RUTGERS
New Jersey Medical School
RESEARCH WITH A HEART

Rutgers, The State University of New Jersey
Ambulatory Care Center
140 Bergen Street, D-Level
Newark, NJ 07103

May 1, 2023

RE: Cover Letter for ClinicalTrials.gov NCT 03058835 (Swaminathan)

This cover letter accompanies the most recent Informed Consent for this trial NCT 03058835 (Swaminathan). Please note that this study closed to enrollment before the study expiration date of the IRB stamped ICF.

Study Title: IN-US-276-1340 : Pre-Exposure Prophylaxis to Prevent HIV Acquisition in US Women: A Demonstration Project

Document Attached:

- **IN-US-276-1340 ICF V 3.0, dated 13Dec2016**

Sincerely,

Shobha Swaminathan, MD
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Division of Infectious Diseases
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Rutgers, The State University Of New Jersey
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RUTGERS
New Jersey Medical School
Department of Medicine

CONSENT TO TAKE PART IN A RESEARCH STUDY

TITLE OF STUDY: IN-US-276-1340: Pre-Exposure Prophylaxis to Prevent HIV Acquisition in US Women: A Demonstration Project

SHORT TITLE OF STUDY: IN-US-276-1340

SPONSOR: Rutgers.

NAME OF VOLUNTEER:_____

WHAT IS PrEP?

PrEP (pre-exposure prophylaxis) is a new treatment available for women who do NOT have HIV that will reduce the risk of getting HIV from an infected partner. PrEP is a pill that must be taken every day and should be used along with condoms and other safer sex practices. PrEP as a pill has been approved by the US food and Drug Administration since July 2012.

This study is sponsored by Rutgers. The doctor in charge of this study at this site is: Shobha Swaminathan, MD. Before you decide if you want to be a part of this study, we want you to know about the study.

This is a consent form. It gives you information about this study. The study staff will talk with you about this information. You are free to ask questions about this study at any time. If you agree to take part in this study, you will be asked to sign this consent form. You will get a copy to keep.

WHY IS THIS STUDY BEING DONE?

WHO MAY TAKE PART IN THE STUDY? AND WHO MAY NOT?

In order to take part in this study you must:

- Be able to sign this consent form
- Be born female
- Be between 18 and 64 years old and HIV negative
- Be “at risk” for HIV, such as having unprotected sex with a man with either known HIV infection or unknown HIV status, planning to continue to have sex with men of known or unknown HIV status, having sex with a known HIV partner, having sex while high,

previously using or sharing drugs or being in a drug treatment program, engaging in sex for money or drugs or housing, or feeling at risk for having HIV
- Not be pregnant or breastfeeding, not trying to become pregnant
- Not have positive hepatitis B infection (by blood test)
- Have normal kidney blood test

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

If you decide to take part in this research study, you will be asked to sign this consent form and will be scheduled for a screening visit to determine if you can join the study. If you enter the study, you will have laboratory testing and a medical visit and a physical exam. You will then be followed in the clinic with blood tests and medical history and physical exams while you are on PrEP for 24 weeks. You will be seen in the clinic about 5 times.

Before you join the study, study personnel will explain the study to you and informed consent will be obtained. This is called the Screening Visit. At the Screening Visit, you will have a short medical history and a physical exam. We will ask you to complete a 47 question survey that will ask you what you know about PrEP and how interested you might be in taking PrEP. The survey will also ask questions on sexual activity and drug use. The survey will take about 30 minutes to complete. Blood testing for HIV and other sexually transmitted diseases, such as syphilis, chlamydia, gonorrhea, will be performed at this visit. We will draw about 2 tablespoons (28 mL) of blood. You will receive safer sex and risk reduction counseling for HIV and other sexually transmitted diseases. Blood will also be collected to check your kidney function and pregnancy and hepatitis B status. All participants will receive male and female condoms. This visit will take about 2 to 2 and a half hours.

If you qualify and enter the study, we will enroll you within 30 days of your screening visit. This visit is called the Enrollment Visit. During the Enrollment Visit, you will be given a prescription to start truvada PrEP and be given instructions on its use. If you are unable to obtain truvada PrEP through your prescription insurance, we will assist you in obtaining truvada through the Gilead Sciences web-based program. At the Enrollment Visit we will update your history and perform a physical exam. We will also obtain blood for HIV and pregnancy testing, and perform risk reduction counseling for HIV and other sexually transmitted diseases. We will draw about 2 teaspoons (9 mL) of blood for blood tests. All participants will receive male and female condoms. This visit will take about 1 and a half to 2 hours.

About 4 weeks after you enroll in the study, you will have a follow-up study visit.
We will perform a history and physical exam and ask about new symptoms and/or illnesses since your last visit. We will draw about 3 teaspoons (16 mL) of blood for blood tests. You will receive risk reduction counseling for HIV and other sexually transmitted diseases, and receive male and female condoms. This visit will take about 1 and a half to 2 hours.

