

IRB APPROVAL DATE: 6/6/07  
EXPIRATION DATE: 6/5/08

UNIVERSITY OF PENNSYLVANIA HEALTH SYSTEM

**A5224s, Version 2.0, 10/31/06:**  
**Long-Term Metabolic Assessments in Subjects Treated with Emtricitabine/Tenofovir or Abacavir/Lamivudine with either Efavirenz or Atazanavir with Ritonavir:**  
**A Metabolic Substudy of A5202**

**CONSENT FORM TO PARTICIPATE IN A RESEARCH STUDY**

**If you are seen at the Hospital of the University of Pennsylvania [HUP], your contacts are:**

Principal Investigator:	Robert Gross, MD, MSCE	(215) 898-2437
Sub Investigators	Pablo Tebas, MD	(215) 615-4321
	Ian Frank, MD	(215) 662-7419
Coordinator:	Joseph Quinn, RN	(215) 349-8092
Study Nurse:	Wayne Wagner, RN	(215) 349-8092
	Kathryn Maffei, RN	(215) 349-8092
	Larisa Zifchak, RN	(215) 349-8092

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

**INTRODUCTION**

You are being asked to take part in the research substudy named above because you will be taking either emtricitabine (FTC)/tenofovir (TDF) or abacavir (ABC)/lamivudine (3TC) and either efavirenz (EFV) or atazanavir (ATV) with ritonavir (RTV) for your HIV infection on the main study A5202. This substudy is sponsored by the National Institutes of Health (NIH). The doctor in charge of this substudy at this site is: Dr. Robert Gross. Before you decide if you want to be a part of this substudy, we want you to know about the substudy.

This consent form gives you information about the substudy. The study staff will talk with you about this information. You are free to ask questions about this substudy at any time. Once you understand the substudy, and if you agree to take part, you will be asked to sign this consent form. You will be given a copy to keep.

Before you learn about the substudy, it is important that you know the following:

- Your participation is entirely voluntary; and
- You may decide not to take part or to withdraw from the substudy at any time and still be in the main study A5202.

**WHY IS THIS SUBSTUDY BEING DONE?**

The purpose of this substudy is to learn about the metabolic changes such as in fat, blood sugar, bone density, and kidney function in participants receiving the anti-HIV drug regimens in A5202.

About 250 participants enrolled in the main study A5202 will enroll in this study over approximately 2 years. You will be in this study between 2 and 4 years depending on when you join.

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WHAT DO I HAVE TO DO IF I AM IN THIS SUBSTUDY?

Entry (Week 0)

We believe the entry visit will last about 2 hours, but it may be shorter or even longer. You must not have anything to eat or drink (fasting), except water and required prescription medications, for at least 8 hours before coming to the clinic. At your entry visit, you will have the following done:

- You will have a physical exam.
- You will be asked about your family medical history. You will also be asked to fill out a form to report on your weight trends including your minimum and maximum lifetime weight.
- You will be asked to fill out a body image questionnaire.
- About 3 tablespoons of blood will be drawn for future study-related metabolic tests. If you are not fasting, you will be asked to return for the metabolic tests when you are fasting. You will NOT be told the results of these tests until the end of the substudy.
- You will be asked to give a urine sample for protein tests. The results of the urine test will NOT be available to you until the end of the substudy.
- You will have a whole body fat and bone mineral density dual-energy x-ray absorptiometry (DEXA) scan. A DEXA 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 DEXA scan, you will lie very still on a table for about 15 minutes. The machine will then take the x-rays. The results of the DEXA scan will NOT be available to you until the end of the substudy.
- You will have an abdominal computed tomography (CT) scan. A CT scan is a special kind of x-ray that takes pictures of the inside of the body using a small amount of radiation. You will be asked to lie quietly while your body is moved inside a large machine and the x-ray is taken. The CT scan takes about 15 minutes. Some people may require sedation in order to have a CT scan done. The results of the CT scan will NOT be available to you until the end of the substudy.

Weeks 24, 48, and every year up to the end of the substudy

We believe the visits will last about 2 hours, but they may be shorter or even longer. You must not have anything to eat or drink, except water and required prescription medications, for at least 8 hours before coming to the clinic. During the substudy, you will have the following done:

- You will have a physical exam at each visit.
- You will be asked to fill out a body image questionnaire at each visit. The form will take about 10 minutes to complete.
- You will be asked to give a urine sample for protein tests at each visit. The results of the urine test will NOT be available to you until the end of the substudy.
- About 3 tablespoons of blood will be drawn for future study-related metabolic tests at each visit. If you are not fasting, you will be asked to return for the metabolic tests while in a fasting state. You will NOT be told the results of these tests until the end of the substudy.
- You will have a whole body fat and bone mineral density DEXA scan at each visit. During the DEXA scan, you will lie very still on a table for about 15 minutes. The machine will then take the x-rays. The results of the DEXA scan will NOT be available to you until the end of the substudy.
- You will have an abdominal CT scan at week 96 only. You will be asked to lie quietly while your body is moved inside a large machine and the x-ray is taken. The CT scan takes about 15 minutes. Some people may require sedation in order to have a CT scan done. The results of the CT scan will NOT be available to you until the end of the substudy.

