HOSPITAL OF THE UNIVERSITY OF PENNSYLVANIA

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

Protocol Title:	**A5360 Version 1.0, dated 1/10/18; Letter of Amendment #1, 6/15/18; Letter of Amendment #2, 8/8/18; Letter of Amendment #3, 2/11/19: A Single-arm Study to Evaluate the Feasibility and Efficacy of a Minimal Monitoring Strategy to Deliver Pan-genotypic Ribavirin-free HCV Therapy to HCV Infected Populations who are HCV Treatment Naïve with Evidence of Active HCV Infection: The MINMON Study** ***A Multicenter Trial of the AIDS Clinical Trials Group (ACTG)***
Principal Investigator:	Pablo Tebas, MD 502 Johnson Pavilion, Philadelphia PA 19104 **(215) 349-8092**
Project Manager:	Eileen Donaghy, MSN, CRNP
24 hr. Emergency Contact:	Immunodeficiency Program Doctor on call (215) 662-6059

Introduction:

You are being asked to take part in this research study because you have been infected with hepatitis C virus (HCV, a virus that affects the liver), and have not been treated before for HCV. You may also be infected with human immunodeficiency virus (HIV, the virus that causes AIDS). You may have compensated liver cirrhosis, which means that the liver is damaged, but is still working. 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.

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. 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. If you agree to take part in this study, you will be asked to sign this consent form. You will get a copy to keep.

Why Is This Study Being Done?

Currently, people who are infected with HCV are often closely monitored by medical staff. This requires patients to come to the clinic at least five times for visits, medication refills, and blood tests over a 12-week course of treatment. These guidelines are based on older HCV medications that had more side effects and were less successful at curing HCV than the medications used in this study. New HCV medications can cure 95 out of 100 infected persons who receive treatment. The medication that is provided in this study is approved by the US FDA for use in persons infected with HCV and coinfected with HCV/HIV. In large clinical trials, the side effects reported by study participants were comparable to a placebo (no medicine).

This study is being done to see if a minimal monitoring approach is effective and safe when providing HCV treatment. The minimal monitoring approach will require fewer study visits and lab tests with no

medication refills. This study is trying to see whether taking an HCV treatment with fewer clinic visits and laboratory tests can cure just as many people as the standard approach that uses more visits and laboratory tests. We will compare the results of this study with what we have observed in other studies using a standard approach.

People are considered cured of HCV if the HCV virus cannot be detected in the blood 12 weeks after they have completed HCV treatment. This is called a sustained virologic response (SVR).

This study will measure the amount of HCV virus in your blood at entry, week 24, week 48, and week 72. The study staff will share these results with you. If the HCV virus is detectable in your blood at week 24 or after, the study staff will let you know, and help you find a health care provider who can discuss your future treatment options. You can become re-infected with HCV after you are cured. The study staff will discuss with you how to remain HCV free after your treatment is completed.

The study will also examine the convenience to you and the cost to cure a person of HCV using this minimal approach.

How Many People Will Take Part in This Study?
About 400 people (men and women age 18 years and older) will take part in this study. 8 people have enrolled at the University of Pennsylvania.

Where Is This Study Being Done?
This study will take place across the world and will include participants from the US and non-US sites.

How Long Will I Be In This Study?
You will be in this study for up to 72 weeks.

