PARTNER PREGNANCY FOLLOW UP CONSENT FORM

Sponsor / Study Title:	**Gilead Sciences, Inc. / "A Phase 3, Randomized, Double-Blind Study to Evaluate the Safety and Efficacy of GS-9883/ Emtricitabine/Tenofovir Alafenamide Versus Abacavir/Dolutegravir/Lamivudine in HIV-1 Infected, Antiretroviral Treatment-Naïve Adults"**
Protocol Number:	**GS-US-380-1489**
Principal Investigator: (Study Doctor)	**Pablo Tebas, M.D.**
Telephone:	**215 349-8092** **215 662-6059 (24 hours)**
Additional Contacts: (Study Staff)	**Joseph Quinn, RN, BSN** **Yan Jiang, RN, BSN, MSN**
Address:	**Hospital of the University of Pennsylvania** **3400 Civic Center Boulevard** **Philadelphia, PA 19104**

WHAT IS PARTNER PREGNANCY FOLLOW UP?

You have been asked to take part in pregnancy follow up to collect information about your pregnancy.

You became pregnant while your partner is or was taking part in a research study. The research study is or was testing the experimental drug named GS-9883/Emtricitabine/Tenofovir alafenamide (GS-9883/F/TAF) for the possible treatment of human immunodeficiency virus (HIV-1) infection. An experimental drug means that the United States Food and Drug Administration (FDA) and European Medicines Agency (EMA) have not approved it for use by the general public.

This study is or was also testing a fixed-dose combination of ABC/DTG/3TC, also known as Triumeq®. Triumeq® is approved by the FDA and the EMA for the treatment of HIV-1 infection.

This form explains the partner pregnancy follow up to you. Your partner's study doctor or study nurse will go over this form with you. Your partner's study doctor or study nurse will answer all your questions you have about the form.

Taking part in the partner pregnancy follow up is voluntary. If you decide not to take part, this will not result in penalty or loss of benefits. If you decide to take part, you may withdraw your consent at any time without any penalty or loss of benefits.

You will be told of any new information that might cause you to change your mind about continuing to take part in the follow up.

If you agree to take part in the pregnancy follow-up, you will be asked to sign and date this form. You will be given a signed and dated copy to keep.

WHAT IS THE PURPOSE OF THE PARTNER PREGNANCY FOLLOW UP?

The purpose of this pregnancy follow up is to provide information about your pregnancy to the Study Sponsor, Gilead Sciences, Inc. (the company that provided the drug).

The effects of the study drugs are not known on the developing fetus (unborn baby) in humans at this time.

The ABC/DTG/3TC that your partner is or has been taking may cause adverse (bad or harmful) events in pregnancy or birth defects in the unborn baby you are carrying. There are no adequate and well-controlled trials in pregnant women, but abacavir had some effects on offspring of pregnant rats.

This information is being collected by the Study Sponsor and will be kept in the Study Sponsor Safety Database. This information may help the Study Sponsor to better understand how GS-9883/F/TAF affects the course of pregnancy and unborn baby in partners of someone taking GS-9883/F/TAF.

WHAT ARE YOUR RESPONSIBILITIES?

Your partner's study doctor will ask you questions about the progress and outcome of your pregnancy.

It is recommended that you receive appropriate prenatal care since GS-9883/F/TAF and ABC/DTG/3TC may include adverse events in pregnancy or birth defects in the unborn baby you are carrying.

HOW MUCH WILL THE PARTNER PREGNANCY FOLLOW-UP COST YOU? WILL YOU BE PAID TO BE PART PARTNER PREGNANCY FOLLOW UP?

There is no cost involved in this partner pregnancy follow up. You will not be reimbursed for taking part.

The Study Sponsor and your partner's study doctor will not be responsible for the costs related to your pregnancy, delivery, or care of your child.

WHAT ARE THE POSSIBLE RISKS OF THE PARTNER PREGNANCY FOLLOW UP?

We do not anticipate any risks if you take part in this partner pregnancy follow up.

WHAT ARE THE POSSIBLE BENEFITS OF THE PARTNER PREGNANCY FOLLOW UP?

There is no direct benefit to you from taking part in the partner pregnancy follow-up. The information may help the Study Sponsor better understand how GS-9883/F/TAF affects the course of pregnancy and unborn baby in partners of someone taking GS-9883/F/TAF.

WHAT ARE YOUR ALTERNATIVE OPTIONS FOR TAKING PART IN THE PARTNER PREGNANCY FOLLOW UP?

The only option is to not participate in the partner pregnancy follow up.

WHO WILL HAVE ACCESS TO YOUR MEDICAL RECORDS?

