensation to the legs. Before the procedure, the area where the needle will be inserted will be cleaned with antiseptics (such as betadine or rubbing alcohol) in order to reduce the risk of infection. A bandage will be placed on the skin where the needle went in, and the participants will be asked to remove it the next day and tell the study doctor right away if any redness or tenderness is present. Participants will be asked to remain lying flat for up to 30 minutes after the procedure and will be given fluid to drink after the procedure. The site staff will ask the participants about history of any allergies to anesthetics and will not perform lumbar puncture in any participant with such history.

Please indicate below if you agree to have any of these procedures and large volume blood collection done. No matter what you decide, it will not affect your participation in the study. You will not receive the results of these studies because they will be done in the future. You do not have to decide about the optional procedures and blood collection until week 48 of the study.

Gut biopsy

_____ (initials) YES, I agree _____ (initials) NO, I do not agree

Lumbar puncture

_____ (initials) YES, I agree _____ (initials) NO, I do not agree

Leukapheresis

_____ (initials) YES, I agree _____ (initials) NO, I do not agree

Optional large volume blood samples (may be collected if leukapheresis is not done)

_____ (initials) YES, I agree _____ (initials) NO, I do not agree

SIGNATURE PAGE: A5354 INFORMED CONSENT FOR OPTIONAL PROCEDURES

This consent is:

☐ the initial consent for this participant. The study staff will provide an overview of the study, required visits, treatment regimen, risk and all elements of consent. The physician investigator(s) or licensed Nurse Practitioner will conduct a focused discussion about risks, benefits and alternatives.

☐ a subsequent consent for this participant that does not alter the risks for investigational product or products, alternatives or benefits. Research staff will conduct the consent discussion.

☐ a subsequent consent for this participant that does alter the risks for investigational product or products, alternatives or benefits. The physician or nurse practitioner investigator will discuss the changes to these sections and the research staff will review changes that were made to other sections.

If you have read this consent form (or had it explained to you), all your questions have been answered, and you agree to take part in the optional procedures that will be done between weeks 60 and 72, please sign your name below.

RESEARCH STAFF CONSENT

Name of Subject (Please Print)	Signature of Subject	Date/Time

Participant's Legally Authorized Representative (print) (As appropriate)	Legally Authorized Representative's Signature and Date/Time

Name of Person Obtaining Consent (Please Print)	Signature	Date/Time

INVESTIGATOR CONSENT

The risks, alternatives, and benefits have been reviewed with me by the Investigator, and I understand what we have discussed.

Name of Subject (Please Print)	Signature of Subject	Date/Time

I verify I have reviewed risks, alternatives, benefits with this subject, who demonstrates good understanding.

Investigator Name (PRINTED)	Signature	Date/Time