UNIVERSITY OF PENNSYLVANIA HEALTH SYSTEM

ING114915: A Phase IIIb, randomized, open-label study of the safety and efficacy of GSK1349572 (dolutegravir, DTG) 50 mg once daily compared to darunavir/ritonavir (DRV/r) 800 mg/100 mg once daily each administered with fixed-dose dual nucleoside reverse transcriptase inhibitor therapy over 96 weeks in HIV-1 infected antiretroviral naïve adult subjects

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

Your contacts for this study at the Hospital of the University of Pennsylvania [HUP] are:

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Coordinator:	Joseph Quinn, RN, BSN	
Study Nurse:	Jenna Lewis, RN, BSN	

Site address: 502 Johnson Pavilion Philadelphia PA 19104
24 Hour Emergency Number (215) 662-6059 Ask for the Immunodeficiency Program Doctor on call

Introduction

You are being invited to participate in a research study. Your participation is voluntary which means you can choose whether or not you want to participate. If you choose not to participate, there will be no loss of benefits to which you are otherwise entitled. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. The research team is going to talk to you about the research study, and they will give you this consent form to read. You may also decide to discuss it with your family, friends, or family doctor. You may find some of the medical language difficult to understand. Please ask the study doctor and/or the research team about this form. If you decide to participate, you will be asked to sign this form.

Financial Disclosure

This research study is supported by money from GlaxoSmithKline on behalf of ViiV Healthcare (the study sponsor). In addition, Dr. Tebas, the person leading this research study receives extra money from GlaxoSmithKline for work that is not a part of this study. Dr. Tebas also receives compensation from Cytheris, which is another company, unrelated to GSK, that manufactures products for people with HIV and other conditions. These activities may include consulting, advisory boards, giving speeches or writing reports. If you would like more information, please ask the researchers or the study coordinator.

Why Is This Study Being Done?

You are invited to join the study, as you have HIV (Human Immunodeficiency Virus). Currently, the standard treatment for HIV is antiretroviral (ART) or anti-HIV drugs. The purpose of this research study is to determine the safety and efficacy of an experimental drug, GSK1349572 (dolutegravir, DTG), compared with darunavir/ritonavir (DRV/r), which is used to treat HIV infection. Approximately 2500 subjects have received at least 1 dose of GSK1349572 in completed or ongoing studies. However, GSK1349572 is not approved for doctors to prescribe to patients. It is expected that approximately 468 subjects will be enrolled in this study globally. About 3-7 people are expected to enroll at the University of Pennsylvania.

What Do I Have To Do If I Am In This Study?

You will be given either GSK1349572 or DRV/r. A computer will put people into groups. Your chances of receiving GSK1349572 are 50% and DRV/r are 50%, just like flipping a coin. Both you and

your doctor will know which treatment you receive. Depending on the treatment group, the study drugs will be administered as one tablet (50 mg) or three tablets (two 400 mg and one 100 mg) and should be taken once a day.

All study participants will also receive another standard drug: fixed-dose dual Nucleoside Reverse Transcriptase Inhibitor (NRTI). Your study doctor will choose for you either abacavir/lamivudine (ABC/3TC) or tenofovir/emtricitabine (TDF/FTC) to be taken once a day also. ABC/3TC comes in a 600mg/300mg tablet. TDF/FTC comes in a 300mg/200mg tablet. The study doctor will choose which other drugs you receive based on some of the blood tests that are done for the study, these tests determine which drug is able to work with the virus you may have. In the case where you are sensitive to all the drugs, the risk for each will be discussed with you and you and the doctor will decide which will work best for you.

If you decide to participate in this research study, you will be asked to make a total of 14 or more visits to the study doctor over the next two years. The table below provides a brief overview of the visits and what will be done at each:

	Screen	Day 1	Week 2	Week 4	Week 8	Week 12	Week 16	Week 24	Week 36	Week 48	Week 60	Week 72	Week 84	Week 96
Medication assessment	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Medical history		X												
Physical Examination		X												
Blood Draws	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Hepatitis B and C testing	X													
Fasting Visits		X				X		X	X	X	X	X	X	X
Urinalysis		X						X		X				X
Electrocardiogram (EKG)		X								X				X
Questionnaires		X		X				X		X				X
Dispense study drugs		X		X	X	X	X	X	X	X	X	X	X	
Pregnancy (for women)	X	X		X	X	X	X	X	X	X	X	X	X	X

- At the Screen visit, you will be asked specific questions to make sure you are a good fit for this study including questions about previous medications you've taken. This visit should last approximately 2 hours.

