UNIVERSITY OF PENNSYLVANIA HEALTH SYSTEM

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A Prospective, Phase III, Open-Label Study of Boceprevir, Pegylated-Interferon Alfa 2b and Ribavirin in HCV/HIV Coinfected Subjects

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

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

Principal Investigator:	Pablo Tebas, MD	(215) 349-8092
Coordinator:	Joseph Quinn, RN, BSN	(215) 349-8092
Study Nurse:	Jenna Lewis, RN, BSN	(215) 349-8092
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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 take part in this research study because you are infected with the HIV virus (the virus that causes AIDS) and the HCV virus (a virus that causes hepatitis), specifically genotype 1 (one of the main types of HCV). This study is sponsored by the National Institutes of Health (NIH). The doctor in charge of this study at this site is: Dr. Pablo Tebas. Before you decide if you want to be a part of this study, we want you to know about the study.

Your participation is voluntary which means you can choose whether or not you want to participate. If you choose not to participate, there will be no loss of benefits to which you are otherwise entitled. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. The research team is going to talk to you about the research study, and they will give you this consent form to read. You may also decide to discuss it with your family, friends, or family doctor. You may find some of the medical language difficult to understand. Please ask the study doctor and/or the research team about this form. If you decide to participate, you will be asked to sign this form. You will get a copy to keep.

This is a consent form. It gives you information about this study. The study staff will talk with you about this information. You are free to ask questions about this study at any time.

Why Is This Study Being Done?

People with both HIV and HCV coinfection, specifically genotype 1 are usually treated with a combination of two drugs in order to fight their HCV virus. This study is being done to see if adding a third drug to this combination is safe and whether it will help people with HIV and HCV better fight their HCV. The third drug that this study is investigating has been approved by the Food and Drug Administration (FDA) recently for the treatment of HCV in people with HCV but without HIV.

Study drugs will be pegylated-interferon alfa 2b given as a weekly injection (under the skin), ribavirin based on your weight (taken twice daily by mouth), and boceprevir (taken every 8 hours by mouth with food; the dosing can range +/- 1 hour from 7-9 hours with food).

All participants (both HCV treatment naïve [individuals who have never taken HCV medications] and treatment experienced [individuals who have previously taken HCV medications]) will be evaluated for a sustained virologic response (SVR) (undetectable HCV RNA levels) 24 weeks after the end of treatment.

What Do I Have To Do If I Am In This Study?

Screening

- After you read and sign the consent form, you will have a screening visit to make sure you are able to join the study. This visit will last about 1-2 hours.
- Your HIV infection will be confirmed. If there is no record available, you will have another HIV test.
- A liver biopsy or HCV FibroSURE™ test (a noninvasive blood test for determining liver disease) will be done if there is no record available of a biopsy done within 2 years prior to study entry showing chronic HCV infection unless previous liver biopsy or FibroSURE™ test was consistent with cirrhosis (scarring of the liver). The study will not pay for the liver biopsy. A liver biopsy is standard of care for persons starting therapy for Hepatitis C so the extent of the infection can be measured.
- You will have a physical exam, eye exam (for subjects with diabetes, high blood pressure, or suspected eye problems) and will be asked about your health and medicines you have taken in the past or are taking now. Also, an EKG (electrocardiogram) will be done at this visit.
- You will have about 3 tablespoons (45 ml) of blood drawn to measure your HCV viral load (the amount of HCV virus in your blood) and genotype (genetic makeup of the virus), to measure your CD4+/CD8+ cell counts (these are cells in your blood that fight infection), and HIV viral load, to measure levels of certain hormones (hormones are chemicals in your blood), and for routine safety tests. You will be told the results of these tests when they become available.
- You will be asked to provide a urine specimen for routine safety tests.
- If you are a woman able to become pregnant, you will be asked to give a urine or blood sample to see if you are pregnant. You will not be able to enroll in this study if you are pregnant. You will be told the result of the test when it becomes available.

If you do not enroll into the study

If you decide not to take part in this study or if you do not meet the eligibility requirements, we will still use some of your information. As part of this screening visit, some demographic (age, gender, race), clinical (disease condition, diagnosis), and laboratory (CD4+ cell count, viral load) information is being collected from you so that ACTG researchers may help determine whether there are patterns or common reasons why people do not join a study.

