SUBJECT INFORMATION AND INFORMED CONSENT FORM AND AUTHORIZATION TO DISCLOSE HEALTH INFORMATION

Sponsor / Study Title:	**Gilead Sciences, Inc. / "A Phase 3b Randomized, Open-label, Controlled Study of the Efficacy, Safety and Tolerability of 12 Weeks of Ledipasvir/Sofosbuvir (LDV/SOF) Treatment for HIV/HCV Co-infected Subjects who Switch to Elvitegravir/Cobicistat/Emtricitabine/Tenofovir Alafenamide (E/C/F/TAF) or Emtricitabine/Rilpivirine/Tenofovir Alafenamide (F/R/TAF) prior to LDV/SOF HCV Treatment, the HIV/HCV Co-STARs study (Co-infection treatment with Single Tablet Antiviral Regimens)"**
Protocol Number:	**GS-US-366-1992**
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WHAT IS A CLINICAL RESEARCH STUDY?

You have been asked to take part in a clinical research study. Research studies are voluntary and include only those who wish to take part. This study will test two HIV-1 infection treatments in combination with a treatment for chronic hepatitis C virus (HCV).

The two HIV-1 infection treatments are called GENVOYA® or Elvitegravir/Cobicistat/Emtricitabine/Tenofovir Alafenamide (E/C/F/TAF) Fixed Dose Combination (FDC) and ODEFSEY® or Emtricitabine/Rilpivirine/Tenofovir Alafenamide (F/R/TAF) FDC and both are currently approved by the Food and Drug Administration (FDA).

The HCV treatment is called HARVONI®, or Ledipasvir/Sofosbuvir (LDV/SOF) FDC and it is currently approved by the FDA for the treatment of certain types of chronic hepatitis C virus infections.

This Subject Information and Informed Consent Form will explain the study to you. Your study doctor or study nurse will go over this form with you. Your study doctor or study nurse will answer all the questions you have about the information in this form.

If you agree to take part in this study, you will be asked to sign and date this form. You will be given a signed and dated copy to keep. No one can force you to take part in this study. Even if you agree to take part now, you can change your mind and stop at any time without penalty.

WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of this study is to test the effectiveness and safety of HARVONI® (LDV/SOF FDC) in HIV/HCV co-infected subjects when it is given for 12 weeks after switching from your current HIV medication regimen to GENVOYA® (E/C/F/TAF FDC) or ODEFSEY® (F/R/TAF) FDC.

Safety, how well your body accepts the study drugs, and tolerability, how stable its effects are, will also be evaluated and are determined by the physical exams, laboratory tests, electrocardiograms (ECGs), and questions asked of you about problems you might experience during the study.

HOW DOES THIS STUDY WORK?

If you agree to take part in this study, you will be one of approximately 120 subjects in this study. The study will take place at about 50 study sites in North America. About 5-7 people are expected to participate at the University of Pennsylvania. This study is open to men and women, 18 years of age or older. Your study doctor has asked you to come to the clinic for a screening visit to see if you are able to take part.

This is a randomized, open-label, 2-part study.

Randomized means the study treatment you take will be chosen by chance - like flipping a coin. For Part 1 of the study, you will be randomized in a 1:1 ratio (equal chance of assignment to study treatment group 1 or 2) to switch to one of two new HIV study drugs:

- **Study Treatment Group 1**: Switch to E/C/F/TAF FDC, once daily
- **Study Treatment Group 2**: Switch to F/R/TAF FDC, once daily

If your HIV virus remains suppressed during Part 1, your study doctor will then determine if you can continue on to Part 2. In Part 2 of the study, all subjects will undergo HCV therapy by taking LDV/SOF FDC once daily for 12 weeks. Additionally, you will continue taking the HIV study drug you were randomized to in Part 1 until the last study visit.

Open-label means you and your study doctor will know what study drugs you will be taking.

E/C/F/TAF FDC, F/R/TAF FDC, and LDV/SOF FDC, will be supplied by Gilead Sciences, Inc., which is also the Sponsor of this study. Your study doctor will tell you how to store your study drugs.

HOW LONG WILL YOU BE ON THE STUDY?

Taking part in this study will last about 36 weeks (or 9 months), not including the screening visit. During this time, you will be required to visit the clinic approximately 9 times (this is called the study period).

This study is made up of the following parts:

- **Screening**: This includes 1 visit lasting approximately 2 to 4 hours.
    - Your study doctor will do some tests or procedures (described below) to see if you meet the requirements for being in the study. If you meet the requirements, you will have up to 42 days from the Screening visit to start the study treatment.
- **Part 1 (On HIV Study Treatment Only)**: 8 weeks of study treatment with E/C/F/TAF FDC or F/R/TAF FDC; this includes 2 visits lasting 1 to 2 hours each.
- **Part 2 (On HCV and HIV Study Treatments)**: 12 weeks of study treatment with LDV/SOF FDC plus E/C/F/TAF FDC or F/R/TAF FDC; this includes 4 visits lasting 1 to 2 hours each.
- **Post-HCV Study Treatment Follow-Up (On HIV Treatment Only)**: 12 weeks of post-HCV study treatment with E/C/F/TAF FDC or F/R/TAF FDC; this includes 2 visits lasting 1 to 2 hours each.
    - If you complete the study through the Post-HCV Study Treatment Week 12 visit (the last study visit), you will be required to return to the clinic 30 days after the completion of the study treatment for a 30-Day Follow-Up visit.

