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

Sponsor / Study Title:	**Gilead Sciences, Inc. / "A Phase 3, Global, Multicenter, Randomized, Open-Label Study to Investigate the Safety and Efficacy of Sofosbuvir/Velpatasvir/GS-9857 Fixed-Dose Combination for 12 Weeks and Sofosbuvir/Velpatasvir for 12 Weeks in Direct-Acting Antiviral-Experienced Subjects with Chronic HCV Infection who Have Not Received an NS5A Inhibitor"**
Protocol Number:	**GS-US-367-1170**
Principal Investigator: (Study Doctor)	**Sergio Rojter, M.D.**
Telephone:	**213-483-1800 (24 hours)**
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WHAT IS A CLINICAL RESEARCH STUDY?

You have been asked to take part in a clinical research study. This study will compare two experimental drugs, named SOF/VEL/GS-9857 FDC (Fixed-Dose Combination) and SOF/VEL FDC for 12 weeks for the treatment of chronic hepatitis C virus (HCV) infection. An experimental drug is one that is currently being tested and has not been approved by the Food and Drug Administration (FDA) for use in the United States. Experimental drugs may be tested in research studies such as this one.

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 questions you have about the information in this form.

If you agree to take part, 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.

WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of this study is to determine the efficacy, safety, and tolerability of sofosbuvir (SOF)/velpatasvir (VEL)/GS-9857 in comparison with SOF/VEL in subjects infected with HCV. Information about any side effects that may occur will also be collected.

HOW DOES THIS STUDY WORK?

If you agree to take part in this study, you will be one of about 380 subjects in this study. The study will take place at about 120 centers located in the United States**,** Canada, New Zealand, Australia, France, Germany, and the United Kingdom. Your study doctor will ask 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 study. Open-label means you and your study doctor will know what study drug you will be taking.

If your screening lab results indicate that you have HCV genotype 1, 2, or 3 you will be randomized to receive either SOF/VEL/GS-9857 or SOF/VEL for 12 weeks.

Randomized means the study treatment you take will be chosen by chance, like flipping a coin. You will have 1 out of 2 chances to receive SOF/VEL/GS-9857 for 12 weeks and 1 out of 2 chances to receive SOF/VEL for 12 weeks.

If your screening lab results indicate that you have HCV genotype 4, 5, or indeterminate which will include those that have genotype 6, you will not be randomized. Instead, you will be given SOF/VEL/GS-9857 for 12 weeks.

SOF/VEL/GS-9857 (400/100/100 mg) FDC and SOF/VEL (400/100 mg) will be supplied by Gilead Sciences, Inc., which is also the Sponsor of this study.

HOW LONG WILL YOU BE ON THE STUDY?

Your participation in this study will last about 36 weeks, not including the screening period. During this time, you will be required to visit the clinic at least 9 times (not including this visit).

WHAT ARE YOUR RESPONSIBILITIES?

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

- You must not get pregnant or get someone pregnant during this study.
- If you are a woman that can have children and are sexually active, you and your partner must use an effective method of birth control during the study until 30 days following the last dose of study drug. Please see the Pregnancy and Breast-Feeding section below for more information.

- Male subjects with female partners of childbearing potential must agree to consistently and correctly use a condom during study treatment and until 30 days after the last dose of study drug.
- 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. This includes vitamins, minerals, and medications that do not require a doctor's prescription. Some medications are not allowed. Your study doctor will discuss these with you in detail. 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 the following medications while in this study:

Type of Drugs	**Medications Not Allowed**
Antibiotics	Clarithromycin, Erythromycin
Acid Reducing Agents	Proton-Pump Inhibitors
Anticonvulsants	Phenobarbital, Phenytoin, Carbamazepine, Oxcarbazepine
Antimycobacterials	Rifabutin, Rifapentine, Rifampin
Cardiac Medications	Amiodarone, Bosentan, Digoxin, Diltiazem, Dronedarone, Olmesartan, Quinidine, Ranolazine, Telmisartan, Valsartan, Verapamil
Herbal/Natural Supplements	St. John's Wort, Echinacea, Milk thistle (i.e., silymarin), Chinese herb sho-saiko-to (or Xiao-Shai-Hu-Tang)
HMG-CoA Reductase Inhibitors	Atorvastatin, Fluvastatin, Lovastatin, Pitavastatin, Pravastatin, Rosuvastatin, Simvastatin
Other	Modafinil, Methotrexate, Sulfasalazine

