Study of Truvada for HIV Pre Exposure Prophylaxis Using Daily Directly Observed Therapy to Look at Potential Interactions Between Truvada and Hormone Therapy

NCT04050371

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UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
SAN FRANCISCO AIDS FOUNDATION

INFORMED CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Research Study Title: I-BrEATHe - Interactions BEtween Antiretrovirals And Transgender Hormones

Sponsor: University of California Office of the President, via the California HIV/AIDS Research Program, Dr. Robert Grant, MD, MPH, and Dr. Maddie B. Deutsch, MD, MPH

Study doctors: Dr. Robert Grant, MD, MPH, and Dr. Maddie B. Deutsch, MD, MPH

Research Site address: 1035 Market Street, SF CA 94103

Daytime Phone number: 415-638-9466

24-Hour Contact Number: 415-350-8909

Participant identification/number:

The I-BrEATHe study is a study looking at Truvada® ® drug levels and the possible interactions between Truvada® ® and femininizing or masculinizing hormones in HIV uninfected transgender people.

Introduction:

This informed consent form provides information about the procedures of this research study.

This is a medical research study. The study staff at the San Francisco AIDS Foundation (SFAF) will explain this study to you. You will be informed of the purpose of the study, what will be asked of you if you participate, and any potential risks or benefits of taking part.

Medical research studies include *only* people who choose to take part. Take your time to make your decision about participating. You may discuss your decision with your family and friends and with your health care team. If you have any questions, you may ask the study doctor(s) or another member of the study team.

You are being asked to take part in this study because you are 18 years or older, were either assigned female sex at birth, and currently identify as a “man”, “transgender man”, genderqueer or other transmasculine identity, or were assigned male sex at birth, and currently identify as a “woman”, “transgender woman”, genderqueer or other transfeminine identity. You are asked to be part of this study also because you have been taking hormone therapy appropriate for your transgender or gender queer identity for at least 6 months.

This consent form has been reviewed by an Independent Review Board (IRB). An IRB reviews research studies to protect the rights and well-being of the people taking part in these studies. Some of the information in this consent form is required by law.

After you have read the entire form, you will be given the chance to ask any questions that you may have. When you have had the chance to ask any questions and they have been answered to your satisfaction, if you decide to take part, we will ask you to sign the pages at the end of this form to show that you agree to be part of the study.

Please remember:

- Your participation is **completely voluntary**
- Even after you have signed this study consent form you can change your mind and decide not to participate in the study. You do not have to give a reason, though we may ask you (for research purposes) why you want to leave the study.
- **If you don’t want to answer any of the questions we ask you, it is your right not to answer**

Before participating please consider if this will affect any insurance you currently have, or may purchase in the future, and seek advice if necessary from your insurance company.

Why is this study being done?

HIV infection continues to be a serious public health issue in the United States and all over the world. Despite progress made in HIV treatment and prevention, new infections continue to occur at an alarming rate. Transgender communities, especially transgender women of color, are extremely vulnerable to HIV infection. By some estimates, transgender women are up to 50 times more likely to be infected with HIV compared with other adults. There is a lack of HIV prevention studies specific to transgender men. Prevalence of HIV infection in transgender men has been shown to be 2-5 % in a small study. Therefore it is important to include transgender men in HIV prevention studies, and to try and develop new ways to prevent infections. One way to prevent HIV infection is to use medications that prevent HIV from establishing infection and making new copies of itself.

Truvada® is a medication that does not allow HIV to make new copies of itself. It has been approved by the United States Food and Drug Administration (FDA) for the treatment and the prevention of HIV acquisition. Prevention of HIV acquisition with Truvada® is called *Pre Exposure Prophylaxis* or PrEP. PrEP involves taking Truvada® once daily. Unfortunately, current research seems to indicate that Truvada® may not accumulate to sufficient levels in the blood of the transgender women who take it. And no studies exist in transgender men.

This study is to find out if the levels of the Truvada® medication in the blood of transgender women and men are low because of medications taken for hormonal therapy. It is possible that these hormones interfere with the accumulation of the drug in the body. This study will also look at whether Truvada® may affect levels of trans therapy hormones in the blood.

What is the study medication?

Truvada® is the combination of emtricitabine 200 mg and tenofovir disoproxil fumarate 300 mg in a single blue pill. Gilead Sciences is the pharmaceutical company that produces and will supply Truvada® for this study.