- At the Entry visit, your medical history will be reviewed. You will be asked about any heart problems you've had or that run in your family. You will also be asked about smoking and drug use. You will be given a complete medical examination that will include an electrocardiogram which will record the electrical activity of your heart. You will also have your height, weight and vital signs taken. This visit should last approximately 2 hours.

- At the Post-entry visits, you will be asked about any changes in your health. You will be given questionnaires to complete to measure how you are feeling. Also, you will be given study drug and asked to return any tablets not taken at your next visit. Each tablet will be counted. These visits should last approximately 1 hour.

- At the last visit, you will have vital signs and another electrocardiogram taken. You will be asked about any changes in your health and any remaining study drug you have will be returned and

counted. You will be given questionnaires to complete to measure how you are feeling. This visit should last approximately 1 hour.

A urine specimen will be taken at the entry visit as well as at Week 24, 48 and the last visit for routine laboratory testing.

Blood samples will be taken at each visit for routine laboratory testing. The amount of blood taken each time will be about 3 tablespoons. At screening some of this blood will be tested for hepatitis. If you test positive for hepatitis B or hepatitis C, this information may be reported to your health authorities if required by local laws. Some of this blood will be tested to find out the genetic makeup of the virus.

You will be asked not to eat any food for 6 hours before the screen visit. The same will be asked for the visits at Weeks 12, 24, 36, 48, 60, 72, 84 and the last visit.

If you are a woman and are able to have children, a urine pregnancy test will be done before your first dose of study medication to see if you are pregnant. The results of the pregnancy testing must be negative prior to receiving study drug. A blood pregnancy test will be done at all other visits except one (at Week 2).

If you decide to participate in the study, consider if you have the time it will take for you to participate, keep appointments, and to follow the study rules. Consider if you have transportation to get to the visits. You will have the following responsibilities while on the study. You will be asked to truthfully tell the study doctor about your complete medical history, and to report any new problems, illnesses, or changes in medication during the study. It will also be your responsibility to follow directions for taking the study medications every day. Only you should take the study drug and you will be responsible for returning unused study drug (even empty containers) to the office. You may be asked to stop eating particular foods or to stop taking some medicines or vitamins during the study. You will be asked to complete questionnaires to measure how you are feeling at the second visit, at Weeks 4, 24, 48 and at Week 96.

If you received DTG during the study, you will be asked at the Week 96 visit if you would like to continue on the extension phase of the study to continue to receive DTG until it is approved and available in your country. Please note the study sponsor will only supply DTG. Any other drugs, including additional antiretroviral (ART) or anti-HIV drugs that you may have been taking during the study, will not be reimbursed or supplied by the study sponsor. You will continue to come in for evaluations every 12 weeks until DTG becomes available to you in your pharmacy. Once DTG is commercially available, your study doctor or primary care physician will work with you to obtain your anti-HIV medication outside of the study.

During the extension phase of the study you will have the following evaluations done every 12 weeks which will take approximately 1 hour:

- You will be asked about any changes in your health, including about any new medications you may be taking.
- A blood specimen will be taken for laboratory testing and storage. If you are a woman capable of becoming pregnant, a pregnancy test will also be performed.
- Also, you will be given study drug and asked to return empty drug containers as well as any tablets not taken at your next visit. Each tablet will be counted.
- Prior to each visit, you should be fasting (no food for at least 6 hours) prior to the visit. During the last visit of the extension phase of the study, vital signs, a blood sample, and a urine specimen will be taken, as well as an electrocardiogram. You will be asked about any changes in

your health and any remaining study drug you have, including empty drug containers will be returned and each tablet counted. This visit should also last approximately 1 hour.

