

# UNIVERSITY OF PENNSYLVANIA HEALTH SYSTEM

## Gilead Sciences, Inc GS-US-292-0109, Amendment 1, 19-FEB-2013

A Phase 3, Open-Label Study to Evaluate Switching from a TDF-Containing Combination Regimen to a TAF-Containing Combination Single Tablet Regimen (STR) in Virologically-Suppressed, HIV-1 Positive Subjects

### CONSENT TO PARTICIPATE IN THE DXA PORTION OF THIS RESEARCH STUDY AND RESEARCH SUBJECT HIPAA AUTHORIZATION

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

Site address: 502 Johnson Pavilion, Philadelphia, PA 19104

Principal Investigator:	Pablo Tebas, MD	(215) 349-8092
Manager:	Joseph Quinn, RN, BSN	(215) 349-8092
Study Nurses:	Wayne Wagner, RN, MSW	(215) 349-8092
	Aleshia Thomas, RN, BSN	(215) 349-8092

24 Hour Emergency Number (215) 662-6059 Ask for the Immunodeficiency Program Doctor on call

### **INTRODUCTION**

You are currently enrolled in the above referenced clinical research study at Philadelphia Fight which is being overseen by Dr. Karam Mounzer. This study requires a DXA scan at five visits during the first 96 weeks of the study as well as in the follow up extension and perhaps at other special time points in the study. DXA scans are not available at your study site, and Dr. Mounzer has made arrangements for these studies to be conducted at the University of Pennsylvania.

### **YOUR RIGHTS**

This consent form tells you about the DXA part of study. Your study doctor or study staff will go over this with you and answer any questions you may have regarding this part of the study. All of the other information regarding this study (purpose, procedures, risk, benefits, etc.) have been provided by the Philadelphia FIGHT staff. If you agree to have the DXA performed at University of Pennsylvania, you will be asked to sign and date this consent form. You will be given a copy of the signed and dated consent form to keep.

Before you agree to volunteer, you must understand the purpose of the study, how your participation may help you, any potential risks to you, and what is expected of you during the study.

### **STUDY PROCEDURES**

#### **Baseline/Day 1**

- Dual energy x-ray scan (called DXA scan) of your spine and hip (prior to taking study drug)

#### **Week 2 to Week 96 and every 12 weeks following Week 96 in the Open Label Extension phase until study completion**

- DXA scan (x-ray) of your spine and hip will be performed at Weeks 24, 48, 72, 96 and every 24 weeks post week 96.

#### **Early Study Drugs Discontinuation (ESDD) Visit**

- DXA scan (x-ray) will be performed if the last scan was more than 12 weeks from the ESDD visit

**RISKS**

**DXA**

Decreases in bone mineral density have been observed in HIV-infected patients. An X-Ray called dual energy X-ray absorptiometry, or a DXA scan, will be performed on your spine and hip to measure changes in bone mineral density.

DXA scan will be performed at the Day 1 (baseline) visit, Weeks 24, 48, 72, and 96 and then continually every 24 weeks after the Week 96 visit.

DXA scans involve exposure to radiation. Therefore, you will receive a radiation dose. This radiation dose is not necessary for your medical care and will occur only as a result of your participation in the study. At doses much higher than you will receive, radiation is known to increase the risk of developing cancer after many years. At the doses you will receive, it is very likely that you will see no effects at all.

**POSSIBLE BENEFITS OF THE STUDY**

There is no guarantee that you will receive personal benefit from participating in this study. The study drugs are not expected to cure you of HIV. However, clinical research studies such as this are a way for doctors to determine if a drug is useful in fighting a disease. By taking part in this study, you and the Sponsor, Gilead Sciences, Inc., may benefit if E/C/F/TAF is effective in treating HIV-1 infection. Your participation in this study may benefit the community, scientists and doctors who work with HIV by providing increased knowledge and information about the treatment of your disease.

**COST OF TREATMENT**

The DXA scans conducted at University of Pennsylvania 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.

**PAYMENT FOR PARTICIPATION**

Compensation for completing the DXA scan is \$50 and will be provided by Philadelphia FIGHT per the terms in the consent you signed for the main study at that site.

**COMPENSATION FOR STUDY-RELATED INJURY**

If you become sick or injured as a direct result of the DXA study procedures, the University of Pennsylvania will provide you with medical treatment. The Sponsor, Gilead Sciences, Inc., will reimburse you or the University of Pennsylvania for the reasonable and necessary costs of such medical treatment. No other form of reimbursement for study-related injury or illness is offered by the Sponsor. You do not give up any legal rights by signing this form. You should immediately contact your Study Doctor at the contact information on page 1 of this form in the event you experience any study-related illness or injury from the DXA scan. Please contact the main study doctor at FIGHT for all other study related issues.

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

**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.

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

**AUTHORIZATION TO USE AND DISCLOSE RECORDS**

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

**What personal health information is collected and used in this study and might also be disclosed?**

The following personal health information will be collected, used for research, and may be disclosed during your involvement with this research study:

- Name and telephone number
- Results of DXA scans you will undergo during this research study

**Why is your personal contact and health information being used?**

Investigators at PENN will record your name and contact information so that we can report to Philadelphia FIGHT the persons who had DXA scans performed at PENN for the study. In addition, we will be able to contact you if necessary. DXA images and any related paperwork will be sent by PENN research staff to the central reading facility contracted by the sponsor.

**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:**

- Pharmaceutical sponsor (Gilead Sciences) and it’s affiliates: This is the company that supplies drugs for the study and the representatives working on their behalf. Information regarding safety and adverse effects needs to be collected and monitored. DXA scan images and related reports will go to BioClinica by study code number.

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. Although efforts will be made to protect your privacy, absolute confidentiality of your records cannot be guaranteed. Data are reported to the sponsor on Case Report Forms that identify you by your unique study number and not your name or medical record number. Information regarding your health, such as side effects of the study medications you experience will be reported only by code number. All samples collected for analysis will be labeled with your study number, visit number and date of your visit.

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

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

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

**Will you be able to access your records?**

Since this is an open-label study, you will be able to access some or all of your medical records after the study is over. The Principal Investigator is not required to release research information to you that is not part of your medical record.

**Can you change your mind?**

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

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

## UNIVERSITY OF PENNSYLVANIA HEALTH SYSTEM

GS-US-292-0109

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

### **WHAT IS AN ELECTRONIC MEDICAL RECORD?**

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

If you are receiving care or have received care within the University of Pennsylvania Health System (UPHS) (outpatient or inpatient) and are participating in a University of Pennsylvania research study, results of research-related procedures (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in your existing EMR maintained by UPHS.

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).

### **WHO CAN I CALL WITH QUESTIONS, COMPLAINTS OR IF I'M CONCERNED ABOUT MY RIGHTS AS A RESEARCH SUBJECT?**

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on page one of this form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Office of Regulatory Affairs with any question, concerns or complaints at the University of Pennsylvania by calling (215) 898-2614.

### **RESEARCH STUDY REGISTRY**

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

## AGREEMENT TO BE IN THE STUDY

## Subject

### Person Obtaining Consent

**Witness (if applicable)**

Page 6 of 6