Entry

If you are eligible for the study, you will come in for an entry visit. This visit will last about 1 hour. You will need to fast for this study visit (fasting means that you have had nothing to eat or drink except prescription medications and water for at least 8 hours). At this visit:

- You will be asked questions about your medical history and any medications you are taking.
- You will have a brief physical exam.
- You will have about 6 tablespoons (90 ml) of blood drawn to measure your HCV viral load, your HIV viral load, your CD4+/CD8+ cell counts, for metabolic tests (to test how your body uses the food that you eat), and for some routine safety tests. You will be told the results of these tests when they become available.
- You will be asked to provide a urine specimen for routine safety tests.
- If you are a woman able to become pregnant, you will be asked to give a urine or blood sample to see if you are pregnant. You will not be able to start study drugs if you are pregnant. You will be told the result of the test when it becomes available.
- You will have about 1 tablespoon (15 ml) of blood drawn for a genetic test to see if we can predict how well you will respond to HCV treatment.

- You will be asked to fill out a questionnaire to see how well you are taking your HIV drugs.
- You will have about 1 tablespoon (15 ml) of blood drawn and stored for HCV genotype 1 confirmation test and for future HCV/HIV studies, including resistance studies. A resistance test is used to determine the genetic makeup of your HCV/HIV viruses. In addition, some of your blood will be stored for future testing required by the study.

All participants (both treatment naïve and treatment-experienced) in this study will take the same study drugs. You and your study doctor will know the drugs that you are taking.

- Pegylated-interferon alfa 2b
- Ribavirin
- Boceprevir

At this visit, study staff will give you enough study drugs to last until the next study visit. You should take ribavirin and boceprevir with food. At each visit, you must return any remaining study drug from the previous visit. If you notice that a dose of boceprevir was missed 2 or more hours before the next boceprevir dose is due, you should take the 800 mg with food, and resume the normal dosing schedule. If it is less than 2 hours before the next dose, the missed dose should be skipped. Please note refrigerated capsules of boceprevir can remain stable until the expiration date printed on the label. Boceprevir can also be stored at room temperature up to 25^0 C (77^0 F) for three months. Keep container tightly closed.

The pegylated-interferon alfa 2b REDIPEN is a single-use injection pen. You will be supervised in the clinic during preparation and administration of the first injection. The solution should be used immediately and cannot be stored for more than 24 hours at 36° -46°F. DO NOT REUSE THE REDIPEN. DISCARD THE UNUSED PORTION. After preparation and administration, the REDIPEN is to be disposed of in a puncture-resistant container provided to you by the clinic.

<u>All Subjects (HCV Treatment Naïve and HCV Treatment-experienced)</u>

<u>Week 2, 4, 6, 8, 10, 12, 16, 20, and 24 Visits</u>

- You will have a brief physical exam.
- You will be asked questions about any medications you are taking.
- You will have about 3 tablespoons (45 ml) of blood drawn for routine safety blood tests, to measure your HCV viral load and future HCV/HIV resistance studies. You will be told the results of these tests when they become available.
- You will have about 1 tablespoon (15 ml) of blood drawn for measuring boceprevir and HIV drug levels in your blood at study weeks 6, 8, 12, 16, 20, and 24 visits.
- You will be asked to fill out a questionnaire to see how well you are taking your HCV drugs.

NOTE: At weeks 6 and 8, study staff will work with you to coordinate the blood draws for pre-dose samples for boceprevir, atazanavir/ritonavir, darunavir/ritonavir or lopinavir/ritonavir (whichever you are taking), so that the study team can measure both boceprevir and your protease inhibitor with a single blood draw.

<u>Week 4, 8, 12, 16, 20, and 24 Visits</u>

- If you are a woman able to become pregnant, you will be asked to give a urine sample or have an additional 1 teaspoon (5 ml) of blood drawn to see if you are pregnant.
- You will have about 1 tablespoon (15 ml) of blood drawn to measure your CD4+/CD8+ cell counts and HIV viral load at weeks 4 (viral load only), 8, 12 and 24 visits.

