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

Sponsor / Study Title:	**Gilead Sciences, Inc. / "A Phase 3b, Multicenter, Open-Label Study to Evaluate Switching From a Regimen of two Nucleos(t)ide Reverse Transcriptase Inhibitors (NRTI) plus a Third Agent to a Fixed Dose Combination (FDC) of Bictegravir/Emtricitabine/Tenofovir Alafenamide (B/F/TAF), in Virologically-Suppressed, HIV-1 Infected African American Participants"**
Protocol Number:	**GS-US-380-4580**
Principal Investigator: (Study Doctor)	**Pablo Tebas, MD**
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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 test a United States Food and Drug Administration (FDA) approved drug named bictegravir/emtricitabine/tenofovir alafenamide (B/F/TAF) fixed dose combination (FDC) for the treatment of HIV-1. This drug has been approved as Biktarvy® in the United States since February 2018.

This Participant Information and Informed Consent Form explains 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 test the effectiveness of switching to FDC of B/F/TAF versus continuing on a regimen consisting of 2 Nucleos(t)ide Reverse Transcriptase Inhibitors (NRTIs) and a third agent in HIV-1 infected adult participants who are virologically suppressed (HIV-1 RNA test < 50 copies/mL).

The safety and how well these drugs are tolerated, will be determined by physical exams, laboratory tests, and any symptoms or 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 480 participants in this study. The study will take place at about 100 centers in the US**.** Your study doctor has asked you to come to the clinic for a screening visit to see if you are able to take part. Entry into screening does not guarantee enrollment into the study. In order to manage the total study enrollment, Gilead, at its sole discretion, may stop screening and/or enrollment at any site or study-wide at any time.

This is a randomized, open-label study. Open label means you and your study doctor will know what study drugs you will be taking.

Randomized means the study treatment you take will be chosen by chance (like flipping a coin) to receive one of the two study treatments listed below.

Study Treatment Group 1: Approximately 320 participants will switch to FDC of B/F/TAF 50 mg/emtricitabine 200 mg/tenofovir alafenamide 25 mg administered orally, once daily with or without food.

Study Treatment Group 2: Approximately 160 participants will remain on their current regimen consisting of 2 NRTIs and a third agent (each taken as prescribed) from Day 1 until Week 24. At Week 24 participants will switch to FDC of B/F/TAF 50 mg/emtricitabine 200 mg/tenofovir alafenamide 25 mg administered orally, once daily with or without food.

The randomization for this study is in a 2:1 ratio, which means that your chance of being assigned to Study Treatment Group 1 is twice as high as your chance of being assigned to Study Treatment Group 2.

FDC of B/F/TAF will be supplied by Gilead Sciences, Inc., which is also the Sponsor of this study. If you are randomized to Study Treatment Group 2, your study doctor will provide a prescription to you and you will be responsible for obtaining your current medication.

Your study doctor or study nurse will review the proper storage of all study drugs with you. All study drugs must be taken once a day, at the same time every day. It is very important that you take your study drugs every day as instructed by the study doctor.

HOW LONG WILL YOU BE ON THE STUDY?

Taking part in this study will last at least 48 weeks (approximately 11 months) not including the screening period which may last up to 30 days. During this time, you will be required to visit the clinic at least 6 times (at Day 1, Weeks 4, 12, 24, 36, and 48). If you are enrolled in Study Treatment Group 2 you will have an additional visit at Week 28. If you choose to continue on study after your initial 48 weeks, you will continue to take FDC of B/F/TAF and attend study visits for up to an additional 24 weeks or until you have access to FDC of B/F/TAF, whichever occurs first.

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 use any other medications for the treatment of HIV, other than the study drugs and what is allowed in combination with the study drugs. Your study doctor will also make you aware of any other medications that you will not be allowed to take should you decide to take part.
- You are not allowed to take the following medications while in this study:
  - Dofetilide, Phenobarbital, Phenytoin, Carbamazepine, Oxcarbazepine, Rifampin, Rifapentine, Rifabutin, St. John's Wort, or any antiretroviral drug that is not part of the study regimen
- You must 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.
- 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.
- You must not share the study drug with anyone else. Keep the study drug out of the reach of children and persons of limited capacity to read or understand.

WHAT WILL HAPPEN AT EACH STUDY VISIT?