Following the end of the study, or after you have withdrawn from the study before its conclusion, your study doctor (or appointed delegate) may seek to establish your long term health status for a period of not more than [1] month, by accessing your hospital records, or publicly available sources such as national registries, newspaper obituaries and social networking websites. Attempts may also be made to contact you or your relatives to ascertain this information. If you do not want this information about you to be collected, you may record your objection with your study doctor at any time.

RISKS OF THE STUDY DRUGS

Certain side effects and discomforts associated with the study may occur. As with taking any drug, there is a risk of allergic reaction. There may also be side effects and discomforts that are not yet known. While taking the study drug, your symptoms may not improve. They may actually worsen. With any drug for HIV, there is a risk that the virus in your body will become resistant, which means that the drug will be less or not effective against your HIV. The risk that taking part in this study will cause your HIV to develop resistance to the study drugs is unknown and will depend on how well the study drugs and the other HIV drugs you will take work against your virus and how well you take all the drugs.

GSK1349572

The following side effects have been seen with GSK1349572 in HIV infected subjects:

Very Common (could affect more than 1in every 10 people)

- Nausea or feeling sick (mild to moderate)
- Headache (mild to moderate)

Common (could affect more than 1to 10 in every 100 people)

- Changes in kidney and liver blood tests

The following have been seen, but it is not known yet if they were caused by GSK1349572:

Very Common (could affect more than 1in every 10 people)

- Diarrhea or loose stools
- Changes in pancreas blood tests
- Protein present in urine
- Changes in lipid levels (cholesterol)
- Mild increase in AST (an enzyme seen in muscle or liver inflammation)
- Changes in magnesium and/or phosphorus levels
- Increased blood glucose (sugar)
- Decreased blood sodium

Common (could affect more than 1 to 10 in every 100 people)

- Cold symptoms like runny nose and sore throat; cough; flu
- Trouble sleeping
- High temperature
- Pain in the stomach
- Changes in liver and muscle blood tests
- Decreased blood glucose (sugar)

- Decreased blood calcium

The highest dose administered in the majority of studies, where more than one dose of study drug was given, is 50mg once daily, which is the same dose as in this study.

Tell the study doctor about any side effects that you have.

In a study in HIV-infected patients receiving HIV treatment for the first time, one person who was receiving GSK1349572 and abacavir/lamivudine had an allergic reaction with significant liver inflammation in the first 2 weeks of taking study medications. Symptoms included fever, rash, joint aches and jaundice (yellowing of the skin and/or eyes). If you develop these symptoms at any time on this study, tell your study doctor immediately.

In one animal study, gastric erosion (mild wearing away of the stomach lining) was seen. We do not expect to see this in humans. However, if you feel heartburn or stomach pain or vomit, please contact your doctor.

Your study doctor will review with you the safety information, including any side effects, of the other HIV treatments that you will take during this study.

There may be other side effects that may happen that are not known now. For example, all drugs can cause an allergic reaction in some patients. Certain problems can be dangerous if not treated quickly; call your doctor right away if you:

- Feel very tired or faint
- Feel pain or sick in your stomach and do not want to eat
- Bruise easily or develop itching
- Have yellow eyes or skin, or dark urine
- Become confused

If you experience certain serious problems (such as an allergic reaction, swelling, difficulty breathing, a bad skin rash, liver or kidney damage, or changes in your heart rhythm), you may be asked to return to the clinic for more assessments, which may include more blood tests. Your doctor will explain these tests to you if they are needed. You may also need to stop taking the study drug after talking with your study doctor.

Darunavir (DRV)

Very Common (could affect more than 1 in every 20 people)

- Headache
- Stomach pain
- Diarrhea
- Upset stomach
- Nausea (feeling sick)
- Vomiting
- Skin rash

Common (could affect more than 1 to 10 in every 100 people)

- Bloating
- Muscle weakness
- Fatigue (tiredness)
- Loss of appetite
- Diabetes

-
- Liver inflammation

As part of the study, you will take a fixed-dose dual NRTI of either ABC/3TC or TDF/FTC. Information on the side effects with these medications is given below; for additional information your doctor may also take you through the patient information leaflet for these medications.

