utmb Health

INFORMED CONSENT FORM (MALE PARTNERS)

Title: Randomized order, controlled, double blind, crossover early Phase 1 pilot study to assess safety and pharmacokinetics of a Tenofovir Disoproxil Fumarate and Emtricitabine (TDF-FTC) releasing IVR over 28 days compared to placebo- Version 3.0

Short Title: PrEP-Pod-IVR-02

PRINCIPAL INVESTIGATOR: Kathleen L. Vincent, MD
301 University Blvd, Route 0587
Galveston, Texas 77555-0587
Office: 409-772-2610

STUDY COORDINATOR: Lauren Dawson
301 University Blvd, Route 0587
Galveston, Texas 77555-0587
409-354-9792

Source of Support: The study is being paid for by the Division of AIDS, US National Institute of Allergy and Infectious Diseases of the National Institutes of Health. The intravaginal rings being used in this study will be provided by the Oak Crest Institute of Science (called "the sponsor").

Questions about the Study: The person in charge of this study at the University of Texas Medical Branch is Kathleen L. Vincent, MD. If you have any questions about the study, concerns or complaints, you can contact the Principal Investigator, Dr. Kathleen L. Vincent (409-772-2610), the study coordinator (409-354-9792).

Why am I being asked to take part in this research study? You are being asked to participate in this research study investigating the safety of an intravaginal ring (IVR) containing tenofovir (TDF) and emtricitabine (FTC) and a placebo IVR (an IVR without the TDF-FTC), because your female sexual partner is participating in this study. Your participation in this study is completely voluntary. You may refuse to participate or stop your participation in this research study at any time without penalty or loss of benefits and without jeopardizing your medical care at UTMB.

Before you decide if you want to join this study, we would like to explain the purpose of the study, how it may help you, any risks to you, and what is expected of you.

STUDY SUMMARY:
The following things you should know about this research study:

- The purpose of the study is to determine if intravaginal rings (IVRs) releasing drugs to prevent HIV are safe, where the drug goes in the body, and what you and other men think about the IVR.
- If you choose to participate, you will be asked to come to the Clinical Research Center twice. It will take approximately 2 months to complete all study visits.

- The study visits will involve discussing your experience with the IVR in an interview.
- Risks or discomforts from this research include being uncomfortable with questions during the discussion.
- The study will not directly benefit you.
- Taking part in this research study is voluntary. You do not have to participate and you can stop at any time.
- Please take your time to read this entire form and ask questions before deciding if you want to take part in this research project.

YOUR PARTICIPATION IS VOLUNTARY

This consent form gives you written information about this study, which will also be discussed with you.

Once you read, discuss and understand this study, and if you agree to take part, you will be asked to sign this consent form. You will be offered a copy to keep. Before you agree to participate in this study, it is important that you ask as many questions as possible and know the following:

- Your participation is entirely voluntary;
- You may decide not to take part or to withdraw from this study at any time without losing the benefits of the routine medical care you are otherwise entitled to.

Your physician may also be involved as an investigator in this research study. Before agreeing to participate, or at any time during your study participation, you may discuss your care with another doctor who is not associated with this research study. You are not under any obligation to participate in any research study offered by your physician.

What is the purpose of this research study?

This research study will try to find out if the intravaginal rings (IVRs), which are silicone rings inserted into the vagina designed to provide controlled release of drugs, are safe. In this study, we are investigating IVRs containing the drugs Tenofovir Disproxil Fumarate and Emtricitabine (TDF-FTC) and the placebo (IVR without the TDF-FTC) to see if they are safe and if there are any bad effects when they are used vaginally for 28 days. The second purpose of the study is to see if the study drugs (TDF and FTC) go into the bloodstream and into the vaginal or rectal tissues. Another purpose of this study is to understand how people feel about using these IVRs.

The pill form of TDF and FTC (Truvada®) is approved in the USA by the Food and Drug Administration (FDA) for both the treatment and prevention of human immunodeficiency virus type 1 (HIV-1) infection. **The IVR form of TDF and FTC is "experimental" for HIV-1 prevention. This means we do not know if the IVR will work to protect against HIV-1 infection. The IVR will not prevent other sexually transmitted infections nor will it prevent pregnancy.** In the future, investigators are hopeful that the IVR containing TDF-FTC will be developed to help prevent HIV-1 infection. In order to do this, we need to make sure that the IVR containing TDF-FTC is safe when used this way **and to understand how people feel about using it.**

WHAT DO I HAVE TO DO IF I AM IN THE STUDY?