WHAT ARE YOUR RESPONSIBILITIES?

If you decide to take part in this study, there are some rules you must follow. Some of the rules are listed below. There could be other rules that your study doctor will review with you.

- You must not get pregnant or get someone pregnant during this study.
- It is very important that you tell your study doctors all of the information you know about your health and medications you are taking now or start taking while in the study. If you do not tell the study doctor everything you know, you may be putting your health at risk.

- You are not allowed to take certain medications and herbal/natural supplements while in this study. Your study doctor will review your current medications and herbal/natural supplements with you to determine if they can be taken while participating in this study. Before starting any new medications or herbal/natural supplements while participating in this study, you must consult with the study doctor first.
- You must bring back all unused study drug and all study drug containers (even if they are empty or used).
- You must follow all instructions given to you while you are taking part in this study. If you do not, you may no longer be able to take part in the study. If you are unsure about what you are supposed to do, ask your study doctor.

WHAT WILL HAPPEN AT EACH STUDY VISIT?

The table below shows what will happen each time you visit the clinic. The procedures or tests are described after the table:

Procedure (what will happen)	Screening (To see if you qualify)	Baseline (Day 1)	Part 1 HIV Study Treatment Only		Part 2						30 Day Follow-Up Visit	ESDD Visit[d]
					HIV and HCV Study Treatment				HIV Study Treatment Only			
			Week 4	Week 6	Week 8	Week 12	Week 16	Week 20	Post-HCV Study Treatment Week 4	Post-HCV Study Treatment Week 12		
Review your health history	X											
Review any changes in your health since last visit		X	X		X	X	X	X	X	X	X	X
Review medications you are taking	X	X	X		X	X	X	X	X	X	X	X
Perform complete physical examination	X	X								X		X
Measure your vital signs (blood pressure, heart rate, breathing rate, and temperature) and record your weight	X	X	X		X	X	X	X	X	X	X	X
Measure your height	X											
Electrocardiogram (ECG)	X											X
Imaging or biopsy of liver to screen for cirrhosis (if required)	X											
Take blood samples for routine health tests, HCV & HIV viral resistance tests, HCV & HIV viral infection test, bone & renal safety tests, study drug levels, inflammation tests, and platelet and coagulation (clotting) function tests	X	X	X	X	X	X	X	X	X	X	X	X
Take blood samples for exploratory tests (biomarkers)		X	X		X	X		X		X		
Take urine samples for routine health tests	X	X	X		X	X	X	X	X	X	X	X
Pregnancy test for women who are able to have children[a]	X	X	X		X	X	X	X	X	X	X	X
Take optional blood and urine sample for future research[b]		X	X		X			X		X		X
Complete health related quality of life questionnaires		X			X			X		X		X
Get study drug[c]		X	X		X	X	X	X	X			
Take study drug in clinic			X		X	X	X	X				
Bring back unused study drug and all containers since last visit			X		X	X	X	X	X	X		X

a. Only for females who are able to have children: blood test at Screening, urine test thereafter (except Week 6). If urine test is positive a confirmation blood test will be required.
b. Optional blood sample only taken for subjects who have agreed and signed the "Future Research Consent" form
c. Part 1: Your HIV study drug (E/C/F/TAF or F/R/TAF) will be dispensed after all Day 1 assessments are completed and randomization occurred, and through the duration of the study. Part 2: If your study doctor determines you are eligible for Part 2 of the study, your HCV study drug (LDV/SOF) will be dispensed at Weeks 8, 12, and 16 only.
d. ESDD: Early Study Drugs Discontinuation Visit

Procedure or Test	**Description**
Electrocardiogram (ECG)	Several small, sticky pads will be placed on your chest, arms, and legs. A wire from each pad goes to a machine that makes a recording of your heart rhythm. This test takes about 15 minutes.
Liver Imaging (if needed)	A study doctor uses an ultrasound test (a test that uses sound waves to "visualize" structures beneath the skin) to see if there is scarring in your liver. This test takes about 1 hour.
Liver Biopsy (if needed)	A study doctor will clean the area on your skin above your liver and then will inject a medicine into the area to make it numb. After the numbing medicine has taken effect, the study doctor will use a needle to take out a very small piece of your liver (or a "biopsy"). This piece is about one centimeter long, representing 1/50,000th of your total liver. This piece of your liver will be viewed under a microscope to see if there is scarring in your liver. You will remain in the hospital or clinic for about 2 to 6 hours after the procedure.
Questionnaires	• The Visual Analogue Scale (VAS) for HIV adherence questionnaire is a visual scale that estimates how much study drug you believe you have taken. • The HIV Treatment Satisfaction Status (HIVTSQs) Questionnaire is a survey to determine how satisfied you are with your current HIV study treatment. • The Medical Outcomes Short Form (SF-36) is a survey that contains questions about your general health and wellness while participating in the study. • The Functional Assessment of Chronic Illness Therapy and Fatigue (FACIT-F) questionnaire is a survey to assess your quality of life while living with chronic illness. • The Chronic Liver Disease Questionnaire (CLDQ-HCV) is a survey to assess your quality of life while living with HCV. • The Work Productivity and Activity Impairment Questionnaire: Hepatitis C, v2.0 (WPAI: Hepatitis C) questionnaire contains questions about your ability to work and perform regular activities while living with HCV.