- You will have about 1 tablespoon (15 ml) of blood drawn to measure your HCV viral load.
- At study week 12 and 24 visits, you will have about 1 tablespoon (15ml) of blood drawn to measure levels of certain hormones. In addition, some of your blood will be stored for future testing required by the study.
- You will have about 1 tablespoon (15ml) of blood drawn for metabolic tests at week 4 and 8 study visits. You will need to fast for these visits.
- At weeks 12 and 24 visits, you will be asked to fill out a questionnaire to see how well you are taking your HIV medications.

If You are Treatment Naïve and Your Viral Load WAS NOT Detectable at Week 8 and You are Without Cirrhosis at Study Screening

You will stop taking study drugs at week 28.

Week 28, 40, 52, 60 and 72 Visits

- You will have a brief physical exam.
- You will be asked questions about your medications you are taking.
- You will have about 3 tablespoons (45ml) of blood drawn to measure your HIV viral load, CD4+/CD8+ cell count, and routine safety tests. You will be told the results of these tests when they become available. Also, some of your blood will be stored for future HCV/HIV resistance studies. Also, at week 72, some of your blood collected will be used to measure levels of certain hormone.
- If you are a woman able to become pregnant, you will be asked to give a urine or a blood sample.
- At the weeks 28, 40, 52 and 72 study visits, you will have about 1 tablespoon (15 ml) of blood drawn for future HCV viral load test.
- You will be asked to fast for the weeks 28 and 52 visits. You will have about 1-2 tablespoons (15 – 30 ml) of blood drawn for metabolic tests and to measure levels of certain hormones. In addition, some of your blood will be stored for future testing required by the study.
- You will have about 1 tablespoon (15 ml) of blood drawn to measure your boceprevir and HIV drug levels study at weeks 28 and 40 visits.
- At the week 40 and 52 study visits, you will be asked to fill out a questionnaire to see how well you are taking your HIV medications.

If You are Treatment Naïve and Your Viral Load WAS Detectable or Missing at Week 8 or If You are Treatment-experienced or If You had Cirrhosis at Study Screening

You will continue taking study drugs until week 48. You will have seven more study visits.

Week 28, 32, 36, 40, 44, 48, 60 and 72 Visits

- You will have a brief physical exam.
- You will be asked questions about any medications you are taking.
- You will have about 1-2 tablespoons (15 – 30 ml) of blood drawn to measure your HCV viral load and for routine safety tests. You will be told the results of these tests when they become available. Also, you will have about 1 tablespoon (15 ml) of blood drawn and stored for future HCV/HIV resistance studies.
- If you are a woman able to become pregnant, you will be asked to give a urine sample or blood sample.
- At weeks 28, 36, 48, and 72 visits, if you are treatment naïve and your viral load was detectable or missing at week 8, some of your blood will be drawn to measure levels of certain hormones in your body.

- At the weeks 28, 40, 48, 60 and 72 visits, you will have about 1 tablespoon (15 ml) of blood drawn to measure your HIV viral load and CD4+/CD8+ cell counts. You will be told the results of these tests when they become available.
- At weeks 28, 48, and 72 visits, you will be asked to fast and you will have about 1 tablespoon (15ml) of blood drawn for metabolic tests. Additionally, some of your blood will be stored future for required testing.
- At weeks 28 and 36 (40 and 48 study visits for those who are cirrhotics [if you have scarring of the liver]), you will have about 1 teaspoon (5 ml) blood drawn for measuring levels of boceprevir and your HIV drugs in your blood.
- You will be asked to fill out a questionnaire to see how well you are taking your HCV drugs at all study visits, except weeks 60 and 72. At weeks 36, 48, 60, and 72 visits, you will be asked to complete a questionnaire to see how well you are taking your HIV drugs.

If You Have to Stop Taking the Study Drugs Early or You Have to Stop the Study Early

If you have to stop taking the study drugs early or you have to stop the study early, you will come to the clinic for an additional visit. This visit will last about 1 hour. You will need to fast for this visit. At this visit:

- You will have a brief physical exam.
- You will be asked questions about any medications you are taking.
- You will have about 5 tablespoons (75 ml) of blood drawn to measure your HCV viral load, your HIV viral load, and your CD4+/CD8+ cell counts, for hormone measurements, for metabolic tests, and for some routine safety tests.
- You will be asked to provide a urine specimen for routine safety tests.
- If you are a woman able to become pregnant, you will be asked to give a urine sample or blood sample. You will be told the result of the test when it becomes available.
- You will have about 1 tablespoon (15 ml) blood drawn for measuring levels of boceprevir and your HIV drugs in your blood if you are on study drugs at the time of premature treatment/study discontinuation visit.
- You will be asked to fill out questionnaires to see how well you are taking your HIV drugs and HCV drugs.
- You will have about 1 tablespoon (15 ml) of blood drawn and stored for future HCV/HIV resistance studies. Additionally, some of your blood will be stored for future required testing.