If you are eligible for the study and decide to participate, including this visit, you will have 2 visits at the UTMB clinic over at about 2 months. During this time, you will complete two video conference interviews with our research partners in Rhode Island to find out about your experience, including what you did and did not like, with the vaginal ring your partner used in this study. The interviewer will be located in Rhode Island and speak to you via videoconference.

Approximately 10 or more men will participate in this study at the University of Texas Medical Branch (UTMB).

PROCEDURES

If you decide to take part in the study, your visit will continue today after you read, discuss, understand, and sign this form. Please, review all the visits described below and ask questions about anything you do not understand.

Both study visits will take approximately 1-2 hours. Each video conference call will take about 45-90 minutes. You will be in the study for about 2 months (depends on when your partner has the vaginal rings in place). The first visit will take place about 1 week after your partner has the first vaginal ring removed. The second visit will take place about 1 week after your partner has the second vaginal ring removed.

You will participate in an audio-taped videoconference call with a member of the study staff to discuss what your experiences were like while your partner was using the IVR.

POTENTIAL RISKS AND DISCOMFORTS

This section describes the risks and/or discomforts of participating in the study.

Risks from Videoconference Calls:
There may be discomfort or embarrassment related to questions dealing with sexual behaviors and personal habits. If some of the questions upset you or make you uncomfortable, you may choose not to answer them.

Risks of Loss of Confidentiality:
Any time information is collected there is a potential risk for loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed.

Risks of Social Harm:
It is possible that your participation may cause problems at your job related to time taken for study visits. It is possible that your involvement in the study could become known to others, and that you may experience stigmatization or discrimination as a result of being perceived as being HIV-infected or at risk for HIV infection. For example, you could be treated unfairly, or could have problems being accepted by your family and/or communities.

This research study may involve risks that are currently unforeseeable.

WHAT ARE THE BENEFITS?
You may get no direct benefit from being in this study.

You or others may benefit in the future from information learned in this study. You may also get some personal satisfaction from being part of research on HIV prevention.

WHAT TREATMENTS OR PROCEDURES ARE AVAILABLE IF I DECIDE NOT TO TAKE PART IN THIS RESEARCH STUDY?
Not applicable

WHAT ARE THE COSTS TO ME?
There is no cost to you for the participating in the videoconference calls.

WILL I RECEIVE ANY PAYMENT?
You will be compensated for your time and effort for your scheduled study visits as follows:

- You will receive $50 for each of the 2 study visits that you complete
- A parking voucher will be provided for each of the 2 study visits that you complete

In total, you may receive up to $100 for your participation in this research study.

You will be issued a UTMB Clincard, which is a debit card that your funds are loaded onto following completion of the screening visit. When a study visit is completed, funds will be approved and loaded onto your card. The funds will be available within 48 hours and can be used at your discretion. You will be issued one card for the duration of your participation. If your card is lost or stolen, you can contact customer service at 1-866-952-3795. We will collect some information about you, including name, address, telephone number, date of birth, email address, if applicable, and your social security number (if a US citizen) in order to issue the debit card. All information is stored in a secure fashion and will be kept confidential. You will also receive a parking token at the end of each visit if needed.

WHAT HAPPENS IF I AM INJURED (EXPERIENCE HARM)?
It is important that you report any illness or injury to the research team listed at the top of this form immediately. Compensation for an injury resulting from your participation in this research is not available from the University of Texas Medical Branch at Galveston. If you are physically injured because of any substance given to you or procedure properly performed on you under the plan for this study, your injury will be treated. You or your insurance company or health care plan, will be billed and you will be responsible for any charges. You will be responsible for paying any costs related to illnesses and medical events not associated with being in this study. There are no plans to provide other forms of compensation. However, you are not waiving any of your legal rights by participating in this study. Questions about compensation may be directed to the study doctor. The U.S. National Institutes of Health (NIH) does not have a program to pay money or give other forms of compensation for injuries.

WHAT ABOUT PRIVACY AND CONFIDENTIALITY? HOW WILL MY PRIVACY BE PROTECTED?

Study records that identify you will be kept confidential as required by law. Federal privacy regulations provided under the Health Insurance Portability and Accountability Act (HIPAA) provides safeguards for privacy, security, and authorized access of your records. These regulations require UTMB to obtain an authorization from you for the use and disclosure of your health information. By signing this consent form, you are authorizing the use and disclosure of your health information for the purpose of completing the research study. Except when required by law, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier in study records disclosed outside of the University of Texas Medical Branch (UTMB). For records disclosed outside of UTMB, you will be assigned a unique code number. The key to the code will be kept in a locked file in Dr. Kathleen Vincent's office.

