HOSPITAL OF THE UNIVERSITY OF PENNSYLVANIA

CONSENT TO PARTICIPATE IN A RESEARCH STUDY AND RESEARCH SUBJECT HIPAA AUTHORIZATION- COHORT 2

Protocol Title:	**A5327/ SWIFT-C version 2.0, 07/02/15**: Sofosbuvir-containing Regimens Without Interferon For Treatment of Acute HCV in HIV-1 infected Individuals (SWIFT-C) A DIVISION OF AIDS/ AIDS CLINICAL TRIALS GROUP (ACTG) Study
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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 are infected with HIV (the virus that causes AIDS) and you have also recently been infected with the hepatitis C virus (HCV, a virus that affects the liver).

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?

People who are recently infected with HCV have a great chance of being cured of the infection when they are treated with a combination of two drugs within the first 6 months of being infected. This study is being done to see if a combination of two new drugs in one pill can replace the old drugs to provide a safer, more effective, and better tolerated treatment for new HCV infection. The names of the new

drugs are ledipasvir (LDV) and sofosbuvir (SOF), and they will replace pegylated-interferon alfa (PEG-IFN, a drug given as a weekly injection under the skin) and ribavirin (RBV).

The fixed-dose combination of LDV and SOF (LDV/SOF) has been approved by the Food and Drug Administration (FDA) for the treatment of chronic HCV genotype 1 in people who do not have HIV. HCV genotype 1 is the most common HCV infection in the United States. LDV/SOF has also been studied in people with HIV and chronic HCV and was found to be safe and effective.

This study started with participants in Group 1 receiving SOF in combination with RBV, a drug also approved by the FDA, for 12 weeks. There were a total of 17 participants in Group 1 and all completed treatment. All participants were monitored for safety and viral response while on treatment. After completing treatment, all participants were evaluated for a treatment response after the end of treatment.

If the treatment response in Group 1 was high enough, the study design allowed for the possibility to decrease the length of therapy for Group 2 to 8 weeks, using the same treatment. However, this did not occur. Combined with the fact that a new and more effective treatment for chronic HCV has been approved since the study started, Group 2 will now receive 8 weeks of LDV/SOF instead of 12 weeks of SOF with RBV.

How Many People Will Take Part in This Study?
About 27 people (men and women age 18 years and older) will take part in Group 2 of this study. About 2-3 people are expected to enroll at the University of Pennsylvania in this study.

How Long Will I Be In This Study?
You will be in this study for approximately 32 weeks.

What Do I Have To Do If I Am In This Study?
If you decide to join this study, 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 need HIV medications during the study that is also acceptable. You will participate in Group 2 and will take LDV/SOF (a pill taken once daily by mouth) for 8 weeks. You will be given the medications at your study visits to take home, and you will need to store the medications in a safe place at room temperature. After you have completed 8 weeks of treatment with LDV/SOF, you will continue to have follow-up visits for 24 weeks.

Everyone who enters the study will take LDV/SOF, which will be given for free 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 10 times during the study. The study staff will tell you about how long each visit could be. You may need to come to the clinic if you have side effects or if you switch or take new anti-HIV drugs. 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 when they are available.

You must fast for the screening, week 4 on-treatment, end of treatment (week 8), week 12 post treatment, and early treatment/study discontinuation visits. You may also have to fast for the entry visit; the study staff will inform you if you must fast for the entry visit. (Fasting means that you should not eat or drink anything for at least 8 hours before your visit. You may only drink water and take your prescription medications during this time. If your medications require food, the study staff will talk to you

about how you should take your medications.) The study staff will remind you to fast before each of these study visits. If you do not fast before these visits, you will be asked to come back later for these tests after fasting.

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

Required Tests
Your blood will be drawn from a vein in your arm and used to measure your HCV and HIV viral load (the amount of HCV and HIV 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), to measure levels of certain hormones (hormones are chemicals in your blood), and for routine safety tests and metabolic tests (to test how your body uses the food that you eat). You will also have a urine test. 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 future HCV/HIV resistance tests required for this study. A resistance test is used to determine if the HCV/HIV viruses still respond to your medications. In addition, some of this blood will be used to understand how the drugs interact with your body and how your body responds to the drugs.

Any remaining blood will be stored for future testing required by the study.

A5327 Group 2 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.