- You must ask your study doctor before you take any new medications during the study.
- If you decide to take part in this study, it is very important that you attend all visits as scheduled, including all of the follow-up visits.
- You should take the study drug exactly as you are told.
- If you are randomized to the group receiving SOF/VEL/GS-9857, you must take every dose of study drug with food.
- If you are randomized to the group receiving SOF/VEL, you must take study drug once daily either with or without food.
- Only you should take the study drug. It must be kept out of the reach of children. Please also keep the study drug away from people who may not be able to read or understand the label.
- You must return all of the used and unused study drug materials (including empty study drug bottles).

- You must follow all instructions given to you while you are participating 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 the study doctor.
- Some insurance companies require people who are renewing a policy or getting a new policy to tell them about participating in a clinical study. You should check with your insurer to determine if taking part in this study will affect your existing insurance policy.

If you cannot follow these restrictions, you should not be in this study.

WHAT WILL HAPPEN AT EACH STUDY VISIT?

If you agree to take part in the study, no study-related procedures can start until this form is signed and dated.

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

Study Procedures Table:

Procedure (what will happen)	Screening[a] (To see if you qualify)	Day 1	Week 1	Week 2	Week 4	Week 8	Week 12/EOT	ET	4 Week FU	12 Week FU	24 Week FU
Review your health history	X										
Physical exam	X	X					X	X			
Height	X										
Weight	X	X					X	X			
Measure your vital signs (blood pressure, heart rate, breathing rate, and temperature)	X	X	X	X	X	X	X	X	X		
ECG	X	X	X				X	X			
Imaging test to make sure you don't have Hepatocellular Carcinoma (HCC)	X										
Review changes in your health since last visit		X	X	X	X	X	X	X	X		
Review medications you are taking	X	X	X	X	X	X	X	X	X		
Get study drug		X			X	X					
Bring back unused study drug and all containers since last visit			X	X	X	X	X	X			
Take blood samples for routine health tests (hematology and chemistry)	X	X	X	X	X	X	X	X	X		
Take blood samples for coagulation tests (to check the ability of your blood to clot)	X	X					X	X			

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Take blood sample for HCV viral infection test	X	X	X	X	X	X	X	X	X	X	X
Take blood sample for HCV viral resistance test		X	X	X	X	X	X	X	X	X	X
Take a blood sample for pharmacokinetic test			X	X	X	X	X	X			
Take blood and/or urine samples for pregnancy test (for women who are able to have children)	X	X			X	X	X	X	X		
Urinalysis, Test your urine for drugs	X										
Take a blood sample to measure what HCV genotype you have	X										
HCV, HBV, HIV Tests (to confirm your diagnosis and rule out all others)	X										
Complete four Health Related Quality of Life questionnaires		X			X		X	X	X	X	X
HbA1c (to measure your blood glucose), Fibrotest® (to measure the degree of possible liver damage)	X										
Take a blood sample for future research (optional)		X					X	X			
Take a blood sample for Pharmacogenomic testing (optional)		X									
Approximate total amount of blood taken (tablespoons)	2	2	2	2	2	2	2	2	1.5	1.5	1.5

a. Screening information from another Gilead Sciences Phase 3 study with SOF/VEL/GS-9857 may be used to determine eligibility and fulfill screening visit assessments for this study.