Lab Tests and Biologic Sample Collection	**Description**
Main study tests	Samples of your blood and urine will be used to help answer the study questions.
Routine health test	Samples of your blood and urine will be tested to check your health. All or some of the following tests will be done at each visit: chemistry, complete blood count (used to evaluate overall health and detect any disorders, CD4+ (white blood cell that fights infection) cell count.
Pregnancy test	If you are a woman who can get pregnant, a sample of your blood will be taken to test for pregnancy at the screening visit. To take part in this study, the pregnancy test must be negative at screening. A sample of your urine will be taken at each visit to test for pregnancy. If the urine test results are positive, a blood sample will be taken to confirm the results.
Viral infection tests for HIV and HCV	Samples will be collected to see how much HIV and HCV virus is in your blood.
HIV proviral genotype, viral load retest, and genotype/phenotype tests (if applicable)	If you do not have a historical genotype report available at the screening visit, samples of your blood will be collected at screening to see if you have any resistance to the study drugs (proviral genotype test). If you do not appear to be responding properly to the HIV study drug, you may be required to return to the clinic for an unscheduled or scheduled visit to confirm whether or not you are truly not responding your HIV study treatment. Your study doctor may decide to check that you have not become resistant to study treatment by conducting a HIV-1 genotype/phenotype testing at this visit. Samples of your blood will be taken to measure the amount of HIV-1 in your blood and for genotype/phenotype testing.
HCV genotype and IL28B genotype tests	Samples of your blood will be collected to obtain information about your HCV virus and your ability to respond to HCV study treatment.
Pharmacokinetic test (PK)	Samples of your blood will be tested to see how much study drug is in your body (ie, drug levels).
Safety tests	Samples of your blood will be tested to check the safety of the study drugs on your bone, kidney, and blood function.
Stored samples from routine health tests	Samples collected for any of these tests may be stored to use for additional testing.
Exploratory tests (biomarkers)	Samples will be collected to study some indicators of bone, kidney (renal), heart (for example how your blood clots), and how your body responds to an infection.

Lab Tests and Biologic Sample Collection	**Description**
Optional tests for future research	If you agree (a separate signature is required), samples will be collected for research purposes regarding the study drug and the disease. If you do not agree, you can still take part in the main study. More information is below.

Study Drug	**Description**
Get study drug	At the visits marked on the table, you will be given study drug to take home with you. Store your study drug in its original container and as described by your study doctor.
Take study drug	HIV study drug (E/C/F/TAF FDC or F/R/TAF FDC) • Take one time per day with food at approximately the same time each day. On the days you have study visits, take your dose at your regular schedule unless your study doctor instructs you otherwise. HCV study medication (LDV/SOF FDC) • Take one time per day with or without food at approximately the same time each day. On the days you have study visits, take your dose at your regular schedule unless your study doctor instructs you otherwise. In Clinic Dosing • On Part 1 Week 4, Part 2 Weeks 8, 12, 16, 20 you will take your study drug dose(s) in the clinic. Please do not take your study drugs on those visits until instructed by your study doctor.
Bring back study drug and containers	Bring back all unused study drug and all study drug containers (even if they are empty or used). Your study doctor or study nurse will count how many doses you have taken. Your study doctor or study nurse will ask about any doses you did not take or if you took any extra doses.

WHAT RESTRICTIONS ARE THERE DURING THIS STUDY?

Fasting (no food or liquids except water) is required for tests at visits Day 1, Week 4, Week 8, Week 12, Week 20, Post-HCV Study Treatment Week 12, and at the early study drugs discontinuation visit (ESDD). You may not eat or drink (except water) for 8 hours prior to each of those visits. Eating or drinking may affect the results of your blood testing. If you have not fasted, the visit may proceed but you will be asked to return to the study center within 72 hours in a fasted state.

You must check with the study doctor before taking any medication or health supplements for the length of the study.

You cannot take any antacids that contain calcium, magnesium, or aluminum (for example, Tums® or Rolaids®), Carafate® (an ulcer medicine), or vitamins/mineral supplements that contain calcium, iron or zinc for a minimum of 2 hours before and 2 hours after any dose of the study drugs.

You may not take the following herbal/natural health supplements while on the study: St. John's Wort (Hypericum perforatum), Echinacea, Milk thistle (ie, silymarin), and the Chinese herb Sho-Saiko-To (or Xiao-Shai-Hu-Tang).

WHAT SAMPLES WILL BE STORED?
WHAT TESTS WILL BE DONE ON THESE SAMPLES?

Some of your blood and urine taken at all visits will be frozen and stored. Your stored samples (including the samples collected for exploratory tests) and the information collected about you during the study may be used by the Study Sponsor or its research partners to help answer study questions about the study drugs, HIV, or HCV. At the end of this study, these samples may be held in storage by Gilead Sciences, Inc. for up to 15 years. You may request that your stored samples be destroyed at any time by writing to the study doctor at the address listed in this form.

WHAT ARE THE POSSIBLE RISKS OF BEING IN THIS STUDY?

ODEFSEY®, or Emtricitabine/Rilpivirine/Tenofovir Alafenamide (F/R/TAF) Fixed Dose Combination (FDC) COMMON ADVERSE EVENTS

FTC/RPV/TAF (F/R/TAF) is a fixed-dose combination (FDC) tablet containing three study drugs: emtricitabine (FTC, F), rilpivirine (RPV, R) and tenofovir alafenamide (TAF). The safety of FTC/RPV/TAF is based on studies of FTC+TAF; and studies of RPV.

