UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Study Title: Evaluation of doxycycline post-exposure prophylaxis to reduce sexually transmitted infections in men who have sex with men and transgender women either on PrEP or living with HIV (DoxyPEP study)

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This is a clinical research study. Your study doctor, Annie Luetkemeyer MD from the UCSF Division of HIV, Infectious Diseases and Global Medicine or Stephanie Cohen, MD from the UCSF Infectious Diseases Division and their research colleagues will explain the study to you.

STUDY SUMMARY

Introduction: We are asking you to continue taking part in a research study that you have already enrolled in. This study is being done by Annie Luetkemeyer and Stephanie Cohen at UCSF

The first part of this consent form gives you a summary of this study. We will give you more details about the study later in this form. The study team will also explain the study to you and answer any questions you have.

Research studies include only people who choose to take part. It is your choice whether or not you want to take part in this study. Please take your time to make a decision about participating. You can discuss your decision with your family, friends and health care team.

The purpose of this study is to understand if taking an antibiotic medication called doxycycline, after sexual contact without a condom, can reduce the risk of being infected with sexually transmitted infections (STIs). This strategy is called "post-exposure prophylaxis" or "PEP." The study will compare the effects of taking doxycycline with not taking the drug, which is the current standard of care, among participants who will also receive standard care for STI

screening.

On 5/13/2022, the independent data and safety monitoring board (DSMB) recommended that this study stop enrollment due to the finding that doxycycline worked to reduce new sexually transmitted infections in people living with HIV and those taking preexposure prophylaxis (PrEP) to prevent HIV. The study will continue to follow all enrolled participants through Month 12 and will offer open label doxycycline to all participants who were originally assigned to receive standard of care (no doxycycline).

- If you choose to stay in the study and you were initially assigned to the doxycycline arm, you will continue to receive doxycycline PEP (200 mg by mouth) within 3 days after sexual contact without a condom.
- If you were not assigned to receive doxycycline, you will now be offered doxycycline PEP for the remainder of your 12 month study participation. It is your decision if you would like to start taking doxycycline or not. Regardless of whether you start taking doxycycline, you have the option of continuing in the study through Month 12.

All study participants will be seen for study visits every three months for a year. During these visits, you will be tested for sexually transmitted infections (chlamydia, gonorrhea and syphilis) by swabs and blood draws, asked about current symptoms and, if you are taking doxycycline PEP, asked how much doxycycline you have taken. You will be asked to record sexual activity using a smartphone app, as well as your doxycycline use if you are taking doxycycline PEP.

You will be in this study for 12 months and visit the research site approximately 5 times for scheduled study visits. You will also be asked to return for an unscheduled study visit if you are diagnosed with a new sexually transmitted infection.

Possible Risks:

There are risks to taking part in a research study. Some of the most likely risks of participation in this study include:

- Nausea
- Diarrhea
- Irritation of the esophagus
- Increased skin sensitivity to the sun
- Rash

There are also rare but serious risks of participation, like:

- Serious allergic reaction, including a severe skin rash
- Elevated pressure in the brain
- Decreases in blood cells (white cells, red cells or platelets)

We'll tell you about the other risks later in this consent form.

Possible Benefits:

You may benefit from participating in the study, but this cannot be guaranteed.

Your Other Options:

You do not have to participate in this study. Your other choices may include:

- Getting treatment to prevent sexually transmitted infections without being in a study.
- Taking part in another study.
- Getting no treatment to prevent sexually transmitted infections

Please talk to your doctor about your choices before agreeing to participate in this study.

The following is a more complete description of this study. Please read this description carefully. You can ask any questions you want to help you decide whether to join the study. If you join this study, we will give you a signed copy of this form to keep for future reference.

DETAILED STUDY INFORMATION

Research studies include only people who choose to take part. Please 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 your study doctor.

You are being asked to take part in this study because you are a man or transgender woman (assigned male gender at birth) who has sex with men (MSM) and who is either living with HIV or who is taking or will start taking pre-exposure prophylaxis (PrEP) to prevent HIV infection. In addition, you have had a sexually transmitted infection (gonorrhea, chlamydia, or syphilis) in the past 12 months and have had oral or anal sex with another man without using a condom, at least once in the in the past 12 months.