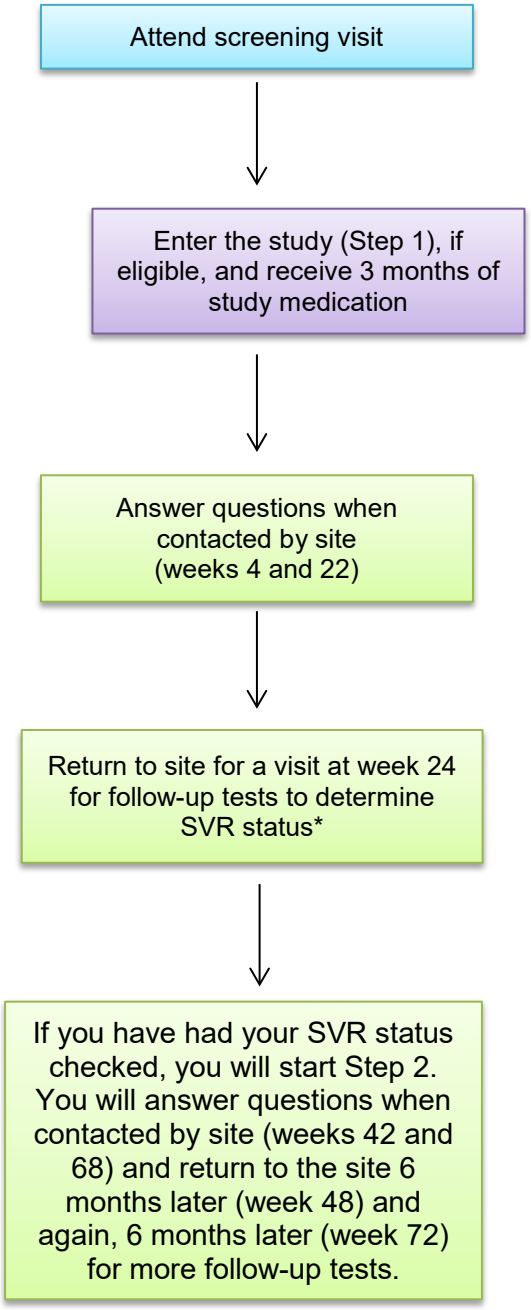
What Do I Have To Do If I Am In This Study?
If you decide to join this study and meet the study requirements after the screening visit, you will be enrolled into the study, unless enrollment has been closed to the subgroup(s) as described below.

Individuals with HIV infection and/or have compensated cirrhosis (liver is damaged but it is still working) are also eligible for the study. Enrollment, however, of HIV-infected individuals or those with compensated cirrhosis will be limited in the study (i.e., only a certain number of persons will be included in the HIV-infected subgroup and compensated cirrhosis subgroup). The study staff will let you know if this limit has been reached for either subgroup, and what this means for you.

At the entry visit, you will be given your study medication for all 3 months to take home. You will need to store the medication in a safe place at room temperature (below 30°C [86ºF]) and take one tablet a day for the 3-month period.

If you are also infected with HIV, you will continue taking your current anti-HIV drugs if you are receiving them. If you are not currently on HIV medications and your provider does not think you will need HIV medications for the next 3 months, this is also acceptable. If your HIV medications include efavirenz (EFV), you will be switched to another HIV medication. This medication will be determined by your HIV care provider. Antiretrovirals are to be paid through your insurance carrier or other programs for which you may qualify. **EFV should not be taken with the HCV study medications.**

A diagram of the study follows.



*After a person has successfully completed treatment for HCV, there is a period when HCV viral load in the blood is so low that even the most sensitive test cannot detect the virus. If this period of "undetectability" lasts for 12 weeks in a row after the end of treatment, it is called SVR (sustained virologic response).

Everyone who enters the study will take a fixed-dose combination of sofosbuvir/velpatasvir (SOF/VEL), which will be provided by the study. Anti-HIV drugs will not be provided by the study.

While you are in this study, you will need to be seen in the clinic about 5 times. The longest visit, which will be your enrollment visit, could take up to 2 hours. Study staff will tell you about how long each visit will be. You may need to come to the clinic more often if you have side effects. More information about the study tests is given below. During the study, you will get the results from any routine tests that are done during the study and relevant to your care when they are 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 (for example, age, gender, race), clinical (for example, disease condition, diagnosis), and laboratory (for example, 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. If you do not want this information to be recorded, you should not sign this consent form and not participate in the study. If you elect not to participate, all information collected thus far by the research team will be destroyed.