Adverse drug reactions that have been identified in studies of subjects treated with F+TAF are as follows:

Very common:
- headache
- diarrhea
- nausea

Common:
- vomiting
- abdominal pain
- indigestion
- passing gas
- rash
- fatigue

Common adverse drug reactions that have been identified in studies of subjects taking RPV include:

- decreased appetite
- depression
- abnormal dreams
- sleep disorders (either difficulty sleeping or feeling sleepy)
- headache
- dizziness
- abdominal pain
- nausea
- vomiting
- rash
- fatigue
- changes in liver tests

Additional adverse reactions from regimens containing RPV (given with FTC+tenofovir disoproxil fumarate (TDF) as FDC) include:

- increased weight
- severe skin reactions including rash accompanied by fever, swelling and liver problems

Across all Phase 2 and Phase 3 studies in which 2,394 subjects received regimens containing F+TAF (given with elvitegravir+cobicistat (EVG+COBI) as FDC), eye disorders were uncommon, balanced between study treatment groups, and most were considered by the study doctor as unrelated to the study drugs. None were definitive for posterior uveitis (inflammation in the back of the eye), and none resulted in permanent discontinuation of study drugs. One subject in Study GS-US-292-0106 had an adverse reaction of intermediate uveitis (inflammation in the middle of the eye) that was considered related to study drug by the study doctor but resolved while the subject continued on study drug without interruption.

GENVOYA®, or Elvitegravir/Cobicistat/Emtricitabine/Tenofovir Alafenamide (E/C/F/TAF) Fixed Dose Combination (FDC) SIDE EFFECTS

GENVOYA can cause serious side effects, including:

- **Build-up of lactic acid in your blood (lactic acidosis).** Lactic acidosis may happen in some people who take GENVOYA. Lactic acidosis is a serious medical emergency that can lead to death. You may be more likely to get lactic acidosis or severe liver problems if you are female, very overweight (obese), or have been taking GENVOYA for a long time.

  Lactic acidosis can be hard to identify early, because the symptoms could seem like symptoms of other health problems. Call your study doctor right away if you get any of the following symptoms which could be signs of lactic acidosis:

- feel very weak or tired
- have unusual (not normal) muscle pain
- have trouble breathing
- have stomach pain with:
  - nausea
  - vomiting
- feeling cold, especially in your arms and legs
- feel dizzy or lightheaded
- have a fast or irregular heartbeat

- **Severe liver problems**. Severe liver problems may happen in people who take GENVOYA. In some cases, these liver problems can lead to death. Your liver may become large (hepatomegaly) and you may develop fat in your liver (steatosis). **Call your study doctor right away if you get any of the following symptoms of liver problems**:

  - your skin or the white part of your eyes turns yellow (jaundice)
  - dark "tea-colored" urine
  - light-colored bowel movements (stools)
  - loss of appetite for several days or longer
  - nausea
  - stomach pain

- **Worsening of Hepatitis B infection.** GENVOYA is not for use to treat chronic hepatitis B virus (HBV) infection. If you acquire the hepatitis B virus (HBV) infection and take GENVOYA, your HBV may get worse (flare-up) if you stop taking GENVOYA. A "flare-up" is when your HBV infection suddenly returns in a worse way than before. Patients with HBV infection at screening are not eligible to enroll in this study.

GENVOYA may cause other serious side effects, including:

- **Changes in body fat can happen in people who take HIV-1 medicine.** These changes may include increased amount of fat in the upper back and neck ("buffalo hump"), breast, and around the middle of your body (trunk). Loss of fat from the legs, arms and face may also happen. The exact cause and long-term health effects of these conditions are not known.
- **New or worse kidney problems, including kidney failure**. Your study doctor should do blood and urine tests to check your kidneys before you start and while you are taking GENVOYA. Your study doctor may tell you to stop taking GENVOYA if you develop new or worse kidney problems.
- **Bone problems** can happen in some people who take GENVOYA. Bone problems may include bone pain, softening or thinning (which may lead to fractures). Your study doctor may need to do tests to check your bones.

Tell your study doctor if you have any side effect that bothers you or that does not go away.

The most common side effect of GENVOYA is nausea.

These are not all the possible side effects of GENVOYA. Please talk to your study doctor for more details on adverse events or see the GENVOYA® package insert for more information.

HARVONI®, or Ledipasvir/Sofosbuvir (LDV/SOF) Fixed Dose Combination (FDC) SIDE EFFECTS

HARVONI may cause serious side effects, including:

- **Slow heart rate (bradycardia).** HARVONI treatment may result in slowing of the heart rate along with other symptoms when taken with amiodarone (Cordarone®, Nexterone®, Pacerone®), a medicine used to treat certain heart problems. Of note, patients who currently take amiodarone, start amiodarone within 60 days prior to the baseline study visit or will need to take amiodarone for heart problems during the study are not eligible to enroll in this study. Get medical help right away if you take amiodarone with HARVONI and get any of the following symptoms:

    - fainting or near-fainting
    - dizziness or lightheadedness
    - not feeling well
    - weakness
    - extreme tiredness
    - shortness of breath
    - chest pains
    - confusion
    - memory problems

The most common side effects of HARVONI include:

- tiredness
- headache
- weakness
- rash
- nausea

Tell your study doctor if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of HARVONI. Please talk to your study doctor for more details on adverse events or see the HARVONI® package insert for more information.