All unused study drugs, in particular Boceprevir and Ribavirin, must be returned at the end of the study in the event of study completion, withdrawal or study discontinuation.

Virologic Failure

If you stop taking the study drug for HIV/HCV virologic failure (the amount of virus in your blood increases) or other reasons, you should return to the clinic for follow-up evaluations until study completion. These visits will last about 30 minutes. You will be asked to fast for these visits. The following evaluations will be done:

- You will have brief physical exam.
- You will be asked about any medications you are taking.
- You will have about 5 tablespoons (75 ml) of blood drawn to measure your HIV viral load, CD4+/CD8+ cell counts, for hormone tests, and for routine safety tests. In addition, some of your blood will be stored for future HIV/HCV resistance studies.

If you experience HIV virologic failure, a blood sample (1 teaspoon) will be collected to do HIV-1 genotype testing. This visit may be combined with another study-scheduled visit. Your study doctor will talk to you about the plan for future HIV treatment.

Other

If you agree, after all of your required study tests are done, we would also like to store your leftover blood to use for future research. This additional blood storage is voluntary. Refusing to have your blood stored will not affect your participation in this study.

- We will not store your samples with any information that will identify you.
- Genetic testing will not be done on these blood samples.
- These samples may be stored for an indefinite period of time.
- You might not receive the results of testing performed on these samples.

Please indicate now if you agree to have your additional leftover blood to be used for future ACTG-approved HIV-related research. You may still change your mind at any time and we will destroy your samples.

_____ YES, I AGREE _____ NO, I DO NOT AGREE

How Many People Will Take Part in This Study?

About 310 people will take part in this study. About 5 people are expected to participate at the University of Pennsylvania.

How Long Will I Be In This Study?

You will be on this study for 18 months.

Why Would The Doctor Take Me Off This Study Early?

The study doctor may need to take you off the study early without your permission if:

- You miss two consecutive visits
- The study is cancelled
- A Data and Safety Monitoring Board (DSMB) recommends that the study be stopped early (A DSMB is an outside group of experts who monitor the study)
- You are not able to attend the study visits as required by the study

The study doctor may also need to take you off the study drug(s) without your permission if:

- You miss the week 12 or week 24 visit
- HCV treatment failure
- You or a female partner of a male participant become pregnant
- Continuing the study drugs may be harmful to you
- You need a treatment that you may not take while on the study
- You are not able to take the study drugs as required by the study

If you must stop taking the study drugs earlier than indicated by the study, the study doctor may ask you to continue to be part of the study and return for some study visits and procedures.

If I Have To Permanently Stop Taking Study-Provided Drugs, Or Once I Leave The Study, How Would Drugs Be Provided?

During the study

If you must permanently stop taking study-provided drugs earlier than indicated by the study, the study staff will discuss other options that may be of benefit to you.

After the study

After you have completed your study participation, the study will not be able to continue to provide you with the drugs you received on the study. If continuing to take these or similar drugs would be of benefit to you, the study staff will discuss how you may be able to obtain them.

What Are The Risks Of The Study?

Risks of Social Harm

Although the study site will make every effort to protect your privacy and confidentiality, it is possible that others could find out that you are participating in this study and that social harms may result (because you could become labeled as being infected with HIV and/or HCV). For example, you could be treated unfairly or discriminated against by family members, friends, and/or the community.

Risks of Drawing Blood

Drawing blood may cause some discomfort, lightheadedness, bleeding, swelling, or bruising where the needle enters the body, and in rare cases, fainting, or infection.

