

UNIVERSITY OF PENNSYLVANIA HEALTH SYSTEM

Schering-Plough Corporation P04999, Version 1.0, 26 FEB 2007  
COVER - Continuing Observation after Vicriviroc (VCV) Exposure Registry

CONSENT FORM & HIPAA Authorization TO PARTICIPATE IN A RESEARCH STUDY

Your contacts at the Hospital of the University of Pennsylvania, Philadelphia for this study are:

Principal Investigator:	Pablo Tebas, MD	(215) 349-8092
Coordinators:	Joseph Quinn, RN	(215) 349-8092
	Deborah Kim, RPh	(215) 349-8092
	Wayne Wagner, RN	(215) 349-8092
	Emily Stumm, BS	(215) 349-8092

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

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**INTRODUCTION**

You are being asked to enroll in this registry because you have previously participated in a clinical trial involving the experimental medication known as vicriviroc (VCV). It is important for you to know that (1) taking part in this study is entirely voluntary; (2) personal benefit to you may or may not result from taking part in the registry, but knowledge may be gained from your participation that will benefit others; and (3) you may withdraw from the registry at any time without any penalty or loss of any benefits to which you are otherwise entitled.

**PURPOSE OF STUDY**

The purpose of this registry is to collect information about subjects who have participated in studies involving the experimental medication known as vicriviroc (VCV). It is hoped that this information will help researchers gain a better understanding of the long-term health effects of being treated with VCV. Subjects who participated in VCV studies are being invited to participate in the registry for five years. This includes subjects who received treatment with VCV and subjects who did not receive VCV. This will give researchers the ability to compare the long-term health effects reported by subjects who received VCV to those reported by subjects who did not receive VCV. The number of subjects to be enrolled in the registry is not predetermined. All eligible subjects at all centers will be requested to participate.

**PROCEDURES**

If you choose to participate in this registry, you understand that the doctor participating in the registry will record some of your medical information (but not your name) in a database. This medical information includes your anti-HIV medications, your medical history, and the results of your HIV RNA and CD4+ lab tests. Every six months, if your most recent HIV RNA is more than 1,000 copies/mL, you will also be asked to have a test called a Viral Tropism Assay, which determines the mechanism by which your HIV gains entry to uninfected cells in your body. This is done by drawing a blood specimen (about one teaspoon), usually from your arm.

In addition to this Informed Consent, you will be asked to sign another form called the Authorization to Share Medical Data. The Authorization to Share Medical Data gives the doctor participating in the registry your permission to contact other doctors who may be treating you in order to obtain additional

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medical information to be recorded in the registry database. Any information collected from other physicians will be handled in the same confidential manner.

#### **EXPECTED DURATION OF THE STUDY AND NUMBER OF SUBJECTS EXPECTED TO PARTICIPATE**

The number of subjects to be enrolled in this study has not been predetermined: all persons completing a phase 2 or phase 3 Vicriviroc trial will be offered participation in this study. Each patient will be in the study for up to 5 years. About 10-20 subjects are expected to participate at the University of Pennsylvania.

#### **RISKS**

The risks of this blood draw are similar to that for any other lab test and include bleeding and bruising at the site of the needle stick, and slight risk of infection. The sample of blood collected is used only for the test and is then discarded. Any serious adverse events resulting from this blood draw should be reported to the sponsor by your doctor.

#### **ALTERNATIVES**

You may choose to participate or to not participate in this registry. Agreeing to participate in this registry will have no bearing on the medical care that you receive – you will receive the exact same standard of care whether or not you agree to participate in this registry. By participating, you are giving your permission for your healthcare provider(s) to record information about your medical condition in an electronic database to be used for research purposes. The expected duration of this registry is five years from the time you stopped receiving study drug in a VCV clinical trial. The alternative to taking part in this registry is to not participate.

#### **COSTS**

The cost of the initial HIV-tropism assay will be covered by Sponsor. All treatments and procedures conducted during this study are considered part of standard care and may or may not be covered by third party payers (such as insurance companies).

