UNIVERSITY OF PENNSYLVANIA HEALTH SYSTEM

Vertex, VX11-950-115 Version 3.0, 22-DEC-2011

An Open-Label Phase 3 Study of Telaprevir in Combination With Peginterferon Alfa-2a (Pegasys®), and Ribavirin (Copegus®) in Subjects Coinfected With Genotype 1 Hepatitis C Virus and Human Immunodeficiency Virus Type 1 (HCV/HIV-1)

CONSENT TO PARTICIPATE IN A DNA SAMPLE COLLECTION

Your contacts for this Study at the Hospital of the University of Pennsylvania [HUP] are:

Site address: 502 Johnson Pavilion, Philadelphia, PA 19104

Principal Investigator:	Pablo Tebas, MD	(215) 349-8092
Sub Investigator:	Valerianna Amorosa, MD	(215) 349-8092
Coordinator:	Joseph Quinn, RN	(215) 349-8092
Study Nurses:	Kathryn Maffei, RN, BSN	(215) 349-8092

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

You are currently taking part in a hepatitis C clinical research study of the drug telaprevir (the "Study"), sponsored by Vertex Pharmaceuticals Incorporated (the "Sponsor"). As a result of your participation in this Study, you are now being asked to take part in an optional part of the Study involving the collection of blood for genetics testing and storage. It is up to you to decide whether to participate.

Please read this consent form carefully. This form explains the things you will be asked to do before, during, and after this part of the Study. If you decide that you would like to take part in this part of the Study, you will be asked to sign this consent form. A copy of the signed and dated consent form will be given to you to keep.

For additional information regarding the Study and who to contact with questions or concerns, please refer to main Study informed consent form.

PURPOSE OF THIS PART OF THE STUDY

Genetic testing is testing of your DNA. DNA (or deoxyribonucleic acid) can be thought of as a 'cook book' that contains the recipe for your body. Your DNA may help us to understand why some people are more likely to get a certain disease, while others are not. Differences in DNA may also help explain why some drugs work and are safe in some people, but not in others.

PROCEDURES FOR THIS PART OF THE STUDY

We are asking your permission to collect 1 blood sample that can be stored and used for research. As scientific discoveries are made, valuable research can be done in the future on samples collected today. Therefore, the Sponsor asks your permission to store your DNA samples to allow for research to be done in the future.

It is only the collective results from everyone who participates in this optional portion of the Study that is important for this research, not the results from individuals. Therefore, the test results cannot be used to make a diagnosis about your health. Neither you nor the Study doctor will be given specific information about the genetics testing results from this part of the Study. These tests are not being performed for your medical care, but only for research purposes.

SAMPLE COLLECTION SCHEDULE

In this optional portion of the Study, a total of 1 additional blood sample will be collected at Day 1.

YOUR RIGHTS AND ALTERNATIVES

Taking part in this additional blood collection is voluntary. That means that you can decide not to take part. If you agree to take part, you can change your mind at any time for any reason without losing any benefits to which you would have received if you were not in the Study. You can continue to take part in the main Study whether or not you choose to take part in this optional genetics testing portion of this Study. Your decision not to take part will not affect the care that you would normally get from your regular doctor.

You may withdraw your consent to take part in this testing any time, by notifying the Study doctor in writing. Please give or send your signed request to one of the researchers listed on page one of this form.

If you withdraw your consent, your research samples will be destroyed and no further testing will be done. However, if your samples have already been tested, any information obtained prior to the withdrawal of your consent may be used by the Sponsor.

RISKS AND DISCOMFORTS

When blood samples are taken from a vein, some people have discomfort or pain. You may feel faint or pass out when having blood taken. There is also a risk of infection (rare), bleeding, or bruising at the site of the skin puncture. The blood sample collected for genetics testing is usually taken at the same time as the routine blood test in the main clinical Study. Therefore, although an additional needle prick is usually not necessary, the blood draw may take a few seconds longer.