Why is this study being done?

The purpose of this study is to understand if taking an antibiotic called doxycycline by mouth as soon as possible after sexual contact without a condom can reduce the risk of sexually transmitted infections (STIs), including gonorrhea, chlamydia and syphilis. As of May 2022 the study has shown that doxycycline does reduce the risk of STIs in both participants living with HIV and those taking PrEP. The goal of the study after May 2022 is to understand the safety and acceptability of doxycycline PEP and the impact that PEP may have on the bacteria that cause STIs as well as on bacteria that normally live on the body. While doxycycline is approved by the Food and Drug Administration (FDA), taking doxycycline immediately after sexual contact to prevent infection is investigational and is not approved by the FDA for this use.

The Division of Microbiology and Infectious Diseases (DMID), which is a part of the National Institutes of Health (NIH), pays for the conduct of this study, including part of Drs. Luetkemeyer and Cohen's salaries.

Mayne, the manufacturer of the drug doxycycline that is being used in this study, is providing doxycycline at no cost to the researcher or research participant.

How many people will take part in this study?

About 650 people will take part in this study and have already been enrolled. About half of these have been be enrolled in San Francisco at 2 sites (City Clinic and the HIV Division HHRC)

What will happen if I take part in this research study?

Before you begin the main part of the study...

You will meet with a research assistant to understand if you qualify to be in the study, which requires the following:

1) You will need to have a history of a sexually transmitted infection (syphilis, gonorrhea or chlamydia) within 12 months
2) You need to be a man who has sex with men or transgender woman (assigned male gender at birth) who is living with HIV or who is taking or plans to start taking HIV pre-exposure prophylaxis (PrEP)

During this screening evaluation, you will be asked questions about your medical history, sexual history, history of sexually transmitted infections, HIV infection history, current use of medicines to prevent HIV, and any medications you are taking or have taken recently, including antibiotics.

During the main part of the study...

If you meet the requirement to be in the study and you choose to take part, then you will need the following tests and procedures:

- You will be asked to sign a release of information to allow the study to access your medical records regarding testing and treatment for STI, HIV and HIV prevention such as HIV pre-exposure prophylaxis from the 12 months before the study and for the duration of your study participation. This will include results from gonorrhea cultures tested for drug resistance through an existing public health surveillance program, if these have been or are collected during the study. If you are found to have drug resistant gonorrhea, you and your partners may be contacted by the local public health department to be sure that your gonorrhea infection has been fully treated.
- You will be asked if you have any current symptoms of an STI, including pain or discharge with urination, throat pain, rectal pain or discharge, genital lesions, or a rash.
- You will be asked if you have any symptoms that can be associated with taking doxycycline.
- You will have testing done for gonorrhea and chlamydia. This will be done by swabbing your throat and rectum with a Q-tip (swabbing may be done by study staff or by you if preferred). You will give a urine sample for gonorrhea and chlamydia testing as well. As noted above, results from tests done before you signed the consent form may also be used for the study with your permission.
- You will have approximately 2 tablespoons of blood drawn. This blood will be used to test you for syphilis infection.
- You may have the option of home collection for STI testing should there be future COVID-

related infection control concerns with returning to the clinic.
- Your medical chart will be reviewed for HIV-related testing that has been done in the past 3 months (HIV antibody, HIV virus testing, and CD4 cell count, a measurement of immune function).
- You will be offered condoms, lubricant and safer sex counseling.

You will also need the following tests and procedures that are part of regular care, but they will be done more often because you are in this study.

- If you are assigned to receive doxycycline PEP you will have your blood tested for a complete blood count and liver function tests at months 3 and 9, if you have not already had these blood tests done with 30 days prior to the study visit. If you now choose to take doxycycline, you will have these blood tests at month 3 and 9 if these visits have not already occurred and if you have not already had these blood tests done within 30 days prior to the study visit.

You will also need the following tests and procedures done that are either being tested in this study or being done to see how the study is affecting your body.