About 12 weeks after the enrollment visit, you will return for another follow-up study visit. Again, we will perform a history and physical exam on you and ask about new symptoms and/or illnesses since your last visit. We will ask you to answer a follow-up 40 question survey that will ask you about your attitudes in taking PrEP daily and being in the study. The survey will also ask questions on sexual activity and drug use. The survey will take about 20 minutes to

complete. We will obtain blood to test for kidney function, drug levels for tenofovir, and perform HIV and pregnancy testing. We will draw about 5 teaspoons (25 mL) of blood for testing. You will receive risk reduction counseling for HIV and other sexually transmitted diseases, and receive male and female condoms. This visit will take about 1 and a half to 2 hours.

About 24 weeks after the enrollment visit, you will return for your final follow-up study visit. Again, we will perform a history and physical exam on you and ask about new symptoms and/or illnesses since your last visit. We will ask you to answer the same follow-up 40 question survey that asks you about your attitudes in taking PrEP daily and being in the study. The survey will also ask questions on sexual activity and drug use. The survey will take about 20 minutes to complete. We will obtain blood to test for kidney function, drug levels for tenofovir, and perform HIV and pregnancy testing, and testing for other sexually transmitted diseases (syphilis, gonorrhea, and chlamydia). We will draw about 4 teaspoon (21 mL) of blood for testing. You will receive risk reduction counseling for HIV and other sexually transmitted diseases, and receive male and female condoms. This visit will take about 1 and a half to 2 hours. At the final study visit we will also help you receive continued PrEP if you desire and help coordinate follow-up care at our clinic.

It is possible participants may have additional contact with the study staff by phone or by visits at the clinic other than the regularly scheduled follow up visits, if this is requested by study participants or if it is deemed necessary by the investigator at any time during the study.

Once you are enrolled in the study, we expect you will make every effort to follow through with the study for the entire 24 week follow-up period. We will collect detailed locator information at all visits.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

Study wide about 124 women will take part in this study. At this site about 50 women will take part in this study

HOW LONG WILL I BE IN THIS STUDY?

You will be in this study for about 24 weeks (6 months).

WHY WOULD THE DOCTOR TAKE ME OFF THIS STUDY EARLY?

The study doctor may need to take you off the study early without your permission if:

- The study is stopped or canceled by the sponsor government or regulatory authorities (including Office for Human Research Protections [OHRP] and the FDA or site IRBs terminate the study prior to its planned end date
- To protect your safety or if you develop severe side effects to PrEP
- You are unwilling or unable to comply with the study requirements
- You become pregnant or are breastfeeding
- You become HIV positive

If you must stop taking the study drug before the study is over, the study doctor will ask you to continue to be part of the study and return for some study visits and procedures.

WHAT ARE THE RISKS OF THE STUDY

You will be taking the PrEP pill truvada which is a combination of 2 drugs: 300 mg of Viread (tenofovir DF) and 200 mg of Emtriva (FTC). Some people in clinical studies of PrEP had early side effects such as upset stomach or loss of appetite, but these were usually mild and usually went away in the first month. Some people also had a mild headache. Some other side effects are listed below. Please note that this list does not include all the side effects seen with PrEP. It is very important that you tell your study doctor of any changes in your medical condition while taking part in the study. At any time during the study, if you believe you are experiencing any of these side effects, you have the right to ask questions on possible and /or known risks.

The following side effects have been associated with the use of tenofovir component of truvada (Tenofovir DF, TDF, Viread®):

- Upset stomach, vomiting, gas, loose or watery stools
- Generalized weakness
- Dizziness
- Depression
- Headache
- Abdominal pain
- Worsening or new kidney damage or failure
- Inflammation or swelling and possible damage to the pancreas and liver
- Shortness of breath
- Rash
- Allergic reaction: symptoms may include fever, rash, upset stomach, vomiting, loose or watery stools, abdominal pain, achiness, shortness of breath, a general feeling of illness or a potentially serious swelling of the face, lips, and/or tongue
- Bone pain and bone changes such as thinning and softening which may increase the risk of breakage
- Muscle pain and muscle weakness

The following side effects have been associated with the use of emtricitabine component of truvada ((FTC, **Emtriva®***)*:

- Headache
- Dizziness
- Tiredness
- Inability to sleep, unusual dreams
- Loose or watery stools
- Upset stomach (nausea) or vomiting
- Abdominal pain
- Rash, itching, which sometimes can be a sign of an allergic reaction
- Skin darkening of the palms and/or soles
- Increased cough
- Runny nose

- Abnormal liver function tests, which could mean liver damage
- Increases in pancreatic enzyme (substances in the blood), which could mean a problem
- with the pancreas
- Increased triglycerides
- Increased creatine phosphokinase (CPK), which could mean muscle damage

Truvada is a pregnancy category Drug B medication, which means that animal studies have failed to demonstrate a risk to the fetus, but there are no adequate studies in pregnant women. If you become pregnant while on PrEP in this study, you will be withdrawn from the study and referred for pre-natal care.