EOT: End of Treatment ET: Early Termination FU: Follow Up

Procedure or Test	**Description**
ECG	You will lie down and have adhesive patches (similar to Band-Aids®) placed on your chest, arms, and legs. In some areas, it may be necessary to shave a small spot of body hair so the adhesive patches can be properly placed on your body. Wires from the machine are then attached to the adhesive patches. These wires record your heart's electrical activity. The ECG test will take approximately 5 minutes.
Imaging for HCC	If you have cirrhosis, a CT scan, MRI, or Ultrasound may need to be done to rule out hepatocellular carcinoma (HCC) which is the most common primary disease of the liver. You will be asked about any findings if you have another test conducted as part of your standard of care.

Lab Tests and Biologic Sample Collection	**Description**
Pregnancy test	If you are a woman who can get pregnant, a sample of your blood or urine will be taken to test for pregnancy. To take part in this study, the pregnancy test must be negative.
Routine health test	Samples of your blood will be collected and tested to check your health.
Viral infection test for HCV	Samples will be collected to see how much virus is in your blood
Viral infection test for HBV and HIV	Samples will be collected to check you do not have HBV or HIV.
Viral resistance test (Viral Sequencing/Phenotyping)	Samples will be collected to see if there are any mutations that may cause resistance to drugs.
Pharmacokinetic test	Samples of your blood will be tested to see how much study drug is in your body.
Optional Pharmacogenomics Test	Blood sample will be collected for future testing. If you do not agree, you can still take part in the main study. More information is below.
Optional non-study test for future research	If you agree, extra blood samples may be collected and archived for future testing. If you do not agree, you can still take part in the main study. More information is below.
Optional non-study test for future research	If you agree, leftover blood samples collected during the study may be used to help answer questions that are not part of the main study. 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 at room temperature (77ºF).
Take study drug	If you are randomized to the group receiving SOF/VEL/GS-9857, take your study drug one time per day **with food**. If you are randomized to the group receiving SOF/VEL, take your study drug one time per day without regards to food. On the Day 1 visit, your study drug will be administered at the clinic.
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.

Once you have completed the screening evaluations, your study doctor will review the results of these tests to determine if you qualify for this study. If you do not qualify for this study, there may be another Gilead Sciences Phase 3 study with SOF/VEL/GS-9857 that you may be asked to participate in. You would be asked to sign and date a different consent form for participation in that study.

WHAT RESTRICTIONS ARE THERE DURING THIS STUDY?

There are no known food and/ or beverages restricted during this study.

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

Some of your leftover blood taken at the study visits will be frozen and stored. Your stored samples 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 drug or HCV. At the end of this study, these samples may be held in storage by Gilead Sciences, Inc. for up to 10 years. You may request that your stored samples be destroyed at any time by writing to the study doctor at the address listed on the first page of this form.

Viral Infections
Some of your blood drawn at the study visits will be frozen and stored. Your stored samples and the information collected about you during the study may be used by the Study Sponsor or its research partners for additional testing. Additional testing may be to test the amount of HCV in your samples as part of the main study, drug levels in your samples, or medical care laboratory data. No human genetic testing will be done without your separate written consent. At the end of this study, these samples may be held in storage by Gilead Sciences, Inc. for up to 10 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.

Viral mutation testing finds changes or "mutations" in parts of the virus being studied. Some mutations can prevent certain drugs or drug treatments from reducing the amount of HCV in your blood.

These tests for mutations may be experimental and may not have been approved by the Food and Drug Administration (FDA). The results of these tests are "for research use only", and the understanding of the test results may not have direct benefit to you.

WHAT ARE THE POSSIBLE RISKS OF BEING IN THIS STUDY?

