

**UNIVERSITY OF CALIFORNIA - SAN DIEGO (UCSD)
CONSENT TO ACT AS A RESEARCH SUBJECT**

**CCTG 603: Randomized Controlled Trial of iTAB plus Motivational Interviewing for PrEP
Adherence in Transgender Individuals (The iM-PrEPT Study)**

Drs. Sheldon Morris, Jill Blumenthal, Joel Trambley, Robert Bolan, and their associates are conducting a research study sponsored by the California HIV Research Program (CHRP) to determine if using text messages and adherence-driven brief motivational interviewing can improve retention and adherence to Pre-exposure Prophylaxis (PrEP) in HIV-negative self-identifying transgender or gender non-conforming individuals who are at risk for HIV acquisition.

Before you can decide whether or not to volunteer for this study, we would like to let you know about the study's purpose, how it may or may not help you, any risks to you, and what is expected of you. This process is called informed consent.

The FDA approved a fixed dose combination of tenofovir disoproxil fumarate/emtricitabine (TDF/FTC) to reduce the risk of HIV infection in uninfected individuals who are at high risk of HIV infection and who may engage in sexual activity with HIV-infected partners. From other studies, we know that the use of PrEP in HIV negative individuals has been shown to reduce acquisition of HIV among at-risk individuals. We also know that the more a person takes the PrEP medication (called adherence), the more effective it is. However, these studies mainly included men who have sex with men (MSM); PrEP data in transgender populations is limited.

The purpose of this study is to evaluate a method of reinforcing PrEP adherence using text message reminders (iTAB) and brief motivational interviewing (MI-b). In this study, we hope to learn if motivational interviewing with text messaging can improve PrEP adherence in transgender individuals.

You have been asked to participate in this study because:

- You self-identify with a gender different from the sex assigned to you at birth
- You are HIV-negative.

Research studies are voluntary and include only people who choose to take part. Please take your time about deciding whether to participate in this study. Before deciding:

- You can discuss this study with friends and family.
- You can also discuss it with your health care provider or request a second opinion.
- If you have any questions, you can ask the researchers for more information before deciding to participate.

DURATION OF THE STUDY:

The study will enroll 300 people at all participating sites in San Diego and Los Angeles Counties. If you participate in the study, you will have approximately 7 visits at either the UCSD AntiViral Research Center (AVRC), the Family Health *Centers* of San Diego (FHCS), or at the LA Lesbian, Gay, Bisexual, and Transgender (LGBT) Center over approximately 1 year and a phone call follow-up 3 months after you complete the study. We plan to enroll up to 100 subjects in San Diego and up to 100 at the LALGBT Center.

Approximately 360 mL (24 tablespoons) of blood will be drawn across 6 scheduled study visits over 48 weeks. An additional 60 mL (4 tablespoons) will be drawn for each additional, unscheduled visit.

PROCEDURES

If you agree to participate in this study, the following will happen:

Screening Visit (this visit will take approximately 1-2 hours):

To see if it is okay for you to participate in this study, you will first come to the clinic for a study visit known as a “screening” visit. At your first visit, this consent form will be reviewed with you and you will be asked to sign it.

At your screening visit, the following procedures will be performed:

- You will be asked to provide contact information so we can contact you.
- A medical and medication history will be taken.
- A targeted physical exam will be performed.
- Samples will be obtained for the below tests. If available, we can use some laboratory results obtained as part of your regular care to avoid repeating tests.
 - A urine sample and approximately 3-4 tablespoons of blood will be drawn for laboratory tests including HIV testing, Hepatitis B screening, and a kidney function tests
 - If applicable, we will use the urine sample for a pregnancy test and ask you about your intention to become pregnant and your contraception use.
- We will ask you to complete confidential questionnaires on a computer-based system. You will have privacy when completing these questionnaires. We will ask you questions about taking PrEP, beliefs about PrEP, willingness to take PrEP, HIV knowledge, sexual behaviors and risks, your partners’ sexual behaviors, and healthcare in a private location so no one can see your answers.