Who is paying for the study and what do they do?

The California HIV/AIDS Research Program (CHRP) of University of California is program that provides money for research on HIV and AIDS that responds to the needs of all people of California, especially those who are often under served. It provide money for research in prevention, education, care, treatment, and a cure for HIV/AIDS.

The CHRP has awarded grants to several teams of researchers to provide and specifically evaluate PrEP among transgender persons at risk for HIV acquisition in California. In this regard, CHRP grants pays the study team at UCSF and SFAF to run this study.

How many people will take part in this study?

About 48 people in total will take part in this study at SFAF (24 "*transgender men*" and 24 "*transgender women*").

What will happen if I participate in this study?

Before you begin the main part of the study you will need to have "screening" exams, or tests, and answer some questions to find out if you can be part of the study. For example, you must get tested to make sure that you do not already have HIV-1 infection before you start taking Truvada®. You will not be able to participate in the study if you have a positive HIV rapid test. The screening procedures are described in detail below.

After the screening procedures have been completed, if you are eligible and choose to participate in this study, you will be enrolled into the study for 4 weeks (28 days). You will come to the clinic every week, and the following procedures will be done as well as you will also participate in video calls every day, at a time that is convenient for you, with a study staff member.

Visit Procedures

All study visits will be done at the SFAF clinic, 1035 Market Street in San Francisco, California. We expect visits to last between ½ hour and 1 hour, it will depend on the visit type.

This study strongly depends on what is called **Directly Observed Therapy or DOT**. DOT means that you will be *taking your pill while being on a phone video call*, or in person in the clinic, with a study staff. The video calls will last approximately 60 seconds in duration and will be focused on watching the tablet be placed into your mouth, swallowed, and your mouth opened to verify the tablet is no longer present. We will also ask you what you have eaten in the hour prior taking the pill, or if you are going to eat. DOT **will happen every day**, even on week-ends and holidays, using a video application such as Face Time or Skype. On these daily calls, we will also ask you to confirm that you have taken your hormonal therapy in the past 24hrs. If you feel you cannot participate in these daily calls, then this study may not be the right fit for you.

We may call and/or email during the study period if there is important information to share with you

In the visit descriptions below when it says “blood test” it refers to a procedure where we will ask you to provide a blood sample from a vein. We will ask you to provide up to 40 ml of blood (which corresponds approximately with the volume contained in 2.7 tablespoons) at visits when we do a blood draw. The blood tests that we will perform at each visit are detailed below. It is possible that we may ask you to provide a blood sample for HIV testing through a fingerprick test at one or more of your visits, using a lancet (a tiny needle) to prick the tip of one of your fingers. We will also collect urine in a cup.

At each study visit you will receive support around taking a pill every day, if it is a challenge for you, and, if you are interested, information around safe sex practices and be provided condoms and lubricant.

It is very important that you let your study doctor know if you start any new medications or change any of your medications during your participation, ***especially if you change or stop using the medications that you use as hormonal therapy***. Let us know about even medicine you buy at a drug store and herbal or dietary supplements (vitamins). This is because they may interact with the study drug and affect the results of the study.

It is also important that you come to your visits as scheduled, that ***every day*** you take the medication as instructed by the study team, while doing the video phone call or at a clinic

visit. If you think you may not be able to come to any of your scheduled visits on time, or take the phone call, please let the study staff know so they can work with you to reschedule the visit or the call.

We will also ask that you keep us informed of any changes to your contact information during your participation.

Screening Visit:
At the screening visit you will come to the clinic and have tests, a medical and personal history, and evaluations, to determine if you are eligible to participate in the study. These procedures are listed below:

- Review of the study eligibility criteria.
- We will ask you for some information, such as your age, gender identity, ethnicity, birth assigned sex, race, employment, education ...
- We will ask you questions about yourself and about your medical history, including about medications, mental health, alcohol, tobacco and drug use. These questions are to better understand the group of people who chose to participate in this study and what factors may affect taking a pill every day.
- We will ask you if you have in your medical records recent results of hepatitis B serology (i.e. if you have been vaccinated or had an infection in the past), we may ask for hormones levels
- We will measure your temperature, blood pressure, and heart rate
- We will collect a blood sample and perform the following tests:
    - Tests to see if you have HIV, and hepatitis B (if we don't have information about your hepatitis B status from your medical chart or your doctor)
    - A test to determine the health of your kidneys and liver

The results of these tests will be reviewed by the study team to see if you are eligible to participate in the study. If you are eligible, and you decide to take part in the study, you may begin the study within 28 days of when you start the screening tests. If you cannot come back to the clinic within 28 days, you may not be able to participate.