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If you decide to stop the substudy early

If you decide that you want to stop this substudy early you will be asked to come to the clinic to have a physical exam, about 3 tablespoons of your blood will be drawn for future study-related metabolic tests, and you will be asked to give a urine sample for a protein test. You will NOT be told the results of these tests until the end of the substudy. You will be asked to fill out a body image questionnaire. The form will take about 10 minutes to complete. You will have a whole body fat and bone mineral density DEXA scan. During the DEXA scan, you will lie very still on a table for about 15 minutes. The machine will then take the x-rays. The results of the DEXA scan will NOT be available to you until the end of the substudy. You will also have an abdominal CT scan if you stop the substudy prior to week 96. You will be asked to lie quietly while the x-ray is taken. The CT scan takes about 15 minutes. Some people may require sedation in order to have a CT scan done. The results of the CT scan will NOT be available to you until the end of the substudy. We believe this visit will last about 2 hours, but it may be shorter or even longer

Fat biopsy study

You will be asked to have a fat biopsy (removal of a small amount of fat) performed at entry and week 96. The purpose of the biopsy is to evaluate how changes in the energy producing cells (called mitochondria) of the fat may be related to some of the HIV drugs. This is a surgical procedure that will be done by an experienced surgeon and will take approximately 1 hour. At these visits, a small amount of numbing medicine (local anesthetic) will be injected into your skin with a needle to reduce discomfort. An incision (about 1-3 inches long, depending on your weight) will be made into the skin of your abdomen below your waistline. A small amount of fat will be removed (about the size of two grapes).

You will also have additional blood drawn (1 tablespoon) during entry and at week 96 for future substudy related testing. These samples may be held for an indefinite length of time. We cannot ensure that you will be told the results of the research done on these samples.

If you decide to stop the substudy prior to week 96 and at or after week 48, you will be asked to have a fat biopsy at that time. In addition, you will have blood drawn (1 tablespoon) for future substudy related testing.

Other

Some of your blood will be stored (with usual protectors of identity, e.g stored only by code number and *not* name, medical record number or social security number) and used for metabolic testing that is required for this study.

Some of your blood that is left over after all required study testing is done may be stored (with usual protectors of identity) and used for AACTG-approved HIV-related research.

These samples may be held for an indefinite length of time. We cannot ensure that you will be told of the results of the research done on these samples.

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**WHAT ARE THE RISKS OF THE SUBSTUDY?**

Risk of Drawing Blood

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 of CT and DEXA scans

This research study involves exposure to radiation from the DEXA and CT scans and 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.

Additionally, you may experience some discomfort from lying still and flat on the table.

Risks of the Fat Biopsy

You may have an allergic reaction to the medication used to numb the area where the biopsy was done. This allergic reaction could include itching, hives, swelling, shortness of breath, difficulty breathing, changes in blood pressure, cardiac rhythm changes, loss of consciousness, or in rare cases, death.

You may experience pain at the site where the fat sample was taken. This pain is usually short-lived (less than 12 hours) and can be relieved with prescription pain medicine that will be prescribed to you by your physician or the surgeon that performed the procedure. You may or may not need to take such medicine. In most cases the pain is minimal and people are able to go back to work on the following day and are able to perform their routine activities. Additionally, there is a very small risk of experiencing fat necrosis (the decay of fat cells from around the sample site) or allergy to the suture material. In addition, you will have a 1-3 inch scar at the site of the biopsy.

There is a very small risk that you may have bleeding from the incision where the sample was taken. Other less common complications include infection or poor wound healing of the site where the sample was taken and hematoma (collection of blood around the incision site) or seroma (collection of fluid in the fat). These complications usually heal without any intervention.

**ARE THERE BENEFITS TO TAKING PART IN THIS SUBSTUDY?**

There is no direct benefit to you from being in this substudy. Knowledge from this substudy may help others with HIV infection in the future.

**WHAT ARE THE COSTS TO ME?**

You will not have to pay anything for the substudy clinic visits or if you stay in the hospital over night.

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**WILL I RECEIVE ANY PAYMENT?**

For your time and inconvenience, you will be compensated \$50 each time you have a DEXA and/or CT visit for this substudy. In addition, every time you have a fat biopsy, you will be compensated \$50.

ALL OTHER INFORMATION CONTAINED IN THE MAIN STUDY (A5202) CONSENT FORM APPLIES TO THIS SUBSTUDY.

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**SIGNATURE**

Your signature below indicates that 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 metabolic substudy.

If you also agree to participate in the fat biopsy study, please check this box

\_\_\_\_\_  
Participant's Name (print)

\_\_\_\_\_  
Participant's Signature

\_\_\_\_\_  
Date/Time

\_\_\_\_\_  
Study Staff Obtaining Consent (PRINT)

\_\_\_\_\_  
Study Staff Signature and Date