Entry Visit (this study visit will take about 2 hours):

The information gathered at your screening study visit will determine if you are able to take part

in this study. If you qualify for the study, you will return to the clinic for your “entry visit” or “Baseline”. At your entry visit, you will have the following procedures done:

- A medical and medication history will be taken. This will include any recent or previous drug history and anti-HIV drugs you have taken.
- A targeted physical exam will be performed.
- Samples will be obtained for the following tests:
 - A urine sample and approximately 3-4 tablespoons of blood will be drawn for laboratory tests including complete blood count, chemistry values, liver function tests, and HIV screening.
 - If applicable, we will use the urine sample for a pregnancy test and ask you about your intention to become pregnant and contraception use.
 - If you are already on PrEP at this visit, some of the blood collected will be stored and used to test the amount of PrEP drug level in your cells at a later date.
 - Some of the blood collected will be stored and used to test the amount of hormone levels in your plasma at a later date, if you consent to the sub-study.
 - Some blood and urine samples will be stored for future study-related tests, if you consent.
 - Screening for sexually transmitted infections (STIs). In addition to the urine and blood sample, a throat and rectal swab will need to be done in order to screen for STIs. These collected samples and swabs will be tested to see if you have gonorrhea, chlamydia, or syphilis. These samples will be taken at entry and every 6 months after your entry visit.
 - The test in your throat and rectum will be self-swabbed by carefully inserting a cotton swab (Q-tip) and gently turning it to collect the sample. You may request that a medical provider perform the swab, if you prefer.
- You may choose to screen for genital STIs using a genital swab instead of urine. Tell your study coordinator if you choose this. You will still need to give a urine sample to test for other labs.
- Two additional rectal swabs will be collected for future studies.
 - If your tests show that you have an STI, our study staff will refer you to your medical provider for treatment. If you do not have a provider, you will be referred to the public health clinic where treatment will be provided at a small fee or free to those who cannot afford this fee. According to California state law, study staff are required to give the public health department the names, contact information and treatment records of people who have a positive test result for HIV, chlamydia, gonorrhea, or syphilis.

- We will ask you to complete confidential questionnaires on a computer-based system. You will have privacy when completing these questionnaires. We will ask you questions about taking medications, substance use, mood, social support, technology use, sexual behaviors and risks, and your partners' behaviors.

PrEP is a fixed-dose combination of two medications, tenofovir and emtricitabine (TDF/FTC, Truvada), in one pill. The study staff will give you detailed information about how to take TDF/FTC and its potential side effects. You will be provided with enough PrEP at this visit to last until your next visit. The study staff will also provide risk reduction and adherence counseling.

At the entry visit, you will also be introduced to the iTAB (Individualized Texting for Adherence Building) system by a study staff member who will help you select and refine 15 personal text message reminders from a list of reminders that you will receive on your cell phone. The study staff will help you to set adherence reminders that are sent at times consistent with when you plan to typically take PrEP. You will be provided with information about how the iTAB texting system works. If you do not have a cell phone, we will help you to obtain one for the purposes of the study. If you are unable to obtain your own cell phone, you will be provided with one at this time at no cost to use during your participation in this study.

At this entry visit, you will also be randomized (assigned by chance, like flipping a coin) into one of two groups. You have an equal chance of being assigned to either group.

- Group 1: PrEP daily, HIV / STI screening, adherence and risk behavior counseling and safety monitoring
- Group 2: PrEP daily, HIV / STI screening, adherence and risk behavior counseling, and safety monitoring as well as brief motivational interviewing (MI-b).

If you are randomized into the group with motivational interviewing, the study staff will introduce you to MI-b. Motivational interviewing is a widely accepted technique that helps patients think about their motivations and strengths, and to use those to change their behavior. If you miss your PrEP doses an MI-B counselor will call you. The counselor will call you and talk with you about things happening in your life that make it hard to stay adherent, and to help brainstorm ideas to improve adherence that works best for your situation. These sessions last about 15 minutes.

Same-Day PrEP (this study visit will take about 3 hours):

You may choose to combine your Screening and Entry visits into one visit and start PrEP on the same day. The information gathered at this visit will determine if you are able to take part in this study, but we'll also make certain assumptions about your health. We'll confirm our assumptions with the laboratory results we'll receive after you complete the visit. If we find that it's not safe for you to continue, we'll call you and let you know to stop taking PrEP.

Follow-up phone call (this will take approximately 15 minutes):

The study coordinator will call you 2 weeks after you begin taking your PrEP. The purpose of the phone call is to check up on you, how well you are adhering to the drug, how well you are tolerating the drug, and if you have any problems with the iTAB system; if you've had any adverse events to the study medication, the study coordinator will go over them with you during this call.