If the tests for hepatitis B, or HIV, are positive (meaning you have one or more of these infections), California regulations require laboratories to report new cases of HIV and hepatitis B infection to the county public health department. The reports include the patient's name, social security number, and other identifying information. Information about these new infections is used to track these diseases statewide and nationwide. Other than this required reporting, your results will be treated confidentially by the study staff. Personally identifying information will not be reported to other departments or agencies.

Study Visits:

If you are eligible to participate based on your screening tests and you decide to participate in the study within 28 days of screening, you will then return to the clinic and have tests and evaluations as described below for the enrolment visit and then every week for 4 weeks of participation.

Enrolment visit: we will provide you a bottle of study medication with 30 tablets in it and ask that you bring it back to the study clinic at your visits at week 1, 2, 3 and 4, even if there are no tablets in the bottle. Alternatively, we may provide you with a pill box with a week's supply. It is important that you bring the bottle and any remaining tablets back to the clinic at these visits.

The procedures at the enrolment visit are listed below:

- Brief physical exam, including looking if you have flu like symptoms, since new HIV-1 infection symptoms include tiredness, fever, joint or muscle aches, headache, sore throat, vomiting, diarrhea, rash, night sweats, and/or enlarged lymph nodes in the neck or groin
- We will measure your weight, height, temperature, blood pressure, and heart rate
- Review of any illnesses since screening visit
- Review of any medications that you are currently taking, or any drugs you may be using
- You will be provided study drug
- Schedule daily video calls and follow up visits
- If you have a uterus and ovaries, and are sexually active with people who have penises, we will do a pregnancy test.
- We will collect some blood and urine to perform the following
    - Tests for the presence of HIV
    - Tests to determine the amount of hormones
    - Test to determine the level of Truvada® in your body
    - Test to determine the function of your kidneys

Weeks 1, 2 and 3:
The procedures at these visits are listed below:

- Return with your medication bottle
- Review of any illnesses or side effects since last visit
- Look if you have any flu like symptoms
- Review of any medications that you are currently taking, or any drugs you may be using
- we will collect a blood sample to determine the level of Truvada® in your body and your kidney function, as well as a urine sample also for kidney function
- Review of video calls DOT and schedule

Week 4 or last visit:

The procedures at this visit are listed below:

- Return with your medication bottle
- Review of any illnesses or side effects since last visit
- Look if you have flu like symptoms
- We will measure your weight, height, temperature, blood pressure, and heart rate
- Review of any medications that you are currently taking, or any drugs you may be using
- we will collect blood and urine samples to
    - Test for the presence of HIV
    - Tests to determine the health of your kidneys and liver
    - Tests to determine the amount hormones
    - Test to determine the level of Truvada® in your body

At the end of the study, you will not take any study drug anymore. However, if you decide that you would like to continue Truvada® for PrEP for HIV prevention, we will refer you to an appropriate program for PrEP.

What will happen if I become infected with HIV during my participation?

If you participate in the study you will be tested for HIV infection with a rapid test at the two initial visits (screening and enrolment). If the rapid test is positive at either of these visits, you will not be able to participate in this study.

However, we will send a specimen to the San Francisco Department of Public Health (SFDPH) for a confirmatory test (currently the Multispot rapid HIV-1/HIV-2 differentiation assay). We will also refer you to the Positive Health Access to Services and Treatment (PHAST) team, a rapid response team that has championed HIV testing and linkage to care (the SFDPH HIV Surveillance Unit phone #: 415/554-9050), or other equivalent programs outside of San Francisco. These services will provide you community resources and will initiate HIV treatment, therefore making sure you are receiving care. At this program you may have other blood test to determine whether you are really HIV-infected, because sometimes rapid tests are inaccurate.

If you were taking Truvada® as part of our study, and discover that you are HIV positive outside of our study procedures, we ask that you inform us of this as soon as possible. Your study clinician will refer you to appropriate care programs at PHAST and make sure you receive the most appropriate HIV treatment, given that you were taking Truvada. You will not be able to continue the study

If you are found to be infected with HIV, California regulations require laboratories to report new cases of HIV and hepatitis B infection to the county public health

department, as described previously in this consent. Cases must also be reported within 7 days to the SFDPH Health Officer.