EPZICOM (abacavir/lamivudine or ABC/3TC)

Very Common (could affect more than 1 in every 20 people)

- Serious allergic reaction
- Skin rash (see below for detailed information)
- Diarrhea
- Nausea
- Headache
- Tiredness; lack of energy
- Insomnia (can't sleep)
- Depression
- Dizziness

Common (could affect more than 1 to 10 in every 100 people)

- Loss of appetite
- Hair loss
- Joint and muscle pain
- Stomach pain
- Vomiting
- High temperature

Anyone taking abacavir (like in ABC/3TC) can develop a hypersensitivity reaction (serious allergic reaction). This reaction can be life threatening and in rare cases has been fatal.

The symptoms of this allergic reaction (see below) can happen at any time during treatment with abacavir, but usually happens within the first 6 weeks of taking the drug. Symptoms get worse quickly, and the reaction may be fatal, if you keep taking ABC/3TC.

You are more likely to develop this reaction if you have a gene called HLA-B*5701, so only people who don't have this gene (or in other words are HLA-B*5701 negative) may receive ABC/3TC as part of this study. But you can also get this reaction even if you are HLA-B*5701 negative. Therefore, you need to call your study doctor immediately for advice on whether you should stop taking study medication if you have symptoms from at least TWO of the following groups:

1. Skin rash
2. Fever
3. Shortness of breath, sore throat or cough,
4. Nausea or vomiting or diarrhea or abdominal pain,
5. Severe tiredness or aches or pains or generally ill feeling

Your study doctor will decide if you are experiencing a hypersensitivity reaction. If you decide to take ABC/3TC as part of your study drugs, then you will be provided with a warning card to remind you about abacavir hypersensitivity and these symptoms. You should keep this card with you at all times.

There have been infrequent (rare or uncommon) reports of hypersensitivity reaction following reintroduction of abacavir where there was only a single symptom (e.g., rash, fever or gastrointestinal symptoms) that occurred before abacavir was initially stopped. On very rare occasions, hypersensitivity reactions have been reported in patients who have stopped and restarted abacavir therapy, and who had no obvious symptoms of a hypersensitivity reaction before initially stopping abacavir treatment.

If you stop taking ABC/3TC for any reason, and particularly due to possible side effects or illness, you must contact your study doctor immediately and NOT restart ABC/3TC before you speak with your study doctor.

If your doctor tells you to stop ABC/3TC because of this hypersensitivity reaction you must never take any medicine that has abacavir in it again (such as Epzicom, Kivexa, Ziagen or Trizivir), because the reaction can return within hours and be much worse and even fatal.

If you become hypersensitive to abacavir, you should return all of your unused ABC/3TC to the study site for proper disposal.

It is not clear if ABC/3TC (and other anti-HIV medications) may increase the risk of having a heart attack. Your study doctor will discuss with you any steps that may be needed to decrease your risk of heart disease, including stopping smoking or treating conditions like high blood cholesterol, diabetes or high blood pressure.

TRUVADA (Tenofovir/emtricitabine or TDF/FTC)

Very Common (could affect more than 1 in every 10 people)

- Dizziness
- Headache
- Diarrhea
- Nausea (feeling sick)
- Difficulty sleeping; abnormal dreams
- Rashes, which may be allergic reactions
- Feeling tired; fatigued
- Depression

Common (could affect more than 1 to 10 in every 100 people)

- Vomiting
- Muscle pain and weakness
- Digestion problems and excessive gas in the stomach or bowel
- Changes in skin color including darkening of the skin in patches
- Other allergic reactions, such as wheezing, swelling of the face, lips, tongue or throat
- Blood test may show: decreases in phosphate; low white blood cell count (blood cells that fight infection); increased fatty acids or sugar; changes in liver and pancreas tests
- Stomach pain

The breakdown of muscle and softening of bones (with bone pain and sometimes resulting in fractures) have also reported in a few patients who had been prescribed TDF/FTC with other anti-HIV drugs.