Required Blood Tests

Your blood will be drawn from a vein in your arm and used to measure your HCV viral load (the amount of HCV virus in your blood), to measure levels of certain hormones (chemical messengers in your blood), to see if the hepatitis B virus (HBV; another virus that affects your liver) is in your body, and for routine safety tests and metabolic tests (to test how your body uses the food that you eat). If you are a woman able to become pregnant, you will have a pregnancy test at the screening and entry visits and at later study visits if you think you might be pregnant. If you are infected with HIV, you will have blood drawn to measure your HIV viral load (the amount of HIV virus in your blood) and your CD4+ cell counts (these are cells in your blood that fight infection). You will be told the results of these tests when they become available.

Some of your blood will also be stored (with no information that will identify you) and used for HCV genotyping (a test to see the genetic makeup of the HCV virus) and sequencing (a test to check for the pattern/code of the genetic makeup of the HCV virus) for this study. HCV genotyping and sequencing are used to see which genotype of HCV you are infected with. Since these stored samples will be tested in the future, the results will not be available to you.

Blood will also be collected and stored for future testing at the end of the study. Some of your blood samples may be shipped and/or stored outside of the country from which they are collected.

Genetic (the message in your DNA) testing

If you agree, any blood left over after all required study testing is done will be used to examine different genes (pieces of your DNA). Results of testing done on these samples may not be given to you because they will be done in the future.

Optional Tests

If you agree, any blood left over after all required study testing is done may be stored (with no information that will identify you) and used for future ACTG-approved research. These blood samples may be stored for an unknown period of time. Results of testing done on these samples may not be given to you because they will be done in the future.

A5360 Study Visits

The study staff can answer any questions you have about individual study visits, the evaluations that will occur, or how long each visit will be. The table below can be used as a quick reference for you, along with the explanations that follow.

Evaluation or test	Screening	Entry	Post-Entry Visits							Unplanned Visits (Entry-Week 24)
			Week 4	Week 22	Week 24/SVR Evaluation	Week 42	Week 48	Week 68	Week 72	
Consent & Contact Information Collected	✓									
Documentation of HCV, HIV, & Cirrhosis Status	✓									
Liver Elastography (if available)		✓			✓		✓		✓	
Physical Exam	✓	✓			✓		✓		✓	✓(if indicated)
Medical & Medication History	✓	✓								
Blood Samples Collected (for laboratory testing)	✓	✓			✓		✓		✓	✓(if indicated)
Blood Samples Stored (for later testing)		✓			✓		✓		✓	✓(if indicated)
Pregnancy Test	✓	✓			✓(if suspected)					✓(if suspected)
Pregnancy Prevention Counseling	✓	✓								
Cirrhosis Counseling		✓			✓		✓		✓	
HCV Risk-reduction Counseling		✓			✓		✓		✓	
Adherence Counseling		✓								
Questionnaires		✓	✓(via remote contact)		✓		✓		✓	✓
Study Drugs Distribution		✓								
Locator Information		✓	✓	✓						
Remote Contact With Participants Outside of Study Visits			✓	✓		✓		✓		

Description of Study Visits

Screening

After you have read and signed the consent form, you will be asked questions about your health, medical history, and medication history. You will have a complete physical exam to check your vitals (temperature, pulse, respiration rate, and blood pressure) and several tests, including blood tests, to make sure that you qualify to join the study. You will have your height and weight recorded.

Up to 42 mL of blood will be drawn during this visit. You will have blood drawn for HCV RNA testing. Some of the blood taken will be shipped to a testing lab and some of the blood will be stored for future testing. Your HCV infection and how long you have been infected will be confirmed. Your HIV infection and cirrhosis status will also be evaluated.

If you are a woman able to become pregnant, you will have a blood draw or urine collected for pregnancy testing. You may not continue with the screening process if your pregnancy test is positive. If you are able to become pregnant or to impregnate a partner, you will receive pregnancy prevention counseling.

