

UNIVERSITY OF PENNSYLVANIA HEALTH SYSTEM

A5247, Version 2.0, 02/09/09

A Phase II, Randomized, Double-Blind, Placebo-Controlled Clinical Trial to Evaluate the Safety, Tolerability, and Immunogenicity of ZOSTAVAX® (Zoster Vaccine Live) in Human Immunodeficiency Virus (HIV) -1-Infected Adults on Potent Combination ART with Conserved Immune Function

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
	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. If you decide to stay in the study, you will not be able to receive the study treatment. In other words, you will not be able to receive further 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 but you will not receive injections of vaccine. There are no anticipated additional risks to you. You and your physician will decide what anti-HIV drug combination would be best for you to continue during your pregnancy. The amount of blood taken for immune responses will be about 2 tablespoons. About 1-2 tablespoons of blood will be drawn for CD4 counts and viral loads. You will also have physical exams according to the study schedule. In addition, after the pregnancy is over, the clinic staff will contact you to find out about any events that happened during your pregnancy and about the health of the baby. Because this study is only 24 weeks, this contact may happen after you have completed the study.

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.

A5247, Vsn 2.0, 2/09/09: Consent for Women Becoming Pregnant While On Study

Long-term follow-up is recommended for a baby whose mother takes anti-HIV 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?

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.

Are There Benefits To Staying In This Study?

If you continue to take part in this study, there may be a benefit to you and your baby, 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.

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

Instead of staying in this study you can choose to end your participation in the study. Please talk to your doctor about the choices available to you.

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 for Human Research Protections (OHRP), the AIDS Clinical Trials Group (ACTG), 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.

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.

A5247, Vsn 2.0, 2/09/09: Consent for Women Becoming Pregnant While On Study

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 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

A5247, Vsn 2.0, 2/09/09: Consent for Women Becoming Pregnant While On Study

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

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. _____