If you chose to start PrEP on the same day, the study coordinator will call you once they receive the results of your safety labs; if we find that it's not safe for you to continue, the study coordinator will ask you to stop taking PrEP during this call.

Clinic Study Visit Weeks 12, 24, 36, and 48 (each study visit will take about 45–60 minutes):

You will come into the clinic at weeks 12, 24, 36, and 48 for a study visit. At these study visits, you will have the following procedures done:

- A medical and medication history will be taken.
- A targeted physical exam will be performed.
- Samples will be obtained for the following tests:
 - A urine sample and approximately 3-4 tablespoons of blood will be drawn for laboratory tests including kidney function tests and HIV screening.
 - If applicable, we will use the urine sample for a pregnancy test and ask you about your intention to become pregnant and contraception use.
 - Some of the blood collected will be stored and used to test the amount of PrEP drug level in your cells at a later date.
 - Some of the blood collected at Week 12 will be stored and used to test the amount of hormone levels in your plasma at a later date, if you consent to the sub-study.
 - Some blood and urine samples will be stored for future study-related tests, if you consent.
 - Screening for STIs. In addition to the urine and blood sample, a throat and rectal self-swab will be done in order to screen for STIs. These collected samples and swabs will be tested to see if you have gonorrhea, chlamydia, or syphilis. These samples will be taken at weeks 24 and 48.
 - You may choose to screen for genital STIs using a genital swab instead of urine. Tell your study coordinator if you choose this. You will still need to give a urine sample to test for other labs.
 - At Week 48, two additional rectal swabs will be collected for future studies.
- We will ask you to complete confidential questionnaires on a computer-based system. You will have privacy when completing these questionnaires. We will ask you questions

about taking medications, substance use, mood, social support, technology use, sexual behaviors and risks, and your partners' behaviors.

- At your final study visit, we will also ask you questions about the study itself and the procedures used, in addition to your plans to continue PrEP after the study.

Study medication use and adverse events will be reviewed by study personnel. You will be provided with enough PrEP to last until your next study visit.

Pregnancy while on study

Should you become pregnant at any point during the course of the study, you will be asked to sign an additional consent form to allow us to continue to follow you during your pregnancy that outlines the risks of taking PrEP while pregnant. You will also be referred to a reproductive health specialist.

Additional Study Visits

If at any time during the study you think you might have gotten an STI, because someone you had sex with tells you they were diagnosed with one or you are having symptoms that you think are those of an STI or acute HIV infection, you need to tell your study staff immediately so you can get an appointment to be checked. If you come for an additional visit because you think you have an STI, tests for STI will be done (blood and urine sample and rectal, vaginal or throat swabs). An HIV test will be done if you think you were exposed to HIV or if you have symptoms of HIV. There is no additional cost for these tests.

If you have a positive test for HIV during the study, additional blood tests will be done to find out the amount of HIV virus in your blood, to check the HIV strain for drug resistance and to look at your immune system (T-cell count). You will be referred for HIV care.

UCSD Only Post-Week 48 Extension Visit (each study visit will take about 45–60 minutes):

Should you reach your week 48 Visit and intend to enroll in the CCTG 605 (HRPP#191001) study you may choose to participate in the study extension if the UCSD IRB has yet to approve CCTG 605. A complete description of the extension procedures are discussed later in this consent form on page 16.

Post-study Follow-up

After your Week 48 visit you will have completed the study. The study staff will work with you to help you get PrEP outside of the study, if you are interested in continuing. We will contact you about 12 weeks after you complete the study for a one-time phone call. We will ask about your HIV and STI status, health insurance status, and if you were able to obtain PrEP on your own. We will also ask you questions similar to those that you completed on the questionnaires over the course of the study. The follow-up phone call will last approximately 15 minutes.

Staying on study, off drug:

You can choose to stop taking PrEP at any time and still be able to stay in the study. If you choose this, you will not be given PrEP during your clinic visits. You will not have your blood drawn for laboratory tests for blood counts, chemistries, liver function and kidney tests. However, you will still be tested for STIs and HIV, and you will still be asked to take the surveys. If you decide to restart PrEP, we will do safety laboratory testing including HIV testing prior to going back on the medication. You may restart PrEP any time before the end of your week 36 visit.