Other risks of participating in the study include risks associated with blood draw. Taking blood may cause some discomfort, bleeding, bruising and/or swelling where the needle enters the body and in rare cases it may result in fainting. There is a small risk of infection.

Additionally, some women may be embarrassed by the personal nature in answering some of the survey questions. You may choose not to answer any question you do not feel comfortable with.

ARE THERE BENEFITS TO TAKING PART IN THIS STUDY?

You will be monitored while you are taking PrEP. Your participation will also help us better understand how women feel about taking PrEP in order to prevent getting HIV, and how receptive they are to taking PrEP. The answers will help us design ways to better give PrEP to women.

WHAT OTHER CHOICES DO I HAVE BESIDES THIS STUDY?

Instead of being in this study you have the option of preventing getting HIV by other prevention options such as condoms or enrolling in other clinical trials looking at other methods of PrEP given as shots.

Please talk to your doctor about these and other choices available to you. Your doctor will explain the risks and benefits of these choices.

WHAT ABOUT CONFIDENTIALITY?

We will do everything we can to protect your privacy. People who may review your records include the Office for Human Research Protections (OHRP) or other government agencies as part of their duties, Food and Drug Administration *(*FDA), Rutgers Health Sciences IRB- Newark campus (a group that protects the rights and well-being of people in research), study staff, study monitors, Gilead Sciences Inc.(the drug company supporting this study), and their designees. The study staff must comply with all local requirements to report communicable diseases and any other reportable condition(s). This means that if you test positive for HIV we will have to report this information to New Jersey Department of Health. The report ***will*** include your name.

If you test positive for HIV during the study, study staff will also inform Gilead Sciences and include de-identified information about you but this information will not contain your name.

If you become pregnant after joining the study your pregnancy will be registered in the Antiretroviral Pregnancy Registry. This registry does not include any identifiers, so none of your personal information will be provided. You can learn more about this registry at www.apregistry.com. Information about your pregnancy will also be provided to Gilead Sciences without identifying information. You will be followed for outcome of your pregnancy, this information is needed for the pregnancy registry. However, it will not contain your name or personal identifiable information.

WHAT WILL HAPPENS IF I TEST HIV POSITIVE DURING THE STUDY?
If you test positive for HIV during the study, we will do additional HIV blood testing as part of standard of care and refer you immediately for treatment and care. You will no longer participate in the study and will no longer take PrEP. The study staff will also inform Gilead Sciences Inc, but the information we provide to Gilead Sciences will not include your name or other identifying information.

WHAT HAPPENS IF YOU BECOME PREGNANT DURING THE STUDY?
Your participation in the study will end if you become pregnant, and you will be referred for prenatal care. As mentioned above, if you become pregnant during the study, you will be registered in the Antiretroviral Pregnancy Registry. The registry will not include your name or any personal identifiers. Information about your pregnancy will also be provided to Gilead Sciences without identifying information. You will be followed for the outcome of your pregnancy.

WHAT ARE THE COSTS TO ME?

There will be no direct cost to you for, study-related visits, physical examinations, laboratory tests, or other study procedures. The truvada PrEP pill will either be provided by your medical insurance (you may have a small co-pay but we will help you obtain a co-pay card to cover the cost if your insurance allows this) or we will help you obtain it through Gilead's web-based patient Medication Assistance Program. If you do not have insurance, you will have to apply for insurance or for charity care. We will provide you with maximum assistance to applying for charity care or Medicaid, but you may be responsible for non-study related laboratory and clinical costs if you are deemed to not be eligible for the same.

WILL I RECEIVE ANY PAYMENT?

You will be given $50 for the screening visit, $25 for the enrollment visit, $25 for the first follow-up visit, $50 for the 2nd follow-up visit at 12 weeks, and $50 for the final follow-up visit at 24 weeks for completing laboratory and medical testing and completing surveys.

You will receive a referral stipend of $20.00 for each participant you refer for this study who completes a screening visit.

You will also receive a stipend if you complete locator information on how to best contact or locate you at week 16 and 20. You may either provide this information by phone OR in person and will receive $10 per for each of these locator encounters.

WHAT HAPPENS IF I AM INJURED?

Participants in this study will be exposed to certain risks of personal injury in addition to those associated with standard forms of treatment (see sections above regarding the study risks). It is also possible that during the course of this study, new adverse effects of the study drugs that result in personal injury may be discovered. The University will make appropriate referrals for medical and/or dental treatment for participants who sustain personal injuries or illnesses as a direct consequence of participation in the research. The participant's health insurance carrier or other third-party payer will be billed for the cost of this treatment; provided that the University shall not submit to federally funded programs, e.g., Medicare, Medicaid or CHAMPUS, for reimbursement first if submission to such programs is prohibited by law. No financial compensation will be provided by the University and no other type of assistance is available from the University.