Switching From a Stable Regimen

You are currently taking medications that are effectively treating your HIV infection. You will be changing from a stable regimen that is working well to a new regimen during this study. When switching from one antiviral regimen to another, there is a risk that the virus will not be controlled with the new regimen, the virus could develop resistance to the medications, and/or the new regimen could cause new side effects. Viral load, possible resistance, and side effects will be frequently and carefully monitored during this study to minimize these risks.

IMMUNE RECONSTITUTION SYNDROME
A condition called immune reconstitution syndrome, some with autoimmune manifestations, can happen in some subjects with advanced HIV infection (AIDS) when combination anti-HIV treatment is started. The risk of this condition occurring when HIV study treatment is used in subjects with already well-controlled HIV is considered to be very low.

BLOOD DRAWS
Collecting a blood sample from a vein may cause pain, bruising, lightheadedness, fainting, and very rarely, infection at the site of the needle stick.

ECG
After you have an ECG, you may have mild irritation, slight redness, and itching on your skin where the recording patches are attached. You may have your chest shaved for this procedure.

QUESTIONNAIRES
Some of the questions may seem personal and may make you feel uncomfortable. If you have any questions or concerns while answering these questions, please talk to your study doctor. You do not have to answer questions if you do not want to.

FASTING
Fasting could cause dizziness, headache, stomach discomfort, or fainting.

ALLERGIC REACTION
Allergic reaction is always possible with a drug you have not taken. Serious allergic reactions that can be life-threatening may occur. Some things that happen during any allergic reaction to any type of medication are:

- rash
- having a hard time breathing
- wheezing when you breathe
- sudden drop in blood pressure
- swelling around the mouth, throat, or eyes
- fast pulse
- sweating

FIBROSCAN®
There are no known risks associated with FibroScan® at this time. FibroScan® uses ultrasound technology to assess the liver. It is a non-invasive procedure that takes only a few minutes to perform. Since this is a new technology, not all study doctors' offices will have access to FibroScan® equipment.

LIVER BIOPSY RISKS
Possible side effects from a liver biopsy include pain, stinging, bruising and/or swelling at the site of injection. It is common to have some soreness around the site and some mild pain in or around your right shoulder. Less common side effects include bleeding from the liver, infection, puncture of the lung or gallbladder when the needle is inserted, moderate or severe pain and rarely (1 in 10,000 cases) death.

Hepatitis Testing: Some of your blood will be tested for hepatitis B, and hepatitis C. The study doctor may be required by law to report the result of these tests to the local health authority.

Privacy Risks of Genetic Testing: If your genetic research data are shared with unauthorized users, you may be at risk of loss of the privacy of your health data. This risk is minimized by protections described in the 'General Statement About Privacy' section below.

UNKNOWN/UNEXPECTED RISKS AND DISCOMFORTS

There are adverse events that are not known or happen rarely when subjects take these study drugs. You will be told of any new information that might cause you to change your mind about continuing to take part in this study.

As with any new drug, extra care has to be taken to monitor the side effects that are not always obvious. If you feel any side effects or unusual symptoms, please notify your study doctor as soon as possible at the phone number listed in this form.

PREGNANCY AND BREAST-FEEDING

Please share this information with your partner if it is appropriate.

The effects of the study drugs on a developing fetus (unborn baby) as well as on exposed infants are not known in humans. Any female able to become pregnant must have a negative blood pregnancy test to enroll. Females who are breast-feeding will not be enrolled in this study. You should be aware that on rare occasions in early pregnancy, the pregnancy test may be falsely negative and that a negative test result does not preclude pregnancy.

It is very important while you are in this study that you do not become pregnant if you are a female, or do not cause others to become pregnant if you are a male. Not having sex is the only certain way to prevent pregnancy.

Male subjects

If you are a man who chooses to have sex with a female partner, you will be required to use effective methods of birth control from the first study drug dose, throughout the study and for 30 days following the last dose of study drug, one of which must be an effective barrier method. Please speak with your study doctor to determine the best method of birth control for you and your female partner during this study.

If you cause your female sex partner to become pregnant while you are in the study or within 30 days after your last dose of study drug, the study drug may or may not harm an unborn baby. If you have a female partner who becomes pregnant or suspects that she has become pregnant while you are in the study or within 30 days after your last dose of study drug, you will be required to notify your study doctor immediately. As the risk to your partner and unborn baby is not known, it is recommended for your partner to receive appropriate prenatal care. If you agree, your partner will be asked to sign a consent form to allow disclosure of medical information related to pregnancy.

Your study doctor may need to disclose to your partner details of this study and your taking part in it. The study sponsor and the study doctor will not be responsible for the costs related to the pregnancy, delivery, or care of your child.

Female subjects
If you are a woman who chooses to have sex with a male partner, you will be required to use effective methods of birth control from the screening visit, throughout the study and for 30 days following the last dose of study drug. Please speak with your study doctor to determine the best method of birth control for you and your male partner during this study.

- Abstinence
- Intrauterine device (IUD)
- Tubal sterilization (tubes tied)
- Essure micro-insert system
- Vasectomy in the male partner
- Combined barrier methods:
    - Diaphragm with spermicide and a male condom without spermicide
    - Cervical cap with spermicide and male condom without spermicide
- Hormonal birth control methods (pills, injections, implants, patches or vaginal rings) and a combined barrier method.

Female subjects must also refrain from egg donation during study treatment and until at least 30 days after the last dose of study drug.

