

Schering-Plough Research Institute P04889 - Site # 28  
Vicriviroc in Combination Treatment With an Optimized ART Regimen in HIV-Treatment  
Experienced Subjects (VICTOR-E4)

*RESEARCH SUBJECT HIPAA AUTHORIZATION*

Principal Investigator:	Pablo Tebas, MD	(215) 615-4321
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Coordinator:	Joseph Quinn, RN	(215) 349-8092
Study Nurse:	Wayne Wagner, RN	(215) 349-8092

*24 Hour Emergency Number (215) 662-6059 Ask for the Immunodeficiency Program Doctor on call*

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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?**

In working with the sponsor, to study the safety and efficacy of the study drug, the trial doctor and other trial site personnel will need to use your personal health information that contains identifying information about you. This personal health information will include information in your medical record and information created or collected during the trial. 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
- 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.

The sponsor including its representatives will use your health information to evaluate the study drug. The sponsor may add your study data to research databases so that it can design better research studies in the future, develop other therapies for patients or gain a better understanding of disease.

**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

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- 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.).

**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:

- Schering-Plough Research Institute and its representatives: This is the pharmaceutical company that will supply the study drug. They will need access to your health information to link this with any adverse experiences that occur with the use of the study drug.
- Monogram Biosciences: Coreceptor tropism, drug susceptibility, HIV envelope sequencing, and HIV RT/P genotyping and phenotyping tests will be performed by this vendor who may require some information.
- Central Reading facility: ECGs will be forwarded to a third party (to be named) for standard readings. Reported only by subject number, but additional information may be required.

Regulatory and safety oversight organizations

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

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 drug you experience, medication you are taking or results of study neurology tests, 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 is my data handled by the sponsor?**

A code number is assigned to the trial data that the trial doctor collects from your personal health information. Using the code number without your name or other identifying information the trial doctor sends the trial data to the sponsor and people, regulatory agencies and companies with whom the sponsor works. The sponsor and those with whom the sponsor works will use the trial data to study the safety and efficacy of the study drug. In addition to studying the safety and efficacy of the study drug, the sponsor may add the trial data to research databases so that it can study better measures of safety and effectiveness, study other therapies for patients, develop a better understanding of disease, or improve the efficacy of future clinical trials. The sponsor along with the people, companies, and regulatory agencies with whom the sponsor works may be located in other

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countries throughout the world including the United States. Some of these countries may not offer the same level of privacy protection as you are used to in your country. However, the sponsor will ensure what is stated in this consent is followed for any information it receives that could be used to identify you.

**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

**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. Information given to the sponsor before you cancel this authorization may still be used by the sponsor. If you withdraw your permission to use your personal health information, you will also be withdrawn from the research study.

If you do not sign this document and give this Authorization then you will not be able to participate in the 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.

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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.

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Name of Subject (PRINT)

\_\_\_\_\_  
Signature of Subject

\_\_\_\_\_  
Date

\_\_\_\_\_  
Name of Person Obtaining Authorization  
(PRINT)

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date