PARTNER PREGNANCY FOLLOW UP CONSENT FORM

Sponsor / Study Title:	**Gilead Sciences, Inc./ "A Phase 3b Randomized, Open-label, Controlled Study of the Efficacy, Safety and Tolerability of 12 Weeks of Ledipasvir/Sofosbuvir (LDV/SOF) Treatment for HIV/HCV Co-infected Subjects who Switch to Elvitegravir/Cobicistat/Emtricitabine/Tenofovir Alafenamide (E/C/F/TAF) or Emtricitabine/Rilpivirine/Tenofovir Alafenamide (F/R/TAF) prior to LDV/SOF HCV Treatment, the HIV/HCV Co-STARs study (Co-infection treatment with Single Tablet Antiviral Regimens)"**
Protocol Number:	**GS-US-366-1992**
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:	**Perelman Center for Advanced Medicine** **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 Emtricitabine/Rilpivirine/Tenofovir Alafenamide (F/R/TAF) Fixed Dose Combination (FDC) for the treatment of human immunodeficiency virus (HIV-1) infection. An experimental drug means that the drug has not yet been approved by governmental regulatory agencies, for example, such as the U.S. Food and Drug Administration (FDA), for use by the general public.

This study is also testing GENVOYA®, or Elvitegravir/Cobicistat/Emtricitabine/Tenofovir Alafenamide (E/C/F/TAF) Fixed Dose Combination (FDC), and HARVONI®, or Ledipasvir/Sofosbuvir (LDV/SOF) FDC. GENVOYA® is currently approved by the Food and Drug Administration (FDA) in United States for the treatment of HIV-1 infection.

HARVONI® is currently approved by the FDA in United States for the treatment of chronic hepatitis C virus (HCV).

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, 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 study drug).

The effects of F/R/TAF, GENVOYA®, and HARVONI® are not known on the developing fetus (unborn baby) in humans at this time.

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 F/R/TAF, GENVOYA®, and HARVONI® affect the course of pregnancy and unborn baby in partners of someone taking F/R/TAF or GENVOYA® and HARVONI®.

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 the risk of F/R/TAF, GENVOYA®, and HARVONI® to you and your unborn baby is unknown.

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 follow up.

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

There is no direct benefit to you from taking part in this follow-up. The information may help the Study Sponsor better understand how F/R/TAF, GENVOYA®, and HARVONI® affect the course of pregnancy and unborn baby in partners of someone taking F/R/TAF or GENVOYA® and HARVONI®.

WHAT ARE YOUR 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 (IRB), the committee that oversees this study to help ensure that the rights and welfare of participants are protected and that this study is carried out in an ethical manner 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.

Authorization to Use and Disclose Records

During this study your Study Doctor, study nurses and other study personnel will record information about you, your health and your participation in the study on forms provided by the Sponsor. These forms are known as case report forms. You will not be able to participate in this study if you do not consent to the collection of this information about you.

The information collected about you, will be held by the study site, the Sponsor and the Sponsor's authorized representatives. To ensure that your personal information is kept confidential, your name and any other information that allows you to be identified directly will not be entered on the case report forms or included in any records or samples your study doctor provides to the Sponsor or the Sponsor's authorized representatives. Instead, you will only be identified by a code. The code is used so that your study doctor can identify you if necessary.

The Sponsor and its authorized representatives will analyze and use the coded information they receive for the purposes of this study. Such purposes include:

- checking your suitability to take part in the study,
- monitoring your treatment with the study drug,
- comparing and pooling your study treatment results with those of other subjects in clinical studies,
- establishing whether the study drug meets the appropriate standards of safety set by
  the authorities,
- establishing whether the study drug is effective,
- supporting the development of the study drug,
- supporting the licensing application for regulatory approval of the study drug anywhere in the world,
- supporting the marketing, distribution, sale and use of the study drug anywhere in
  the world, and/or
- as otherwise required or authorized by law.

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).

If necessary for these purposes, 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 study is voluntary and you may withdraw from the study at any time by informing your Study Doctor. By signing this consent, you authorize the collection and use of information about you as described in this consent. You may revoke (take back) this authorization for the collection and use of information about you by informing your Study Doctor in writing at the address listed on the first page of this form. If you withdraw from the study or if you revoke your authorization for the collection and use of information about you, your participation in the study will end and the study personnel will stop collecting information from you. The Sponsor will need to keep and use any research results that have already been collected. The Sponsor must do this to comply with its legal obligations and to maintain the scientific integrity of the study. Your decision to withdraw from the study or to revoke your authorization for the collection and use of information about you 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 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 telephone number listed on the first page of this form.

GETTING ANSWERS TO YOUR QUESTIONS OR CONCERNS ABOUT THE STUDY

You can ask questions about this consent form or the study (before you decide to start the study, at any time during the study, or after completion of the study). Questions may include:

- Who to contact in the case of a research-related injury or illness;
- Payment or compensation for being in the study, if any;
- Your responsibilities as a study subject;
- Eligibility to participate in the research;
- Results of tests and/or procedures;
- Other questions, concerns, or complaints.

Contact the study doctor or study staff listed on the first page of this form with any questions, concerns or complaints.

GETTING ANSWERS TO YOUR QUESTIONS ABOUT YOUR RIGHTS AS A RESEARCH SUBJECT

This study has been reviewed by an Institutional Review Board (IRB). This Committee reviewed this study to help ensure that your rights and welfare are protected and that this study is carried out in an ethical manner.

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

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

Please reference the following number when contacting the Study Subject Adviser: Pro00016357.

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)	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