UNIVERSITY OF PENNSYLVANIA HEALTH SYSTEM

Gilead Sciences, Inc. GS-US-248-0122, Amendment 1, 19-JUN-2012

A Long Term Follow-up Registry for Subjects Who Achieve a Sustained Virologic Response to Treatment in Gilead-Sponsored Trials in Subjects with Chronic Hepatitis C Infection

CONSENT TO PARTICIPATE IN A RESEARCH STUDY AND RESEARCH SUBJECT HIPAA AUTHORIZATION

Your contacts for this study are:

Site address: 502 Johnson Pavilion, Philadelphia, PA 19104

Principal Investigator:	Pablo Tebas, MD	(215) 349-8092
Manager:	Joseph Quinn, RN, BSN	(215) 349-8092
Study Nurses:	Yan Jiang, RN, BSN	(215) 349-8092

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

INTRODUCTION

You have been asked to volunteer for this clinical research study because you have previously participated in a Gilead-sponsored study for treating chronic hepatitis C (HCV) infection and you responded to that treatment. This response is called a sustained virologic response otherwise known as SVR. This study is a long term follow-up to continue to evaluate your response.

Before you agree to volunteer for this study, please be sure to ask your Study Doctor or study staff to explain any words or information in this Subject Information and Informed Consent Form you do not understand. You should understand the purpose of the study, how your participation may help you, any potential risks to you, and what is expected of you during the study.

Some insurance companies require people who are renewing a policy or getting a new policy to tell them about participating in a clinical study. You should check with your insurer to determine if taking part in this study will affect your existing insurance policy.

YOUR RIGHTS

This consent form tells you about the study. Your study doctor or study nurse will go over this with you and answer any questions you may have regarding this study. If you agree to volunteer, you will be asked to sign and date this consent form. You will be given a copy of the signed and dated consent form to keep. No one can force you to take part in this study.

Even if you agree to participate now, you are free to change your mind and stop at any time without penalty or loss of benefits to which you would otherwise be entitled.

PURPOSE OF THE STUDY

The purpose of this study is to continue to evaluate the response that you had after participating in a Gilead-sponsored HCV treatment study.

DESIGN OF THE STUDY

This is a long term follow-up Registry study. A registry is an observational study that looks back on what was done without dictating a treatment plan, in other words, collecting information on what happens after you completed the treatment study. No study medication will be administered.

IRB Approved: 19-Aug-2015 To: 18-Aug-2016

If you agree to participate in this study, you will be one of many subjects from over 100 clinical sites world-wide. This study is open to any subject that had an SVR from a Gilead-sponsored study after receiving at least one Gilead antiviral oral medication.

You must meet other entry criteria as required by the study and indicated by your study doctor. If during the course of the study you have a re-occurrence of your HCV infection or you decide to start a new HCV treatment you will be discontinued from this study. If re-infection occurs, your study doctor will discuss the treatment options available to you.

DURATION OF THE STUDY

Your participation in this study may last up to 3 years.

STUDY PROCEDURES

Your first clinic visit will be at Baseline. The Baseline visit will occur within 90 days from your last visit in the treatment study.

You will need to sign this informed consent form before having any procedures performed at the Baseline visit.

At every clinic visit your doctor will assess how well your liver is functioning, your blood will be drawn, and you will be asked to complete a quality of life survey. Please refer to the table below for a complete listing of assessments performed at each visit.

		Visit identified by study week						
Clinical Assessments	**Day 1 (Baseline) [a]**	**24**	**48**	**72**	**96**	**120**	**144**	**Early Termination**
Complete a quality of life survey	X	X	X	X	X	X	X	X
Adverse events related to study procedures	X	X	X	X	X	X	X	X
Assessment of liver function [b]	X	X	X	X	X	X	X	X
Obtain blood for laboratory tests [c]	X	X	X	X	X	X	X	X

a Baseline visit to be conducted within 90 from the last visit in the initial Gilead-sponsored treatment protocol.

b Includes, clinical signs and symptoms, laboratory abnormalities and Child Turcotte Pugh Score.

c Laboratory test include: safety blood tests, test for blood clotting, HCV RNA levels (amount of virus in blood) and viral sequencing (determine the specific type of virus).