COMMON SIDE EFFECTS FOR SOF/VEL/GS-9857

The safety profile for the 3 drug combination of SOF 400 mg, VEL 100 mg, and GS-9857 100 mg (SOF/VEL/GS-9857), is based on the safety information from 3 Phase 2 clinical studies in which SOF/VEL, together as a single pill, was given with GS-9857 to over 420 HCV infected subjects. In these studies, SOF/VEL and GS-9857 were given for 4 to 12 weeks. Most of the side effects were considered to be mild. The most common side effects (≥ 10%) reported by subjects taking SOF/VEL and GS-9857 together were:

- Headache (23%)
- Nausea (17%)
- Fatigue (tiredness) (17%)
- Diarrhea (15%)

Three subjects decided on their own to stop taking SOF/VEL and GS-9857 because of side effects. One subject stopped SOF/VEL and GS-9857 treatment because of moderate tiredness (fatigue). The second subject stopped SOF/VEL and GS-9857 treatment because of moderate diarrhea and moderate vomiting which caused the subject to have mild water loss from the body (dehydration) and moderate feelings of weakness (asthenia). The third subject stopped SOF/VEL and GS-9857 due to moderate stomach irritation (gastritis).

There were no serious drug-related side effects reported by subjects taking SOF/VEL and GS-9857. However, one subject experienced a serious side effect (atrial fibrillation) 1 day after completing 3 days of GS-9857 alone; this event was considered related to study drug by the study doctor.

For people that are lactose intolerant, please note that combined SOF/VEL/GS-9857 tablets contain small amounts (less than 400 milligrams per tablet) of lactose. It is unknown whether this amount of lactose may lead to symptoms of lactose intolerance. For comparison, one cup of low-fat milk contains 12,000 milligrams of lactose.

COMMON SIDE EFFECTS FOR SOF/VEL

The safety profile of SOF/VEL is based on the combined safety information from 3 Phase 3 clinical studies. In these studies, 1035 HCV infected subjects took the fixed dose combination of SOF/VEL (400mg/100 mg) for 12 weeks.

Most side effects reported by subjects taking SOF/VEL for 12 weeks were mild. The most common side effects (≥ 10%) reported when SOF/ VEL was given to 1035 subjects were:

- Headache (29%)
- Fatigue (tiredness) (25%)
- Nausea (14%)
- Nasopharyngitis or cold symptoms (12%)

Only 2 (0.2%) of the patients taking SOF/VEL stopped treatment because of side effects in these studies. There were no serious drug-related side effects reported in any of the patients taking SOF / VEL.
It is not expected that you will have any of these side effects. Other side effects may occur that are not listed here or were not seen before. Please speak to your study doctor for more information. Side effects are usually temporary and can often be treated. However, it is very important that you report all side effects to your study doctor as it is possible that side effects may suggest a serious or fatal health problem.

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.

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 doctors' offices will have access to FibroScan® equipment.

CT (Computed tomography) SCAN
Risks and complications of a CT scan are very low but may include:

- Exposure to radiation in the form of X-rays. The amount of radiation received is about the same as the average person receives from background radiation in three years.
- An allergic reaction to the dye (contrast material).
- If you have diabetes or take metformin (Glucophage), the dye may cause problems. Your doctor will tell you when to stop taking metformin and when to start taking it again after the test so you will not have problems.

ULTRASOUND
For standard diagnostic ultrasounds there are no known harmful effects on humans.

LIVER BIOPSY RISKS
Liver biopsy is a common test used to confirm the diagnosis for hepatitis. Many doctors also do a liver biopsy to help confirm the extent of liver damage. Risks and complications of liver biopsy may include:

- Pain and discomfort located at or near the puncture site and radiating upwards toward the right shoulder region
- Bleeding at the biopsy site
- Possible internal bleeding for up to a few hours after the procedure
- Infections at the biopsy site or internal organs
- Puncture of internal organs (gall bladder, lung, intestine or kidney)
- Allergic reaction to the anesthetic

VIRAL RESISTANCE
Treatment with drugs that directly inhibit the hepatitis C virus has been shown to lead to development of hepatitis C virus that is resistant to that drug and other drugs with the same type of action (such as protease inhibitors). These resistance mutations have been observed in the body as late as 4 to 5 years after treatment has ended. It is unknown whether having these resistance mutations might reduce the chance of treatment success with future drugs with the same type of action or with different types of action. It is possible that if you are treated with the drugs in this study and treatment doesn't work, you might have resistance mutations that would make future treatment less successful.