As part of the study, Dr. Kathleen Vincent and her study team will report the results of your study-related questionnaires and interviews to the following recipients: FDA, National Institutes of Health, and Oak Crest Institute of Science. The sponsor of this study may further disclose this information to regulatory agencies or other recipients. While the sponsor and other recipients may understand the importance of protecting the confidentiality of your information, UTMB cannot guarantee the confidentiality of your information or protect from further disclosures once these recipients receive your information.

If you sign this form, you are giving us permission to collect, use and share your study-related questionnaires and interviews. You do not need to sign this form. If you decide not to sign this form, you cannot be in the research study. We cannot do the research if we cannot collect, use and share your study-related questionnaires and interviews. Whether or not you agree to the research project or give us permission to collect, use or share your study-related questionnaires and interviews will not affect the care you will be given at UTMB. Dr. Kathleen Vincent will use and disclose your study related information to complete the research study. These would include study-related questionnaires and interviews. The results of the study-related questionnaires and interviews will NOT be recorded in your medical record. All of the above results may be reported to Oak Crest Institute of Science, National Institutes of Health, and/or the FDA. Additionally, the results of this study may be compared to results obtained in other studies that you may have participated in with Dr. Vincent's team.

Your records may be reviewed in order to meet federal or state regulations. Reviewers may include, for example, representatives of Oak Crest Institute of Science, the Food and Drug Administration, UTMB, UTMB IRB, and the National Institutes of Health. This authorization for the use and disclosure of your study-related questionnaires and interviews as described above expires upon the conclusion of the research study except for FDA regulated studies. This study is an FDA regulated study and for FDA regulated studies, the study sponsor and government agencies, such as the FDA may review your study records after the study ends.

If you change your mind later and do not want us to collect or share your study-related questionnaires and interviews, you need to contact the researcher listed on this consent form by telephone. You need to say that you have changed your mind and do not want the researcher to

collect and share your study-related questionnaires and interviews. You may also need to leave the research study if we cannot collect any more health information. We may still use the information we have already collected. We need to know what happens to everyone who starts a research study, not just those people who stay in it. The results of this study may be published in scientific journals without identifying you by name.

This study is being conducted according to ethical guidelines. Efforts will be made to keep your personal information private. Only your study ID, **NO** personal identifiers (e.g., your name, address, date of birth, social security number), will be collected as part of the questions you will answer by video conference call. Videoconference calls will be conducted in private via a secure connection and audiotaped; no video will be recorded. You should NOT identify anyone during the videoconference calls. The audio files will be transcribed (put in writing) by the person interviewing you or by another person who does not know you and does not have your identifying information. All records, including audiotapes, will be kept in a secure, double locked location and only study staff will have access to the records. The audio recordings will be destroyed at the end of the study.

We have rules to protect information about you. Federal and state laws and the federal medical Privacy Rule also protect your privacy. By signing this form, you provide your permission, called your "authorization," for the use and disclosure of information protected by the Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and information from your medical records. This could include information about HIV and genetic testing, or treatment for drug or alcohol abuse or mental health problems.

The research team will know your identity and that you are in the research study. Other people at UTMB, particularly your doctors, may also see or give out your information. We make this information available to your doctors for your safety. If you think this study might affect your clinical care, please inform your doctor.

People outside of UTMB may need to see or receive your information for this study. This study will be reviewed periodically to monitor its conduct. Therefore, as mentioned above, your records may be reviewed by government agencies and the groups listed below as part of routine audits:

- US National Institutes of Health (NIH)
- Food and Drug Administration (FDA)
- Office for Human Research Protections (OHRP)
- Oak Crest Institute of Science (OCIS)
- University of Texas Medical Branch Institutional Review Board (an IRB is a committee of volunteers who are responsible for protecting the rights and welfare of research participants)

- Study staff
- Study monitors including members of data safety monitoring boards

We cannot do this study without your authorization (permission) to use and give out your information. You do not have to give us this authorization. If you do not, then you may not join this study.

We will use and disclose your information only as described in this form; however, people outside UTMB who receive your information may not be covered by this promise or by the federal Privacy Rule. We try to make sure that everyone who needs to see your information keeps it confidential – but we cannot guarantee that your information will not be re-disclosed.

The use and disclosure of your information has no time limit. You may revoke (cancel) your permission to use and disclose your information at any time by notifying the Principal Investigator of this study by phone or in writing. If you contact the Principal Investigator by phone, you must follow-up with a written request that includes the study number and your contact information. The Principal Investigator's name, address, phone and information are on page one of this consent form.