#### **PAYMENT FOR PARTICIPATION**

There are no additional costs to you for your participation in this registry. You will be compensated \$25 for each visit to cover transportation costs, parking, etc.

#### **COMPENSATION FOR INJURY**

If you have 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 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.

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In the event that you are hurt or injured as a direct result of taking the study drug or the study procedures in this research study, please contact the investigator listed on page one of this form.

In the event of any such 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 Sponsor.

#### **POSSIBLE BENEFITS OF THE STUDY**

You may not receive a direct benefit from this study, however, other patients may benefit from the information learned from the study.

The research data and specimen samples collected during the study may be used in the research and development of the study drug. The Sponsor does not intend to provide you with ownership or financial benefits that may result from the research or future commercial products.

#### **REMOVAL FROM THE STUDY**

Possible reasons you may be withdrawn from the study:

- The investigator decides that participation in the study is no longer in your best interest
- You are not able to follow study instructions
- The study is cancelled by the sponsor (SPRI) or the University of Pennsylvania's Institutional Review Board.

Your doctor may withdraw you from this registry at anytime without your consent.

#### **RIGHT TO WITHDRAW FROM THIS STUDY**

Taking part in this study is up to you. You may choose not to take part or you may leave the study at any time. Choosing not to take part or leaving the study will not result in any penalty. You will not lose any benefits to which you are otherwise entitled. Your decision will not affect your access to medical care in the future.

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

#### **CONFIDENTIALITY**

The information gathered will be treated as confidential. Your doctor will identify your data (information) by a subject number. This information will be kept by your doctor and by Outcome, the company managing this registry.

While maintaining strict confidentiality, the registry information may be reviewed by Outcome, The University of Pennsylvania's Institutional Review Board (IRB), a Data Safety Monitoring Board (DSMB), and Schering-Plough. Results of this registry may be used in scientific publications or presentations

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and will be shared with relevant health authorities, but in all cases your identity will remain confidential.

#### **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
- Personal and family medical history, including mental health records
- Current and past medications or therapies
- Results of tests you will undergo during this research study : HIV Tropism assay

#### **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.).

#### **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:

Your personal data generated during this study may be passed on to the appropriate authorities, to the Sponsor, Schering Plough and its representatives. However, information that directly identifies you, such as your name and address, will not be transmitted. The Sponsor may use the collected information to determine if the study drug is safe and effective, to compare the study drug to other drugs, for regulatory activities and for future research activities that are unanticipated at this time.

#### Regulatory and safety oversight organizations

- The study Data and Safety Monitoring Board
- Foreign health authority (ies)

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

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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 will expire in 50 years.

The Sponsor may add your information to a research repository (database) so that it can design better research studies in the future, develop other therapies for subjects or gain a better understanding of disease. 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 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.

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Indicate your agreement to the use and sharing of your records by checking the box below and signing:

I agree to the use and sharing of my medical records and health information related to this study as described above.

\_\_\_\_\_  
 Signature of Participant or Legal Representative

\_\_\_\_\_  
 Date

**CONTACT INFORMATION**

For questions about this study or a research-related injury, contact:

- Pablo Tebas, MD (215-349-8092)
- 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

**CONSENT**

When you sign this form, you are agreeing to take part in this research study. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer. Your signature also means that 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 operations of this study.

A copy of this consent/HIPAA Authorization form will be given to you. 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.

This Consent Form contains important information to help you decide if you want to be in this study. If you have questions that are not answered in this form, please ask one of the study staff.

\_\_\_\_\_  
 Name of Subject (Please Print in BLOCK LETTERS)

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

\_\_\_\_\_  
 Date

\_\_\_\_\_  
 Name of Person Obtaining  
 Consent (Please Print)

\_\_\_\_\_  
 Signature

\_\_\_\_\_  
 Date

For subjects unable to give authorization, the authorization is given by the following authorized subject representative:

\_\_\_\_\_  
 Authorized subject representative [PRINT]

\_\_\_\_\_  
 Authorized subject representative Signature

\_\_\_\_\_  
 Date

Provide a brief description of above person authority to serve as the subject's authorized representative.