Risks of Study Drugs

For those persons taking HIV medicines, there is a risk of drug interactions between HIV medicines and boceprevir. Boceprevir has not been studied with all HIV medicines. Drug interactions that increase the levels of medicine in your blood may increase the chances of side effects. Drug interactions that lower the levels of boceprevir in your blood may decrease your chances for a cure of hepatitis C and/or cause drug resistance. Drug interactions which lower the levels of HIV medicines in your blood could cause drug resistance, meaning the drugs no longer work to prevent virus from replicating. Drug resistance may also prevent other medicines from working in the future. In a recent drug interaction study, coadministration of boceprevir with atazanavir/ritonavir, darunavir/ritonavir, or lopinavir/ritonavir resulted in reduced exposures of the HIV-1 medicines and boceprevir, indicating these drug-drug interactions may be clinically important for HIV-1 infected patients by potentially impacting the effectiveness of the medicines. The risks of drug-drug interactions are more serious, and development of drug resistance against boceprevir may be more likely, for people who have been treated for HIV or HCV unsuccessfully in the past.

The drugs used in this study may have side effects, some of which are listed below. Please note that these lists do not include all the side effects seen with these drugs. These lists include the more serious or common side effects with a known or possible relationship. If you have questions concerning study drug side effects please ask the medical staff at your site.

There is a risk of serious and/or life-threatening side effects when non-study medications are taken with the study drugs. For your safety, you must tell the study doctor or nurse about all medications you are taking before you start the study and also before starting any new medications while on the

study. Also, you must tell the study doctor or nurse before enrolling in any other clinical trials while on this study.

Pegylated-interferon alfa 2b

A variety of mood and personality changes have been reported. Some of the more common and severe changes are listed below:

- Mental health symptoms
  - Suicide
  - Depression
  - Sleep disturbances
  - Memory loss
  - Loss of concentration
  - Nervousness
  - Anxiety
  - Confusion
  - Agitation
  - Aggressive behavior
  - Personality changes
  - Participants with history of drug addiction may experience relapse
- Heart disease
- Heart attacks
- Abnormal heart rhythms
- Enlarged heart
- Infections
- Autoimmune disease of the blood, thyroid gland (controls how quickly the body uses energy, makes proteins and controls how sensitive the body should be to other hormones) , joints, kidney and skin (diseases where the immune system attacks the body's own tissues or organs)
- Flu-like symptoms
- Fever
- Tiredness
- Muscle and joint pain
- Headaches
- Chills
- Gastrointestinal symptoms
  - Nausea and vomiting
  - Diarrhea
  - Stomach pain
  - Loss of appetite
  - Altered sense of taste
- Weight loss
- Skin and hair changes
- Hair loss
- Itching
- Dry skin
- Rash
- Blood cell changes
- Anemia (reduction in red blood cells that may cause weakness, dizziness, and tiredness)
- Low white blood cells
- Low platelets (a component of blood that helps stop bleeding after injury)
- Dizziness

- Elevated liver function tests
- Enlarged liver
- Altered thyroid functions
- Inflamed large intestine
- Inflamed pancreas
- Lung disease
- Eye disease

Ribavirin

- Anemia. Anemia can worsen existing heart and pulmonary conditions.
- Temporary changes in blood platelet levels
- Temporary changes in liver function tests (a measure of your liver activity)
- Stomach and intestinal
  - Nausea
  - Vomiting
  - Indigestion
  - Stomach discomfort
  - Skin disorders
- Upper respiratory tract inflammation
- Teratogenicity (risk to an unborn baby)
- Nervous system
  - Depression
  - Insomnia (inability to sleep)
  - Nervousness
  - Skin tingling
  - Drowsiness
  - Light-headedness
- Hyperuricemia (excess of uric acid in blood which can lead to gout, a painful swelling of joints and may lead to kidney disease).

NOTE: There are reports indicating that HIV-infected people taking treatment for HIV and HCV have developed high lactate (an acid that can build up in the bloodstream and cause life-threatening illness) levels with worsening liver disease. It is not clear if ribavirin is the cause. This may be more common if ribavirin is taken with didanosine (ddI, Videx) for HIV infection. There may be an increased risk of inflammation of the pancreas when didanosine is taken with ribavirin. Because of these risks, didanosine use is not allowed in this study.

