

UNIVERSITY OF PENNSYLVANIA HEALTH SYSTEM

A5258, Version 1.0, 12/17/08

Phase II, Double Blind, Randomized, Exploratory Study of Chloroquine for Reducing HIV-Associated Immune Activation

CONSENT FORM TO PARTICIPATE IN A RESEARCH STUDY
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:	Wayne Wagner, 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, but will not continue study treatment during your pregnancy.

This is a consent form. It 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 whether you should start anti-HIV therapy. 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 choose to stay in this study, you will need to stop all study treatment. You will continue to have study visits and tests as stated in the study A5258 informed consent. In addition, you will be contacted by telephone after the pregnancy has ended to see how you and the baby are doing.

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 is recommended for a baby whose mother takes anti-HIV drugs or other study drugs during pregnancy. The study 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?

There are no additional risks to you or your baby from remaining on study beyond what was discussed in the main study A5258 informed consent.

Are There Benefits To Staying In This Study?

If you continue to take part in this study, you may receive benefit by being closely observed for your HIV, but no guarantee can be made. It is also 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.

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What Other Choices Do I Have Besides Staying In The Study?

Instead of being in this study you have the choice of:

- treatment with prescription drugs 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 U.S. Food and Drug Administration, University of Pennsylvania IRB, National Institutes of Health (NIH), Office for Human Research Protections (OHRP), the ACTG, study staff, and study monitors. 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.

Will I Receive Any Payment?

If you continue study visits according to the schedule, you will be compensated the amounts noted in the main consent for this study.

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. The cost for this treatment will be charged to you or your insurance company. There is no program for compensation either through the University of Pennsylvania or the 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 Subject?

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?

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.

Name of Subject (Please Print)	Signature of Subject	Date
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Name of Person Obtaining Consent (Please Print)	Signature	Date
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For subjects unable to give authorization, the authorization is given by the following authorized subject representative:

Authorized subject representative [print]	Authorized subject representative Signature	Date
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Provide a brief description of above person authority to serve as the subject's authorized representative.