- You will have a swab of your rectum to look at the types of bacteria that live in your intestines and what antibiotics they are sensitive to. This may include testing for bacteria that can cause STIs, such as Mycoplasma genitalium.
- You will have a swab of your nose and throat to look for different types bacteria which can normally live in the throat or nose, called Staph aureus and Neisseria. If these bacteria are found, they will be tested for what antibiotics they are sensitive to.
- If you are assigned to receive doxycycline PEP, you have the option of providing a stool sample if you are one of the first 50 people enrolled in the study who is living with HIV or among the first 50 people enrolled who is taking PrEP. This sample will be evaluated for the kinds of bacteria and the presence of drug resistant bacteria. A separate section to consent for this collection is at the end of the consent form.
- When you have every three month testing of your urine for chlamydia and gonorrhea, some urine from this specimen will be stored for future testing for Mycoplasma genitalium, a bacteria which can cause a genitourinary infection. As this is not a routine STI test, specimens will be stored and batch tested to better understand the frequency of this organism in this population. You will not receive the results of this testing.
- You will be given a survey asking your opinion on taking doxycycline, if you are taking doxycycline PEP.
- You will be asked to provide a small hair sample to look for signs of doxycycline in your system over the past 3 months (collected at month 6 and month 12).
- If you have a new or suspected diagnosis of chlamydia, gonorrhea or syphilis, you will be asked to return to the research site for a swab of the infected area or, for syphilis, a swab of your mouth if you have no skin lesion that can be swabbed or for a urine collection, if you have urinary symptoms. These samples will be used to test for drug resistance to doxycycline and other antibiotics, as well as to investigate the strain of the infection and how it may be related to strains in the community. Your urine may be tested for Mycoplasma genitalium, bacteria which can cause urethral infection, and for the presence of drug resistance in this bacteria. You will receive treatment for your infection with chlamydia, gonorrhea, and/or syphilis through the clinical care available in association with the research site. If you have already received treatment for your sexually transmitted

infection elsewhere, you will be asked to return to the research site for a swab or urine sample if the treatment was less than 7 days ago.

- If you have a smartphone, you will be given instructions on how to download and register for an application called Black Book that will be used by the study to track your sexual activity, STI, and doxycycline use. You will be asked to use the app to record timing and type of sexual activity. If you are taking doxycycline PEP, you will be asked to use the app to record when you take doxycycline. You will also be able to provide information about sexual partners – the amount of information you provide about each partner is up to you. The app will send you a reminder once a week to record sexual activity.
    - The study does not provide smart phones nor does it pay for cellular data required for app use. If you don't have a smart phone or lose access to your phone through the study, the study staff will give you information about how to obtain a cell phone for free if you qualify. This is not part of the study.

You have already been "randomized" into one of the study groups described below. Randomization means that you are put into a group by chance. A computer program has placed you in one of the groups. If you were assigned to the no doxycycline PEP group, you are now being offered doxycycline.

- **If you are in group 1 (doxycycline PEP),** you will be provided with a supply of the antibiotic doxycycline. You will be asked to take 200 mg of doxycycline (1 pill) within 24 hours, and no later than 72 hours, after sexual contact without a condom. You will receive doxycycline PEP every three months for 12 months. You will be asked to record doxycycline use and sexual activity using a smartphone app provided by the study. The smartphone will not be provided by the study. You will be asked to bring unused doxycycline and all empty bottles of doxycycline to your next study visit. You will continue to receive standard care for sexually transmitted infection testing and prevention which includes testing for sexually transmitted infections every 3 months, treatment for STDs if you have a positive test or symptoms, counseling to reduce your risk, and condoms and lubricant.

- **If you are in group 2,** you are now being offered doxycycline PEP for the remainder of your participation in the study. If you choose to take doxycycline as PEP in this study, you will be asked to take 200 mg of doxycycline (1 pill) within 24 hours, and no later than 72 hours, after sexual contact without a condom. You will receive doxycycline PEP every three months for 12 months. You will be asked to record doxycycline use and sexual activity using a smartphone app provided by the study. The smartphone will not be provided by the study. You will be asked to bring unused doxycycline and all empty bottles of doxycycline to your next study visit. You will continue to receive standard care for sexually transmitted infection testing and prevention which includes testing for sexually transmitted infections every 3 months, treatment for STIs if you have a positive test or symptoms, counseling to reduce your risk, and condoms and lubricant.