Boceprevir

The following side effects are reported more frequently when boceprevir is given in combination with pegylated-interferon alfa 2b and ribavirn as compared with pegylated-interferon alfa 2b and ribavirin alone.

- Blood Disorders
  - Anemia (In combination with other medications that cause anemia [such as Ribavirin], this side effect can be worse.)
  - Low white blood cells
- Stomach and intestinal problems
  - An abnormal, or bad, change in taste
  - Nausea
  - Vomiting

  - Diarrhea
  - Dry mouth
  - Loss of appetite
- General Disorders
  - Fatigue
  - Chills
  - Weakness
  - Joint aches
- Nervous system
  - Insomnia
  - Dizziness
  - Irritability
- Skin Disorders
  - Hair loss
  - Dry skin
  - Rash
- Breathing Disorders
  - Shortness of breath with activities

Rare risks
Serious acute hypersensitivity reactions (itching, hives, swelling of the face, eyes, lips, tongue, or throat) have been observed with combination therapy (Boceprevir, peginterferon alfa and ribavirin). If you have some or all of these symptoms, you should seek medical attention promptly. Persons who have experienced a sensitivity to Boceprevir in the past, should not take it again.

Are There Risks Related To Pregnancy?

The drugs or drug combinations in this study may be unsafe for unborn babies. If you are having sex that could lead to pregnancy, you must agree not to become pregnant or make a woman pregnant. Note that if you become pregnant or your partner becomes pregnant, study drugs will be stopped and you will be followed to post pregnancy.

Because of the risk involved, you and your partner must use at least two methods of birth control that you discuss with the study staff. You must continue to use both methods until 6 months after stopping study drugs. You must choose two of the birth control methods listed below:

- Condoms (male or female) with a spermicidal agent
- Diaphragm or cervical cap with spermicide
- Intrauterine device (IUD)
- Tubal ligation

If you can become pregnant, you must have a pregnancy test within 72 hours prior to starting the study drugs. The test must show that you are not pregnant. Pregnancy tests will also be performed at most study visits.

Some of the methods listed above may not prevent the spread of HIV to other people. You should discuss your contraceptive choices with your health care provider to choose the best way for you to both prevent pregnancy as required by this study and to prevent the spread of HIV to your partner.

If you think you may be pregnant at any time during the study, tell your study staff right away. Pregnancy will result in immediate discontinuation of the study drugs, and counseling on ribavirin teratogenicity (ability to cause birth defects). We will provide referrals to maternal-fetal specialist to follow your pregnancy if you do not have a OB/GYN. It is important to inform your doctor about the drugs you took on this study. You will be followed on study, including male participants whose partners become pregnant, until study completion. You will be asked to return to the clinic 6 months after the end of your pregnancy to follow up on any side effects. Male participants whose partners become pregnant will undergo treatment discontinuation and the same follow-up visit at 6 months after the end of your partner's pregnancy. Pregnancies will be reported to the Ribavirin Pregnancy Registry. Information on your pregnancy will be gathered from you and if you give your permission, through your medical records and contact with your obstetrician.

Are There Benefits to Taking Part in This Study?

If you take part in this study, there may be a direct benefit to you, but no guarantee can be made. It is also possible that you may receive no benefit from being in this study. Information learned from this study may help others who have HIV and HCV.

What Other Choices Do I Have Besides This Study?

Instead of being in this study you have the choice of:

- treatment with prescription drugs available to you
- treatment with experimental drugs, if you qualify
- no treatment

Please talk to your doctor about these and other choices available to you. Your doctor will explain the risks and benefits of these choices.

What About Confidentiality?

We will do everything we can to protect your privacy. In addition to the efforts of the study staff to help keep your personal information private, we have obtained a Certificate of Confidentiality from the U.S. Federal Government. This certificate means that researchers cannot be forced to tell people who are not connected with this study, such as the court system, about your participation. Also, any publication of this study will not use your name or identify you personally.

Your personal information may be given out if required by law. If you test positive for HIV, by law we have to report the infection to the City of Philadelphia Health Department/PA Department of Health. We would report your name, gender, racial/ethnic background, and the month and year you were born. This is to keep track of how many people in the U.S. have HIV infection. It is also to make sure that states get enough money from the federal government to support the medical care of people living with HIV. The Health Department does not share the names of HIV infected people with anyone else. It removes all personal identifiers, such as your name, before giving information on the number of HIV infections to the federal government. Please note that it is likely that this information has been already reported to the PA Health Department as the HIV test being done for this study is not the first test for you.