WHAT ARE MY RIGHTS AS A RESEARCH PARTICIPANT?

Taking part in this study is completely voluntary. You may choose not to take part in this study or leave this study at any time. Your decision will not have any impact on your participation in other studies conducted by the university and will not result in any penalty or loss of benefits to which you are otherwise entitled.

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, let the study staff know.

WHAT DO I DO IF I HAVE QUESTIONS OR PROBLEMS?

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

Shobha Swaminathan, MD
Rutgers New Jersey Medical School
Department of Medicine
973-972-1057

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

Rutgers Health Sciences IRB- Newark Campus Director: 973-972-3608

AUTHORIZATION TO USE YOUR HEALTH INFORMATION FOR RESEARCH PURPOSES

Because information about you and your health is personal and private, it generally cannot be used in this research study without your written authorization. If you sign this form, it will provide

that authorization. The form is intended to inform you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law. Please read it carefully before signing it.

What is the purpose of this research study and how will my health information be utilized in the study?
The purpose of this research study is to see how well women accept PrEP in preventing their risk of getting HIV. The information will help us decide how to better give PrEP to women who want to prevent getting HIV.

Do I have to sign this authorization form?

You do not have to sign this authorization form. But if you do not, you will not be able to participate in this research study or receive research-related treatment. Signing the form is not a condition for receiving any medical care outside the study.

If I sign, can I revoke it or withdraw from the research later?

If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your health information (and to discontinue any other participation in the study) at any time. After any revocation, your health information will no longer be used or disclosed in the study, except to the extent that the law allows us to continue using your information (e.g., necessary to maintain integrity of research). If you wish to revoke your authorization for the research use or disclosure of your health information in this study, you must contact:

Shobha Swaminathan, MD
Rutgers- New Jersey Medical School
Department of Medicine, I-609D, 185 S. Orange Ave.
Newark, NJ 07103
973-972-1057

What personal information will be used or disclosed?

Your health information related to this study may be used or disclosed in connection with this research study, including, but not limited to, information in a medical record, certain information indicating or relating to a your medical condition, physical examinations, etc.

Who may use or disclose the information?

The following parties are authorized to use and/ or disclose your health information in connection with this research study:

Office for Human Research Protections (OHRP) or other government agencies as part of their duties, Food and Drug Administration *(*FDA), Rutgers Health Sciences IRB- Newark campus IRB (a group that protects the rights and well-being of people in research), study staff, study monitors, Gilead Sciences Inc., the drug company supporting this study, and their designees.

Who may receive or use the information?

The parties listed in the preceding paragraph may disclose your health information to the following to persons and organizations for their use in connection with this research study: Office for Human Research Protections (OHRP) or other government agencies as part of their duties, Food and Drug Administration *(*FDA), Rutgers Health Sciences IRB- Newark campus IRB (a group that protects the rights and well-being of people in research), study staff, study monitors, Gilead Sciences Inc., the drug company supporting this study, and their designees.

Your information may be re-disclosed by the recipients described above, if they are not required by law to protect the privacy of the information.

When will my authorization expire?

Your authorization for the use and /or disclosure of your health information does not have an expiration date.

Will access to my medical record be limited during the study?

To maintain the integrity of this research study, you may not have access to any health information developed as part of this study until it is completed. At that point, you would have access to such health information if it were used to make medical or billing decision about you and was included in your official medical record.

Signature of Participant:

I have read this entire form, or it has been read to me, and I understand it completely. All of my questions regarding this form or this study have been answered to my complete satisfaction. I agree to participate in this research study.

Participant:

_____ _____ _____
Name (typed or printed) Signature Date

Witness: (if applicable)

_____ _____ _____
Name (typed or printed) Signature Date

Signature of reader/translator if participant does not read English well:

The person, who has signed above, _____, does not read English well. I read English well and am fluent in (name of the language) _____, a language the participant understands well. I have

translated for the participant the entire content of this form. To the best of my knowledge, the participant understands the content of this form and has had an opportunity to ask questions regarding the consent form and the study, and these questions have been answered to the complete satisfaction of the participant.

Reader/Translator:

_____	_____	_____
Name (typed or printed)	Signature	Date

Witness: (if applicable)

_____	_____	_____
Name (typed or printed)	Signature	Date

Signature of Investigator/Individual Obtaining Consent:

To the best of my ability, I have explained and discussed the full contents of the study including all of the information contained in this consent form. All questions of the research participant have been accurately answered.

Investigator/Person Obtaining Consent:_____

Signature:_____ Date: _____