If you have hepatitis B infection as well as HIV, it is especially important not to stop your ABC/3TC or TDF/FTC treatment without taking to your doctor first. Some patients have blood test or symptoms showing that their hepatitis has gotten worse after stopping lamivudine (in ABC/3TC), tenofovir or

emtricitabine (both in TDF/FTC). You may need to have blood tests for several months after stopping treatment.

In rare cases, a life threatening condition called lactic acidosis (caused by a buildup of lactic acid in the blood and tissues) with an enlarged, fatty liver have been seen in patients receiving these drugs. Pancreatitis (inflammation of the pancreas) has been seen in some patients receiving these drugs although it is unknown whether this was caused by the drugs or the HIV disease.

If you have side effects from ABC/3TC or TDF/FTC, then you and your study doctor can switch these medicines one time. Your study doctor will explain the side effects of this new medicine if a change is made.

Within the first few weeks of treatment with anti-HIV medicines, some people, particularly those that have been HIV positive for a long time, may develop inflammatory reactions (e.g. pain, redness, swelling, high temperature) which may look and feel like an infection and may be severe. It is thought that these reactions are caused by an improvement in the body's ability to fight infections due to a reduction in the HIV. If you become concerned about any new symptoms or any changes in your health after starting HIV treatment, please discuss with your doctor.

Changes in fat distribution have been reported with anti-HIV medicines. These changes may include loss of fat from legs, arms and face, increased fat in the abdomen (belly) and other internal organs, breast enlargement and fatty lumps on the back of the neck ('buffalo hump'). Changes in the amounts of fatty substances and glucose in the blood have also been reported.

Some patients taking combination anti- HIV therapy may develop a bone disease called osteonecrosis (death of bone tissue caused by loss of blood supply to the bone). The length of combination anti-HIV therapy, corticosteroid use, drinking alcohol, severe reduction in ability to fight off infection, higher body weight, among others, may be risk factors for developing this disease. Signs of osteonecrosis are joint stiffness, aches and pains (especially of the hip, knee and shoulder) and difficulty in movement. If you notice any of these symptoms please inform your doctor.

In addition, you might experience some discomfort from the needle stick where blood is drawn during study visits. Swelling, bleeding or bruising may occur where the needle meets the skin. Additionally, discomfort may occur from removing the electrocardiogram pads during study visits. Small areas of hair may need to be shaved in order to place pads.

RISK FOR STUDY PROCEDURES

Blood Draws
In addition to risks associated with the study drug, drawing blood from a vein may cause local pain, bruising, occasional lightheadedness, fainting, and very rarely, infection at the site of the blood draw.

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

Reproductive Risks
There may be a possibility that the study treatment may damage an unborn child or nursing infant, and for this reason, if you are breast-feeding, pregnant or plan to become pregnant, you may not

participate in this study. Females of childbearing potential must use a method of birth control acceptable to you, the study doctor, and the sponsor. The methods of birth control considered acceptable for this study are as follows:

- Complete abstinence (not having sex) from 2 weeks prior to first taking study drug throughout the study and for at least 2 weeks after you stop taking all study medications

- Double barrier method which is strictly following one of these three methods while having sex:
  (1) using a male condom while also using spermicide or
  (2) using a male condom while also using a diaphragm or
  (3) using a diaphragm while also using spermicide

- Women who are only having sex with a man who has been sterilized before you entered the study

- Certain types of hormonal birth control are acceptable. They may include birth control pills taken by mouth, birth control implanted into body tissue, injected under the skin, absorbed from a patch on the skin, or placed in the vagina. Talk to your study doctor to make sure your type is acceptable.

- Certain types of intrauterine devices (IUD) which are implanted into the uterus are acceptable. Talk to your study doctor to make sure your type of IUD is acceptable.

Also, if you are chosen to take DRV/r, there are alternative methods of non-hormonal contraception that are recommended. Your study doctor will explain these to you.

If you become pregnant during the study, you should immediately stop taking all study drugs. You should tell the study doctor immediately and the doctor will talk with you about what you should do. Your participation in the study will be stopped. If you get pregnant, information regarding the pregnancy, such as estimated date of delivery, current medications, will be reported to the study sponsor within 2 weeks of the study staff learning of the pregnancy.