- **Timing of study visits and procedures:**
  - The initial enrollment visit will take approximately 45 minutes.
  - Scheduled follow up visits will happen every 3 months and will take approximately 30 minutes
  - Visits that occur for treatment of a new diagnosis of a sexually transmitted infection will take approximately 30 minutes.

- **Study location:** All study procedures will be done at Zuckerberg San Francisco General Research unit on the 4th floor of Building 80 or at San Francisco City Clinic, located at 356 7th Street, San Francisco.

- **Blood drawing (venipuncture – every 3 months):** A blood sample will be drawn by inserting a needle into a vein in your arm. Testing at months 0, 6, and 12 will require 2 teaspoons of blood at each visit. Testing in group 1 (doxycycline arm) at months 3 and 9 will require up to 6 teaspoons at each visit and testing in group 2 (standard of care) will include an additional 2 teaspoons at the month 12 visit. You will have the option to provide blood to be stored for future testing which will require 2 teaspoons at month 0 and 12. A total of up to 7 $^{1}/_{3}$ tablespoons will be drawn for the whole study. (8 $^{2}/_{3}$ tablespoons if you provide the additional blood for future testing).

- **Swabs and urine for sexually transmitted infections (every 3 months):** You will have a swab (using a special Q-tip) of your throat and anus to test for gonorrhea and chlamydia. Study staff can conduct the swab or you may swab yourself if you prefer – the study staff will provide guidance on how to do so. You will have a urine specimen collected for STI testing every three months. If an STI is suspected and your doctor decides to treat you before the test results are back, you will have a repeat test of the affected area (swab of throat or rectum, or urine collection). If you have an STI diagnosed, you will have a repeat swab or urine collection depending on where the infection is at the time you return for treatment of your infection. Swabbing will take approximately 5 minutes. Urine collection will take approximately 5 minutes. If gonorrhea is suspected or diagnosed, you will be offered swabs of the throat, rectum and urethra/urethral discharge as part of non-research public health surveillance program to detect gonorrhea resistance. You may have the option of self collection of urine, swabs and fingerstick blood collection for routine STI testing if there are future restrictions on in-person clinic visits due to increased COVID activity.

- **Swabs for nasal and oral bacteria (every 6 months):** The study staff will swab the inside of your nose and the back of your throat to look for bacteria that can commonly live in the body. Swabbing will take approximately 5 minutes. You may swab yourself if this is preferred.

- **Rectal swabs (every 3-6 months):** The study staff will insert a Q-Tip into the rectum to get a sample of normal bacteria (every 6 months) and a separate swab to look for M.genitalium and other microbes that may be associated with sexually transmitted infections (every 3 months). You may swab yourself if this is preferred. You will also be asked to have a rectal swab to look at normal bacteria if you are in group 2 and choose to switch to taking doxycycline PEP; this swab will be done at the visit where you are provided with doxycycline.

- **Stool collection (every 6 months):** You will be asked to provide a specimen of your stool which can be collected at home and brought back to the clinic, ideally within 4 hours. This will be tested for normal bacteria that lives in the gut. Stool sample collection should take approximately 5-10 minutes. This stool sample collection is optional and will be limited to 100 participants.

- **Hair collection (6 and 12 months):** For this study, you will be asked to have a small sample of hair (about 100 strands) cut from your head so that we can measure levels of doxycycline in this small hair sample, regardless of which arm you are assigned to. The hair collection will be done during the study visits at months 6 and 12, and will take about 5 minutes. Drug levels in hair samples can tell research investigators how much medication gets into a person's body. Hair may be saved to look at levels of HIV PrEP medications if you are taking these. Levels in hair may give us a better idea of long-term exposure to a drug. Of note, humans lose about 100 hairs from their head every day naturally so this amount of hair removal should not be noticeable. There is a small chance of cutting or nicking the scalp from the cutting of the hair sample.

- **In-depth interview:** Some participants will be given the option to participate in an in-depth interview at the end of the study to share your opinions on the experience of taking doxycycline, if you took doxycycline during this study. Participation in this interview is voluntary and you will be provided with a separate consent.

