

**A5185s, SUBSTUDY of AACTG 5175, Version 2.0, 8/02/06:  
EFFECT OF INITIAL ANTIRETROVIRAL TREATMENT ON GENITAL COMPARTMENT VIRUS IN INDIVIDUALS  
FROM RESOURCE-LIMITED SETTINGS**

**CONSENT FORM TO PARTICIPATE IN A RESEARCH 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:	Wayne Wagner, RN	(215) 349-8092
	Larisa Zifchak, RN	(215) 349-8092

**If you are seen at Presbyterian Medical Center [PMC], your contacts are:**

Principal Investigator:	Jay Kostman, MD	(215) 662-9908
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*24 Hour Emergency Number (215) 662-6059 Ask for the Immunodeficiency Program Doctor on call*

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**WHY IS THIS SUBSTUDY BEING DONE?**

This study is being done to see what happens to the type and amount of HIV in genital secretions when you take antiretroviral drugs (ART).

**PROCEDURES**

You may decide not to join this substudy or join it and leave before it is completed and still stay in the main A5175 study. About 315 people will take part in this substudy. It will last about 2 ½ to 3 years, the same time as A5175.

You can schedule study visits on the same day as the main A5175 study visits.

**Eligibility**

If you qualify and decide to take part in this study, you will be asked to sign this consent form.

**Study Entry and Evaluations**

You will be asked to give genital secretions on the day you begin the study, once every year, if you change your ART regimen, and at the end of the study (about 5 times). Results of the genital secretion tests will not be available until the end of the study.

Genital Secretions Collection:

**For Men Only**

You may not have any sexual activity for 48 hours before to giving your semen specimen. You will need to cleanse your penis and then masturbate (without lubricants other than water) in a private room at the clinic and put your semen in a sterile container given to you. If you can bring your sample to the clinic within 2 hours, you may do this at home.

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#### For Women Only

You may not have any sexual activity, or douche, or use any vaginal products in or around your vagina area for at least 48 hours before specimens are obtained.

You will have a pelvic exam (the same exam used to do a Pap smear) performed to obtain specimens. A speculum (an instrument that stretches the opening of the vagina) will be eased into the vagina. Tiny absorbent strips will be inserted into the entrance of the cervix (the cervix is the opening of the womb or uterus) and left in place for about 1 minute to absorb the sample.

#### Leaving the Substudy Early

If you decide to leave this substudy before it ends, you will be asked to return to the clinic and give a genital specimen.

#### RISKS AND/OR DISCOMFORTS

##### Risks of Genital Secretions Collection

The risks of collection of genital secretions (male or female) are pain and discomfort.

#### PREGNANCY AND BREAST-FEEDING

If you become pregnant during this study, you may continue to take part in this substudy and have genital secretions collected during your pregnancy. You will not have specimens collected during labor or if you have signs of vaginal bleeding or rupture of membranes. You may have genital secretions collected again 6 weeks after delivery. Women who are breast-feeding may take part in this substudy.

#### BENEFITS

There will be no direct benefit to you from being in this study. However, knowledge gained from this study may help others who have HIV/AIDS in the future.

#### WILL I RECEIVE ANY PAYMENT?

For the additional time and inconvenience, you will receive \$50 for each visit when genital secretions are required; this amounts to \$250 if you complete all the study scheduled visits.

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**SIGNATURE**

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.

*All other information in the main A5175 study consent that you signed, applies to this substudy consent as well.*

\_\_\_\_\_  
Participant's Name (print)

\_\_\_\_\_  
Participant's Signature

\_\_\_\_\_  
Date/Time

\_\_\_\_\_  
Study Staff Obtaining Consent (PRINT)

\_\_\_\_\_  
Study Staff Signature and Date