If you agree to take part in the study, you will be asked to come to the clinic for a screening visit. You will have screening tests and procedures to help the study doctor decide if you qualify to take part in this study. You will need to be seen at the study center within 30 days before the study starts. 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)	Day 1	Week 4	Week 12	Week 24	Week 28 (for Treatment Group 2 Only)	Week 36	Week 48	Week 60	Week 72	30-Day Follow-Up	ESDD
Informed Consent	X											
Review your health history; obtain demographic information; height	X											
Review any changes in your health since last visit, including any adverse effects experienced		X	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	X
Complete physical examination (may include urogenital/anorectal exam) or Symptom-Directed Physical Exam	**X**	**X**	X	X	**X**	X	X	**X**	X	**X**	X	**X**
Measure your vital signs (blood pressure, heart rate, breathing rate, and temperature) and weight	X	X	X	X	X	X	X	X	X	X	X	X
ECG (recording of your heart)	X											
Take blood and urine samples for routine health tests (chemistry, hematology, viral load, blood & urine pregnancy test for women)	X	X	X	X	X	X	X	X	X	X	X	X
Take blood samples for Hepatitis B Testing	X (Everyone)	X (Co-Infected)			X (Co-Infected)			X (Everyone)				X (Co-Infected)
Take blood samples for Hepatitis C Testing	X							X		X		
Take blood sample for HIV DNA archiving		X			X (Treatment Group 2 only)							X
Fasting		X			X			X		X		
Patient Reported Questionnaires		X	X	X (Treat-ment Group 2 only)	X	X		X				

Procedure (what will happen)	Screening (To see if you qualify)	Day 1	Week 4	Week 12	Week 24	Week 28 (for Treatment Group 2 Only)	Week 36	Week 48	Week 60	Week 72	30-Day Follow-Up	ESDD
Optional blood sample for pharmacogenomics testing		X										
Estimated total amount of blood in mL that will be drawn (5 mL= approx. 1 teaspoon)	55.5	52.5	42.5	42.5	54.5	42.5	42.5	50.5	42.5	42.5	30.5	54.5
Get study drug		X (Treat-ment Group 1 only)	X (Treat-ment Group 1 only)	X (Treat-ment Group 1 only)	X	X	X	X	X	X		
Bring back unused study drug and all containers since last visit			X (Treat-ment Group 1 only)	X (Treat-ment Group 1 only)	X	X	X	X	X	X		

Procedure or Test	**Description**
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.
Obtain demographic information	This includes obtaining gender at birth, sexual orientation, and gender identity

Lab Tests and Biologic Sample Collection	**Description**
Blood Samples for Routine Health Testing	Samples of your blood will be tested to check your health. The test will measure: • How well your liver and kidneys are working • If your ability to clot (stop bleeding) is normal • If your blood counts, chemistry and fat levels are normal
Pregnancy and FSH Tests	If you are a female, blood and urine samples will be taken to test for pregnancy. To take part in this study, the pregnancy tests must be negative. If you are a female that no longer menstruates, blood samples will be taken to test the levels of FSH (follicular stimulating hormone) in your blood and confirm ovarian hormonal failure.
Blood Samples for HIV Viral Load and HIV DNA Archive Testing	Blood samples will be taken at every visit to measure how much HIV is in your blood and how your body is reacting against the virus. In addition, the blood samples will be used to look at the genetic sequence of the virus. If the amount of HIV in your blood is too high, the blood samples will be used to see if there are any mutations in certain regions of the HIV-1 gene at screening and throughout the study. Some mutations can prevent certain anti-HIV drugs or drug regimens from reducing the level of HIV-1 in your blood. When this occurs, HIV-1 becomes “resistant” to that drug and possibly other similar drugs.
Hepatitis B and Hepatitis C Testing	Blood samples will be taken to test for the presence of Hepatitis B and Hepatitis C viruses. For participants who meet the definition of Hepatitis B infection at any visit, the central laboratory will conduct tests to confirm the Hepatitis B at Day 1, Week 24, Week 48 and ESDD. For participants who do not meet the definition of Hepatitis B or C infection at any visit, the central

	laboratory will conduct tests to confirm Hepatitis B or C at Screening and Week 48, and Week 72 for Hepatitis C only. The study doctor may be required by law to report the result of these tests to the local health authority.
Optional Blood sample for pharmacogenomics testing	Pharmacogenomics is the study of how a person's genes affect a person's response to drugs or HIV-1. If you agree, an extra 6mL (about 1 tsp) may be collected at the Day 1 visit for optional future potential biomarkers. If you do not agree, you can still take part in the main study. More information is at the end of this consent form.
Additional optional non-study test	If you agree, leftover blood and urine from the 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. If you are in Study Treatment Group 1, you will be given study drug starting at Day 1, If you are in Study Treatment Group 2, you will be given study drug starting at Week 24. Store your study drug as instructed by your study doctor.
Take study drug	Take your study drugs 1 time per day with or without food at approximately the same time each day.
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.