I. Study Schedule

Evaluation or test	Screen	Pre-Entry	Entry	Post-Entry Visits			Other Visits	Early discontinuation
				On-treatment Visits	End of treatment	Off-treatment Visits		
Consent	✓							
Clinical assessments	✓		✓	✓	✓	✓		✓
ECG	✓							
Samples collection & laboratory testing	✓	If required	✓	✓	✓	✓	✓	✓
Urine sample			✓	✓	✓	✓		✓
Pregnancy test	✓	✓	✓	✓	✓	✓	✓	✓
Pharmacokinetic (PK) studies			✓	✓	✓	✓	✓	✓
Pregnancy prevention counseling			✓	✓	✓	✓		✓

Evaluation or test	Screen	Pre-Entry	Entry	Post-Entry Visits			Other Visits	Early discontinuation
				On-treatment Visits	End of treatment	Off-treatment Visits		
Adherence assessments				✓	✓			✓
Study drugs distribution & storage			✓					

II. 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 several tests, including blood tests, to make sure that you qualify to join the study. Some of the blood taken will be shipped to a testing lab. Your new HCV infection and how long you've been infected will be confirmed. You must come to the visit fasting. If you are not fasting within the past 8 hours before this visit, you will be asked to come back fasting. Also, an electrocardiogram (ECG) will be done at this visit.

If you are a female, you will have blood or urine taken for pregnancy testing.

Pre-entry
You may be asked to return to the study clinic to have a repeat HCV viral load to confirm that you still have the infection. If you do still have the infection, you will come back for the entry visit. If you do not have evidence of ongoing infection, you will not enter the study. You will be referred back to your doctor for followup to ensure the virus does not come back. If you are a female, you will have blood or urine taken for pregnancy testing.

Entry
When all of the results from your screening tests are available, you will come back to the clinic to have a few tests done before starting the study. You will have urine and blood samples collected for routine safety tests. If you are a female, you will be asked to provide blood or urine sample for pregnancy testing. You may need to come to the clinic fasting for this visit (fasting means that you should not eat or drink anything for at least 8 hours before your visit). The study staff will inform you before the entry visit if you have to be fasting. If you are not fasting within the past 8 hours before this visit, you will be asked to come back fasting.

At this visit, you will get your study drugs. The study staff will give you enough study drugs to last until the week 8 visit. You do not need to take the study drugs with food. If you forget to take the study drugs at the correct time, it may be taken later in the day. Then the next day you should continue with the usual schedule that you take the study drugs. You should never cut or split your study medications.

You will have an extra evaluation (pharmacokinetic [PK] testing) done at the entry visit. This evaluation is described below.

Post-entry visits

You will be seen at treatment weeks 1, 2, 4, and 8 (end of treatment) AND at post-treatment weeks 2, 4, 8, 12, and 24 after taking the last dose of study drugs. These visits will last about 1-1½ hours each.

You must return any remaining study drug during the post-treatment visits.

If you are a woman, you will be asked to provide blood or urine sample for pregnancy testing.

Other visits
During the study, you may have to come back to the clinic for extra visits for testing of any lab results that are not normal, or to followup on a specific side effect or symptom.

Virologic Failure Confirmation
If laboratory tests show there is evidence of virologic failure (which is detectable HCV when you were previously undetectable or your virus has not gone down as quickly as expected), you will be asked to return to the clinic to confirm your lab results. If virologic failure is confirmed, you will then complete an early discontinuation study visit as described below.

Early discontinuation
There are two types of discontinuation (stopping study treatment or leaving the study early) in which you will be asked to come to the clinic for an extra visit in a fasting state.

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 some 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. You will be asked to complete some evaluations before being taken off the study.

III. Description of Study Evaluations

Consent
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 to be tested to see if you qualify for the study.

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

Physical examination
You will have a physical exam. The study staff will check the different systems in your body such as head, neck, eyes, ears, nose, throat, mouth and tongue, chest (excluding breasts) for respiratory, heart for cardiovascular, 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, and your height and 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. Once you are on treatment, 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.

Electrocardiogram
You will have an electrocardiogram (ECG) done. An ECG is a test to measure the heartbeat. An ECG machine will be used to do an electrical tracing of your heart that can show how hard it is working. You will have to lie very still for at least 5 minutes while the ECG is being done.

