

UNIVERSITY OF PENNSYLVANIA HEALTH SYSTEM AND SCHOOL OF MEDICINE

A5257: A Phase III Comparative Study of Three Non-Nucleoside Reverse Transcriptase Inhibitor (NNRTI)-Sparing Antiretroviral Regimens for Treatment-Naïve HIV-1-Infected Volunteers

RESEARCH SUBJECT HIPAA AUTHORIZATION

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:	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

You have agreed to participate in the study mentioned above and have signed or will sign a separate informed consent that explains the procedures of the study and the risks and benefits of participation. This authorization form gives more detailed information about how your personal health information may be used and disclosed by the University of Pennsylvania Health System (UPHS), the School of Medicine and the individual Principal Investigator, subject to University of Pennsylvania procedures.

What personal health information is collected and used in this study and might also be disclosed?

The following personal health information will be collected, used for research, and may be disclosed during your involvement with this research study:

- Name, address, telephone number, date of birth
- Social security number (for W-9 so you can receive payments)
- Personal and family medical history
- Current and past medications or therapies
- Information from a physical examination that generally also includes blood pressure reading, heart rate, breathing rate and temperature
- Results of tests and procedures you will undergo during this research study as described in the informed consent form(s)

Why is your personal contact and health information being used?

Your personal contact information is important for the research team to contact you during the study. Your personal health information and results of tests and procedures are being collected as part of this research study. In some situations, your personal health information might be used to help guide your medical treatment.

Which of our personnel may use or disclose your personal health information?

The following individuals may use or disclose your personal health information for this research study:

- The Principal Investigator and the Investigator's study team
- Authorized members of the workforce of the UPHS and the School of Medicine, and University of Pennsylvania support offices, who may need to access your information in the performance of their duties (for example: for research oversight and monitoring, to provide treatment, to manage accounting or billing matters, etc.).

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Who, outside of UPHS and the School of Medicine, might receive your personal health information?
As part of the study, the Principal Investigator, the study team and others listed above, may disclose your personal health information, including the results of the research study tests and procedures. This information may be disclosed to those listed below:

Individuals or organizations responsible for administering the study:

- AACTG Data Coordinating Center (FSTRF): Data will be recorded on case report forms, keyed into a central database and electronically submitted to the Data Coordinating Center. Statistical Data Analysis Center (SDAC): Approved data will be downloaded from FSTRF to the statistical data center for the AACTG at the Harvard School of Public Health. Specific study reports will be periodically provided to the study team and data safety review board.
- Contract Research Organization (PPD, Inc): Monitors from PPD will visit the AACTG on a quarterly basis to review data and correct mistakes before the data are sent to SDAC for analysis.
- Pharmaceutical Sponsors: Drug companies (Bristol-Myers Squibb, Inc., Gilead Sciences, Inc., Merck & Co., Inc and Tibotec Therapeutics) who supply treatment for the study will have access to safety information.
- Government Agencies: Data from this study will be made available to the Food and Drug Administration and to the Division of AIDS (DAIDS) of the National Institute for Allergy and Infectious Disease, for them to evaluate the safety and efficacy of the treatments being used in this study.

Regulatory and safety oversight organizations

- The Food and Drug Administration
- The Office of Human Research Protections
- The study Data and Safety Monitoring Board

Once your personal health information is disclosed to others outside of UPHS or the School of Medicine, it may no longer be covered by federal privacy protection regulations. Data are reported to the sponsor on Case Report Forms that identify you by your unique study number and not your name, date of birth or medical record number. Information regarding your health, such as side effects of the study vaccine you experience will be reported only by code number. All samples collected for analysis will be labeled with your study number, visit number and date of your visit.

The Principal Investigator or study staff will inform you if there are any additions to the list above during your active participation in the trial. Any additions will be subject to University of Pennsylvania procedures developed to protect your privacy.

How long may UPHS and the School of Medicine be able to use or disclose your personal health information?

Your authorization for use of your personal health information for this specific study does not expire.

Your information may be held in a research repository (database). However, UPHS and the School of Medicine may not re-use or re-disclose information collected in this study for a purpose other than this study unless:

- You have given written authorization to do so
- The University of Pennsylvania's Institutional Review Board grants permission after ensuring that appropriate privacy safeguards are in place
- As permitted by law

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Will you be able to access your records?

During your participation in this study, you might not be able to access some or all of your medical records. For example, access to portions of your medical records may be denied in studies where your knowledge of study results included in such records could affect the reliability of the study. You will have access to your medical record information when the study is over or earlier, if possible. The Principal Investigator is not required to release research information to you that is not part of your medical record.

Can you change your mind?

Yes, at any time you may withdraw your approval to allow the use and disclosure of your personal health information as described here. You must do so in writing to the Principal Investigator at the address on the first page. Even if you withdraw your permission, your personal health information that was collected before we received your written request may still be used and disclosed, as necessary for the study. If you withdraw your permission to use your personal health information, you will also be withdrawn from the research study.

If you withdraw your permission to use any blood or tissue obtained for the study, the Principal Investigator will ensure that these specimens are destroyed or will ensure that any information that could identify you is removed from these specimens.

You will be given a copy of this Research Subject HIPAA Authorization describing your confidentiality and privacy rights for this study. You will also be given the UPHS and School of Medicine's Notice of Privacy Practices that contains more information about the privacy of your personal health information.

By signing this document you are permitting the UPHS and the School of Medicine to use and disclose personal health information collected about you for research purposes as described above.

Name of Subject (PRINT)

Signature of Subject

Date

Name of Person Obtaining Authorization
(PRINT)

Signature

Date