People who may review your records include the University of Pennsylvania institutional review board (IRB), National Institutes of Health (NIH), Office for Human Research Protections (OHRP), Food and Drug Administration (FDA), AIDS Clinical Trials Group (ACTG), the DSMB, study staff, study

monitors, the drug company supporting this study (Merck & Co., Inc.), and its designees. Having a Certificate of Confidentiality does not prevent you from releasing information about yourself and your participation in the study.

Even with the Certificate of Confidentiality, if the study staff learns of possible child abuse and/or neglect or a risk of harm to yourself or others, we will be required to tell the proper authorities.
A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

HIPAA AUTHORIZATION

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
- Personal and family medical history
- Current and past medications or therapies
- Information from questionnaires administered in the study
- Results of tests and procedures you will undergo during this research study
- Social Security Number
- Medical record number

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 Companies: Merck & Co, Inc. who supplies drug for the study.
- ACTG Data Coordinating Center, Frontier Science Technology Research Foundation (FSTRF): Data for this study will be recorded on case report forms, keyed into a central database and electronically submitted to the Data Coordinating Center. The data will be stored at this facility until it is ready to be analyzed.
- 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 to monitor if the trial is safe.
- 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.
- Government Agencies: Data from this study will be made available to the Food and Drug Administration and to the National Institutes of Health/Division of AIDS (DAIDS)/National Institute for Allergy and Infectious Disease (NIAID), for them to evaluate the safety and efficacy of the treatments being used in this study.

Regulatory and safety oversight organizations

- The Food and Drug Administration
- The Office of Human Research Protections
- The Study Monitoring Committee
- Institutional Review Board

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 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 database. However, 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
- The University of Pennsylvania's Institutional Review Board grants permission
- As permitted by law

Can I change my mind about giving permission for use of my information?

Yes. You may withdraw or take away your permission to use and disclose your health information at any time. 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, you will not be able to stay in this study.

What if I decide not to give permission to use and give out my health information?
Then you will not be able to be in this research study.

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.

What Are the Costs To Me?

Taking part in this study may lead to added costs to you and your insurance company. In some cases it is possible that your insurance company will not pay for these costs because you are taking part in a research study.

If you take antiretroviral drugs (medicines to fight your HIV infection) while you are on this study, you must provide those drugs or obtain them from outside of the study. This study will not provide antiretroviral drugs. The study will provide pegylated-interferon alfa 2b, ribavirin, and boceprevir.

Will I Receive Any Payment?

You will receive $10 for the first screening visit, then $25 for each of the study required visits. If you are in Group A, you will come to the clinic for 15 or 18 visits depending if you have cirrhosis and the amount of HCV viral load, or $385 and $460, respectively. If you are in Group B, 18 visits are required with a maximum compensation of $460. Payments will be given as cash. You will be compensated for visits attended, if you come off the study or off the study treatment you will be compensated for the visit required for follow up by the study. If you are required by the study staff to come in for any additional unscheduled visits (usually to check a lab value or have a repeat fasting lab test), you will be compensated $25 for every 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 a Individual Tax Identification number or Social Security Number for tax purposes.

What Happens If I Am Injured?

If you are injured as a result of being in this study, you will be given immediate treatment for your injuries. The cost for this treatment will be charged to you or your insurance company. There is no program for compensation either through this institution or the NIH. You will not be giving up any of your legal rights by signing this consent form.

If you think you have been injured as a result of taking part in this research study, tell the person in charge of the research study as soon as possible. The researcher's name and phone number are on page one of this consent.

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).

What Are My Rights As a Research Subject?

Taking part in this study is completely voluntary. You may choose not to take part in this study or leave this study at any time. Your healthcare provider will treat you the same no matter what you decide.

We will tell you about new information from this or other studies that may affect your health, welfare, or willingness to stay in this study. If you want the results of the study, let the study staff know.

What Do I Do If I Have Questions Or Problems?

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 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.

Name of Subject (Please Print)	Signature of Subject	Date
Name of Person Obtaining Consent (Please Print)	Signature	Date