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. Approximately 144 mL (10 tablespoons) of blood will be drawn during any study visit. These may include: routine safety lab tests such as kidney and liver function, HIV viral load (a test that shows how much HIV is in your blood), CD4+/CD8+ counts (a test that shows how many infection-fighting cells you have in your blood), HCV viral load (a test that shows how much HCV is in your blood).

You will be asked to fast before some of the visits. This means that you should not eat or drink anything except prescription drugs and water for at least 8 hours before the visit.

Resistance testing
Blood will be drawn and stored for future HCV/HIV resistance testing that is required for this study. A resistance test is used to determine if the HCV/HIV viruses still respond to your medications.

Genetic testing
If you agree blood will be drawn for testing your genes (pieces of your DNA) to understand if you naturally were born with a better or worse chance of responding to the medications. Some of your blood cells will also be tested to see if your responsiveness to the therapy is associated with different genes related to IFN use. An IFN is an antiviral compound that is produced in response to many types of infections. You will not receive the results of these studies because they will be done in the future.

PK Studies
Blood will be drawn to measure the levels of the study drugs in your blood and to understand how the drugs interact with your body and how your body responds to the drugs.

Urinalysis
Urine samples will be collected for routine safety tests.

Pregnancy test
If you are a woman, you will have blood or urine taken prior to study entry. After you enter the study, you will be asked to provide blood or urine samples for pregnancy testing.

Pregnancy prevention counseling
All participants, male and female, will be counseled on the risk of the study drugs in pregnancy and on how to prevent pregnancy.

Adherence assessments
You will be asked about how well you take your medications. The study staff will give you information and encouragement to help you take your medications as prescribed.

Study drugs distribution and storage
You will be given an 8-week supply of study drugs at entry. You will be asked to store the study drugs as instructed on the medicine bottle label.

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.
- a Study Monitoring Committee (SMC) recommends that the study be stopped early (A SMC is an outside group of experts who monitor the study).
- your doctor thinks 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 experience HCV treatment failure.
- you or a female partner of a male participant 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.
- you are not able to take the study drugs as required by the study.
- you do not have, or are not able to, have required study visits and evaluations

If you must stop taking the study drugs earlier than indicated by the study, the study doctor will ask you to remain on the study and complete the post discontinuation visits at 2 weeks, 4 weeks, 8 weeks, 12 weeks, and 24 weeks from the date that you took the last dose of study treatment.

If I have to permanently stop taking study drugs through the study, or once I leave the study, how can I get study drugs?

If you must permanently stop taking SOF and RBV 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 FDC LDV/SOF 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 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

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 HIV medicines in your blood could cause drug resistance, meaning the drugs no longer work to prevent virus from reproducing. Drug interactions that lower the levels of SOF or LDV in your blood may decrease your chances for a cure of hepatitis C and/or cause drug resistance.

Bradycardia, or slow heart rate, may happen in persons who are taking amiodarone (a medicine that is used to treat heart rhythm problems) particularly for those also taking beta blockers (medications that reduce blood pressure) or those with a heart disorder and/or advanced liver disease. Because of this risk it is not recommended to take LDV/SOF with amiodarone and persons taking amiodarone will not be allowed to participate in this study. It is also not recommended to take LDV/SOF with other medicines that contain SOF.

For those persons taking HIV medicines, there is no clear risk of drug interactions between HIV medicines and SOF. Although SOF has not been studied with all HIV medicines, it has been studied with all first-line HIV medication drug classes and there are no recognized clinically significant interactions. This is also true for LDV with the exception of one of the HIV medications named tenofovir (TFV). LDV increases TFV levels in your body. With most other HIV drug combinations this increase is not felt to lead to significant risk unless your kidneys don't work normally. However, if TFV and LDV are used with HIV protease inhibitors that are combined with ritonavir (RTV) or with a drug named cobicistat (COBI), that is not an HIV drug but is used to increase the level of your HIV drugs in your blood stream, the potential risk of kidney toxicity may be higher. The combination of HIV protease inhibitors or COBI and LDV and TFV has not been studied in HIV-infected patients. For this reason there will be monitoring of the kidney function for all participants in this study.