We may also use some of the blood collected at your study visits to analyze the virus using more sensitive tests. These results may or may not be returned to you or your provider.

How long will I participate in this study?

Your expected participation in this study will last a maximum of 4 weeks or approximately 28 days. You will be asked to come to 6 visits, including the screening visit. Since screening and enrolment visits may last from ½ hour to 1 hour, and the follow up visits up to 20 min, we expect you're you will spend a maximum of 3 hours 20 min in the clinic for the study. During this time, we will ask you to get tests, visit the clinic on schedule, and tell the study staff about any changes to your health. In addition, we will ask that you participate in daily video calls, for 1 minute every day, for a total of approximately 28 days, which is an extra ½ hour, but could be more if calls are dropped, or missed and rescheduled, up to an extra 2 hours over the whole study, bringing the total of study participation to approximately 5 hours.

Please keep in mind how the study tests and visits described here may affect your work and family schedules. You will assigned to a visit schedule that requires you to come to the clinic EVERY week for 4 weeks and that you do phone video call EVERYDAY. Please consider if you need transportation to and from the clinic. You may find that these tests, visits and phone calls need some planning.

What about contraception and intercourse during the study?

If you have a uterus and ovaries, and are sexually active with people who have penises and may be of child bearing potential, it is not known if TRUVADA® can harm your unborn baby. If you become pregnant while being on the study, you will not be able to continue the study. We will do a pregnancy test at the enrolment visit, if the test is positive, you will not be able to participate in the study

What side effects can I expect from this study?

You may have side effects while on the study. These symptoms or adverse effects may be due to participation in the study or due to illnesses that have no relation to the study, like a cold or flu. Everyone taking part in the study will be watched carefully for any side effects. However, doctors don't know all the side effects that may happen. Side effects may be mild or very serious. You should talk to your study doctor about any side effects that you experience while taking part in the study. Many side effects may go away as soon as you stop taking the study drug. In some cases, side effects can be serious, lasting or may never go away.

There may be other side effects that may happen that are not known now. For example, all drugs can cause an allergic reaction in some patients. Certain problems can become worse if not treated quickly.

You should talk to your study clinician about any side effect you experience while taking part in the study.

Side effects that may arise in the first weeks of Truvada® use -- nausea, abdominal cramping, vomiting, dizziness, headache, and fatigue usually go away without treatment interruption. These potential risks can be effectively managed by your study doctors.

More serious side effects, though much less frequent, can occur:
Too much lactic acid in your blood (lactic acidosis) which is a serious medical emergency. Symptoms of lactic acidosis include weakness or being more tired than usual, unusual muscle pain, being short of breath or fast breathing, nausea, vomiting, stomach-area pain, cold or blue hands and feet, feeling dizzy or lightheaded, and/or fast or abnormal heartbeats.
Serious liver problems: your liver may become large and tender, and you may develop fat in your liver. Symptoms of liver problems include your skin or the white part of your eyes turns yellow, dark “tea-colored” urine, light-colored stools, loss of appetite for several days or longer, nausea, and/or stomach-area pain.
If you have hepatitis B, your hepatitis B may become worse after stopping Truvada®.
Kidney problems: we will check your kidney before and during your study participation.
Bone problems: including bones getting more fragile, though it is unlikely given the short duration of the study.
Changes in body fat: some people have seen changes while taking Truvada® for an extended period of time.

What will happen if I experience a side effect?

If you develop a symptom from Truvada® while the medication is still in your body, every effort to treat the side effect will be taken. The amount of drug will decrease overtime and will eventually disappear.

If you experience certain other serious problems (such as an allergic reaction, swelling, difficulty breathing, a bad skin rash, liver or kidney damage, or changes in your heart rhythm), you may be asked to return to the clinic to see your clinician, who will do the necessary to mitigate the side effect. Alternatively, your clinician may refer you to your doctor or other services for follow up.

If you want to, you may be referred to another clinician within SFAF who is not part of the research team. In this case, the study team may share information from your study participation relevant for your care to the SFAF clinician, and the study team

may also review any relevant information in your referral visit clinical chart. Only information important for the management of the potential side effect will be shared.

You may also need to stop taking the study drug after talking with the study clinician.