Results of testing done for research only (stool collection, rectal swabs for normal stool bacteria, testing for syphilis and chlamydia antibiotic resistance, urine/rectal swab testing for M. genitalium and other microbes) will not be available to you or your providers, just to the researchers in the study.

The table below shows the study visits and what will happen at these visits.

Month	*0*	*3*	*6*	*9*	*12*	Visit when STI treated or diagnosed
Instruction on how to use the smart phone application	√					
Doxycycline pills given out*	√*	√*	√*	√*		
Review of remaining doxycycline pills and how many were taken since last visit		√*	√*	√*	√*	
GC/CT testing (throat & rectal swab, urine collection)	√	√	√	√	√	
Blood for syphilis testing	√	√	√	√	√	
Blood for complete blood count and liver function tests (control arm only at month 12)		√*		√*	√	
Stored blood for future testing *(optional)*	√				√	
Swabs & urine collection at time of new STI treatment or diagnosis						√
Swab of nose and throat	√		√		√	
Stool sample (optional)	√*		√*		√*	
Swab of rectum for future analysis of bacterial diversity and drug resistance genes***	√		√		√	
Swab of rectum for future mycoplasma genitalium and other microbial testing	√	√	√	√	√	
Collection of hair			√		√	
$25 reimbursement	√	√	√	√	√	√**
Questions about recent sexual contact	√	√	√	√	√	√
Questions about acceptability of taking doxycycline*			√*		√*	
One-time, in-depth qualitative interview* (Offered to subset, separate consent)		3-12 months				
The star (*) means only done if you are assigned to take doxycycline (group 1) or now choose to take doxycycline (group 2) *The two stars (**) mean reimbursement provided if an extra visit is required to the clinic at the time of STI diagnosis, for additional swab & urine collection* *The three stars (***) mean you will be asked to provide a rectal swab at the time of starting doxycycline PEP (group 2)*						

How long will I be in the study?

You will be in the study for 12 months. If you are assigned to take doxycycline PEP or now chose to take doxycycline PEP, you will be asked to take doxycycline every time you have oral, anal or vaginal sex without a condom during these 12 months.

Can I stop being in the study?

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

It is important to tell the study doctor if you are thinking about stopping so any risks from the doxycycline can be evaluated by your doctor. Another reason to tell your doctor that you are thinking about stopping is to discuss what follow-up care and testing could be most helpful for you.

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

What side effects or risks can I expect from being in the study?

You may have side effects while on the study. 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. Your health care team may give you medicines to help lessen side effects. Many side effects go away soon after you stop taking the doxycycline. In some cases, side effects can be serious, long lasting, or may never go away.

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

Risks and side effects related to doxycycline, for those participants assigned to the doxycycline PEP group:

<u>Likely</u>

- Nausea
- Diarrhea
- Decreased appetite
- Trouble swallowing, especially if doxycycline not taken with enough liquid
- Abdominal pain
- Skin sensitivity to the sun

<u>Less likely</u>

- Yeast infection of the genitals
- Abnormalities of the blood, including:
    - low red cell count (known as anemia, which can cause tiredness)
    - low white cell count (which may reduce the body’s ability to fight infection)

    - low platelets, a part of the blood that helps control bleeding and if low, may lead to easy bruising or bleeding

- Bacteria in the body developing drug resistance to doxycycline, meaning that this antibiotic may not work to treat some future infections
- Weight gain- weight gain has been reported in some people who have taken a similar type of antibiotic for other kinds of infection. It is not known if doxycycline PEP may lead to weight gain.

Rare but serious

- Serious allergic reaction, which may include trouble breathing, hives, and involvement of skin and other organs in the body
- Serious skin reaction
- Pancreatitis
- Inflammation around the heart known as pericarditis
- Elevated pressure in the brain which can cause headaches and blurred vision

Randomization risks: You were initially assigned to receive doxycycline or to not receive doxycycline by chance, and the group to which you were assigned may prove to be less effective or to have more side effects than the other study treatment or other available treatments. If you were assigned to not receive doxycycline, you are now being offered the option of taking doxycycline for the remainder of your study participation.