If you are female and become pregnant or suspect that you have become pregnant while in the study and within 30 days of last dose of study drug, you will be required to stop taking all the study drugs and to notify your study doctor immediately. You will be discontinued from the study. The study doctor will request to track your pregnancy and will report the pregnancy and outcome to Gilead.

Other not yet identified side effects could occur to you, your embryo or fetus should you become pregnant during the time you participate in the study or after you have completed the study.

GENVOYA® (E/C/F/TAF FDC) Package Insert Pregnancy Summary
The effects of GENVOYA have not been fully evaluated on the developing fetus in humans. There are no adequate and well-controlled studies in pregnant women. Animal studies do not indicate direct or indirect harmful effects of the study drugs with respect to pregnancy; however, animal reproduction studies are not always predictive of human response.

GENVOYA® (E/C/F/TAF FDC) Package Insert Nursing Mothers Summary

The Centers for Disease Control and Prevention recommend that HIV-infected mothers not breastfeed their infants to avoid risking postnatal (i.e., after birth) transmission of HIV. Studies in rats have demonstrated that elvitegravir, cobicistat, and tenofovir are secreted in milk. It is not known whether elvitegravir, cobicistat, or TAF is excreted in human milk.

In humans, samples of breast milk obtained from five HIV-1 infected mothers show that emtricitabine is secreted in human milk. Breastfeeding infants whose mothers are being treated with emtricitabine may be at risk for developing viral resistance to emtricitabine. Other emtricitabine-associated risks in infants breastfed by mothers being treated with emtricitabine are unknown.

Because of both the potential for HIV transmission and the potential for serious adverse reactions in nursing infants, mothers should be instructed not to breastfeed if they are receiving GENVOYA.

HARVONI® (LDV/SOF FDC) Package Insert Pregnancy Risk Summary

The effects of Harvoni have not been evaluated on the developing baby in humans. There are no adequate and well-controlled studies with HARVONI in pregnant women. In animal reproduction studies, no evidence of adverse developmental outcomes was observed with the administration of ledipasvir or sofosbuvir. However, animal reproduction studies are not always predictive of human response.

The background risk of major birth defects and miscarriage for the indicated population is unknown; however, the estimated background risk in the U.S. general population of major birth defects is 2-4% and of miscarriage is 15-20% of clinically recognized pregnancies.

HARVONI® (LDV/SOF FDC) Package Insert Nursing Mothers Summary

It is not known whether HARVONI and its breakdown products (other molecules formed when the liver metabolizes a medicine) are present in human breast milk. When administered to lactating rats, ledipasvir was detected in the plasma of suckling rats likely due to the presence of ledipasvir in milk, without clear effects on nursing pups. The breakdown product of sofosbuvir was the primary component observed in the milk of rats which were producing milk, without effect on nursing pups. The development and health benefits of breastfeeding should be considered along with the mother's clinical need for HARVONI and any potential adverse effects on the breastfed infant from HARVONI or from the underlying maternal condition. Of note, female patients that are currently breastfeeding are not eligible to enroll in the study.

Condom Use for Male Subjects

It has been proven that condom use decreases the risk of spreading HIV between sexually active individuals. To decrease your risk of transmitting the virus to another individual and to decrease the risk of being infected with a different strain of HIV, we recommend that condoms (except for lambskin) be used for all sexual activity to include oral, vaginal, and anal sexual contact. Condom use is recommended in addition to your current form of birth control. The use of spermicide is not recommended.

Male subjects must agree to use condoms during heterosexual intercourse and avoid sperm donation while enrolled in the study and for 30 days after administration of the last dose of study drug.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

You may not receive benefit from taking part in this study. Your disease may improve, stay the same, or worsen while you are participating in this study. Studies are a way for doctors to see if a drug is useful in fighting a disease.

Your taking part in this study may help people with HIV/HCV co-infection understand more about the treatment of HIV/HCV co-infection. By taking part in this study, your health will be monitored closely at study visits.

WHAT ARE YOUR TREATMENT OPTIONS?

Your study doctor will discuss appropriate treatment options and the risks and benefits with you.

You may discuss if you want to have any treatment or if you want to choose other HIV and/or HCV treatments. These treatments include those that are already approved and sold.

WHAT HAPPENS IF YOU DO NOT WANT TO TAKE PART IN THIS STUDY?
WHAT HAPPENS IF YOU NO LONGER WANT TO TAKE PART IN THE STUDY?

Your decision to take part in this study is voluntary. You can refuse to take part or stop taking part at any time without giving a reason. If you decide to stop the study at any time, your exit from this study will not affect medical care which you otherwise may receive. No matter what decision you make, there will be no penalty or loss of benefits to you.

Your participation in this study may be stopped at any time by your study doctor, Gilead Sciences, Inc., or regulatory authorities.

Your study doctor may decide for your medical safety to stop your study drug(s) or take you off the study. You may be taken off the study if your study doctor learns you did not give a correct medical history or did not follow instructions for the study. If you are taken off the study, you will no longer receive the study drug(s). If your study drug(s) is stopped, your study doctor will closely monitor your overall health.

HOW MUCH WILL STUDY TREATMENT COST YOU?

The study drugs used in this study will be given to you at no charge. All study visits and fees for lab tests and procedures that are part of this study will be provided at no cost to you.

You or your usual health care payer will be responsible for any other health care costs.

WILL YOU BE PAID TO BE PART OF THIS STUDY?