In addition, there is also a risk of loss of confidentiality. This risk is very small because your samples will not be labeled with your name or other personal information; however, absolute confidentiality cannot be guaranteed.

A Federal law called the Genetic Information Nondiscrimination Act (GINA) generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. GINA does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. GINA also does not protect you against discrimination based on an already-diagnosed genetic condition or disease.

BENEFITS

There will be no direct benefit to you from participation in the additional blood collection.

COST OF TREATMENT/ PAYMENT FOR PARTICIPATION

There will be no cost to you for participating in the additional blood collection portion of the Study.

You will not be paid for taking part in this optional portion of the Study. The Sponsor will not offer any payment to you as a result of the development or commercial sale of the final product created as a result of this Study or any future studies.

SAMPLE AND INFORMATION USE

The Sponsor will use the information collected as a result of the main Study (gender, age, demographics, medical history, side effects, etc.) and this optional research testing in the research and development of telaprevir and other medicines and diagnostics and in publications and presentations. Information that could identify you (like your name) will not be used. Your blood samples will not be tested immediately, and the tests to be done are not known at this time. The site staff, the Sponsor, and its representatives will have access to the samples.

The Sponsor has taken several steps to keep your identity and results confidential. These are described below:

Labeling of samples

Your samples will not be labeled with any information to identify you (name or initials) so that the laboratory staff testing the samples will not know your identity. The samples will be labeled with your Study number and an independent sample number.

Only your Study doctor will know your name and address. Only your Study doctor will be able to link you to your DNA sample.

Restricted access to your sample

The site staff, the Sponsor, and its representatives will have access to the samples. Your samples will be sent and stored at Vertex Pharmaceuticals Incorporated Biological Sample Repository, 200 Sidney Street, Cambridge, MA 02139 USA or a laboratory chosen by the Sponsor. Your samples will be stored in a secure room where only authorized staff is allowed to enter. The Sponsor will control your DNA sample. Your samples may be transferred to other research partners working with the Sponsor. Your samples will not be sold, loaned, or given to any other independent groups for their own use. Research partners working with the Sponsor are not allowed to share these samples.

Restricted access to your information

The Sponsor will store the testing results from your samples. Your name or initials will not be in these records. This is to protect your privacy. The results of the testing on your samples may be presented in public meetings, published, or added to public databases. However, you will not be identified in any publication or presentation on the results of the research. Only employees, research partners, or other people hired by the Sponsor who have signed a confidentiality agreement will handle your DNA test results. Regulatory authorities (FDA, EMEA) and members of Independent Ethics Committees / Institutional Review Boards may also look at your results to make sure the Study is properly done. Unless the law requires it, your results will not be given to anyone else who is not listed above. Research partners working with the Sponsor may not use or share your results without permission from the Sponsor.

Storage of samples

Your sample will be stored in a specimen bank to allow for more research to be done in the future. The Sponsor will store the sample for up to 15 years. Your samples will be destroyed after 15 years, when the quality of the sample is no longer usable or when you withdraw your consent.

SOURCE FOR ADDITIONAL 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 to participate in optional samples collection research

By signing below, you are documenting (showing) that you have read the information provided in this document, that you understand the information, risks, and what will be required of you and that you voluntarily agree to be in this optional portion of the Study.

You are also documenting that you have been given enough time to ask all the questions that you need to about the Study and that the questions have been answered to your satisfaction.

You are documenting that you understand that you are free to leave the Study at any time without giving the reason for doing so and without it affecting your medical care now or in the future.

By signing this document, you are giving permission to review, disclose, and use your confidential information as described above.

By signing this consent, you are not giving up any of your legal rights.

_____
Subject's name

_____ _____ _____
Subject's signature Date Time

Person Obtaining Consent

_____
Consenter's name and title (print)

_____ _____ _____
Consenter's signature Date Time