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

Sexually transmitted infection testing risks: You may also feel some discomfort from using the oral and rectal swabs. Being tested for gonorrhea, chlamydia and syphilis may cause anxiety regardless of the test results. If you test positive for one or more of these infections, the study team will coordinate treatment at the clinic associated with the study. Receiving a new diagnosis of a sexually transmitted disease may make you upset. If other people learn about your positive test results, this may be embarrassing to you or possibly lead to discrimination. If your tests are negative, there is the possibility that you could be infected with a sexually transmitted infection at some time in the future. Test results for gonorrhea, chlamydia and syphilis are required by law to be reported to the San Francisco Department of Public Health, which may reach out to you to ensure that you have been appropriately treated.

Privacy and confidentiality risks: We will make every effort to protect your confidentiality during the study. However, it is possible that others may learn that you are part of this study and they may think that you are infected with HIV or are at high risk for infection with HIV or that you may have or be at risk for a sexually transmitted infection. The most common risks we know about are family or friends worrying, getting upset or angry, or assuming that you are HIV infected or that you have a sexually transmitted infection and treating you unfairly as a result.

You should think very carefully before deciding to tell anyone about your participation in this study.

Although every reasonable effort has been taken, confidentiality during mobile app communication procedures cannot be guaranteed and it is possible that additional information beyond that collected for research purposes may be viewed by others not associated with this study for unauthorized purposes.

Because you will receive notification messages and answer questions about sexual behavior and substance use, it is possible that someone else who has access to your phone may see these notification messages or your data entries, revealing your participation in the study.

Standard message rates apply for text messages (such as survey reminders) that are sent to your personal phone. Using the study Black Book app on your personal phone may also use part of your data plan and may cost you money. Please review your current text message and data use plan to estimate what, if any, additional charges you may be billed for.

Unknown Risks: Use of doxycycline for post-exposure prophylaxis to prevent STIs may have side effects that no one knows about yet. The researchers will let you know if they learn anything that might make you change your mind about participating in the study.

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

Are there benefits to taking part in the study?

Taking doxycycline PEP has now been shown to reduce your chances of getting a sexually transmitted infection after condomless sexual contact for people who took doxycycline in this study.

If you are in the group that does not receive doxycycline PEP and choose not to take doxycycline for the remainder of the study, you may have less side effects associated with doxycycline compared to those who do take doxycycline, but this cannot be guaranteed.

What other choices do I have if I do not take part in this study?

Your other choices may include leaving this study and:

- Taking doxycycline prescribed to you by a medical provider outside of a study
- Taking part in another study.
- Getting no post-exposure prophylaxis (PEP) after sexual contact without a condom.

Please talk to your doctor about your choices before deciding if you would like to leave this study.

How will my specimens and information be used?

Researchers will use your specimens and information to conduct this study. Once the study is done using your specimens and information, we may share them with other researchers so they can use them for other studies in the future. We will not share your name or any other personal information that would let the researchers know who you are. We will not ask you for additional permission to share this de-identified information.

Research results: There may be times when researchers using your information or specimens may learn new information. The researchers may or may not share these results with you, depending on a number of factors.

How will information about me be kept confidential?

Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total privacy. Some information from your medical records will be collected and used for this study. The results of your STD/HIV and other laboratory tests may become part of both your clinic medical record and study record. All other information collected as part of this study will be part of your study record only and will not include your name or other identifying information with the exception of your local medical record number which will be included in the study data base. All study records will be stored in a locked location or under password protection on study computers. Only study staff will have access to your study record. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Your personal information may be given out if required by law.

Authorized representatives from the following organizations may review your research data for the purpose of monitoring or managing the conduct of this study:

- Representatives of the San Francisco Department of Public Health
- Representatives of the study protocol team including study monitors
- Representatives of the University of California
- Representatives of the US National Institutes of Health
- Representatives of the US Office for Human Research Protections
- Representatives of the US Food and Drug Administration

All reviewers will take steps to keep your records private.

To help us protect your privacy, this study is covered by a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers can use the Certificate to legally refuse to disclose information or documents that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings.

Information or documents protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except as described below; if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

Exceptions to confidentiality
A Certificate of Confidentiality does not prevent researchers from voluntarily disclosing information about you, without your consent, if required by federal, state or local law. For example, we will voluntarily disclose information about incidents such as child abuse, and intent to hurt yourself or others.