Baseline/Day 1 Visit

At the Baseline visit your doctor will assess how well your liver is functioning, approximately 3 tablespoons of blood will be drawn, and you will be asked to complete a quality of life survey.

Study Weeks 24, 48, 72, 96, 120, and 144

 IRB Approved: 19-Aug-2015 To: 18-Aug-2016

You will be asked to return to the clinic at study Weeks 24, 48, 72, 96, 120, and 144. At these visits your doctor will assess how well your liver is functioning, approximately 3 tablespoons of blood will be drawn, and you will also be asked to complete a quality of life survey.

RISKS

Blood draw: Drawing blood from a vein may cause local pain, bruising, occasional lightheadedness, fainting, and very rarely, infection at the site of the blood draw.

Breach of confidentiality**:** Theoretically there is always a chance your confidentiality could be breached. This is minimized for the study because all data are entered into a secure, passcode protected computer using a code number. In addition, all blood samples collected from you, including those used to perform detailed testing on your HCV virus are analyzed also by code number. Your clinical trials chart, which has personal information about you is kept in a locked office in a locked cabinet and can only be accessed by the research team.

UNKNOWN/UNEXPECTED RISKS AND DISCOMFORTS

You will be informed in a timely manner, both verbally and in writing of any new information, findings or changes to the way the research will be done that might influence your willingness to continue your participation in this study.

POSSIBLE BENEFITS OF THE STUDY

It is not expected that subjects will receive a direct medical benefit from participating in this study. However, clinical research studies such as this are a way for doctors to determine if a medication is useful in fighting a disease. By participating in this study, you and the Sponsor, Gilead Sciences, Inc. may benefit in learning more about effectively treating HCV. Your participation in this study may benefit the community, scientists and doctors who work with HCV by providing increased knowledge and information about the treatment of your disease. In addition, during your participation you will have close medical monitoring of your health condition by blood tests and other evaluations during clinic visits.

ALTERNATIVES TO THIS STUDY

You have the option to discuss with your Study Doctor not to participate in this long term follow-up study. Your Study Doctor will discuss appropriate alternative options with you. You will be made aware of any new findings that become available during the course of the study that may affect your willingness to take part.

WITHDRAWAL FROM STUDY AND REFUSAL TO PARTICIPATE

Your participation in this clinical research study is voluntary and you can refuse to participate or stop at any time without stating a reason. Your withdrawal will not affect your access to other medical care to which you would otherwise be entitled.

Dr. Tebas will supervise any discontinuation of this study with your health as the first priority. Your participation in this study may be terminated at any time by a) your Study Doctor, b) Gilead Sciences, Inc, c) US Food and Drug Administration, d) the Independent Institutional Review Board, (a review group that gives approval to your Study Doctor to conduct this study), and other appropriate regulatory agencies.

If it is discovered that you did not give an accurate medical history or did not follow the instructions for the study given by your Study Doctor and/or study nurse you may be taken off the study at any time.

IRB Approved: 19-Aug-2015 To: 18-Aug-2016

COST OF TREATMENT

All clinic, professional, diagnostic, and laboratory fees for tests and procedures that are part of this study will be provided at no cost to you. You or your usual health care payer will be responsible for any other health care costs.

PAYMENT FOR PARTICIPATION

You will be paid $50.00 for each visit attended for this study (Baseline and weeks 24, 48, 72, 96,120, and 144). Thus if you attend the 7 required visits for the study, the maximum payment you can receive is $350. If you need to come in for an unscheduled visit that is requested by the study staff, you also will be paid $10 for that visit.

Please note that if you receive more than $600.00 compensation in one year for participation in research studies at the University of Pennsylvania, you must provide an Individual Tax Identification Number or Social Security Number for tax purposes.

