

UNIVERSITY OF PENNSYLVANIA HEALTH SYSTEM

AACTG 5202

A Phase IIIB, Randomized, Trial of Open-Label Efavirenz or Atazanavir with Ritonavir in Combination with Double-Blind Comparison of Emtricitabine/Tenofovir or Abacavir/Lamivudine in Antiretroviral-Naïve Subjects

RESEARCH SUBJECT AUTHORIZATION
CONFIDENTIALITY AND PRIVACY RIGHTS

If you are seen at the Hospital of the University of Pennsylvania [HUP], your contacts are:

Principal Investigator:	Robert Gross, MD, MSCE	(215) 898-2437
Sub Investigators	Pablo Tebas, MD	(215) 615-4321
	Ian Frank, MD	(215) 662-7419
Coordinator:	Joseph Quinn, RN	(215) 349-8092
Study Nurse:	Wayne Wagner, RN	(215) 349-8092
	Kathryn Maffei, RN	(215) 349-8092
	Cathi Lee Ybarra, RN	(215) 662-6434

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

Introduction

You have agreed to participate in AACTG study 5202. This is an authorization form that gives more detailed information about how your health information will be protected and includes:

- What personal health information about you will be collected in this study
- Who will use your information within the institution and why
- Who may disclose your information and to whom
- Your rights to access research information about you
- Your right to withdraw your approval for any future use of your personal health information

By signing this Authorization Form 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 processing of this study.

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

Personal health and contact (phone number, address) information collected as part of this AACTG study is recorded in your AACTG chart. This record is separate from your medical chart. Data collected for the study is reported to the study team on a case report form, which includes the information listed below, but not your name or other identifying information. Results of laboratory tests or study procedures will be copied and sent to your primary care physician by name, at your request only.

Personal health information that is collected and will be disclosed to the agencies listed on the following page as part of this research study is:

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- Demographics (Race, Gender and use of IV drugs)
- Study medication compliance and toxicities
- Signs and symptoms you experience while on the study
- Current and past medical diagnoses
- Current and past medications and therapies
- Allergies
- Information from a physical exam: weight, blood pressure, heart rate, temperature
- Data from laboratory tests (blood chemistry and hematology tests), CD4 count, viral load, hepatitis serologies
- Responses from study questionnaires, adherence assessments

Why is your personal health information being used?

Personal contact information, such as phone number and address, will be used only by AACTG staff to get in touch with you while you are participating in AACTG5202. Your health information and results of tests and procedures are being collected as part of the research study and for the advancement of medicine and clinical care. The Principal Investigator will use the results to monitor your safety and ability to tolerate the study medications.

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

The following individuals and organizations may use or disclose your personal health information for this research project:

- The Principal Investigator and other University staff associated with this study;
- The University of Pennsylvania Institutional Review Boards (the Committees charged with overseeing research on human subjects) and the University of Pennsylvania Office of Regulatory Affairs
- Authorized members of the University of Pennsylvania and the University of Pennsylvania Health System and School of Medicine work force who may need to access your information in the performance of their duties, for example, to provide treatment, to ensure the integrity of the research, accounting or billing matters, etc.

Who, outside of the University of Pennsylvania Health System and the School of Medicine, might receive your personal health information?

As part of the study the Principal Investigator, study team and others listed above, may disclose your personal health information, including the results of the research study tests and procedures to the following:

- 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.

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- 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 (Abbott Laboratories, Bristol-Myers Squibb, Inc., Gilead Sciences, Inc. and GlaxoSmithKline, Inc.) 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.

Study staff will inform you if there are any changes to this list above during your active participation in the trial. Once information is disclosed to others outside the University of Pennsylvania Health System or School of Medicine the information may no longer be covered by federal privacy protection regulations.

In all disclosures outside the University of Pennsylvania Health System or School of Medicine, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier, unless disclosure of the direct identifier is required by law. Personal health information will be disclosed by a unique code number. Only AACTG staff can break the code and identify you to your code.

How long will the University of Pennsylvania Health System and the School of Medicine be able to use or disclose your personal health information?

Your authorization for use of your personal information for this specific study does not expire. This information may be stored in a database (research repository). However, the University of Pennsylvania Health System and the School of Medicine may not re-use or re-disclose your personal health information collected for this study for another purpose other than the research described in this consent form unless you have given written permission to the Principal Investigator to do so. However, the University of Pennsylvania Institutional Review Board may grant permission to the Principal Investigator or others to use your information for another purpose after ensuring that appropriate safeguards are in place. The Institutional Review Board is a committee whose job is to protect the safety and privacy of research subjects. Results of all tests and procedures done solely for this research study and not as part of your regular care will not be included in your medical record unless you want them to be sent to your primary care provider. You will need to complete a medical records release of information to allow us to provide study data to your doctor.

Will you be able to access your records?

You will be able to request access to your medical record when the study is completed. During your participation in the study, you will not be able to access your medical records. This will be done to prevent the knowledge of study results affecting the reliability of the study. Your information will be available should an emergency arise that would require your treating physician to know the

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information to best treat you. You will have access to your medical record and study information that is part of that record when the study is over. The Investigator is not required to release to you research information that is not part of your medical record.

Can you change your mind?

You may withdraw your permission for the use and disclosure of any of your personal information for research, but you must do so in writing to the Principal Investigator at 502 Johnson Pavilion. Even if you withdraw your permission, the Principal Investigator for the research study may still use your personal information that was collected prior to your written request if that information is necessary to the study. If you withdraw your permission to use your personal health information that means you will also be withdrawn from the research study.

PERMISSION

You will be given a copy of this Research Subject Authorization form describing your confidentiality and privacy rights for AACTG5202 with the study specific consent form. 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.

By signing this addendum you are permitting the University of Pennsylvania Health System and School of Medicine to use and disclose personal health information about you for research purposes as described in this addendum.

Participant's Name (print)

Participant's Signature

Date/Time

Study Staff Obtaining Authorization (PRINT)

Study Staff Signature and Date