UNIVERSITY OF PENNSYLVANIA HEALTH SYSTEM

IMPAACT 1077HS, Version 2.0 9-OCT-2012: HAART Standard Version of the PROMISE Study (Promoting Maternal and Infant Survival Everywhere)

CONSENT FOR WOMEN WHO BECOME PREGNANT WHILE ON STUDY SUPPLIED DRUG

Your contacts for this study are:

Principal Investigator:	Pablo Tebas, MD	(215) 349-8092
Address: 502 Johnson Pavilion Philadelphia, PA 19104		
Investigator:	Steven D. Douglas, MD	(215) 590-3561
Address: 1211 Abramson, Philadelphia, PA 19104		
Coordinator:	Joseph Quinn, RN, BSN	(215) 349-8092
Study Nurse:	Wayne Wagner, RN	(215) 349-8092

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

INTRODUCTION:

This is a consent form for women who become pregnant while taking HIV medicines given to them from the PROMISE study, Because you are now pregnant, you are being asked if you want to continue taking HIV medications from the study. This form gives information on how HIV medicines may affect you, your pregnancy and your baby. It is important to have this information before deciding if you want to continue taking HIV medicines from the study.

The study staff will talk with you about this information. You may also talk with your own health care provider and you are free to ask questions at any time. If you choose to continue taking HIV medicines from the study, you will be asked to sign this form. You will get a copy to keep..

WHAT DO I HAVE TO DO IF I STAY ON THE STUDY MEDICATIONS?

There will be no change to your study visits regardless of whether you choose to continue taking HIV medicines from the study. You will continue to have study visits and tests as stated in the consent form that you signed when you first joined the study. If you are still pregnant at your last study visit, the study staff will contact you to find out the outcome of your pregnancy.

The study will not provide care related to your pregnancy or the delivery of your baby. The study will not provide care of your baby after birth. You must arrange for this care outside of this study. The study staff can tell you about places to go for this care, if you wish.

Long-term follow-up is recommended for babies whose mothers take HIV medicines during pregnancy. The study staff will talk with you about options for long-term follow-up that may be available when your participation in this study ends.

WHAT ARE THE RISKS RELATED TO STAYING IN THE STUDY?

The possible risks of taking part in this study were described in the consent form that you signed when you first joined the study. This form describes additional possible risks for you and your baby from taking HIV medicines during pregnancy.

Risks to You if You Stay on Study Drug(s):

1. Different side effects or more severe side effects may occur in pregnant women taking HIV medicines. This may make it more difficult for you to take your HIV medicines. Not taking your medicines as directed could cause the medicines not to work on the HIV in your body.
2. The amount of HIV medicine in the blood may change during pregnancy. Because of this, the amount of medicine in your body may be decreased and the medicines may not work as well as usual. This could also cause the HIV in your body to become resistant. When resistance occurs, a medicine no longer works against HIV, which can limit the choices of HIV medicines a person can take in the future.
3. It is not known if some risks of pregnancy might be made worse by HIV medicines, possibly resulting in death.

Risks to Your Baby if You Stay on Study Drug(s):

1. It is not known if some HIV medicines may cause babies to be born early or dead.
2. It is not known if some HIV medicines may cause babies 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.

The World Health Organization recommends the use of several HIV medicines during pregnancy that are available through the study, including zidovudine (ZDV), lamivudine (3TC), tenofovir (TDF), and lopinavir-ritonavir (LPV-RTV). In the US, only ZDV is approved by the Food and Drug Administration to decrease the risk of passing HIV from mother to baby. The US Public Health Service recommends that women take ZDV with other HIV medicines to decrease the risk of passing HIV from mother to baby.

In the places where the PROMISE study is being done, it recommended that women take a combination of at least three HIV medicines during pregnancy to try to keep their babies from getting HIV during pregnancy and delivery. If you choose not to continue taking HIV medicines from the study while you are pregnant, it is important that you take HIV medicines from another program or provider outside the study to decrease the risk of passing HIV to your baby

BREASTFEEDING
Breastfeeding is not recommended for HIV-infected women where safe formula feeding is available. HIV can pass through breast milk and taking HIV medicines during breastfeeding cannot be guaranteed to protect against this. Babies may also receive some amounts of HIV medicines taken by their mothers through breast milk. It is not known whether this may cause harm to babies. Because of both the potential for HIV transmission and the potential for serious adverse reactions in nursing infants,you should not breastfeed if you are receiving NORVIR.

ARE THERE BENEFITS TO STAYING IN THIS STUDY?
The possible benefits of taking part in this study were described in the consent form that you signed when you first joined the study. This form describes additional possible benefits for you and your baby from taking HIV medicines during pregnancy.

HIV medicines, whether given to you from the study or obtained from outside the study, can decrease risk of passing HAV from mother to baby. These medicines are used throughout the world for this purpose. Information learned from this study may help others who have HIV in the future.

WHAT OTHER CHOICES DO I HAVE BESIDES STAYING ON STUDY DRUGS?
Instead of continuing to take HIV medicines from the study, you have the choice of taking HIV medicines from another program or provider outside the study. The study staff will talk with you about these choices, their risks and benefits. You should also talk with your own health care provider about these choices.

WHAT ABOUT CONFIDENTIALITY?
The consent form that you signed when you first joined the study explained the efforts that will be made keep information about you and your participation in this study confidential. There will be no change to this regardless of whether you continue to take HIV medicines from the study.

WHAT ARE THE COSTS TO ME?
There are no additional costs to you as a result of continuing to take HIV medicines from the study while you are pregnant. If you take HIV medicines from another program or provider outside the study, you or your health insurance will need to pay for the medicines, unless the medicines are available free of charge. The study cannot pay for medicines obtained from other programs or providers.

As stated above, this study will not cover any costs related to your pregnancy, delivery of your baby, or care for your baby.

WILL I RECEIVE ANY PAYMENT?
You will receive $25.00 for each study visit you attend, as described in the main consent.

WHAT HAPPENS IF I AM INJURED?
If your baby or you are injured as a result of being in this study—including as a results of taking HIV medicines from the study-- you will both be given immediate treatment for your injuries. However, you or your insurance may have to pay for this care . There is no program for compensation either through the University of Pennsylvania or the US National Institutes of Health (NIH). 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 and to take HIV medicines from the 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 any new information from this study or other studies that may affect your health, welfare, or willingness to continue taking HIV medicines from the study. We will also tell you about new information that may affect your willingness to stay in the study.

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 take part in this research 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.

If you have read this consent form (or had it explained to you), all of 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 and Date/Time
_____	_____
Study Staff Conducting Consent Discussion (print)	Study Staff Signature and Date
_____	_____
Witness's Name (print) (As appropriate)	Witness's Signature and Date