RISKS/DISCOMFORTS:

Participation in this study may involve some added risks or discomforts. These include:

Risks of Truvada: Truvada is a combination of two antiretroviral medications: tenofovir disoproxil fumarate (TDF) and emtricitabine (FTC). Truvada is categorized in a class of drugs called nucleoside reverse transcriptase inhibitors (NRTI). These drugs may have side effects, some of which are listed below. Please note that these lists do not include all the side effects seen with these drugs. These lists include the more serious or common side effects.

If you are infected with hepatitis B (HBV) and are using Truvada, you could experience a flare of HBV with liver injury when this medication is stopped. Also, if you become HIV-infected while using Truvada, your virus may develop resistance to Truvada and other drugs in its class. If taking Truvada does not prevent an HIV infection, other drugs in its class may not be effective in treating the HIV infection as well. Although other drugs may be used to treat your HIV infection, this resistance effect may make HIV treatment more difficult, although this has not been proved in studies.

Risks of Tenofovir Disoproxil Fumarate (TDF, Viread)

The following side effects have been associated with the use of tenofovir:

- Kidney damage or failure
- Inflammation or swelling and possible damage to the pancreas
- Lactic acidosis, a buildup of lactic acid, which causes the blood to become more acidic.
- Shortness of breath
- Low phosphate, a chemical in the blood
- Allergic reaction, which may include fever, rash, upset stomach, vomiting, loose or watery stools, abdominal pain, body aches, shortness of breath, or a general feeling of illness.
- Changes in bone growth and strength were seen in study animals given tenofovir. Bone thinning has been seen in adults and children taking tenofovir.
- Upset stomach, vomiting, gas, loose or watery stools
- Dizziness
- Abdominal pain
- Lack of energy

- Rash
- Generalized weakness
- Depression
- Headache
- Liver problems. If you are developing liver problems, you may have one or more of the following symptoms:
 - Yellowing of the skin or whites of your eyes,
 - Dark urine,
 - Pain on the right side of your stomach,
 - Loss of appetite, upset stomach or vomiting,
 - Pale colored stools,
 - Itchy skin.
- Muscle pain and muscle weakness
- Sleeping problems

Risks of Emtricitabine (FTC, Emtriva):

The following side effects have been associated with the use of emtricitabine:

- Changes in the liver, which could mean liver damage
- Lactic acidosis (which may make you feel weak, tired, have unusual muscle pain, trouble breathing, nausea, vomiting, feel dizzy or have a fast or irregular heartbeat)
- Increased creatine phosphokinase (CPK), which could mean muscle damage
- Inflammation of the pancreas
- 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
- Increased triglycerides or fats found in the blood

A small number of people in this study may have these side effects or other side effects that we do not know about. However, we will screen your kidney function and overall health before you join the study. This will reduce the chances of having any side effects.

Risks of Drawing Blood: You may experience temporary discomfort from the blood draws. The needle sticks may cause local pain, bleeding, bruising and swelling, as well as lightheadedness,

dizziness and rarely, blockage of the vein, fainting and/or a local infection.

Risks of Text Messaging Adherence Reminders: You may feel increased stigma or intrusions of privacy or confidentiality when receiving text message reminders to take your medication.

Risks of Drug Resistance: In previous studies, it was found that a few people became HIV infected despite taking the study drug. If you were to acquire HIV in spite of taking PrEP and following the program, there is a small possibility that your virus may be resistant to some or all of the medications you take during this trial which may compromise your HIV treatment in the future, however, this has not been observed in any of the PrEP studies completed to date.

Risks of Sexually Transmitted Infections (STIs) Testing: You may experience some anxiety or embarrassment when being tested for sexually transmitted infections. If you are found to have a sexually transmitted disease, an appropriate referral for treatment will be made to one of several free public health clinics in your area.

Infectious Disease Referrals and Risks: There may be a chance that you may be diagnosed with HIV and/or HBV infection. The study staff will talk with you about your options and provide you with referrals of doctors and/or facilities that can provide treatment for your HIV and/or HBV infection if you are found to be infected with HIV and/or HBV. The diagnosis of HIV and/or HBV may result in earlier treatment and/or prevention of many complications from the illnesses.

Awareness of a diagnosis of HIV and or HBV may have serious personal or social consequences. Some of these consequences include possible difficulty obtaining health insurance or employment and difficulty traveling to some foreign countries.