MEDICAL TREATMENT AND COMPENSATION FOR STUDY-RELATED INJURY

If you become sick or injured as a direct result from taking part in this study, University of Pennsylvania will provide you with medical treatment. The Sponsor, Gilead Sciences Inc., will reimburse you or University of Pennsylvania for the reasonable and necessary costs of such medical treatment, *provided* that you have followed the instructions of the Study Doctor. No other form of reimbursement for study-related injury or illness is offered by the Sponsor. You do not give up any legal rights by signing this form. You should immediately contact your Study Doctor at the contact information shown above in the event you experience any study-related illness or injury.

If you receive Medicare benefits, the Sponsor, Gilead Sciences, Inc., is required by law to report payments made to you for treatment, complications, and injuries that arise from this Study. Information that you are taking part in the Study, medical treatments received, Medicare claims, and other personal information about you such as your name, social security number, and date of birth, will be provided to the Centers of Medicare and Medicaid Services and its agents and/or contractors for this purpose.

STATEMENT ABOUT PRIVACY

Records identifying you will be kept confidential and, to the extent permitted by applicable laws and/or regulations, will not be made publicly available. In the event of any publication regarding this study, your identity will remain confidential.

Representatives from government agencies, including the U.S. Food and Drug Administration ("FDA"), institutional review boards, the Sponsor and/or the Sponsor's authorized representatives may need access to your original medical records and study records for the purpose of checking data collected for the study. By signing this consent form, you authorize this access.

Your coded study information and samples may also be used for additional unanticipated medical and/or scientific research projects in the future relating to Hepatitis C Virus or the development of the study medications (but at all times in compliance with applicable laws and regulations).

The Sponsor and its authorized representatives will analyze and use the coded information they receive for the purposes of this study. Such purposes include:

- checking your suitability to take part in the study,

- supporting the development of the study medication you received in the treatment protocol,
- supporting the licensing application for regulatory approval of the study medication you received in the treatment protocol anywhere in the world,
- supporting the marketing, distribution, sale and use of the study medication you received in the treatment protocol anywhere in the world, and/or
- as otherwise required or authorized by law.

A description of this clinical trial will be available on http://www.clinicaltrials.gov, as required by the U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

AUTHORIZATION TO USE AND DISCLOSE RECORDS

The authorization part of the consent 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 (if you receive more than $600 for participating in studies at PENN, we will need your SSN for the W-9)
- Personal and family medical history
- Current and past medications or therapies
- Results of physical exams, laboratory tests and procedures you will undergo during this study

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:

- Pharmaceutical sponsor (Gilead Sciences): This is the company that is running the study. Information regarding safety and adverse effects will be collected and monitored.
- Contract Research Organization: Data will be reviewed on a regular basis to assure accuracy and completeness of information before the data are analyzed.

Regulatory and safety oversight organizations

- The Food and Drug Administration and regulatory agencies in other countries
- The Office of Human Research Protections

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 or medical record number. Information regarding your health, 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

Will you be able to access your records?
You will be able to access some or all of your medical records after the study is over. 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 blood obtained for the study, the Sponsor may need to retain and use any samples that have already been collected to comply with its legal obligations and to maintain the scientific integrity of the study. In other words, any results acquired through analyzing the samples prior to the time of withdrawal will still be retained, but going forward no additional samples will be banked.

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.

WHO CAN I CALL WITH QUESTIONS, COMPLAINTS OR IF I'M CONCERNED ABOUT MY RIGHTS AS A RESEARCH SUBJECT?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on page one of this form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Office of Regulatory Affairs with any question, concerns or complaints at the University of Pennsylvania by calling (215) 898-2614.

WHAT IS AN ELECTRONIC MEDICAL RECORD?

An Electronic Medical Record (EMR) is an electronic version of the record of your care within a health system. An EMR is simply a computerized version of a paper medical record.

If you are receiving care or have received care within the University of Pennsylvania Health System (UPHS) (outpatient or inpatient) and are participating in a University of Pennsylvania research study, results of research-related procedures (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in your existing EMR maintained by UPHS.