The study sponsor takes part in a Pregnancy Registry for Antiretroviral Therapies, which is an international registry sponsored by manufacturers or licensees of products including the study drug. The purpose of the ART pregnancy registry is to look at pregnancy outcomes after an unborn baby is exposed to certain HIV drugs. Information that is collected includes APGAR scores, weight and physical condition. The study sponsor will forward this information to the ART Pregnancy Registry. This registry is strictly confidential, and there is no way to link the report to you. All information goes to the registry through the study sponsor, so the registry will never contact you nor will they contact your study doctor.

What Benefits Can I Expect From This Study?

By taking part in this study you may contribute new information that may benefit other patients in the future. You personally may or may not improve while taking part in this study. It cannot be promised that you will receive any benefit.

What Other Choices Do I Have Besides This Study?

If you decide not to participate in this study, you may choose to receive the standard treatment(s) for HIV. Your study doctor can discuss alternative treatments with you.

What Are the Costs To Me?

The study drugs will be made available to you at no charge and you will not be required to pay for any study tests or procedures. You or your insurance company may be billed for any standard medical care that is not required for the research study.

Will I Receive Any Payment?

You will be compensated $50 for the screening visit and then $50 for each of the study required visits (14 total visits). Compensation will be given as cash. The total amount of compensation for the main study if all study visits are attended is $700. If you have to come in for an unscheduled visit as requested by the study team, you will be compensated $25. If you qualify and continue on the extension phase past week 96, you will continue to receive $50 for each visit attended until Dolutegravir is commercially available or you come off the study.

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 I Am Injured?

GSK will pay your costs for reasonable and necessary care if you are hurt by the study drug or a procedure that is done to you only because you are part of this study. To pay these medical expenses, GSK will need to know some information about you like your name, date of birth, and social security number. This is because GSK has to check to see if you receive Medicare, and, if you do, report the payment it makes to Medicare. GSK will not use this information for any other purpose.

No other payment is available from the sponsor or the study doctor in the event of injury. You are not waiving any legal rights by signing this form, accepting medical care or accepting payment for medical expenses.

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

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

What If There Is New Information About The Study Drugs?

Your study doctor will tell you in a timely manner of any information learned during the course of this study that may relate to your willingness to continue your participation in this study.

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

What Are My Rights As a Research Subject?

Your participation in this study is voluntary. You do not have to take part in this study. If you start the study, you may leave the study at any time. You will not be penalized or lose benefits if you do not take part in the study, or if you stop the study at any time. If you decide to stop participation in the study before the last study visit, tell the study doctor and follow instructions.

The study may be stopped by the sponsor or the study doctor, even if you want to continue to participate. You may be asked to stop the study for your safety, if you become pregnant, if you decide you want to become pregnant, because you need additional treatment, or because you do not follow the study rules.

If your participation in the study is stopped early such as before the last study visit, you may be asked to complete end of study procedures for your safety (such as a final medical examination or blood tests). You will also be asked to return any leftover study drug.

There may be problems after stopping the study drug, such as:

- An increase in your HIV number after it has gone down while you took the study drug
- A decrease in immune cells, such as CD4 cells, after they have increased while you took the study drug.

If you leave the study, no more information about you will be collected for the study. But all the information you gave us before you left the study will still be used for the study.

Organizing And Funding The Study

ViiV Heathcare is a global specialist HIV company that develops drugs and advances in the treatment and care for people with HIV. The sponsor of this study is ViiV Healthcare.

GlaxoSmithKline is a company that creates and makes medicines and other health products. It is also called "GSK". In this case, GSK is running the study for ViiV Healthcare.

GSK pays the study doctor and hospitals to cover their costs of conducting the study.

Information about this study is confidential. This information belongs to ViiV Healthcare. We ask that you keep it private. You can discuss this information in private with your doctor or family to talk about your healthcare or to decide about taking part in this study.