Entry

If all of the results from your screening tests show that you are eligible, you will be enrolled in the study. You will be asked about your health and the medications you are taking. You will also have a brief physical exam to check your vitals (temperature, pulse, respiration rate, and blood pressure). You will have your weight recorded.

Up to 51 mL of blood will be drawn during this visit. You will also have additional samples collected and stored for later testing. If you are a woman able to become pregnant, you will be asked to provide a blood or urine sample for pregnancy testing. You may not enroll in the study if your pregnancy test result is positive.

If available at the site, liver elastography (scan of your liver) will be performed. This is described below in more detail. If you had a liver elastography done as part of standard care, this measurement will be recorded but it is not required for enrollment into the study.

You will be asked for your primary preferred contact information as well as a second contact (spouse, friend, neighbor, etc.) in order for the study staff to reach you throughout the study. This is known as locator information. If you are not able to be reached through the primary contact information, then the study staff will try to reach you through the second contact you provide.

At this visit, you will be given your study drugs. The study staff will give you enough study drugs to last 12 weeks (3 months). Study staff will watch you take your first dose before leaving the site. You can take the study medication (SOF/VEL) with or without food. You will receive adherence education and counseling on the study drug, as described below. You will be given instructions on how to take the study medication and what to do if you forget to take it. There will be instructions on the study medication bottle asking you to call the site when you finish taking the last pill of the last bottle (bottle #3), or you can write the date of when you took the last pill on the label of bottle #3 and bring the bottle with you to your week 24/SVR evaluation visit. You may also note the date you finished the last pill within your phone or write it down on a separate piece of paper, as long as you bring this date with you to your week 24/SVR evaluation visit. You will also receive two flyers with information on two types of other medications (proton pump inhibitors and H2 inhibitors [e.g., heartburn medication]) that you should not take while taking study medication.

You will be asked to complete questionnaires that asks how you are doing and feeling, if you went to the hospital within the past 4 weeks, and if you use any substances such as alcohol, cigarettes, and other drugs. If you have compensated cirrhosis, you will also receive counseling for your cirrhosis, as described below. If you are able to become pregnant or to impregnate a partner, you will receive pregnancy prevention counseling. You will also receive HCV risk-reduction counseling and adherence counseling, as described below.

Post-entry visits

Since you will be given enough study drugs to last you for 12 weeks of the treatment period, you will not need to come back to the clinic until week 24 (3 months later). Study staff will contact you by the preferred contact at weeks 4 and 22 to update your contact (locator) information and at week 4, to collect information about whether you are taking your study medication. If study staff are unable to reach you after two tries, they will try to reach you via your second contact. While you are taking the study drug, if you are not feeling well or have any questions about the study medication, you should contact the study site directly at 215 349-8092 (Clinical Trials Unit).

All participants will be seen post-treatment at week 24. If you miss the week 24 visit, you may come back to the site to have your SVR status checked any time after week 24, up until week 72. Following your SVR status check, you will be followed through week 72. You will need to make two more visits to the site -- one at week 48 and one at week 72, which is Part 2 of the study. These visits will last about 1-1½ hours each.

At the week 4 remote contact, you will be asked how you are doing with taking your study medication. At the week 24/SVR evaluation visit, you will be asked how you did with taking your study medication.

At weeks 24, 48, and 72, you will have blood samples collected for routine safety tests and for a few required blood tests (HCV RNA). Up to 76 mL of blood will be drawn during each of these visits. You will also have additional samples collected and stored for later testing. You will be asked about your health and any changes in your medicines since your last visit. You will have your weight recorded. You will be asked to complete questionnaires that asks how you are doing and feeling, if you went to the hospital within the past 4 weeks, and if you use any substances such as alcohol, cigarettes, and other drugs.

Based on other tests done, the study staff will calculate different scores that will measure liver and kidney function and cirrhosis status. If you have compensated cirrhosis, you will also receive counseling for your cirrhosis, as described below.

If available at the study site where you were enrolled, you will have a liver elastography done at weeks 24, 48, and 72.