Risk of Pregnancy while taking PrEP: Through the course of the study, you could become pregnant if you are not using contraceptive methods (e.g., condoms, birth control pill) to prevent pregnancy. PrEP is protective against HIV infection but not pregnancy. PrEP with TDF/FTC has been evaluated in only a few women during and after pregnancy. The human data available suggests that TDF/FTC does not increase your risk for major birth defects. However, because studies in humans cannot rule out the chance of harm, TDF/FTC should be used during pregnancy only if is clearly needed. If you become pregnant while taking TDF/FTC in this study, we will carefully consider whether it should be continued. Should you become pregnant over the course of the study, you will be asked to sign an additional consent form that outlines the risks of taking PrEP while pregnant. You will also be referred to a reproductive health specialist.

Risks of Email Communications: There are limitations to the confidentiality of email communications. Do not include any sensitive health information if you choose to contact the study team via email. The study team will include minimal information in study visit reminder emails if you choose to receive them.

Other Risks: No prevention technology is 100% effective, even if you follow your providers'

instructions exactly. Since this is an investigational study, there may be other unknown risks that are unforeseen or at this time cannot be predicted. You will be told of any significant new risks. If you have questions concerning the study, ask the study staff. You may also feel discomfort in answering questions about sexual behaviors, personal habits, lifestyle or drug and alcohol use. If you experience discomfort due to any of the study procedures, staff members will be available to you to discuss these issues. You may also refuse to answer any question you wish. Although the study site will make every effort to protect your privacy and confidentiality, it is possible that your involvement in the study could become known to others, and that social harms may result (i.e., because you could become known as HIV-infected or at “high risk” for HIV infection). For example, you could be treated unfairly or discriminated against, or could have problems being accepted by family or community members.

Risk of Loss of Confidentiality: A risk of taking part in this study is the possibility of a loss of confidentiality. Loss of confidentiality includes having your personal information shared with someone who is not on the study team and was not supposed to see or know about your information. The study team plans to protect your confidentiality. Their plans for keeping your information private are described in the “Confidentiality” section below.

Personal Questions Risk: You will be asked questions about personal issues during this study. Answering personal questions may cause you stress or discomfort. You can skip or stop answering questions that make you feel uncomfortable.

Unknown Risks: There may be other unknown risks that are unforeseen or at this time cannot be predicted. You will be told of any significant new risks. If you have questions concerning the study, ask the study staff.

STORED SAMPLES

Some of your blood, urine, swab (throat, genital, rectal) specimens obtained as part of this study will be stored indefinitely and may be used for approved HIV/AIDS-related research in the future. You will not be identified by name in any testing and your confidentiality will be maintained. Specimens will be identified only by an identification number (your name will not be listed on the sample). All of the individuals receiving these specimens will be scientific partners in this study. Your blood, urine, and swab specimens and the DNA that it contains may also be used in additional research to be conducted by the University of California personnel collaborating in the research. This blood, urine, and swab specimens and its derivatives may have significant therapeutic or commercial value. You will consent to such uses below.

The University has policies and procedures to ensure your confidentiality. We will use our best efforts to ensure that your identity and test results will not become known outside the research program, which if released, could affect your employment and ability to obtain insurance.

If you decide later that you do not want the specimens collected from you to be used for future research, you may tell this to Dr. Morris or the study staff, who will use their best effort to stop

any additional studies. However, in some cases, such as if the material within your samples are found to be generally useful, it may be difficult or impossible, to stop such future research once the materials have been widely shared with other researchers. Dr. Morris, his associates, or their successors in these studies will keep your DNA specimen or the information derived from it indefinitely.

BENEFITS

There may or may not be a direct benefit to you from the procedures done as part of this study. However, information learned from this study may help the study doctor/staff learn more about different ways to help high-risk, HIV-negative people reduce their risk of acquiring HIV.

WHAT IF YOU WANT TO END THE STUDY EARLY?

You can your participation in this study at any time for any reason. If you end your participation, you can tell a member of the study staff. In San Diego, call (619) 543-8080. In Los Angeles, call (323) 993-7400.

REASONS FOR WITHDRAWAL FROM THE STUDY WITHOUT YOUR CONSENT

You may be taken off this study without your consent for any of these reasons:

- The study is canceled by the UCSD AVRC study doctor, or the UCSD Institutional Review Board (IRB). An IRB is a committee that watches over the safety and rights of research subjects.
- You experience a high level of drug toxicity.
- You acquire HIV.
- You become pregnant prior to study enrollment.

ALTERNATIVES TO TAKING PART IN THE STUDY

You may decide not to take part in this study. The alternatives to participating in this study are to receive counseling on HIV prevention and testing for sexually transmitted infections and HIV infection from your current primary care doctor. The study medication TDF/FTC could be obtained from your doctor.