HEPATITIS B AND HIV TESTING RISKS
As part of the screening procedure you will be tested for Hepatitis B and HIV virus infection. If either test is positive local laws may require that the test results be reported to local health authorities.

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

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 on the first page of this form.

PREGNANCY AND BREAST-FEEDING

The risks of these study drugs to an unborn baby or nursing child are unknown and may be hazardous. If you are a woman who is pregnant or intend to become pregnant, you cannot be 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 prevent pregnancy. If you think that you have become pregnant during the study or within 30 days of taking the last dose of study drug, you must tell the study doctor immediately. If a determination of pregnancy is made during the study, you will be removed from the study and the study doctor will refer you to seek obstetrical care and request to track your pregnancy and report the outcome including that of your infant to the Sponsor and the IRB. Neither the study Sponsor, the study site nor its study doctors will be responsible for providing routine medical care relating to your pregnancy.

If you are currently nursing (breastfeeding), you must discontinue nursing before starting study drug. Female subjects must also refrain from egg donation and in vitro fertilization during study treatment and until at least 30 days after the last dose of study drug.

You must protect yourself or your partner from becoming pregnant before, during, and after the study. Women, and men with female partners capable of becoming pregnant, must use effective methods of birth control as described below. Your study doctor will need to document what type(s) of birth control you are using. You must also not rely on hormone-containing contraceptives as a form of birth control during this study.

Women only:

Women who can get pregnant should not take study drug unless they and their partner do not engage in intercourse or are using one of the following methods of birth control from Screening and for 30 days after last dose of the study drug, or longer as directed by your study doctor.

- Intrauterine device (IUD)
- Tubal sterilization
- Bilateral tubal occlusion
- Vasectomy in the male partner (provided that the partner is the sole sexual partner and has received medical assessment of the surgical success)
- Female barrier method (diaphragm or cervical cap) with spermicide (where locally available)

A condom must also be used in addition to one of the above methods. Unacceptable birth control methods include periodic abstinence (e.g., using a calendar to predict ovulation, symptothermal (using body temperature to predict ovulation), post-ovulation methods (predicting when ovulation is over by detecting changes in cervical mucus), withdrawal (coitus interruptus; man withdraws his penis from a woman's vagina before sperm is released), spermicides only, and the lactational amenorrhea method (LAM; temporary infertility that occurs when a woman is breastfeeding and not having a menstrual period)).

You must tell your study doctor immediately if you become pregnant while in this study and through the follow up period, or for as long as you have been directed by your study doctor to use contraception. The study doctor will tell you about the possible risks to your unborn child and options available to you.

In the event of a positive urine pregnancy result, you will be instructed to stop study drug immediately and return to the study clinic as soon as possible for a serum (blood) pregnancy test. The pregnancy will be followed to its completion and the outcome, including any premature termination (abortion), must be reported to the Sponsor. You should be counseled and monitored by your own doctor. As the risk to the unborn baby is unknown, it is recommended you seek medical supervision from your own doctor during the pregnancy and for the baby after it is born. Neither the study Sponsor nor the study doctor will be responsible for providing routine medical care relating to the pregnancy.

Men only:

Male subjects with female partners of childbearing potential must agree to consistently and correctly use a condom during treatment and until 30 days after the last dose of study drug. If their female partner is of childbearing potential, their female partner must use 1 of the methods of birth control listed above from the date of Screening until 30 days after the last dose of study drug.

Male subjects must also not donate sperm during treatment and for at least 30 days after the last dose of study drug.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

You may not benefit from taking part 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 HCV understand more about the treatment of your disease. 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 can discuss if you want to have any treatment or if you want to choose another treatment for your disease.

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 and you will not be penalized or lose any benefits to which you are otherwise entitled.

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 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. If your study drug is stopped, your study doctor will closely monitor your overall health.

HOW MUCH WILLSTUDY TREATMENT COST YOU?

The study drug 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 not be paid to take part in this research study. However, as reimbursement for your travel expenses you will receive $20.00 per completed regular study visit. If you do not complete this study for any reason, you will be compensated for the visits you do complete. You will be reimbursed at the end of each visit.