You will receive HCV risk-reduction counseling, as described below. If you have compensated cirrhosis, you will also receive counseling for your cirrhosis, as described below.

Unplanned visits

If you have any side effects during the treatment period, you must contact the study site. The study staff may require you to come in to the study site for an in-person evaluation. It is possible samples are collected for routine safety laboratory tests, or stored for future testing. If suspected, pregnancy testing and counseling will be done up to week 22. Up to 52 mL of blood could be drawn during this visit.

If you come to the study site for an unplanned visit, you will be asked to complete questionnaires that asks how you are doing and feeling, and if you went to the hospital within the past 4 weeks.

Early discontinuation
There are two types of discontinuation (stopping study treatment or leaving the study early). If at any point in the study, you want to discontinue study treatment or discontinue the study, you must contact the site immediately.

1. Stop study treatment early
   You or your doctor may decide to stop the study medication that you began at entry.

   If you must stop taking the study medication early, the study doctor may ask you to stay in the study and come in for the scheduled visits and tests.

2. Leave study early
   You or your doctor decides that you will no longer stay in the study or you are notified the study is stopped early.

Description of Study Evaluations

Consent and contact information collected
After you read the consent form and have had a chance to ask questions about the study, you will sign the consent form if you want to continue the screening process.

Documentation of HCV, HIV, and cirrhosis status
Study staff will check your medical records for the availability of test results for HCV, HIV, and cirrhosis. If these results are not available, then you will have these tests done as part of the screening visit.

Liver Elastography
At entry, a liver elastography measurement (if available) will be recorded. A liver elastography is an easy, simple, and safe ultrasound procedure that measures the stiffness of the liver by placing a small probe over the area of the liver while you lie on your back.

Clinical Assessments
You will have the following clinical evaluations in this study:

Physical examination
You will have a physical exam. At screening, the study staff will check the different areas of your body such as head, neck, eyes, ears, nose, throat, mouth and tongue, chest (excluding breasts), heart, abdomen, skin, hair, nails, and muscles and joints. The study staff will also check your vital signs such as temperature, pulse, blood pressure, and respiratory rate. Your height and weight will be recorded. After screening, the physical exam will be more limited and based on symptoms or problems that you are experiencing. Your weight will be recorded.

Medical and medication history
You will be asked questions about your health and about any medicines you have taken or are taking now. At week 24/SVR evaluation visit, you will be asked about any signs or symptoms that you are experiencing and any changes in other medications that you have had since your last visit.

Sample collections and laboratory testing
You will have the following samples collected and tested in this study:

Blood collected: Blood will be taken from a vein in your arm for various tests during the study.

Stored blood: Additional blood will also be collected from you and stored for testing at the end of the study.

Pregnancy test: If you are a woman who is able to become pregnant, you will have blood or urine taken for pregnancy testing at screening and entry. After you enter the study, you will have blood drawn or urine collected for pregnancy testing, if pregnancy is suspected up to week 22.

Pregnancy prevention counseling
All participants in the sexually reproductive age group will be counseled on family planning options for the duration of treatment (12 weeks). There is limited data on the safety of this medication during pregnancy and risk to the baby. Female participants who become pregnant during the course of treatment will be required to contact the site immediately and come in for a study visit as soon as possible.

Cirrhosis Counseling
If you have compensated cirrhosis, you will be counseled by study staff on managing your cirrhosis. Even though you may be cured of HCV, you will still have cirrhosis.

HCV Risk-reduction Counseling
You will be counseled by study staff on how HCV can be passed onto others and how to reduce your risk for HCV reinfection. HCV risk-reduction counseling will be done at entry, and weeks 24/SVR evaluation, 48, and 72. Study staff will talk with you about how you could become reinfected with HCV after being cured and ways to decrease risk of re-infection.

Adherence Counseling
You will get some adherence counseling from the study staff. The study staff will explain to you in detail how to take your study medication and help you find ways to take the medication correctly.