Your partner's study staff will collect personal and medical information related to your pregnancy and the outcome of your pregnancy. Information about you and your baby will be kept confidential. Your name will not be included in any records sent to the Study Sponsor, Gilead Sciences, Inc. You will be identified by a code and only the date of birth of your baby may be used for identification purposes. Your name will not be used if any data is published.

The Study Sponsor may provide the information collected about you and your baby to its research partners. The Sponsor's research partners are involved in the research study that your partner is or was participating in. The Institutional Review Board or Independent Ethics Committee: the committee that oversees the study at the study site, may also need to access your personal information. Government agencies (such as the Food and Drug Administration (FDA) or the Department of Health and Human Services) may also need access to your medical records. These people, companies, and agencies may be located in the United States or other countries outside the United States that do not offer the same level of privacy protection.

You have certain rights to gain access to and correct any mistakes in information held about you and your baby. If you have any questions about the collection and the use of this information, you should ask your partner's study doctor.

Your consent to the collection and processing of information about you and your baby is voluntary. You may withdraw your consent at any time by informing your partner's study doctor in writing. If you do so, your partner's study personnel will stop collecting information from you, but the Study Sponsor may continue to use and disclose information already collected before you withdrew your consent.

GENERAL STATEMENT ABOUT PRIVACY

Records identifying you and your baby will be kept confidential and, to the extent permitted by applicable laws and/or regulations, will not be made publicly available. In the event of any publication regarding this study, your identity will remain confidential.

Representatives from government agencies, including the U.S. Food and Drug Administration ("FDA"), institutional review boards, the Sponsor and/or the Sponsor's authorized representatives may need access to your original medical records. 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, 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 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:

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

Regulatory and safety oversight organizations

The Food and Drug Administration and regulatory agencies in other countries

The Office of Human Research Protections

The Study Monitoring Committee

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

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

How long may 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.

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).

Your partner's study staff will collect personal and medical information related to your pregnancy and the outcome of your pregnancy. Information about you and your baby will be kept confidential. Your name will not be included in any records sent to the Study Sponsor, Gilead Sciences, Inc. You will be identified by a code and only the date of birth of your baby may be used for identification purposes. Your name will not be used if any data is published.

The Sponsor and its authorized representatives will analyze and use the coded information they receive to better understand how GS-9883/F/TAF affects the course of pregnancy and the unborn baby in partners of someone taking GS-9883/F/TAF.

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

As explained in this consent form, your participation in this follow up program is voluntary and you may withdraw from the follow up program at any time by informing your partner's Study Doctor. By signing this consent, you authorize the collection and use of information about you and your baby as described in this consent. You may revoke (take back) this authorization for the collection and use of information about you and your baby by informing your partner's Study Doctor in writing. If you withdraw from the follow up program or if you revoke your authorization for the collection and use of information about you and your baby, your participation in the follow up program will end and your partner's study staff will stop collecting information from you. The Sponsor will need to keep and use any information that has already been collected. Your decision to withdraw from the follow up program or to revoke your authorization for the collection and use of information about you and your baby will not result in any penalty or loss of access to treatment or other benefits to which you are entitled.

This authorization has no expiration date, unless and until you revoke it. In California and any other state that requires an expiration date, the Authorization will expire 50 years after you sign this authorization document.

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

WHAT HAPPENS IF YOU ARE INJURED?

We do not anticipate that the collection of information in this partner pregnancy follow-up will result in any injury to you. No compensation for injury is offered by your partner's study doctor or the Study Sponsor.

If you believe that you have suffered an injury related to this partner pregnancy follow up, you should contact the study doctor at the telephone number listed on the first page of this form.

WHO SHOULD YOU CONTACT IF YOU HAVE QUESTIONS?

If you have any questions, please contact the study doctor or the study staff at telephone number listed on the first page of this form.

If you have questions regarding the pregnant partner follow up or your rights as a participant you may also discuss them with an administrator of the Institutional Review Board (IRB):

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

Please reference the following number when contacting the Study Subject Adviser: Pro00014039.

AGREEMENT TO BE IN PARTNER PREGNANCY FOLLOW UP

By signing this Partner Pregnancy Follow up Consent Form, I acknowledge that:

(1) I have carefully read and understand the information in this form.
(2) The purpose and description of this partner pregnancy follow up have been fully explained to me, and I have had the opportunity to ask questions.
(3) All of my questions were answered to my satisfaction.
(4) I have been informed of the possible risks and benefits that I might reasonably experience as a result of taking part in this partner pregnancy follow up.
(5) I understand that I am free to withdraw my consent and stop my participation at any time without penalty or loss of benefits.

Subject (or legally authorized representative as applicable)

Subject Printed Name (or legally authorized representative, if applicable)	Signature	Date

<Description of Legal Representative's Authority (e.g., parent or legal guardian)>

Person Obtaining Consent

Printed Name & Title	Signature	Date

Witness (if applicable)

Witness Printed Name	Signature	Date