COSTS OR PAYMENTS TO YOU

There is no cost to you for the study-related medications, clinic visits, procedures, examinations, or laboratory tests in this study. The cost of any drugs you may need to treat other medical conditions, and any other medical costs for your treatment outside this study, will be the responsibility of you or your insurance company.

In addition, there is no cost to you for the cell phone provided and its service related to the study text messages during this study if you do not have a cell phone. Also, if you have a cell phone

with limited text messaging, the study will compensate you for expenses you experience due to the study related text messages sent to you during your participation in this study.

As compensation for your time and any inconvenience you may experience as a result of your participation in this study, you will receive \$25 after you complete your screening visit and \$50 after you complete your entry and your weeks 12, 24, 36, and 48 visits. If you choose to do same-day PrEP, you will be compensated \$50 for completing the in-clinic visit and \$25 for completing both sets of questionnaires. You may complete both sets in-clinic or do one set in-clinic and the other at home. The most you can receive for study participation is \$275. Should the study staff ask you to come for an Interim Visit, you will receive \$10 for each completed visit. You will not receive compensation for visits that are not completed, or for Interim Visits that you request.

The study will provide a stipend to help you with travel at every visit. The stipend is based on the average commute time from your pre-screen residence to and from the study clinic. You will receive \$5 for every 20 minutes of commute (rounded up) up to \$50. The most you can receive from this stipend is \$300 over the course of the study.

Family Health Centers of San Diego (FHCS) The Night Clinic (TNC) will be reimbursing their participants with Target gift cards instead of cash. The gift card amounts will reflect the compensation amounts described above.

You will receive \$50 as well as a travel stipend for any extension visits completed after week 48.

CONFIDENTIALITY

Your records will be confidential to the extent provided by the law. You will be identified by a code, and personal information from your records will not be released without your written permission. You will not be personally identified in any publication about this study. However, your records may be reviewed, under guidelines for the Federal Privacy Act, by the U.S. Food and Drug Administration (FDA); National Institute of Health, the sponsors of this research study, the study monitors and/or any person or company working for the sponsors; and the UCSD Institutional Review Board (IRB).

Because the University of California complies with the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and its privacy regulations, and all other applicable laws that protect your privacy, in addition to this informed consent form, you will be asked to read and sign the attached HIPAA Authorization Form prior to your participation in this research study.

The U.S. Department of Health and Human Services (DHHS) has issued a Confidentiality Certificate to this research project to help protect your identity. This certificate means that researchers cannot be forced to release any research data in which you are identified, even under court order or subpoena, without your written consent. If we learn something that would

immediately endanger you or others, we may discuss it with you, if possible, or seek help from others to protect you or others. Having a Certificate of Confidentiality does not prevent you from releasing information about yourself and your participation in the study.

All cases of sexually transmitted infections, and hepatitis B and C must be reported to the county public health department. According to California state law, study staff is required to give public health department staff the subject's name, contact information, and treatment records if requested.

Per California law, we will report information about known or reasonably suspected incidents of abuse or neglect of a child, dependent adult or elder including physical, sexual, emotional, and financial abuse or neglect. If any investigator has or is given such information, he or she is required to report such information to the appropriate authorities.

RESEARCH-RELATED INJURY

If you are injured as a result of participation in this research, the University of California will provide any medical care needed to treat those injuries. The University does not pay any other form of compensation if you are injured. You may call the UCSD Human Protections Program Office at (858) 246-4777 for more information about this, to inquire about your rights as a research subject, or to report research-related problems.

PROBLEMS OR QUESTIONS

Dr. Sheldon Morris, and/or _____ has explained this study to you. He or she has answered your questions. If you have more questions or concerns about the study, you may reach Dr. Sheldon Morris at (619) 543-8080 or Dr. Bolan in Los Angeles at (323) 993-7400. After working hours or in an emergency, call the Antiviral Research Center (AVRC) doctor on call at (619) 543-6737.

You are free to take part in the study or not. You can leave the study at any time, for any reason. Not taking part in the study or leaving early will not affect any medical care you get at UCSD, FHCSD, or LALGBT, or result in loss of any benefits to which you are entitled.

You have received a copy of this consent form to keep. You have also received a copy of “The Experimental Subject's Bill of Rights” to keep.

You agree to participate.

