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 SPECIMEN STORAGE AND FUTURE USE

Your contacts for this study are:

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Study Nurse:	Wayne Wagner, RN	(215) 349-8092

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

INTRODUCTION:

You have decided that you will participate in this research study to help us find the best ways to keep mothers healthy after receiving anti-HIV drugs to prevent their babies from being infected with HIV. In addition to the tests that you have as part of the study, we are asking now for your permission to save some blood and cells from your blood for future use. These specimens would be saved in a place called a repository, which is a special laboratory with freezers to store the specimens.

Researchers can learn a lot from a study, but as time goes by the tests that they use get better or brand new tests are developed, and more can be learned with these better or new tests by using them on stored specimens. If a researcher wants to do a test on specimens from the repository in the future, he or she will write up the idea and it will have to be approved by the leaders of the study team and other groups to make sure the research is worthwhile. If the idea is approved, then coded specimens and coded information will be given to the researcher. They would never know your name.

Because of the location of the repositories and/or the place where the tests will be conducted, these stored samples may be shipped to another country for storage and/or future use.

WHAT ABOUT CONFIDENTIALITY?

There are no names on any of the specimens, only a special study number. The people who run the repository and the scientists who later use the specimens will not know your name or any other information about you that might identify you. As explained when you agreed to join the study, records associated with the specimens may be reviewed by the study sponsor (the US National Institutes of Health) or its agents, the US Office for Human Research Protections (OHRP), pharmaceutical supporters, national regulatory authorities and the institutional review board (IRB) or ethics committee (EC) that oversee the research.

HOW OFTEN WILL THESE SPECIMENS BE COLLECTED?

As described to you when you agreed to join the study, blood will be collected for study tests at each study visit. After all testing that is planned to be done for the study has been completed, some of your blood and cells from your blood may be leftover. It is these leftover specimens that you are being asked to have stored for future use. You are not being asked to give additional specimens for long term storage and future use.

WHAT KIND OF TESTS MIGHT BE DONE ON MY SPECIMENS?
Tests that might be done include tests to see how much HIV is in the blood, how the body responds to HIV, how HIV causes disease, the levels of HIV drugs in the blood, and how drugs cause side effects. The tests might also look at other infections like malaria or other conditions like diabetes that people with HIV may get. The tests might look at how a person's genetic makeup (your DNA) either protects them or puts them at greater risk. This kind of information is important for scientists who are working on an HIV vaccine.

WILL I GET THE RESULTS OF THESE TESTS?
Most of the time, you will not get results from these tests. This is because research can take a long time. Results from research using the specimens may not be ready for many years.

The researchers who use stored samples for a study approved by NIH will not contact you with the results of their study because they will use samples with codes and will not know who to contact. If their findings could provide important information for your medical care, then the investigators would contact the research staff at your site with the results, and the staff at your clinic can link the code with your name and notify you of the results. If you would like to be contacted with this sort of information, you must notify the site staff of any changes in your address or phone number.

HOW LONG WILL THE SPECIMENS BE STORED?
There is no time limit on how long the samples will be stored.

WHAT IF I DON'T WANT MY SAMPLES SAVED FOR FUTURE USE?
You may decide that you do not want your samples stored for future research studies. You can still participate in this study even if you make this decision. Any leftover specimens from you will be destroyed at the end of the study.

WHAT IF I AGREE TO HAVE MY SPECIMENS STORED AND THEN CHANGE MY MIND?
People always have the right to stop participating in research. If you decide that you do not want researchers to be able to use the specimens in the repository, you can contact the clinic staff. They will tell the repository that the specimens with your study code number should not be studied, and these specimens will be destroyed. If you change your mind after your specimens have already been shipped for testing, the samples that have been shipped will still be tested but your specimens still remaining in the repository will be destroyed.

WHAT ARE THE BENEFITS TO ME FROM AGREEING TO STORE SPECIMENS?
There are no direct benefits to you from storing your specimens. You may be helping people in the future from the results of studies using the stored specimens.

WHAT ARE THE RISKS TO ME FROM AGREEING TO STORE SPECIMENS?
These specimens are collected as part of this study and there is no additional risk from collecting them. They are stored by code number so there is no risk of loss of privacy.

WHAT ARE THE COSTS TO ME?
There is no cost to you for having your specimens stored.

WILL I RECEIVE ANY PAYMENT?

You will not receive any payment for providing these specimens for storage. Your samples will not be sold or directly used to produce commercial products. In the future, some of the research may help to develop new products, such as tests and drugs (commercial products). If this does happen and these tests or drugs make money, there are no plans to share that money with the people who gave the specimens.

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.

____ I give my permission for storage and future testing of my specimens as discussed in this consent form (including genetic testing).

____ I give my permission for storage and future testing of my specimens as discussed in this consent form EXCEPT for genetic testing.

____ I do NOT give my permission for storage and future testing of my specimens.

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