Call the study clinician right away if you have any of these side effects:
- Feel very tired or faint
- Feel pain or sick in your stomach and do not want to eat
- Bruise easily or develop itching
- Have yellow eyes or skin, or dark urine
- Become confused
- Develop a new rash
- Have trouble breathing

Call your study clinician if you have any other medical problems between visits.

What other possible risks are there to being in this study?

The following are other possible risks you may experience if you participate in this study:

- **Unknown risks:** Truvada®may have side effects that no one knows about yet, though it is unlikely since Truvada® has been in use for a long time in many people. However, the researchers will let you know if they learn anything that might make you change your mind about continuing to participate in the study.

- **Blood drawing (venipuncture) risks:** Drawing blood may cause temporary discomfort from the needle stick, bruising, infection, or fainting.

- **Sensitive information risks**: some of the questions the study team ask may make you uncomfortable or relate to drug use, please remember you don't have to answer if you do not want to.

- **HIV testing risks:** Being tested for HIV may cause anxiety regardless of the test results. A positive rapid test may indicate that you have been infected with the HIV virus. If you test positive with the HIV rapid test at our clinic, we will send a specimen for confirmatory testing and will refer you to a source of medical care and treatment. Receiving positive results may make you very upset. If other people learn about your positive test results, you may face discrimination. If your HIV rapid test is negative, there is still the possibility that you could be infected with the HIV virus and test positive at some time in the future.

- **HIV infection and drug resistance:** Although highly effective, PrEP is not 100 % protective and does not protect against Hepatitis C, gonorrhea, chlamydia, or other sexually transmitted diseases (STIs). Prevention methods known to be effective against other STIs, like using condoms during sex and

keeping your number of sexual partners low, are still recommended. If you become infected with HIV during this study while you are receiving Truvada® there is a risk that you may have a virus that could be resistant to one or both of the medications that constitute Truvada® (tenofovir and emtricitabine), or to lamivudine (a medication similar to emtricitabine). This resistance could limit your options for HIV treatment. You will be able to discuss treatment and resistance to medications with the study clinicians.

- **Risk of loss of privacy or confidentiality:** Participation in this study may involve a loss of privacy, but your information will be handled with maximum confidentiality (as described below). We will do everything possible to assure that the personal information recorded in your medical record is managed with the maximum privacy. However, you may run into someone you know while going to the clinic. There are some risks associated with the use of video calls using video applications. The information could be captured by the application provider or third party entities. The application may capture metrics on your phone such as location.

- **Risks associated with the video DOT for Truvada®**: while you are doing your daily video calls for the Directly Observed Therapy of your study medication, someone (a family member, a friend, an acquaintance …) may stumble upon you and question what you are doing. This may create discomfort, difficult questions, concerns, or unexpected reactions from the person. Finding your bottle of Truvada® may generate similar effects.

For more information about risks and side effects, ask your study clinician.

What happens if I am injured because I took part in this study?

It is important that you tell your study clinician if you feel that you have been injured because of taking part in this study. You can also contact the study Principal Investigator, Dr. Grant, at 415-350-8909, if you feel that you have been injured because of your study participation.

Treatment and Compensation for Injury: If you are injured as a result of being in this study, the University of California will provide necessary medical treatment. The costs of the treatment may be billed to you or your insurer just like any other medical costs, or covered by the University of California or the study sponsor, depending on a number of factors. The University and the study sponsor do not normally provide any other form of compensation for injury. For further information about this, you may call the office of the Institutional Review Board at 415- 476-1814.

If UCSF pays your costs for reasonable and necessary care if you are hurt by the study drug or a procedure that is done to you only because you are part of this study, UCSF will need to know some information about you like your name, date of

birth, and social security number. UCSF has to check to see if you receive Medicare, and, if you do, report the payment it makes to Medicare. UCSF will not use this information for any other purpose.

What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, *you may leave the study at any time*. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care.

We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

You do not lose any of your legal rights by signing this form.

What benefits can I expect from this study?

We will test you for HIV at the beginning and the end of this study. If you wish, we may provide counseling to help you to avoid HIV (and other STIs), and may give you tools that help with taking a pill every day. If you have a positive rapid HIV test, we will refer you for care and/or treatment.

At the beginning of the study you will have tests to check on the health of your kidneys, of your liver and test to measure levels of certain hormones. If any health problems are found, you will be referred for care. At every visit, if you'd like, you may receive condoms and lubricants free of charge.

There may be no other direct benefit to you from participating in this study.