SIGNATURE OF THE PARTICIPANT

Name of Participant

Signature of Participant

Date

CONSENT FOR STORED SPECIMENS

We would like your permission to store some of your blood, urine, and swab samples for future HIV/AIDS-related, DNA-related, and other infections-related research. If you agree, some of your blood, urine, swabs (throat, genital, rectal), and oral specimens that are collected at any visit may be stored for future use for approved research. As scientific discoveries are made, valuable research can be done in the future on samples collected today. Your left over blood may be stored for an indefinite length of time. Because research using your left over blood will be done in the future, you will not be told the results of the research done on these samples. You may cancel your permission to store and use your left over blood at any time and still remain in this study.

Please indicate below whether or not you agree to have your blood, urine, and swabs (throat, genital, rectal), and oral samples stored, which were obtained as part of this study.

Do you consent to allow left over samples to be used for HIV-related research?	
_____ (initials) I agree that left over samples can be used for HIV-related research	_____ (initials) I do not agree that left over samples can be used for HIV-related research

Do you consent to allow left over samples to be used for DNA-related research?	
_____ (initials) I agree that left over samples can be used for DNA-related research	_____ (initials) I do not agree that left over samples can be used for DNA-related research

Do you consent to allow left over samples to be used for other infections-related research?	
_____ (initials) I agree that left over samples can be used for other infections-related research	_____ (initials) I do not agree that left over samples can be used for other infections-related research

CONSENT FOR E-MAIL COMMUNICATIONS

If you agree, the study team will email you appointment visit reminders for each visit. You do not have to agree to receive email reminders to participate in this study.

Do you consent to be contacted through email for appointment reminders?	
_____ (initials) I agree to be contacted through email for appointment reminders	_____ (initials) I do not agree to be contacted through email for appointment reminders

CONSENT TO BE CONTACTED FOR FUTURE RESEARCH

There may be other studies that are being conducted at the UCSD AVRC for which you may qualify. You may be asked to participate in one or more of these additional studies. Please initial.

Do you consent to be contacted for future research?	
_____ (initials) I agree to be contacted for future studies by our research staff	_____ (initials) I do not agree to be contacted for future studies by our research staff

CONSENT TO LINK DATA BETWEEN CCTG STUDIES

If you participated in any other CCTG studies, we would like to connect your data between these studies.

Do you consent to allow us to link your data between CCTG Studies?	
_____ (initials) I agree to allow data to be linked between studies	_____ (initials) I do not agree to allow data to be linked between studies
N/A; did not participate in any other CCTG studies	

PHARMACOLOGY OF PREP IN TRANSGENDER PERSONS SUB-STUDY

This study has a related sub-study that will look at the effects of hormone replacement therapy (HRT) on PrEP levels and, vice-versa, the effects of PrEP on hormone levels. In this sub-study, you will be asked additional questions in the confidential questionnaires about your use of and satisfaction with your hormone therapy. We will also ask about your satisfaction with your physical characteristics. Some of these questions will ask about personal details (for example, about your genitalia), which may make you feel uncomfortable. The purpose of asking these questions is to evaluate how hormone and body satisfaction affects adherence to PrEP.

Participation in this sub-study is not a requirement of the main study and will not prevent you from participating in the main study. All clinical and laboratory evaluations for this sub-study will be done as part of the main study’s regular procedures.

In this sub-study, we will:

- Use collected blood that will be drawn as part of the main study to measure your hormone levels.
- Ask you specific questions about your current HRT use, including type, route, and frequency.
- Ask you to complete confidential questionnaires about your general hormone therapy satisfaction, body image satisfaction, and substance use.

Do you consent to participating in the pharmacology sub-study?	
_____ (initials) I agree to participate in the sub-study	_____ (initials) I do not agree to participate in the sub-study
N/A	

POST-WEEK 48 EXTENSION VISITS (UCSD ONLY)

Should you reach your week 48 Visit and intend to enroll in the CCTG 605 (HRPP#191001) study you may choose to participate in the study extension if the UCSD IRB has yet to approve CCTG 605.

The study extension will provide you with PrEP until you are able to enroll in the CCTG 605 study. Study visits will take place in 12-week intervals up to 24 weeks after week 48.

Participation in the extension visits is not a requirement of the main study and will not prevent you from participating in the main study.

If you agree to participate, you have up to 2 additional visits at the UCSD AVRC after week 48.