Drug resistance may prevent other medicines from working in the future. HIV viral load will be monitored regularly to ensure that evidence of early failure of the HIV regimen is identified quickly. In addition, multiple drug interactions studies have been completed to ensure that HIV medications can be safely dosed with SOF, and there is no evidence to suggest that giving SOF or LDV and any antiretroviral allowed in this study will lead to HIV regimen failure. The risk is thought to be very low. To date only two out of over 3,000 patients have developed resistance to SOF, so this risk is also thought to be extremely low. Risk of resistance to LDV is high for patients who fail therapy, with most patients developing resistance. At this time the effect of resistance to LDV or similar medications is not clear, but it may increase the risk of other HCV treatments not working.

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.

Sofosbuvir (SOF) or Ledipasvir/sofosbuvir (LDV/SOF)

- Depression

- Irritability
- Sleep disturbances
- Tiredness
- Muscle pain
- Headaches
- Chills
- Nausea and vomiting
- Stomach pain
- Rash
- Anemia
- Lymphopenia
- Itching
- Loss of appetite
- Diarrhea
- Dizziness
- Elevated liver function tests

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 medications is short, 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 provider.

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 after delivery.

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 or more of the birth control methods listed below:

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

If you can become pregnant, you must have a pregnancy test within 72 hours before 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. You will be followed on study 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. In addition, pregnancy complications and/or pregnancies outcomes will be reported to the Antiretroviral Pregnancy Registry.

Are There Benefits to Taking Part in This Study?

If you take part in this study, there may be a direct benefit to you. Your health may be watched more closely than usual while you are on the study, which may help you to feel better. 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 currently available to you
- treatment with other experimental drugs, if you qualify
- no treatment; some people may clear the HCV infection on their own over the first year of infection, although over 9 in 10 people clear in the first 12 weeks of the new infection

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 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.

The following people might review your records: the University of Pennsylvania institutional review board (IRB) a group that makes sure that your rights and safety are protected while in the study, US National Institutes of Health (NIH), Office for Human Research Protections, AIDS Clinical Trials Group (ACTG), study staff, study monitors, and other government agencies supporting this study and the pharmaceutical company supporting this study. Having a Certificate of Confidentiality does not prevent you from releasing information about yourself and your participation in the study.

A description of this clinical trial will be available on www.ClinicalTrials.gov. This website will not include information that can identify you. At most, the web site will include a summary of the results. You can search this website at any time.

Your personal information may be given out if required by law. Positive for HIV or Hepatitis C or if a CD4 or viral load is done at a study visit, by law we have to report the result 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. If hepatitis B and hepatitis C tests are positive, they will be reported to the local department of health.

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, 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
- Questionnaires
- Results of tests and procedures you will undergo during this research
- 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:

<u>Individuals or organizations responsible for administering the study:</u>

- <u>ACTG Data Coordinating Center, Frontier Science Technology Research Foundation (FSTRF):</u> 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 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 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.
- Pharmaceutical sponsor (Gilead Sciences, Inc): The pharmaceutical company that is supplying the drug for this study
- 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 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 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 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 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.

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.

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?

There will be no cost to you for study-related visits, physical examinations, laboratory tests or other procedures. You or your insurance company, or your health care system will be responsible for the costs of your regular medical care as well as for the costs of drugs not given by the study.

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.

Will I Receive Any Payment?

You will be compensated $50 for the required 12 study visits (screen, pre-entry, entry, and on treatment weeks 1, 2, 4, 8 and post-treatment weeks 2, 4, 8, 12 and 24) you attend, for a total of $600. 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?

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 National Institutes of Health. You will not be giving up any of your legal rights by signing this 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, let the study staff know.

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

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.

Additional Tests

If you agree, your blood will be drawn and used for future testing. Results of testing done on these samples may not be given to you because they will be done in the future.

Please initial below if you agree to have any of your blood used for future ACTG-approved research. You may change your mind at any time and your samples will be destroyed.

_____ YES _____ NO

Genetic (the message in your DNA) testing

If you agree, your blood will be drawn and 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.

Please initial below if you agree to have any of your blood used for ACTG-approved genetic testing. You may change your mind at any time and your samples will be destroyed.

_____ YES _____ NO

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.

Please initial below if you agree to have any of your leftover blood used for future ACTG-approved research. You may change your mind at any time and reasonable efforts will be made to destroy your samples, though this may not always be possible.

_____ YES _____ NO

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/Time

Name of Person Obtaining Consent (Please Print)	Signature	Date