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: Pablo Tebas, MD  (215) 349-8092
Coordinator: Joseph Quinn, RN  (215) 349-8092
Study Nurse: Kathryn Maffei, RN  (215) 349-8092
Aleshia Thomas, RN  (215) 349-8092
Wayne Wagner, 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:
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 anti-HIV drugs, or 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 research staff at any time.

What Do I Have To Do If I Stay In This Study?
If you stay in this study, you will continue to be followed as described in the A5257 Informed Consent. You will come to the clinic for regularly scheduled study visits, however, you will not be required to fast for any visits.

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 anti-HIV drugs 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.

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 A5257 study consent you already signed.
Risks to You if You Stay on Anti-HIV Drugs
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. The amount of anti-HIV drugs in the blood may change during pregnancy. This means that the amounts of anti-HIV drugs in your blood may decrease and not work as well or cause the HIV to become resistant to the drugs.

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 Anti-HIV Drugs:
• It is not known if some study medicines may cause you to have a baby that is born early or dead.
• 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.
• 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.

Breastfeeding
After delivery, if you decide to breast-feed your baby you may not continue to 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?
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 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?
We will do everything we can 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 ACTG, FDA, University of Pennsylvania IRB, OHRP, National Institutes of Health (NIH), 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. Zidovudine taken during pregnancy or at the time of delivery will not be supplied by the study.

**Will I Receive Any Payment?**
You will continue to be compensated for your participation in the study if you attend the visits as outlined in the main study at the same level.

**What Happens If My Baby or I Am Injured?**
If your baby or you are injured as a result of being in this study, you will both be given immediate treatment for your injuries. You should go to the nearest emergency room. You may contact the Principal Investigator or Emergency contact listed on page one of this form. You may also contact your own doctor, or seek treatment outside of the University of Pennsylvania. Be sure to tell the doctor or his/her staff that you are in a research study being conducted at the University of Pennsylvania. Ask them to call the telephone numbers on the first page of this consent form for further instructions or information about your care.

In the event that you are hurt or injured as a result of participation in this research study, please contact the investigator listed on page one of this form.

In the event of any physical injury resulting from research procedures, medical treatment will be provided without cost to you. There is no program for compensation either through this institution or the National Institutes of Health. If you have an illness or injury during this research trial that is not directly related to your participation in this study, you and/or your insurance will be responsible for the cost of the medical care of that illness or injury.

You do not give up your legal rights by signing this form.

**What Are My Rights As a Research Subject?**
Taking part in this study is completely voluntary. You may choose not to take part in this study or leave this study at any time. Your healthcare provider will treat you 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?

For questions about this study or a research-related injury, contact:
- Pablo Tebas, MD (215-349-8092)
- Clinical Trials Unit (215 349-8092)

For questions about your rights as a research subject, contact:
- Director of Regulatory Affairs at the University of Pennsylvania by phoning (215) 898-2614

CONSENT

When you sign this form, you are agreeing to continue your participation in this study after becoming pregnant while on study. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer. Your signature also means that you are permitting the University of Pennsylvania Health System and the School of Medicine to use your personal health information collected about you for research purposes within our institution. You are also allowing the University of Pennsylvania Health System and the School of Medicine to disclose that personal health information to outside organizations or people involved with the operations of this study.

A copy of this consent form will be given to you. You will also be given the University of Pennsylvania Health System and School of Medicine’s Notice of Privacy Practices that contains more information about the privacy of your health information.

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

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