HIPAA AUTHORIZATION

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

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

- Name, address, telephone number, date of birth
- Information from questionnaires administered in the study

- Personal and family medical history
- Current and past medications or therapies
- Results of tests and procedures you will undergo during this research study
- Social Security Number

Why is your personal contact and health information being used?
Your personal contact information is important for the research team to contact you during the study. Your personal health information and results of tests and procedures are being collected as part of this research study. In some situations, your personal health information might be used to help guide your medical treatment.

Which of our personnel may use or disclose your personal health information?
The following individuals may use or disclose your personal health information for this research study:

- The Principal Investigator and the Investigator's study team
- Authorized members of the workforce of the UPHS and the School of Medicine, and University of Pennsylvania support offices, who may need to access your information in the performance of their duties (for example: for research oversight and monitoring, to provide treatment, to manage accounting or billing matters, etc.).

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

Individuals or organizations responsible for administering the study:

- ViiV Healthcare : The sponsor of the study will be able to view all study data.
- Staff of Pharmaceuticals Product Development (PPD) Contract Research Organization : an agency hired by GlaxoSmithKline/ViiV Healthcare to review study procedures and data and correct mistakes before the results are given to the sponsor and government agencies funding and/or monitoring study safety.
- Government Agencies: Data from this study will be made available to the Food and Drug Administration for them to evaluate the safety and efficacy of the treatments being used in this study.

Regulatory and safety oversight organizations

- The Food and Drug Administration
- The Office of Human Research Protections

Once your personal health information is disclosed to others outside of UPHS or the School of Medicine, it may no longer be covered by federal privacy protection regulations. Data are reported to the sponsor on Case Report Forms that identify you by your unique study number and not your name, date of birth or medical record number. Information regarding your health, such as side effects of the study drug you experience will be reported only by code number. All samples collected for analysis will be labeled with your study number, visit number and date of your visit.

Also, the study data may be transferred to other countries for processing, including countries not covered by Data Protection legislation.

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

How long may UPHS and the School of Medicine be able to use or disclose your personal health information?
Your authorization for use of your personal health information for this specific study does not expire.

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

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

Can I access my study records?
While the study is in progress, your access to your study records will be temporarily suspended. You will be able to access your information when the research study is completed. You have the right to see and copy the medical information collected from you in the course of the study for as long as that information is maintained by the study personnel and other entities subject to federal privacy regulation.

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 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, you will not be able to stay in this study.

What if I decide not to give permission to use and give out my health information?
Then you will not be able to be in this research study.

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

What do ViiV Healthcare and GSK do with the study information?
Study information will be labeled with a code number, and will not include your name or other information that directly identifies you.

ViiV Healthcare and GSK will keep the study data and may:

- Analyze it by computer to find out what this study is telling us.
- Share it with officials who approve new drugs, or with groups that check that studies are done properly.
- Share it with other companies or universities to better understand HIV or to further develop the study drug or other drugs.
- Use it to plan new studies to further develop the study drug or learn more about HIV and/or other diseases or conditions.
- Share it, and other information from the study, with other ViiV Healthcare and GSK offices here

and in other countries worldwide. If the information is sent to another country anywhere in the world, ViiV Healthcare and GSK will apply the same level of protection to your information, to the extent permitted by local law.

ViiV Healthcare intends to:

- Post a study summary on a publicly available study register on the internet.
- Post the study results on a publicly available study results register on the internet.
- Write up the results for medical journals.

Your name will not appear in any of these reports.

ViiV Healthcare will be the owner of the study results and plans to use the results, and may get patents, or sell the drug in the future, or make profits other ways. You will not be paid any part of this

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 (i.e. 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 (e.g. health insurance company, disability provider, etc).

PHARMACOGENETICS PART OF THE STUDY

The purpose of the pharmacogenetics part of this study is to see why different people may react differently to medicines. This research is called "pharmacogenetics" and can include analyzing DNA. Scientists will look for differences in people's genes that might explain this. We get our genes from our parents, and different genes may affect how a body reacts to a drug.

As mentioned earlier, if you take part in the study, you will be asked to give blood samples for studying how well GSK1349572 works compared to DRV/r. Similar to information, samples may be used by ViiV Healthcare or GSK or shared by ViiV Healthcare or GSK with other companies or universities to better understand HIV, other diseases or conditions, or to further develop the study

drug or other drugs.