Post-Week 48 Extension Study Visits (each study visit will take about 45–60 minutes)

At these study visits, you will have the following procedures done:

- A medical and medication history will be taken.
- A targeted physical exam will be performed.
- Samples will be obtained for the following tests:
 - Approximately 3-4 tablespoons of blood will be drawn for laboratory tests including kidney function tests and HIV screening. A urine sample will be collected if clinically indicated.
- Study medication use and adverse events will be reviewed by study personnel. You will be provided with enough PrEP to last until your next study visit.

Compensation: You will receive \$50 as well as a travel stipend for any extension visits completed after week 48. You can receive a maximum of \$100 for participating in the extension visits.

Do you consent to participating in the Post-Week 48 Extension Visits?	
_____ (initials) I agree to participate in the week 48 extension visits.	_____ (initials) I do not agree to participate in the week 48 extension visits.
_____ N/A	

DIVERSITY AND PREVALENCE OF NEISSERIA GONORRHOEAE-REDUCED ANTIMICROBIAL SUSCEPTIBILITY SUB-STUDY (UCSD ONLY)

This study has a related sub-study that you may choose to participate in. The purpose of this sub-study is to see which of the strains of gonorrhea-causing bacteria are less affected by antimicrobial medicines.

Participation in this sub-study is not a requirement of the main study and will not prevent you from participating in the main study.

If you agree to participate, the following will happen:

- You will proceed through the regular main study schedule of evaluations, including the collection of swabs and urine for STI testing.
 - If you are diagnosed with gonorrhea, study staff will contact you with the results. You will be asked to return to the clinic for a follow-up visit.
 - At the follow-up visit, we will collect another sample (urine or swab) at the site(s) of infection.
 - You will be given treatment for gonorrhea at the clinic.

The follow-up in-clinic visit will take 15 minutes of your time.

Do you consent to participating in the gonorrhea sub-study?	
_____ (initials) I agree to participate in the sub-study	_____ (initials) I do not agree to participate in the sub-study

IMPACT OF BIOLOGIC FACTORS ON CVF TFV LEVELS SUB-STUDY (UCSD ONLY)

This study has a related sub-study that you may choose to participate in. The purpose of this sub-study is to see if biologic factors (such as inflammation and the vaginal microbiome) can affect drug levels in the cervix and vagina.

Participation in this sub-study is not a requirement of the main study and will not prevent you from participating in the main study.

If you agree to participate, the following will happen:

Entry Visit

At your entry visit, the following samples will be collected either by trained study staff or via self-collection:

- A cotton swab (Q-tip) will be carefully inserted into your vagina, to collect a sample to measure cytokines. Cytokines are proteins that can tell us about inflammation.
- A cotton swab (Q-tip) will be carefully inserted into your vagina to collect a sample to measure your microbiome. The microbiome are naturally occurring organisms in the body that may affect inflammation.

The sub-study will take 5 additional minutes of your time.

Week 24 Clinic Study Visit

At your Week 24 visit, the following samples will be collected either by trained study staff or via self-collection:

- A cotton swab (Q-tip) will be carefully inserted into your vagina to collect samples to measure cytokines and microbiome, the same as your Entry Visit.
- Additional swabs will be carefully inserted into your vagina to collect samples to look for genital viruses and bacteria that are known to cause inflammation.
- A specimen aspirator will be carefully inserted into your vagina that will be used to collect cervicovaginal fluid (CVF) through suction. The sample collected through the aspirator will be used to measure the amount of study drug in your CVF.

The sub-study will take 10 additional minutes of your time.

To reduce discomfort, all samples will be collected when samples for the main study will be collected. All of the samples collected at this visit will be stored until tested at a later date.

Once you complete the sub-study, you will continue with the main study as normal.

Risks of Genital Swab and CVF aspiration: There may be some mild discomfort associated with insertion of genital swabs and CVF aspirator, similar to inserting a tampon. The discomfort will stop as soon as the tests are completed.

Compensation: For the CVF sub-study, you will receive \$25 after you complete your entry visit and \$25 after you complete your Week 24 visit. You will receive a maximum of \$50 for participating in the sub-study.

Do you consent to participating in the CVF sub-study?	
_____ (initials) I agree to participate in this sub-study	_____ (initials) I do not agree to participate in this sub-study
N/A	

SIGNATURE OF PERSON OBTAINING CONSENT

Name of Person Obtaining Consent

Signature of Person Obtaining Consent

Date