However, this study will help us find out more about Truvada® drug levels in transgender persons, as well as the potential impact of Truvada® on hormonal therapy. We hope this information will help HIV prevention in the transgender communities.

UCSF and the study investigators, Drs. Grant and Deutsch, will be the owners of the study results. UCSF and the study sponsors plan to use the results to inform care in transgender persons. You will not be paid any part of this.

Are there alternatives to taking part in this study?

The goal of this research study is to provide scientific information. You may not receive any medical benefit. The alternative choice is to not participate in the study. You can still access Truvada® for PrEP without being part of this study.

Will I receive payment to be part of this study?

In return for your time, effort, and travel expense you will receive $60.00 in cash at the screen and at the enrolment visits. You will receive a total of $100 at each follow up visits at the end of a week of DOT. If you complete all study visits and calls, you will receive $520 for your participation.

Payments you receive for being in this study will not be taxable since only income over $600 received from SFAF in one year is taxable. However, if you are participating in other studies with stipends provided by SFAF, your income may be taxable. Let your study know if it is the case. We may need to collect your social security number.

Will I have to pay anything to be part of this study?

As part of the study, you will receive the study drug and all the study tests and procedures at no cost to you.

Can I stop being in the study?

Yes. *You can decide to stop at any time*. Tell the study clinician if you are thinking about stopping or decide to stop. He or she will tell you how to stop your participation safely.

The study clinician may stop you from taking part in this study at any time if he/she believes it is in your best interest, if you acquire HIV, if you do not follow the study rules, or if the study is stopped.

You may choose to stop taking part in the study at any time, without giving a reason. However, the reason for leaving the study is important information for the researchers. Therefore if you choose to leave early, the study staff may ask you a few questions to help understand why you leave the study.

Your decision will not affect your medical care now or in the future. It will not affect other benefits you receive outside of the study.

If you leave the study early the data and samples collected before you left the study will still be used for the study.

UCSF, the study sponsors, the IRB, or the study clinicians may choose to stop the study at any time. If this happens we will give you the reason at that time.

How will information about me be kept confidential?

Participation in this study may involve a loss of privacy, but we will do everything possible to assure that the personal information recorded in your medical record is managed with the maximum privacy. All the information we collect for this research study will be stored in locked file cabinets and kept in secure computer files, protected by passwords. Your name will not appear in your study file or your specimens. We will create a unique code that will be used on the research information we collect from you, and all the laboratory specimens we use for testing. The study data in the medical chart will be kept separate from your identifying information and study code.

The video calls will be scheduled at times and locations that you find safe and convenient, and the study team will use a phone password protected and solely dedicated to this study. The study team will use video applications that are encrypted, but for security reasons, we advise you not to discuss any health related information on the video call. If you want to discuss side effects or other pill taking concerns, we will discuss in an immediate phone call back to you or at the next visit. In case of loss or theft of the study phone, we will use an application that allows to remotely destroy the data on the phone.

If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. However, we cannot guarantee total privacy. Your personal information may be given out if required by law.

California regulations require laboratories to report new cases of HIV, or hepatitis B infection to the county public health department. The reports include the patient's name, social security number, and other identifying information. Information about these new infections is used to track these diseases statewide and nationwide. Other than this required reporting, your results will be treated confidentially by the study staff. Personally identifying information will not be reported to other departments or agencies.

Individuals or organizations that can look at and/or copy information from your unidentified medical records and study documents for research, quality assurance, and data analysis include:

- Study staff and monitors
- University of California, San Francisco's Institutional Review Board
- The United States Food and Drug Administration
- Gilead Sciences (the pharmaceutical company that manufactures the medication)

The study staff may also ask you if we can collect information regarding your hormone levels, or Hepatitis B status from your existing medical records if available. Or we may ask you if the information collected as part of this study may be used to inform medical care if you chose to engage in one of the SFAF clinical services. We will ask you to sign a HIPAA research authorization form (which we will explain separately).

What happens to my blood and urine samples?

If you take part in this study, we will ask you to give blood and urine samples for testing. Similar to information collected in the study, your samples will be deidentified. They may also be used by the study investigators and shared with other laboratories, companies or universities to research the levels of study drug and hormones in the blood, HIV, other diseases or conditions, or, to understand further how the study drugs or other drugs interact, and to inform development of new drugs. These results will not be returned to you.

We may use specimens to assess for evidence of HIV infection, these assessments may include HIV resistance testing, or characterization of the virus and/or the host response to infection. These assessments may be performed retrospectively; results will not be returned to you.

