

UNIVERSITY OF PENNSYLVANIA HEALTH SYSTEM

A5232, Version 2.0, 09/03/08

Optimizing Vaccine Responsiveness in HIV-1 and HCV Infections by Identifying Determinants of Responsiveness: A Pilot Study

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) 615-4321 |
| Coordinator: | Joseph Quinn, RN | (215) 349-8092 |
| Study Nurse: | Kathryn Maffei, 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. If you decide to stay in the study, you will not be able to receive the study vaccinations while you are pregnant.

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. 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 are staying in the study you will continue to have the study visits, as noted in the study consent that you already signed. The amount of blood taken for immune responses will be smaller. About 1-2 tablespoons of blood will be taken from a vein in your arm for these tests.

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.

What Are The Risks Related To Staying In The Study?

It is not known whether the vaccines used in this study cause harm to unborn babies. 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.

There are no foreseeable additional risks to you, now that you are pregnant, other than those described in the study consent that you already signed.

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Are There Benefits To Staying In This Study?

If you stay in this study there will more than likely not be any direct benefit to you. Information learned from this study may help others who are infected with HIV-1 and/or HCV.

What Other Choices Do I Have Besides Staying On Study Drugs?

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

- Receiving the hepatitis A and B and the diphtheria/tetanus vaccine (Decavac) from your doctor
- 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. In addition, 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), Office of Human Resource Protections (OHRP), study staff, 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.

Your records may be reviewed by the U.S. Food and Drug Administration (FDA), University of Pennsylvania IRB, National Institutes of Health (NIH), study staff, study monitors.

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 unborn child, or care of your unborn child.

Will I Receive Any Payment?

You will receive \$25 for any study related visit you attend.

What Happens If My Baby Or I Am Injured?

If you have a medical emergency during the study 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

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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, but financial compensation is not otherwise offered from the University of Pennsylvania 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.

What Are My Rights As a Research Subject?

Continuing to take 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 (215-615-4321)
- 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

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

Provide a brief description of above person authority to serve as the subject's authorized representative. _____