

UNIVERSITY OF PENNSYLVANIA HEALTH SYSTEM

AACTG 5175, Version 2.0, 8/02/06:

A Phase IV, Prospective, Randomized, Open-Label Evaluation of the Efficacy of Once-Daily Protease Inhibitor and Once-Daily Non-Nucleoside Reverse Transcriptase Inhibitor-Containing Combinations for Initial Treatment of HIV-1-Infected Individuals from Resource-Limited Settings (PEARLS) Trial

CONSENT FORM WOMEN WHO BECOME PREGNANT ON A5175

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

Principal Investigator:	Pablo Tebas, MD	(215) 615-4321
Coordinator:	Joseph Quinn, RN	(215) 349-8092
Study Nurse:	Larisa Zifchak, RN	(215) 349-8092
	Wayne Wagner, 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 and come for the same study visits whether or not you continue study medicines during your pregnancy

This is a consent form. It gives you more information about how continuing on this study may affect your pregnancy and your baby. The research 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, if you should remain on study-provided antiretroviral drugs (ART), or choose other ART. 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 research staff at any time.

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

It is not known if some of the drug combinations in this study harm unborn babies. Tests in pregnant animals do show some risk for some drugs. If you become pregnant while taking efavirenz (EFV), your doctor will tell you to stop taking it and replace it with another anti-HIV medicine, according to the current DHHS treatment guidelines.

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 you and your baby's care outside of this study. Long-term medical follow-up is recommended for a baby whose mother takes ART during pregnancy. The research staff will talk with you about long-term follow-up and the possibility of enrolling your baby in a long-term follow-up study.

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WHAT ARE THE RISKS RELATED TO STAYING IN THE STUDY?

Now that you are pregnant, there are some possible risks you should know. These possible risks to you and your baby are in addition to the risks that are described in the A5175 study consent you already signed.

Risks to You if You Stay on ART:

1. Different side effects or more severe side effects may occur in pregnant women taking anti-HIV medicines. This may make it more difficult for the medicines to work on the HIV in your blood.
2. The amount of ART in the blood may change during pregnancy. This means that the amounts of ART in your blood may decrease and not work as well or cause the HIV to become resistant to the drugs.
3. It is not known if some risks of pregnancy might be made worse by study medicines and may result in death.

Risks to Your Baby if You Stay on ART:

1. It is not known if some study medicines may cause you to have a baby that is born early or dead.
2. It is not known if some study medicines may cause your baby to be sick or have birth defects. Not all birth defects are seen at birth. Some birth defects are seen later as the baby grows.
3. In the U.S., only zidovudine (ZDV, Retrovir) is approved by the FDA to decrease the risk of passing HIV from mother to baby. The U.S. Public Health Service recommends that women discuss with their doctor the use of ZDV alone and with other anti-HIV drugs to decrease the risk of passing HIV to their baby.

There is little safety information regarding the use of TDF, FTC and ATV in pregnancy.

BREAST-FEEDING

After delivery, if you decide to breast-feed your baby you may continue taking study medicines.

A mother who is infected with HIV may infect her baby through breast milk. It is recommended that HIV-infected mothers who are able to obtain baby formula and clean water not breast-feed their babies. It is unknown whether the study medicines pass through the breast milk and may cause harm to your infant. It is also unknown whether study drugs may reduce the chances that HIV can pass to your baby through your breast milk.

ARE THERE BENEFITS TO STAYING IN THIS STUDY?

Use of combination anti-HIV drugs during later pregnancy significantly decreases the chance that the baby will become HIV-infected during pregnancy. However, if you continue to take part in this study, no guarantee can be made of a benefit to you or your baby. It is possible that you and your baby will

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receive no benefit from continuing in this study. Information learned from this study may help others who have HIV.

WHAT OTHER CHOICES DO I HAVE BESIDES STAYING ON STUDY DRUGS?

Instead of staying on the study medicines you have the choice of:

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

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?

Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. 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), study staff, study monitors, drug companies supporting this study, and their designees.

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. Having a Certificate of Confidentiality does not prevent you from releasing information about yourself and your participation in the study. 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.

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WILL I RECEIVE ANY PAYMENT?

If you decide to stay on study and continue with study visits either on or off treatment, you will still receive \$20 for each visit you attend for the study to compensate you for your time, inconvenience and transportation.

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.

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.

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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