Early Study Drug Discontinuation (ESDD) Visit

If you are unable to complete your study drug dosing prior to the Week 48 Visit, you will be asked to return to the clinic within 72 hours of stopping the study drug for the ESDD Visit. You will be asked to continue attending the scheduled study visits though the Week 48 Visit. If you are in Study Treatment Group 2 and discontinue your current regimen due to an adverse event prior to Week 24, you will be asked to continue attending the scheduled study visits through the Week 24 visit. Please reference the Procedures Table for a listing of procedures that will be performed at this visit.

30-Day Follow-Up
If you complete the study drug through Week 48 and do not wish to participate in the study after the Week 48 visit, you will be required to return to the clinic 30 days after stopping the study drug for the 30-Day Follow Up visit. If you prematurely discontinue the study drug and refuse to continue in the study through the Week 48 visit, you will be asked to return to the clinic 30 days after the completion of the ESDD visit for the 30-Day Follow-Up Visit. Please reference the Procedures Table for a listing of procedures that will be performed at this visit.

WHAT RESTRICTIONS ARE THERE DURING THIS STUDY?

Fasting (no food or liquids except water) is required for tests at visits Day 1 Visit, Weeks 24, 48, and 72. 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 urine and blood testing. If you have not fasted, the visit may proceed but you will be asked to return to the clinic within 72 hours in a fasted state.

Concentration of study drug may decrease with antacids. You may not take antacids (such as, Tums or Rolaids) containing Aluminum, Magnesium or Calcium for a minimum of 2 hours before and 2 hours after any dose of FDC of B/F/TAF.

Do not take the study drug under fasting conditions with vitamins and supplements that contain calcium or iron for a minimum of 2 hours after any dose of FDC of B/F/TAF. Supplements that contain calcium or iron can be taken together with FDC of B/F/TAF and food.

Taking metformin and the study drug has risks and benefits that should be discussed with your study doctor.

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

Some of your blood and urine taken at each visit (except the Screening visit, the 30-Day Follow-up visit, and Unscheduled visit) will be 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 study drug or HIV. Additional testing may be to test the amount of HIV 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 15 years. After 15 years, the samples will be destroyed. 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 document.

Viral Infections HIV

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 HIV in your blood and urine. These tests for mutations are optional and may be

experimental and may not have been approved by the US FDA. The main assays for efficacy are approved by the FDA; however, additional assays may need to be completed to understand how the virus has changed over the course of treatment and the viruses may be studied using novel methodology. This may include deep sequencing and cloning of the virus from the samples. Potential future experiments may include sequencing parts of the HIV genome or sequencing the complete HIV genome. It is possible that parts of the viruses will be tested for their ability to be inhibited by new drugs that are being discovered. These assays may not have yet been developed. There is a separate section at the end of this consent that you can consent to this optional testing for viral mutations.

The results of these tests are "for research use only", and the understanding of the test results may not have direct benefit to you; therefore, the results of these tests will not be provided to you.

Blinded Results
Information provided from tests done on your samples will not be given to you or your study doctor. This information will not be placed in your medical records and will have no effect on your medical care.

WHAT ARE THE POSSIBLE RISKS OF BEING IN THIS STUDY?

B/F/TAF COMMON ADVERSE EVENTS

B/F/TAF (50/200/25 mg) is a fixed dose combination tablet containing three medications: bictegravir (BIC, B, GS-9883), emtricitabine (FTC, F) and tenofovir alafenamide (TAF). The safety information known about this tablet is from studies GS-US-380-1489 and GS-US-380-1490, in which 634 patients who had never been treated for HIV received B/F/TAF (50/200/25 mg) for 48 weeks. Adverse drug reactions that have been identified are as follows:

Very common (more than or equal to 10%):
- headache
- diarrhea

Common (greater than or equal to 1% and less than 10%):
- nausea
- vomiting
- abdominal pain
- indigestion
- passing gas
- fatigue (feeling tired)
- rash

If you are infected with hepatitis B virus (HBV), there is a possibility of an unexpected worsening of hepatitis B if you stop taking B/F/TAF.