Questionnaires
You will be asked to complete a questionnaire that will ask how you are feeling and how you are doing with your daily activities. If you had stayed at a hospital or been to an emergency room, you will be asked to complete a questionnaire when you come in for your visits at entry, weeks 24/SVR evaluation, 48, 72, and unplanned visits (if any). You will also be asked about substance use such as alcohol, cigarettes, and other drugs at your entry and weeks 24/SVR evaluation, 48, and 72 visits.

See remote contact section below for information on what questions will be asked during the week 4 and 22 remote contacts.

Study drugs distribution and storage
You will be given a 12-week supply of study medication at entry. Study staff will watch you take your first dose, before you leave the site. You will be asked to store the study medication as instructed on the medicine bottle label. There will be instructions on the study medication bottle asking you to write down the date of, or call the site when, you finish taking the last pill of the last bottle (bottle #3).

If you lose your study medication, you will be able to return to the site and receive replacement medication (one-time replacement only).

Locator Information
Study staff will ask you about the best way to reach you when they need to contact you remotely at weeks 4, 22, 42, and 68. They will also ask you for a second way to contact you (for example, through a spouse or friend) if they are unable to reach you.

Remote contact with participants outside of study visits
Study staff will contact you using your preferred method at week 4 to ask questions about adherence information (if you are taking your study drug), to update your contact information, and to remind you to return to the site to have your SVR status checked at week 24.

During Part 1 of the study while you are taking the study (HCV) medication, you will be asked at week 4 if you are currently taking your study medication.

At week 22, study staff will contact you to schedule your week 24 visit to have your SVR status checked and to update your contact information.

During Part 2 of the study, after the week 24 visit, you will be contacted using your preferred remote method at weeks 42 and 68 to update contact information, if needed, and remind you of your upcoming study visits at weeks 48 and 72.

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:

- the study is cancelled
- the doctor believes the study is no longer in your best interest
- The site investigator thinks that you are at significant risk of failing to comply with the requirements of the protocol.

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

- You become pregnant.
- You are breastfeeding.
- Continuing the study drugs may be harmful to you.
- You need a treatment that you may not take while on the study.

If you must stop taking the study drugs before the study is over, the study doctor will 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 Can I Get Study Drugs?

If you must permanently stop taking SOF/VEL before the study is over, the study staff will talk with you about other options.

After you have finished the study, you will not be able to get SOF/VEL through the study.

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 harm may result (because you could become labeled as being infected with HCV and/or HIV). 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 Drug
The study drug (SOF/VEL) is relatively safe and in controlled clinical trials it was found to have a safety profile similar to a placebo (no medicine). The most common side effects you may experience are headache, nausea, vomiting, fatigue and diarrhea.

SOF/VEL has limited drug interactions with HIV medications with the exception of three HIV medications- efavirenz, etravirine, and tipranavir/ritonavir. If you are taking any of these medications, your doctor will talk to you about these interactions in detail and what symptoms to look out for. Your doctor may modify your HIV medications after discussing it with you so that you can be included in this study.

SOF/VEL also has some interactions with other types of medications. There is risk of slow heartbeat if you also take amiodarone (a medication to help control heart rate). While you are on the study, you will be instructed not to take any of the prohibited medications (for example, heartburn medication mentioned earlier). The study staff will explain the prohibited and precautionary medications and discuss alternative options if you must take any of these concomitant medications.

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.

Other Risks
There is a risk that your stored samples may be misused. There are laws against this kind of misuse, but they may not fully protect you. The chance that this will happen is considered small because of the security taken with your samples.

Your genetic information is unique to you. There is a risk in genetic research that someone using your samples may identify you. However, this risk is very small, but may increase with the progress of science. Researchers will inform you of any newly identified risks.

If you are cured of your HCV, you could still become infected again with HCV. You can get HCV from coming in contact with blood and/or sexual fluid that is infected with HCV.