In addition, a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it. Finally, the Certificate may not be used to withhold information from the Federal government needed for auditing or evaluating Federally funded projects or information needed by the FDA.

State and local regulations require that health care workers, including study staff at the clinic, report known or likely cases of child abuse, including child sexual abuse. Health care workers must report a participant's intention to harm others to the police and to the intended victim. We may also need to break privacy if a participant is a danger to himself or others. In cases of elder or dependent adult abuse, a report may need to be made to the proper authorities. Details of injuries by criminal acts, including domestic violence may also be reported. These exceptions are to help assure your safety and well-being and public safety.

If you test positive for reportable sexually transmitted infections (syphilis, gonorrhea, or chlamydia), we are required by California law to report your results to state and local health departments with your name and other identifying information, as needed. Information about these new infections is used to track these diseases statewide and nationwide. In addition, the public health department may contact you about your partners who may have been exposed to a sexually transmitted infection. As part of gonorrhea public health reporting and surveillance, if you have a gonorrhea infection, you will be asked to provide a swab for gonorrhea culture to look for drug resistance, as part of public health surveillance for drug resistant gonorrhea.

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.

Are there any costs to me for taking part in this study?

Two types of procedures will be done during this study. Some are part of your standard medical care and others are only for research. You or your insurer will be billed for the standard medical care. You will be responsible for your co-pays, deductibles, and any other charges that your insurer will not pay. There is a possibility that your insurer may not cover all standard medical care costs if you are receiving medical services out of network.

Regular testing for sexually transmitted infections is considered part of standard medical care for the populations enrolled in this study. In the event that this testing is not covered by your current medical care and/or insurer, the study will pay for the cost of STI testing, as these tests are a required component of this research.

Any procedures done only for research will not be charged to you or your insurer.

The study will provide doxycycline at no cost for those assigned to the doxycycline PEP group and to those in the standard of care arm who now choose to take doxycycline for the remainder of the study.

Will I be paid for taking part in this study?

In return for your time, effort and travel expenses, you will be paid $25.00 at the end of the re-enrollment visit and the month 3, 6, 9 and 12 visits and if you need to return for an unscheduled visit for STI treatment or additional swabs due to a recent STI diagnosis. Participants who take part in the optional stool sample collection will be paid an additional $25 for each of the three visits in which the stool sample is provided. You will not be paid for other unscheduled visits or to get more doxycycline if needed.

If you complete all study visits, you will receive $125.00 in total, plus $25.00 for any return visits for STI treatment and collection of additional swabs, and $25 for each stool sample collection for those who take part.

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

It is important that you tell your study doctors, Annie Luetkemeyer and Stephanie Cohen, if you feel that you have been injured because of taking part in this study. You can tell the doctor in person or call her at 415-476-4082 ext. 130 (Dr. Luetkemeyer) or 628-217-6674 (Dr. Cohen).

> **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 depending on a number of factors. The University does 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.

The sponsor of the protocol, the National Institutes of Health, has no program for monetary compensation or other forms of compensation for such injuries.

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. You can still get your medical care from our institution.

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. In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

Who can answer my questions about the study?

You can talk to your study doctor about any questions, concerns, or complaints you have about this study. Contact your study doctor Annie Luetkemeyer at 415-476-4082 ext. 130 or Stephanie Cohen at 628-217-6674.

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 call the office of the Institutional Review Board at 415-476-1814.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

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OPTIONAL RESEARCH

Please note: This section of the informed consent form is about an optional research study that is being done with people who are taking part in the main study. You may take part in this optional study if you want to. You can still be a part of the main study even if you say "no" to taking part in this optional study.

You can say "yes" or "no" following the description of this study. Please mark your choice.

We would like to collect a blood sample (about 2 teaspoons) at month 0 and month 12 to store for future research related to this study, including potential testing of the blood for herpes antibodies. This testing will not involve genetic testing. If you consent to provide this blood, you will not be asked about future testing and will not be provided these test results, which will be conducted for research purposes only

- ☐ I *do* want to provide to provide blood to be stored for future research
- ☐ I *do not* want to provide blood to be stored for future research

CONSENT

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.

_____	_____
Date	Participant's Signature for Consent
_____	_____
Date	Person Obtaining Consent