In a study in pregnant rats, a possible effect on the fertility of male and female baby rats born to mothers given BIC 300 mg/kg/day was observed. The decreases in fertility were slight and remained within the range seen in animals not given any drug in other studies. At the next-lowest dose, 10 mg/kg/day, no effects were noted in the baby rats. At this dose, the mother's BIC plasma exposure was approximately 8-times higher than the estimated blood concentrations of BIC in humans when administered as B/F/TAF (50/200/25 mg).

Please talk to your study doctor for more details on adverse events or see the B/F/TAF package insert for more information.

Risks of Switching From a Stable Regimen
You are currently taking medications that are effectively treating your HIV infection. You may be asked to change from a stable regimen that is working well to a new regimen during this study. There are risks associated with switching from one antiretroviral regimen to another, including the risk that the virus will not be controlled with the new regimen, that the virus could develop resistance to the medications, and that the new regimen could cause new side effects. Viral load, possible resistance, and side effects will be carefully monitored during the study to minimize these risks.

BLOOD DRAW RISKS
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 RISKS
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.

QUESTIONNAIRE RISKS
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.

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

PRIVACY RISKS
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 Privacy section below.

ALLERGIC REACTION RISKS
Allergic reaction is always possible with a drug you have not taken. Serious allergic reactions that can be life-threatening may occur. If you experience some or all of these reactions, seek medical help as quickly as possible. 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 participants 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.

A recent study found that babies born to women taking dolutegravir, an allowed baseline regimen for this study, at the time of becoming pregnant or early in pregnancy may have a higher risk for a type of birth defect called neural tube defects, such as spina bifida. These defects occur early in pregnancy before many women even know they are pregnant. Please speak with your Study Doctor if you have any questions about dolutegravir and the potential risk for neural tube defects.

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.

During the study, male participants with persons of childbearing potential should use condoms when engaging in intercourse of reproductive potential.

If you are a woman who chooses to have sex with a male partner, you will be required to use highly 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.

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. Subjects who become pregnant while on study who do not have pre-natal care that includes a routine second trimester ultrasound will be referred for ultrasonography as part of study follow-up.

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.

CONDOM USE

It has been proven that condom use decreases the risk of spreading HIV and hepatitis B 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 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. Male participants must agree to use condoms during heterosexual intercourse.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

You may or may not receive 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 HIV-1 infection 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 other antiretroviral medications (ARVs) to treat your disease. 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.

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?

If you are randomized to Study Treatment Group 1, B/F/TAF will be given to you at no charge. If you are randomized to Study Treatment Group 2, your study doctor will provide you a prescription and you will be responsible for obtaining your current medication as you do currently from Day 1 to Week 24. At Week 24, B/F/TAF 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 reimbursed $50.00 per visit for each completed visit during this study. This money is meant to help pay for things like travel costs, child care costs, missed hours from work, that you may have because you are taking part in this study. You will be paid at the end of each study 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.

Compensation for the screening visit will be cash; compensation for the other study visits will be given by ClinCard debit card.

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.

WHAT HAPPENS IF YOU ARE INJURED?

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

There are no plans for the University of Pennsylvania to pay you or give you other compensation for the injury. You will not lose any of your legal rights or release the Sponsor, the study doctor, the study staff, or study site from liability for mistakes or intentional misconduct by signing this consent document.

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

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.

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, Medicare Beneficiary Identifier (MBI) and date of birth, will be provided to the Centers of Medicare and Medicaid Services and its agents and/or contractors for this purpose.

WHOM TO CONTACT ABOUT THIS STUDY

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study, please contact the Investigator at the telephone number listed on the first page of this consent document. If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, contact**:**

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

Please reference the following number when contacting the Study Subject Adviser: Pro00028460.