Your blood samples will be given the same code as your other study information and kept in locked storage. Anyone who works with your samples will hold the information and results in confidence.

Joining this part of the study is optional. This means that you may:

- Choose not to join the pharmacogenetics part of the study but still take part in the main study.
- Choose to join and then change your mind before your sample is taken or at any time in the study.
- Choose to not join at this time, but decide to join later. If so, please talk to your study doctor.

If you choose to stop the pharmacogenetics part of the study after giving a sample, we will destroy it within 30 days. If you stop the main part of the study after giving a sample, you can ask us to destroy it. If your sample is being processed we will have to wait until all steps are done before we can destroy it. This might be longer than 30 days. GSK will not use your data for analysis.

If you choose to take part in the pharmacogenetics study, we will draw about 2 teaspoons of your blood. If there is a problem looking at your blood sample, we may ask to take the sample again.

When you give blood, you may feel faint, or experience mild pain, bruising, irritation or redness at the site. In rare cases, you may get an infection.

If you take part in the pharmacogenetics part of the study and agree to give a sample, you may help scientists understand why people react to or handle GSK1349572 or other drugs in this study differently. This may help identify who is more likely to benefit from GSK1349572 and who may have side effects.

A new 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 [US only].

Once your personal or medical information is shared with someone who is not a health care provider, it is not protected by the US federal privacy rules (called HIPAA).

What Do I Do If I Have Questions Or Problems?

For questions about this study or a research-related injury, contact:

- Pablo Tebas, MD (215-349-8092)
- Clinical Trials Unit (215 349-8092)

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

- Director of Regulatory Affairs at the University of Pennsylvania by phoning (215) 898-2614

CONSENT

When you sign this form, you are agreeing to take part in this research study. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer. Your signature also means that you are permitting the University of Pennsylvania Health System and

the School of Medicine to use your personal health information collected about you for research purposes within our institution. You are also allowing the University of Pennsylvania Health System and the School of Medicine to disclose that personal health information to outside organizations or people involved with the operations of this study.

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.

GSK1349572 STUDY

I have read and understand the statements in this informed consent form. I have had the opportunity to ask questions and I am satisfied with the explanations provided by the consent process. I voluntarily consent to participate in the study and I authorize the use and disclosure of my information in connection with the study. I will receive a signed and dated copy of this consent and authorization form.

SUBJECT

Printed Name of Subject	
Signature of Subject	Date of Signature Handwritten by Subject

LEGALLY AUTHORIZED REPRESENTATIVE

Printed Name of Legally Authorized Representative	
Signature of Legally Authorized Representative	Date of Signature Handwritten by Legally Authorized Representative
Describe the Representative's authority to act for the subject or relationship to Subject:	

PERSON CONDUCTING INFORMED CONSENT DISCUSSION

Printed Name of Investigator/Delegate	
Signature of Investigator/Delegate	Date of Signature Handwritten by Investigator/Delegate

SUBJECT'S STATEMENT OF CONSENT AND AUTHORIZATION FOR THE
PHARMACOGENETICS PART OF THE GSK1349572 STUDY

I have read and understand the statements in this informed consent form. I have had the opportunity to ask questions and I am satisfied with the explanations provided by the consent process. I voluntarily consent to participate in the study and I authorize the use and disclosure of my information in connection with the study. I understand that I will receive a signed and dated copy of this consent and authorization form.

SUBJECT

Printed Name of Subject	
Signature of Subject	Date of Signature Handwritten by Subject

LEGALLY AUTHORIZED REPRESENTATIVE

Printed Name of Legally Authorized Representative	
Signature of Legally Authorized Representative	Date of Signature Handwritten by Legally Authorized Representative
Describe the Representative's authority to act for the subject or relationship to Subject:	

PERSON CONDUCTING INFORMED CONSENT DISCUSSION

Printed Name of Investigator/Delegate	
Signature of Investigator/Delegate	Date of Signature Handwritten by Investigator/Delegate