If you have never received care within UPHS and are participating in a University of Pennsylvania research study that uses UPHS services, an EMR will be created for you for the purpose of maintaining any results of procedures performed as part of this research study. The creation of this EMR is required for your participation in this study. In order to create your EMR, the study team will need to obtain basic information about you that would be similar to the information you would provide the first time you visit a hospital or medical facility (i.e. your name, the name of your primary doctor, the type of insurance you have). Results of research procedures performed as part of your participation in the study (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in this EMR.

Once placed in your EMR, these results are accessible to appropriate UPHS workforce members that are not part of the research team. Information within your EMR may also be shared with others who are determined by UPHS to be appropriate to have access to your EMR (e.g. health insurance company, disability provider, etc).

STORAGE AND USE OF BLOOD OR BIOLOGICAL SAMPLES AND STUDY INFORMATION

A portion of your blood sample drawn at every visit will be frozen and stored. Your stored blood samples and the information collected about you during the study may be used by the Sponsor or its research

partners to study the amount of HCV in your blood, changes in your HCV's response to the study medications, or measurements of how your body was affected by HCV or the medications.

Your Samples will be assigned a unique code that may contain your initials and date of birth, but not your name or other individually identifiable information. At the conclusion of this study, these Samples may be retained in storage by the Sponsor for a period up to 15 years.

The results of these tests are designated for research use only, and the interpretation of the test results may not have direct benefit to you.

The storage and use of your samples and study information is OPTIONAL. This means that you can still participate in the study and not have your samples/information used for future research. If you do not want your medical information (note: this information is by code number only and cannot be linked to you as it does not contain any identifying data) or your samples used, you should check "NO" for below.

Do you agree to have your personal information, medical data and laboratory test results collected or learned about you from this study used in possible future scientific research of the Sponsor relating to Hepatitis C Virus? _____ Yes _____ No

Do you agree to have your biological samples collected from this study used in possible future scientific research of the Sponsor relating to Hepatitis C Virus? _____ Yes _____ No

IRB Approved: 19-Aug-2015 To: 18-Aug-2016

AGREEMENT TO BE IN THE STUDY

This Subject Information and Informed 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. Please answer the following questions by placing your **INITIALS** in the line for **"Yes"** or **"No"**.

1. Have you understood this Subject Information and Informed Consent Form? _____ Yes _____ No
2. Have you had the opportunity to ask questions and discuss the study? _____ Yes _____ No
3. Have you received answers you find acceptable to all of your questions? _____ Yes _____ No
4. Have you received enough information about the study to make an informed decision? _____ Yes _____ No
5. Do you understand you are free to stop the study at any time without having to give a reason and without affecting your medical care to which you would otherwise be entitled? _____ Yes _____ No
6. Do you understand your historical medical records may be reviewed and how the information contained in them will be used? _____ Yes _____ No
7. Do you understand the **General Statement About Privacy** and agree to sign the Authorization to Use and Disclose Records section? _____ Yes _____ No
8. Do you understand that the research done with your Study Information may generally help the Sponsor develop new commercial medications or new treatments for diseases and that you will not receive any direct benefit or compensation if this occurs? _____ Yes _____ No
9. Do you understand that you must notify the Study Doctor if there is any change in the medication prescribed for you by doctors outside the study or if you take any medicines bought without a prescription? _____ Yes _____ No

If you answered NO to any of the 9 questions listed above you should not sign this form.

Once you have had all your questions answered and you are comfortable to participate in this study, please sign below.

By signing this form I agree that I am freely consenting to be in this study and I agree to all of the conditions of the study described in this form and agree to follow the instructions of the Study Doctor and Study nurse.

Subject
(or legally authorized representative)

Person Obtaining Consent

Printed Name & Title	Signature	Date

Witness (if applicable)

Witness Printed Name	Signature	Date

IRB Approved: 19-Aug-2015 To: 18-Aug-2016