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, or if a CD4 or viral load is done at a research study visit, by law we have to report the result to the

City of Philadelphia Health Department/PA Department of Health. Personal identifiers such as name, sex, date of birth, address, and phone number will be reported. For more information about the requirements reporting infectious diseases to the City of Philadelphia Health Department, please visit https://hip.phila.gov/ReportDisease. For more information about the requirements reporting infectious diseases to the PA Health Department, please visit: http://www.health.pa.gov/Your-Department-ofHealth/Offices%20and%20Bureaus/epidemiology/Pages/Reportable-Diseases.aspx#V620aZ3D9eU.

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.

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 (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 information about me may be collected, used or shared with others?
The following personal health information will be collected, used for research, and may be disclosed during your involvement with this research study:

- Name, address, telephone number, 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
- see if the research was done right
- evaluate and manage research functions

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

- The Principal Investigator and the Investigator's study team
- Other authorized personnel at Penn, including offices that support research operations.
- Other research personnel with access to the databases for research and/or study coordination and as otherwise approved by the IRB

Who, outside the School of Medicine, might receive my information?
As part of the study, the Principal Investigator, the study team and others listed above, may disclose your personal health information, including the results of the research study tests and procedures. This information may be disclosed to those listed below:

Individuals or organizations responsible for administering the study:

- 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, date of birth or medical record number. Information regarding your health, such as side effects of the study drug you experience will be reported only by code number. All samples collected for analysis will be labeled with your study number, visit number and date of your visit.

The Principal Investigator or study staff will inform you if there are any additions to the list above during your active participation in the trial. Any additions will be subject to University of Pennsylvania procedures developed to protect your privacy.

How long may the School of Medicine be able to use or disclose your personal health information?

Your authorization for use of your personal health information for this specific study does not expire.

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

- You have given written authorization
- The University of Pennsylvania's Institutional Review Board grants permission
- As permitted by law

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

Yes. You may withdraw or take away your permission to use and disclose your health information at any time. You must do so in writing to the Principal Investigator at Infectious Disease Division, 502 Johnson Pavilion Philadelphia PA 19104. Even if you withdraw your permission, your personal health information that was collected before we received your written request may still be used and disclosed, as necessary for the study. If you withdraw your permission, you will not be able to stay in this study.

What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study.

You will be given a copy of this Research Subject Informed Consent form and HIPAA Authorization describing your confidentiality and privacy rights for this study. You will also be given the UPHS and School of Medicine's Notice of Privacy Practices that contains more information about the privacy of your personal health information.

What is an Electronic Medical Record?

An Electronic Medical Record (EMR) is an electronic version of the record of your care within a health system. An EMR is simply a computerized version of a paper medical record.

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

If you are receiving care or have received care within the University of Pennsylvania Health System (UPHS) (outpatient or inpatient) and are participating in a University of Pennsylvania research study, information related to your participation in the research (for example, laboratory tests, imaging studies and clinical procedures) may be placed in your existing EMR maintained by UPHS. Information related to your participation in clinical research will also be contained in the CTMS.

If you have never received care within UPHS and are participating in a University of Pennsylvania research study that uses UPHS services, an EMR will be created for you for the purpose of maintaining any information produced from your participation in this research study. The creation of this EMR is required for your participation in this study. In order to create your EMR, the study team will need to obtain basic information about you that would be similar to the information you would provide the first time you visit a hospital or medical facility (for example, your name, the name of your primary doctor, the type of insurance you have). Information related to your participation in the study (for example, 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).

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

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

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.

A copy of this consent form will be given to you. You will also be given the University of Pennsylvania Health System and School of Medicine's Notice of Privacy Practices that contains more information about the privacy of your health information.

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RESEARCH STAFF CONSENT

Participant

Participant Printed Name	Signature	Date

Person Obtaining Consent

Printed Name & Title	Signature	Date

Witness (if applicable)

Witness Printed Name	Signature	Date

INVESTIGATOR CONSENT

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

Participant

Participant Printed Name	Signature	Date

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

Investigator

Printed Name & Title	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 and urine 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 participants 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.

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 and urine samples collected during this study for future research **outside of the main study**, including viral mutations testing**.**

Your samples may be stored and used for up to 15 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 blood sample for optional pharmacogenomics testing. Pharmacogenomics is the study of how a person's genes affect a person's response to drugs or HIV-1. An additional 6 mL (about 1 tsp) of blood will be collected on your Day 1 visit. Your sample may be stored and used for this research for up to 15 years after the end of the study.

I agree to provide additional biologic samples for future research.

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