

UNIVERSITY OF PENNSYLVANIA HEALTH SYSTEM

A5235, Version 2.0, 10/30/07

Phase II, Randomized, Placebo-Controlled, Double-Blind Study of Minocycline in the Treatment of HIV-Associated Cognitive Impairment

CONSENT FORM TO CONTINUE PARTICIPATE IN A RESEARCH STUDY FOR SUBJECTS BECOMING 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
Investigator:	Dennis Kolson, MD, PhD	(215) 349-8146
Coordinator:	Joseph Quinn, 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 drug or placebo anymore.

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 should remain on anti-HIV drugs or choose other anti-HIV drugs. 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.

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 DO I HAVE TO DO IF I STAY IN THIS STUDY?

If you become pregnant during Part 1 of the study and decide to stay in the study, you will continue to have the study visits, as noted in the study consent that you already signed. You will no longer take the study drug or placebo. You will not have any of the spinal taps. The amount of blood taken for immune responses and other routine safety tests will be smaller. About 1-2 tablespoons of blood will be taken from a vein in your arm for immune responses and other routine safety tests. You will be told the results of the routine safety tests as soon as the information becomes available. If you become pregnant during Part 2 of the study, you will be asked to come in for a discontinuation visit. No further visits will be required.

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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?

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 take part in this study there will more than likely not be any direct benefit to you. Information learned from this study may help others who have HIV.

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 gotten 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 (FDA), University of Pennsylvania IRB, National Institutes of Health (NIH), 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 baby or care of your baby.

WILL I RECEIVE ANY PAYMENT?

You will be compensated on the reimbursement schedule described in the main study consent.

WHAT HAPPENS IF MY BABY OR I AM INJURED?

If you or your baby has 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

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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 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 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

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SIGNATURE PAGE

If you have read this consent form (or had it explained to you), all 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

Participant's Legal Guardian (print)
(As appropriate)

Legal Guardian's Signature and Date

Study Staff Conducting
Consent Discussion (print)

Study Staff Signature and Date

Witness's Name (print)
(As appropriate)

Witness's Signature and Date