

UNIVERSITY OF PENNSYLVANIA HEALTH SYSTEM

AACTG 5202, Version 2.0, 10/31/06:

A Phase IIIB, Randomized, Trial of Open-Label Efavirenz or Atazanavir with Ritonavir in Combination with Double-Blind Comparison of Emtricitabine/Tenofovir or Abacavir/Lamivudine in Antiretroviral-Naïve Subjects

CONSENT FORM FOR WOMEN WHO BECOME PREGNANT WHILE ON 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
	Aleshia Thomas, RN	(215) 349-8092
	Larisa Zifchak, RN	(215) 349-8092

If you are seen at Presbyterian Medical Center [PMC], your contacts are:

Principal Investigator:	Jay Kostman, MD	(215) 662-9908
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24 Hour Emergency Number (215) 662-6059 Ask for the Immunodeficiency Program Doctor on call

INTRODUCTION

Because you are now pregnant, you are being asked if you want to continue taking part in this research study. This study was designed so that women who were pregnant could not join the study. However, because you were already in the study when you became pregnant, you will be allowed to stay in the study.

This consent form gives you more information about this study and how it may affect your pregnancy and your baby. The study staff will talk with you about this information. You may also talk with your own doctor about what is best for you and your baby and if you should choose other anti-HIV drugs. If you agree to stay in this study, you will be asked to sign this consent form. You will get a copy to keep. You are free to ask questions of the study staff at any time.

WHAT DO I HAVE TO DO IF I STAY IN THIS STUDY?

If you decide to continue to participate in this study while you are pregnant, you must permanently stop taking study drugs. Study drugs will not be provided and you should discuss other treatment options with your own doctor.

You will be asked to come to the clinic within 14 days after stopping study drugs. We believe this visit will last about 1 hour, but it may be shorter or even longer. A physical exam and about 2 tablespoons of your blood will be drawn for routine safety tests, a routine urine test, and to determine your viral load and CD4 cell counts (white blood cells that fight infection) before you stop. About 1 teaspoon of blood will be drawn for metabolic testing including cholesterol, triglycerides, and glucose. You must not have anything to eat or drink, except water and required prescription medications, for at least 8

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hours before coming to the clinic. You will be told the results of these tests as soon as the information becomes available. You will also be asked to fill out the form about how you take your study medications. The form will take about 10 minutes to complete.

You will continue to attend all of your study visits for the duration of the study. You will be followed on-study but off-study treatment. About 1 tablespoon of blood will be drawn at each visit to determine your viral load and CD4 cell counts. You will be told the results of these tests as soon as the information becomes available. We believe these visits will last about 30 minutes, but it may be shorter or even longer.

At the end of your pregnancy, study drugs will be provided for you if you choose to start study treatment again. This study will not provide care related to your pregnancy, the delivery of your baby, or the care of your baby. You must arrange for your care and your baby's care outside of this study.

Long-term follow-up care is recommended for a baby whose mother takes anti-HIV drugs during pregnancy. The study staff will talk with you about long-term follow-up care and the possibility of enrolling your baby in a long-term follow-up study.

WHAT ARE THE RISKS RELATED TO STAYING IN THE STUDY?

There are no additional risks to you or your baby by remaining on the study beyond what was discussed in the A5202 study informed consent.

BREAST-FEEDING

After delivery, if you decide to breast-feed your baby you may not take study drugs, but will be asked to continue study visits. Researchers know that HIV can pass through breast-milk and taking study drug(s) has not been proven to decrease the chance of passing HIV through your breast milk to your baby.

ARE THERE BENEFITS TO STAYING IN THIS STUDY?

If you continue to take part in this study, there may be a benefit to you and your baby, but no guarantee can be made. It is also possible that you and your baby will receive no benefit from continuing in this study.

WHAT CHOICES DO I HAVE IF I CHOOSE NOT TO CONTINUE IN THIS STUDY?

You can be treated by your primary care provider with:

- treatment with prescription drugs available to you
- treatment with experimental drugs being studied for use during pregnancy, if you qualify
- no treatment

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

WHAT ABOUT CONFIDENTIALITY?

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

People who may review your records include: the U.S. Food and Drug Administration (FDA), University of Pennsylvania IRB, National Institutes of Health (NIH), the Office for Human Research Protections (OHRP), study staff, study monitors, drug companies supporting this study, and their designees. Having a Certificate of Confidentiality does not prevent you from releasing information about yourself and your participation in the study.

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

WHAT ARE THE COSTS TO ME?

In addition to any costs that are described in the study consent you already signed, this study will not cover any cost related to your pregnancy, delivery of your baby, or care of your baby.

WHAT HAPPENS IF MY BABY OR I AM INJURED?

In the event of any physical injury resulting from the research procedures, you will both be given immediate treatment for your injuries. This medical treatment will be provided without cost to you. There is no program for compensation either through the University of Pennsylvania or the National Institutes of Health (NIH). If the injury is related to the investigational product/procedure, the Sponsor may reimburse for medical expenses incurred by you as a result of participation in the study.

You or your third party payer, if any, may be billed for medical expenses associated with this study only if they are deemed medically necessary and if such expenses would have been incurred independent of the study.

You will not be giving up any of your legal rights by signing this consent form.

WHAT ARE MY RIGHTS AS A RESEARCH PARTICIPANT?

Continuing to take part in this study is completely voluntary. You may choose not to continue in this study or leave this study at any time. You will be treated the same no matter what you decide.

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

WHAT DO I DO IF I HAVE QUESTIONS OR PROBLEMS?

If you wish further information regarding your rights as a research subject, you may contact the Director of Regulatory Affairs at the University of Pennsylvania by telephoning (215) 898-2614. If you ever have questions pertaining to your participation in this research study or about research-related injuries, you may contact the investigators or study nurse listed on the first page of this form.

SIGNATURE

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 this study, please sign your name below.

Participant's Name (print)

Participant's Signature

Date/Time

Study Staff Obtaining Consent (PRINT)

Study Staff Signature and Date