Are There Risks Related To Delaying HIV Therapy?
You are not required to be on HIV medications to enter this study. If you are not on HIV medications at the time of your HCV infection and you and your doctor do not think you need to start HIV medications, we will not exclude you from the study. We also do not recommend delaying HIV medications for entry into the study if your doctor feels they are medically necessary. Although the dosing period of the HCV medication is short (84 days), a delay in necessary HIV medications could allow for progression of HIV disease, which can increase your risk of opportunistic infections and long-term after effects of HIV infection. If you have any concerns about these risks, we suggest that you discuss them with your medical provider.

Are There Risks Related To Pregnancy?
The drugs or drug combinations in this study have not been studied extensively in pregnancy. If you are having sex that could lead to pregnancy, you must agree not to become pregnant or to impregnate your partner while you are taking the study medication and for 6 weeks after stopping study medication. Note

that if you become pregnant, study drug will be stopped and you will be asked to remain on the study. If you think you may be pregnant at any time during the study, tell your study staff right away. Pregnancies occurring on study will be reported to the Antiretroviral Pregnancy Registry, and study staff will request permission from you to obtain additional information after the baby is born.

Because of the risk involved, you must use at least one method of birth control that you discuss with the study staff. You must continue to use at least one method as long as you are taking study medication and for 6 weeks after stopping study medication. You must agree to one or more of the birth control methods listed below:

- A condom (male or female) with or without a spermicide
- Diaphragm or cervical cap with or without spermicide
- An intrauterine device (IUD)
- Tubal ligation
- Hormone-based contraceptives

Male and female participants not of reproductive potential are not required to use contraceptives.

Some of the methods listed above may not prevent the spread of HIV to other people. If you are also infected with HIV, 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.

Male participants should not donate sperm while on study treatment and for six weeks after stopping study medication.

Are There Benefits to Taking Part in This Study?

If you take part in this study, there may be a direct benefit to you. The study is designed to treat your HCV infection with an approved study medication and you may be cured of your HCV. 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 HCV and/or HIV.

What Other Choices Do I Have Besides This Study?

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

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

Please talk to your doctor about these and other treatment choices available to you and 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 a Certificate of Confidentiality from the US 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 records may be reviewed by the ACTG, the US Office for Human Research Protections (OHRP), or other local, US, and international regulatory entities as part of their duties, University of Pennsylvania

institutional review board (IRB) (a committee that protects the rights and safety of participants in research), National Institutes of Health (NIH), study staff, study monitors, drug companies supporting this study, and their 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 www.ClinicalTrials.gov as required by US 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.

Your personal information may be given out if required by law. If you test positive for HIV, or if a CD4 or viral load is done at a research study visit, by law we have to report the result to the City of Philadelphia Health Department/PA Department of Health. Personal identifiers such as name, sex, date of birth, address, and phone number will be reported. For more information about the requirements reporting infectious diseases to the City of Philadelphia Health Department, please visit https://hip.phila.gov/ReportDisease. For more information about the requirements reporting infectious diseases to the PA Health Department, please visit: http://www.health.pa.gov/Your-Department-ofHealth/Offices%20and%20Bureaus/epidemiology/Pages/Reportable-Diseases.aspx#V620aZ3D9eU. .

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 information about me may be collected, used or shared with others?
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, email address, dates directly related to you such as date of birth and clinic visits.
- 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
- Social Security Number, Medical record number

Why is my information being used?
Your information is important for the research team to contact you during the study. Your information and results of tests and procedures are used to:

- do the research
- oversee the research
- see if the research was done right
- evaluate and manage research functions

Who may use and share information about me?
The following individuals may use or share your information for this research study:

- The Principal Investigator and the Investigator's study team
- Other authorized personnel at Penn, including offices that support research operations.