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?

MEDICAL TREATMENT AND COMPENSATION FOR STUDY-RELATED INJURY

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, *provided* that you have followed the instructions of the Study Doctor. No other form of reimbursement for study-related injury or illness is offered by the Sponsor. You 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: Pro00014327.

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. In the event of any publication regarding this study, your identity will remain confidential.

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

Your coded study information 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.

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

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.

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 below.

You have the option to allow genetic research on your sample. If your genetic research data are shared with unauthorized users, you may be at risk of loss of the privacy of your health data.

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.

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.

You may choose to take part in **none, some, or all** of the future research, listed below.

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.

1) Store and use your leftover blood samples collected during this study for future research outside of the main study. Your samples may be stored and used for up to 10 years after the end of the study.

I agree to allow my leftover biologic samples to be stored after the main study testing is complete and used for future research outside of the main study.

☐ Yes_____ *(initial)* ☐ No _____ *(initial)*

2) Collect, store and use additional blood samples for future research outside of the main study. This optional sample will be collected at Day 1 and End of Treatment or Early Termination. Your samples may be stored and used for up to 10 years after the end of the study.

I agree to provide additional biologic samples for future research.

☐ Yes_____ *(initial)* ☐ No _____ *(initial)*

3) Collect, store, and use additional blood samples for future research outside of the main study to do pharmacogenomic testing. Pharmacogenomics is the study of how genes affect a person's response to drug. This optional sample will be collected at Day 1 or at any time during the study. Your samples may be stored and used for this research for up to 10 years after the end of the study.

   I agree to provide additional blood samples to be used for pharmacogenomics testing outside of the main study.

   ☐ Yes_____ *(initial)* ☐ No _____ *(initial)*

HIPAA Authorization Agreement
Permission to Review, Use and Release Information about You

If you decide to be in this study, the study doctor and research team will use and share health data about you to conduct the study. Health data may include:

- Your name
- Address
- Phone number
- Date of birth
- Medical history
- Information from your study visits, including all test results

Health data may come from your study records or from existing records kept by your doctor or other health care workers.

For this study, the research team may share health data about you with authorized users. Authorized users may include:

- Representatives of Gilead Sciences, Inc.
- Representatives of PRA Health Sciences.
- Representatives of Chesapeake IRB (a Research Ethics Review Board that reviews this study).
- The Food and Drug Administration (FDA) and other US governmental agencies.
- Government agencies to whom certain diseases (like HIV, hepatitis, and STDs) must be reported.
- Governmental agencies of other countries.
- Labs working with the sponsor on this study.
- Other authorized users.

The sponsor and those working for the sponsor may use the health data sent to them:

- To see if the study drug works and is safe.
- To compare the study drug to other drugs.
- For other research activities related to the study drug.

Once your health data has been shared with authorized users, it may no longer be protected by federal privacy law.

Your permission to use and share health data about you will not end unless required by state law. If state law applies, your permission to use and share health data about you will end on December 31, 2065.

You may take back your permission to use and share health data about you at any time by writing to the study doctor. If you do this, you will not be able to stay in this study. No new health data that identifies you will be gathered after your written request is received.

However, health data about you that has already been gathered may still be used and given to others as described in this form.

Your right to access your health data in the study records will be suspended during the study to keep from changing the study results. When the study is over, you can access your study health data.

If you decide not to sign this form, you will not be able to take part in the study.

STATEMENT OF AUTHORIZATION

I have read this form and its contents were explained. My questions have been answered. I voluntarily agree to allow study staff to collect, use and share my health data as specified in this form. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing this form.

_____ ____/____/____
Signature of Research Subject Date

_____
Printed Name of Research Subject

STATEMENT OF PERSON EXPLAINING AUTHORIZATION

I have carefully explained to the subject the nature and purpose of this form. I have been available to answer any questions that the subject has about this form.

_____ ____/____/____
Signature of Person Explaining Authorization Date

_____
Printed Name of Person Explaining Authorization