Your blood samples will be given the same code as your other study information and kept in locked storage. Anyone who works with your samples will hold the information and results in confidence. The study team may store your blood samples for an undefined period of time after the end of the study after which time your samples will be destroyed.

Who can answer my questions about the study?

You can talk to the study coordinator, Marion Pellegrini at 415-638-9466 or email TransPKstudy@gmail.com. You can contact the Principal Investigator of the study, Dr. Robert Grant, about any questions, concerns, or complaints you have about this study. Contact Dr. Grant at 415-350-8909.

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please contact the Office of the Institutional Review Board (IRB) by calling 415-476-1814, emailing irb@ucsf.edu, or writing to: Institutional Review Board, UCSF, Box 0962, San Francisco, CA 94143. IRB is a group of people who watch over the conduct of the study to protect your rights.

CONSENT FOR FUTURE CONTACT

We may want to contact you to participate in research studies in the future.

To do this we will need your permission, so please read the following statement carefully and then check YES or NO, whichever of the options better expresses your decision. No matter what you decide, it will not affect your healthcare or your participation in the I-BrEAThe study.

"Someone may contact me in the future to ask me if I want to participate in other research."

YES	NO

CONSENT FOR GENETIC TESTING

This section describes genetic testing. Joining this part of the study is optional. You can choose not to join the genetic testing part of the study and still take part in the main study.

The purpose of genetic testing is to see why different people may react differently to medicines. We get our genes (DNA) from our parents, and different genes may affect how a body reacts to a drug.

Scientists will look for differences in people's genes (DNA) that might explain this. This may include genes involved in the way drugs work (both good and bad) or how drugs are processed in the body.

If you choose to take part in genetic testing, we will use the specimens collected for the study.

Your blood sample will be given the same code as your other study information and kept in locked storage. Anyone who works with your sample will hold your sample and results in confidence.

How will my genetic information be shared?

Genetic information (also known as genotype data) and the medical record data (also known as phenotype data) may be shared broadly in a coded form for future genetic research or analysis. We may give certain medical information about you (for example, diagnosis, blood pressure, age if less than 85) to other scientists or companies not at UCSF, including to a (public or controlled access) government health research database, but we will not give them your name, address, phone number, or any other identifiable information. Research results from these studies will not be returned to you.

Donating data may involve a loss of privacy, but information about you will be handled as confidentially as possible. Study data will be physically and electronically secured. As with any use of electronic means to store data, there is a risk of breach of data security. Genetic information that results from this study does not have medical or treatment importance at this time. However, there is a risk that information about taking part in a genetic study may influence insurance companies and/or employers regarding your health. Taking part in a genetic study may also have a negative impact or unintended consequences on family or other relationships. It is possible that future research could one day help people of the same race, ethnicity, or sex as you. However, it is also possible through these kinds of studies that genetic traits might come to be associated with your group. In some cases, this could reinforce harmful stereotypes.
There will be no direct benefit to you from allowing your data to be kept and used for future research. However, we hope we will learn something that will contribute to the advancement of science and understanding of health and disease. If the data or any new products, tests or discoveries that result from this research have potential commercial value, you will not share in any financial benefits. If you decide later that you do not want your information to be used for future research, you can notify the investigator in writing to Dr. Robert Grant at robert.grant@ucsf.edu; and any identifiable sample found in their possession will be destroyed, and any remaining data will be destroyed. However, we cannot retract any data has been shared with other researchers.

Please put your initials in the "YES" or "NO" box to indicate your answer.

1. My specimens and associated data may be kept for use in research to learn about, prevent, or treat HIV.

YES	NO

2. My specimens and associated data may be kept for use in research to learn about, prevent or treat other health problems (for example: diabetes, Alzheimer's disease, or heart disease).

YES	NO

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

You have been given copies of this consent form and the Experimental Subject's Bill of Rights to keep.

You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to participate or to withdraw at any point in this study without penalty or loss of benefits to which you are otherwise entitled.

If you wish to participate in this study, you should sign below.

_____	_____
Participant name (print)	Participant signature and date

I have explained this consent to the participant and answered all of his questions. In my opinion, the participant fully understands the purpose, procedures, confidentiality, risks, and benefits as described in this consent form.

_____	_____
Name of the person obtaining consent (print)	Signature of the person obtaining consent and date