- Other research personnel with access to the databases for research and/or study coordination and as otherwise approved by the IRB

Who, outside the School of Medicine, might receive my 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:

- ACTG Data Coordinating Center, Frontier Science Technology Research Foundation (FSTRF): Data for this study will be keyed into a central database and electronically submitted to the Data Coordinating Center. The data will be cleaned and 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 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.
- Gilead Sciences: The pharmaceutical company that is supplying the drug for this study.
- Contract Research Organization (PPD, Inc): Monitors from PPD will visit the site on a quarterly basis to review data and adherence to protocol requirements.
- 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 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, 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 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 Infectious Disease Division, 502 Johnson

Pavilion Philadelphia PA 19104. 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 Informed Consent form and 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 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.

A clinical trial management system (CTMS) is used to register your information as a participant in a study and to allow for your research data to be entered/stored for the purposes of data analysis and any other required activity for the purpose of the conduct of the research.

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, information related to your participation in the research (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in your existing EMR maintained by UPHS. Information related to your participation in clinical research will also be contained in the CTMS.

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 information produced from your participation in 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). Information related to 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 the Costs To Me?
Taking part in this study may lead to added costs to you or your insurance company. In some cases, it is possible that your insurance company or health care system will not pay for these costs because you are taking part in a research study. All study related procedures and treatments will be provided at no cost to you or your insurance.

Will I Receive Any Payment?
You will be compensated $50 for study visits that require a clinic visit (screen, entry and weeks 24, 48 and 72. For visits when you are contacted by telephone, you will receive $25 (weeks 4, 22, 42 and 68). Compensation will be given as a ClinCard (a debit card). The maximum amount of compensation for the

study is $350 if all regular study required visits are completed. If you are required to come to the clinic for any additional visits you will be compensated $25.

There is no other form of compensation available such as reimbursements for parking, tokens or child care. In order to be compensated for your participation in this study, you must provide your Social Security Number. Additionally, please note that the University of Pennsylvania is required to report to the IRS any cumulative payments for participation in research studies that exceed a total of $600 in a calendar year.

What Happens If I Am Injured?

We will offer you the care needed to treat injuries directly resulting from taking part in this research. We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but you may also be responsible for some of them.

There are no plans for the University of Pennsylvania or the National Institutes of Health to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this 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 listed in the consent form.

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, tell the study staff .

What Do I Do If I Have Questions Or Problems?

If you have questions about this study or a research-related injury, please contact the research team listed on page 1 of this consent form.

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

This consent is the initial consent for this participant. The study staff will provide an overview of the study, required visits, treatment regimen, risk and all elements of consent. The physician investigator(s) or licensed Nurse Practitioner will conduct a focused discussion about risks, benefits and alternatives.

Genetic Tests

Please initial below whether you are willing to have any of your leftover blood used for ACTG-approved future unspecified genetic testing. You may change your mind at any time and your samples will be destroyed. You may also disagree to have genetic testing done and your left over samples will be destroyed.

_____ YES. I agree to have my blood used for ACTG approved future unspecified genetic testing.

_____ NO. I do not agree to have my blood used for ACTG approved future unspecified genetic testing.

Optional Tests

Please **initial below** whether you are willing to have some of your leftover blood (that is stored at the study site and/or at a central laboratory without information that could identify you) used for future ACTG-approved HIV-related research. These samples may be stored for an indefinite period. Results of testing performed on these samples will not be given to you. You may withdraw your consent for research on stored specimens at any time and the specimens will be discarded. No matter what you decide, it will not affect your participation in this study.

_____ YES. I agree to have my leftover blood stored.

_____ NO. I do not agree to have my leftover blood stored.

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.

RESEARCH STAFF CONSENT

Name of Subject (Please Print)	Signature of Subject	Date/Time

Name of Person Obtaining Consent (Please Print)	Signature	Date/Time

INVESTIGATOR CONSENT

The risks, alternatives, and benefits have been reviewed with me by the Investigator, and I understand what we have discussed.

Name of Subject (Please Print)	Signature of Subject	Date/Time

I verify I have reviewed risks, alternatives, benefits with this subject, who demonstrates good understanding.

Investigator Name (PRINTED)	Signature	Date/Time

IRB APPROVAL FROM: 03/25/2019 TO: 03/20/2020