You will be paid $50.00 for the screening and baseline visits. For visits thereafter, Part 1 (week 4 and week 6); Part 2 (weeks 8, 12, 16 and 29 and post HCV treatment visits weeks 4 and 12), you will be paid $40 for every visit you attend. An additional payment of $10 will be made at these visits if you bring back the study medication bottles dispensed at the last visit (empty or with any unused study drugs). Thus if you attend all required visits (10) and return your medication bottles for the study, the maximum payment you can receive is $500. If you stop taking study drugs early and complete the Early Study Drug Discontinuation Visit and return the study medication bottles, you will be compensated $50. You will be compensated $50 for the 30-Day Follow-Up Visit that occurs after the Early Study Drugs Discontinuation Visit. You will be compensated $50 for any unscheduled visits requested by the study staff. The total payment you will receive for the study depends on how long you participate.

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

If you discontinue early from the study, you will receive a pro-rated (partial) reimbursement amount based on how many study visits you completed.

WHAT HAPPENS IF YOU ARE INJURED?

If you become sick or injured as a direct result of taking the study drug and/or following the study procedures, the study site will provide you with medical treatment. The Sponsor, Gilead Sciences, Inc., will reimburse you or the study site for the reasonable and necessary costs of such medical treatment. No other form of reimbursement for study-related injury or illness is offered by the Sponsor. You should immediately contact your Study Doctor at the contact information shown below in the event you experience any study-related illness or injury.

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

You do not give up any legal rights by signing this form. You are not precluded from seeking to collect compensation for injury related to malpractice, fault, or blame on the part of those involved in the research.

GETTING ANSWERS TO YOUR QUESTIONS OR CONCERNS ABOUT THE STUDY

You can ask questions about this consent form or the study (before you decide to start the study, at any time during the study, or after completion of the study). Questions may include:

- Who to contact in the case of a research-related injury or illness;
- Payment or compensation for being in the study, if any;
- Your responsibilities as a study subject;
- Eligibility to participate in the research;
- The study doctor's or study site's decision to exclude you from participation;
- Results of tests and/or procedures;
- Other questions, concerns, or complaints.

Contact the study doctor or study staff listed on the first page of this form with any questions, concerns or complaints.

GETTING ANSWERS TO YOUR QUESTIONS ABOUT YOUR RIGHTS AS A RESEARCH SUBJECT

This study has been reviewed by an Institutional Review Board (IRB). This Committee reviewed this study to help ensure that your rights and welfare are protected and that this study is carried out in an ethical manner.

For questions about your rights as a research subject, contact:

- By mail:
  Study Subject Adviser
  Chesapeake IRB
  6940 Columbia Gateway Drive, Suite 110
  Columbia, MD 21046
- or call **toll free**: 877-992-4724
- or by **email**: adviser@chesapeakeirb.com

Please reference the following number when contacting the Study Subject Adviser: Pro00016357.

WHO WILL HAVE ACCESS TO YOUR MEDICAL RECORDS?

GENERAL STATEMENT ABOUT PRIVACY

Records identifying you will be kept confidential and, to the extent permitted by applicable laws and/or regulations, will not be made publicly available. Your personal information may be given out if required by law. If you test positive for HIV, Hepatitis B or Hepatitis C, 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. In the event of any publication regarding this study, your identity will remain confidential.

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

Your coded study information may also be used for additional unanticipated medical and/or scientific research projects in the future relating to your disease or similar diseases and development of the study drug (but at all times in compliance with applicable law and regulation).

By signing this consent form you agree that you will not be able to have access to your personal health information related to this study until the study is over. This is done to maintain the scientific integrity of the study. After the study is complete, you can obtain access to your information through your Study Doctor.

A federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans and most employers to discriminate against you based on your genetic information.

This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that the sponsor will get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that the sponsor will get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

All health insurance companies and group health plans and all employers with 15 or more people must follow this law.

Be aware that this Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance or long-term care insurance.

Authorization to Use and Disclose Records

The authorization part of the consent gives more detailed information about how your personal health information may be used and disclosed by the University of Pennsylvania Health System (UPHS), the School of Medicine and the individual Principal Investigator, subject to University of Pennsylvania procedures.

What personal health information is collected and used in this study and might also be disclosed?
The following personal health information will be collected, used for research, and may be disclosed during your involvement with this research study:

- Name, address, telephone number, date of birth
- Social Security Number (if you receive more than $600 for participating in studies at PENN, we will need your SSN for the W-9)
- Personal and family medical history
- Current and past medications or therapies
- Results of physical exams, laboratory tests and procedures you will undergo during this research study

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
- to see if the research was done right
- to 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.

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:

- Pharmaceutical sponsor (Gilead Sciences): This is the company that supplies drugs for the study. Information regarding safety and adverse effects needs to be collected and monitored.
- Contract Research Organization: Monitors will visit the site on a regular basis to review data and assure accuracy and completeness of information before the data are analyzed.

Regulatory and safety oversight organizations

The Food and Drug Administration and regulatory agencies in other countries

The Office of Human Research Protections

The Study Monitoring Committee

Once your personal health information is disclosed to others outside of UPHS or the School of Medicine, it may no longer be covered by federal privacy protection regulations. Data are reported to the sponsor on Case Report Forms that identify you by your unique study number and not your name or medical record number. Information regarding your health, such as side effects of the study medications 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 use or disclose my personal health information?
Your authorization for use of your personal health information for this specific study does not expire.