If you do cancel your authorization to use and disclose your information, your part in this study will end and no further information about you will be collected. Your revocation (cancellation) would not affect information already collected in the study, or information we disclosed before you wrote to the Principal Investigator to cancel your authorization.

Finally, please specifically authorize the use of your private health information relating substance abuse, psychiatric information, or HIV/AIDS, if applicable, for the above-described purposes.

Initial: _____

Certificate of Confidentiality: To help us further protect your privacy, the investigators have obtained a Confidentiality Certificate from the National Institutes of Health (NIH) a branch of the Department of Health and Human Services (DHHS).

With this Certificate, the investigators cannot be forced (for example by court subpoena) to disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings. Disclosure will be necessary, however, upon request of DHHS for audit or program evaluation purposes.

You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. Note however, that if an insurer or employer learns about your participation, and obtains your consent to receive research information, then the investigator may not use the Certificate of Confidentiality to withhold this information. This means that you and your family must also actively protect your own privacy.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

A description of this clinical trial will be available on www.clinicaltrials.gov, as required by US 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 any time.

WHAT ARE MY RIGHTS AS A RESEARCH PARTICIPANT?

Taking part in this study is completely voluntary. You may choose not to participate in this study at any time. You will be treated the same no matter what you decide.

We will tell you about new information from this or other studies that may affect your health, welfare or willingness to stay in this study. If you want the results of the study, please let study staff know.

WHY MIGHT I BE WITHDRAWN FROM THE STUDY WITHOUT MY CONSENT?

You may be withdrawn from the study without your consent for the following reasons:

- The study is cancelled by the NIH, OCIS, IRB, FDA, OHRP, or the local government or regulatory agency
- Study staff believes that participating in this study would cause injury that could be harmful to you.
- You are not able to complete the videoconference calls.
- Other reasons that may prevent you from completing the study.

If you are withdrawn early from the study, any identifiable research or medical record information recorded for, or resulting from, your participation in this study prior to the date that you were formally withdrawn from the study without your consent may continue to be used and disclosed by the investigators for the purposes described above.

MAY I WITHDRAW, AT A FUTURE DATE, MY CONSENT FOR PARTICIPATION IN THE STUDY?

You can, at any time withdraw from this study. You can also withdraw your authorization for us to use your identifiable medical information for the purposes described above. This means that you will also be withdrawn from further participation in this research study. Any identifiable research or medical information obtained as part of this study prior to the date that you withdrew your consent will continue to be used and disclosed by the investigators for the purposes described above.

To formally withdraw from this study, you should provide a written and dated notice of this decision to the principal investigator of this research study at the address listed on the first page of this form. Your decision to withdraw from this study will have no effect on your current or future relationship with the University of Texas Medical Branch, on your current or future medical care at a UTMB hospital or affiliated health care provider or your current or future relationship with a health care insurance provider.

WHO CAN I CONTACT WITH QUESTIONS ABOUT THIS RESEARCH STUDY?

If you have any questions, concerns or complaints before, during or after the research study, or if you need to report a research related injury or bad side effect, you should immediately contact Dr. Kathleen L. Vincent at 409-772-2610 or, if after normal office hours the study coordinator Lauren Dawson at 409-354-9792.

This study has been approved by the Institutional Review Board. If you have any complaints, concerns, input or questions regarding your rights as a subject participating in this research study or you would like more information about the protection of human subjects in research, you may contact the Institutional Review Board Office, at (409) 266-9400 or irb@utmb.edu.

****

VOLUNTARY CONSENT: The purpose of this research study, procedures to be followed, risks and benefits have been explained to me and I was given the opportunity to ask questions, and all of my current questions have been answered to my satisfaction. I have been told who to contact if I have additional questions and I understand that I am encouraged to ask questions about any aspect of this research study during the course of this study, and that such future questions will be answered by the researchers listed on the first page of this form. Any questions which I have about my rights as a research participant will be answered by the University of Texas Medical Branch Institutional Review Board Office at (409) 266-9475. By signing this form, I am confirming that I have read this consent form and I voluntarily agree to participate as a subject in this research study. A copy of this consent form will be offered to me.

_____
Participant's Printed Name

_____ _____
Participant's Signature Date and Time

CERTIFICATION OF INFORMED CONSENT: I certify that I have explained the nature and purpose of this research study using language that is understandable and appropriate to the above-named individual, and I have discussed the project, potential benefits, and possible risks of study participation. Any questions the individual has about this study have been answered, and we will always be available to address future questions as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

_____
Printed Name of Person Obtaining Consent

_____ _____
Signature of Person Obtaining Consent Date and Time