Your information may be held in a research repository (database). However, UPHS and the School of Medicine may not re-use or re-disclose information collected in this study for a purpose other than this study unless:

- You have given written authorization to do so
- The University of Pennsylvania's Institutional Review Board grants permission after ensuring that appropriate privacy safeguards are in place
- As permitted by law

Can you change your mind?
Yes, at any time you may withdraw your approval to allow the use and disclosure of your personal health information as described here. You must do so in writing to the Principal Investigator at the address on the first page. Even if you withdraw your permission, your personal health information that was collected before we received your written request may still be used and disclosed, as necessary for the study. If you withdraw your permission to use your personal health information, you will also be withdrawn from the research study.

If you withdraw your permission to use any blood or tissue obtained for the study, the Sponsor may need to retain and use any samples that have already been collected to comply with its legal obligations and to maintain the scientific integrity of the study.

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 if I decide not to give permission to use and give out my health information?
If you decide not to give permission to use and give out your health information, then you will not be able to be in this research study.

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 (that is, 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 (for example, health insurance company, disability provider, etc).

Your coded study information may also be used for additional unanticipated medical and/or scientific research projects in the future relating to your disease or similar diseases and development of the study drug (but at all times in compliance with applicable law and regulation).

If necessary for these purposes, the Sponsor may share your information with its affiliates, people and companies with whom the Sponsor works, and regulatory or other governmental agencies. Although efforts will be made to protect your privacy, absolute confidentiality of your records cannot be guaranteed. Your medical information and records may be re-disclosed and no longer protected by federal privacy law.

As explained in this consent form, your participation in this study is voluntary and you may withdraw from the study at any time by informing your Study Doctor. By signing this consent, you authorize the collection and use of information about you as described in this consent. You may revoke (take back) this authorization for the collection and use of information about you by informing your Study Doctor in writing at the address listed on the first page of this form. If you withdraw from the study or if you revoke your authorization for the collection and use of information about you, your participation in the study will end and the study personnel will stop collecting information from you. The Sponsor will need to keep and use any research results that have already been collected. The Sponsor must do this to comply with its legal obligations and to maintain the scientific integrity of the study. Your decision to withdraw from the study or to revoke your authorization for the collection and use of information about you will not result in any penalty or loss of access to treatment or other benefits to which you are entitled. This authorization has no expiration date, unless and until you revoke it. In California and any other state that requires an expiration date, the Authorization will expire 50 years after you sign this authorization document.

If you have any questions about the collection and use of information about you, you should ask your Study Doctor.

WHERE CAN YOU FIND MORE INFORMATION ABOUT THIS STUDY?

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

AGREEMENT TO BE IN THE STUDY

By signing this informed consent form, I acknowledge that:

(1) I have carefully read and understand the information in this form.
(2) The purpose and procedures of this research study have been fully explained to me. I was able to ask questions and all of my questions were answered to my satisfaction.
(3) I have been informed of the drugs and procedures of the study that are being tested. I have been informed of possible risks as a result of taking part in this study that could happen from both known and unknown causes.
(4) I understand that I am free to withdraw my consent and to stop my participation in this study at any time. The possible effect on my health, if any, of stopping the study early has been explained to me.
(5) I understand that stopping the study will not impact my medical care and treatment options.

Subject

Subject Printed Name	Signature	Date

Person Obtaining Consent

Printed Name & Title	Signature	Date

Witness (if applicable)

Witness Printed Name	Signature	Date

Optional Future Research Consent

You are being asked to take part in future research. If you decide to not take part in this future research, you can still take part in the main study.

This research may help scientists to better understand:

- How your disease and related diseases work
- The effect of the study drug and/or other medications on the body
- How the study drug is processed by the body
- Who could benefit from the study drug
- Why some people have adverse events

The results of the tests done on your blood samples (also called biologic sample(s)) will not be given to you or your study doctor. Information from these tests may be printed in a medical journal or presented at scientific meetings. Only a summary of data from all subjects will be used.

The results of this research may lead to an approved product for the treatment, prevention, or confirmation of disease. You understand and agree that by consenting to the storage and testing of your samples for possible future research, you authorize the use of your sample, the by-products of the sample, and any products developed from the sample as described by this form. The Study Sponsor, other researchers, or companies may patent or sell discoveries that result from this research. You will not be paid any money if this happens.

If you decide you no longer want to take part in this future testing of your biologic sample(s), your unused sample(s) will be destroyed. The Study Sponsor may continue to use and disclose the results from samples that were tested before you withdrew your consent.

If you decide to no longer take part in the main study or are taken off the main study by your study doctor, the biologic samples you provided for future research will still be kept and may be used for future testing. If you decide you no longer want to take part in this future testing, then your unused sample(s) will be destroyed.

For this study, you are being asked to let the Study Sponsor store and use the samples listed below for future testing.

Carefully read the sentences below and think about your choice(s).
Check the 'Yes' or 'No' box and initial next to your choice.

Collect, store and use **additional** blood samples collected at Day 1, Weeks 4, 8, 20, Post-HCV Study Treatment Week 12, and early study drugs discontinuation (ESDD) visits for future research **outside of the main study**. One sample of approximately 6mL (1 teaspoon) will be collected at each of these visits. There are no additional risks outside of those described previously associated with the collection of these additional blood samples. Your samples may be stored and used for up to 15 years after the end of the study. You can request that your samples be destroyed at any time by writing to the study doctor at the address listed on the first page of this form.

I agree to provide additional biologic samples for future research.

☐ Yes _____ *(initial)* ☐ No _____ *(initial)*

_____	_____	_____
Printed Name	Signature	Date