

PrEP Script:

“This trial includes a period of time where you will need to stop taking effective antiretroviral treatment (ART) in order to answer scientific questions. We expect that your HIV viral load may increase, or ‘rebound’ when you pause your HIV treatment. We expect that all study participants will no longer be ‘undetectable’ in a few weeks after stopping their medications. We will be in frequent contact with you and we will evaluate you closely during this part of the trial to try to minimize any risks to your health.”

“There is a potential risk that is more difficult for researchers to address, and that is the possibility that you could transmit HIV to a sex partner(s) or be exposed to or even acquire a new HIV viral strain during the time when you have paused taking your HIV treatment. Both of these consequences need to be avoided. This could complicate treatment options in the future for you and your sex partner(s). Is it okay for us to discuss this now?”

<pause>

“In this trial, you will be pausing your HIV treatment to help researchers answer some important scientific questions. While we are making steady progress in developing HIV cure-related strategies, most participants will see their HIV viral load become detectable or ‘rebound’ during the treatment interruption.”

“This is where partner protections come into play. Because HIV has ‘rebounded,’ you will no longer be ‘undetectable,’ and you are at risk of transmitting HIV to sex partner(s) or people with whom you share needles or works at any time during this part of the trial. Once you pause taking your HIV treatment, you should assume that your viral load may be (or become) detectable. The ‘U = U’ message (Undetectable means Untransmittable) does not apply during your treatment interruption. You may need to take other steps to help keep your sex partner(s) safe from HIV.”

Do you have any questions about what is expected to happen during the treatment interruption phase?

<pause>

“Now I would like to ask for your permission to ask some questions about your sex life and preferences for preventing sex partner(s) from acquiring HIV. Is this OK? You can decline to answer any question that makes you uncomfortable. Also, if this is not the right time, or if you might feel more comfortable speaking with someone else, please let me know and we will accommodate your preferences.”

<pause>

“Because HIV will no longer be ‘undetectable’ during this part of the study, we are recommending that, in addition to condoms, your sex partner(s) without HIV use PrEP to prevent new HIV transmissions during the trial. Have you heard of PrEP before? What do you know about PrEP and how do you feel about it?”

<Pause>

“PrEP stands for ‘pre-exposure prophylaxis’ and is a highly effective HIV prevention method that can reduce the risk of acquiring HIV through sex. PrEP needs to be taken by a person without HIV before they are exposed to HIV and must be taken consistently to prevent HIV transmission. While it prevents transmission of HIV, it does not prevent other sexually transmitted diseases. Use of condoms can help reduce those risks. There are

many resources to learn more about PrEP, where and how to access PrEP here in our community, and about testing and treatment for other STIs.”

How do you feel about using condoms and PrEP during your treatment interruption?

<pause>

“There is still a risk of transmission for a period of time after you re-start your HIV treatment. At a minimum, the research team will ask you to wait to resume unrestricted sexual activity until your viral load has become undetectable for a period of time, typically 6 months.”

<pause>

“Are you aware that many states may criminalize exposure to HIV (or press charges under other statutes)? The risk of criminal charges is greatly increased if HIV transmission occurs. During the pause in taking your HIV treatment, there will be an increased chance of unintentionally passing HIV to sex partners. You may wish to take some time before then to learn about what the law requires in our area in terms of your responsibilities to protect any sex partner(s) from acquiring HIV. HIV criminalization is a potential risk to all persons living with HIV, whether or not they volunteer to participate in clinical research.”

“Locally, you may wish to contact < [Research Team enters agency, contact name and telephone number](#) >. You may also wish to contact our local Health Department < [Research Team enters Contact name and telephone number](#) >. You can also review information at The Sero Project (www.seroproject.com), The Center for HIV Law and Policy (www.hivlawandpolicy.org), and the Elizabeth Taylor AIDS Foundation (<https://elizabethtayloraidsfoundation.org>) and (<https://www.hivisnotacrime-etaf.org>).”

“We will discuss ways to reduce or minimize the possibility of HIV transmission during your study participation, including the use of barrier protection, PrEP, and other considerations.”

<pause>

“We have developed several resources for you to discuss the treatment interruption with your partner(s) and to help them access resources like condoms, safer sex education, PrEP and STI testing and treatment. I’d like to review these with you now if that is OK.”

“When you speak with your sex partner(s) about resources to protect them from HIV, you will need to disclose your own HIV status and provide the information about the trial that they need and want.”

“Have you disclosed your HIV status with your partner(s)?”

“Many people have concerns about a negative reaction, or even abuse or other negative consequences after disclosing their status. If there are current partner(s) with whom you have not disclosed your status, do you have any concerns about disclosing your status to them?”

<pause>

*“The first resource is the **HIV Treatment Interruption Participation Disclosure Sheet**. This resource is meant to help you discuss your participation in our trial with your sex partner(s) if you wish to do so. It provides helpful tips for discussing why you are participating in the trial and why you will be stopping your HIV treatment during the study.”*

<pause to review **HIV Treatment Interruption Participation Disclosure Sheet**>

*“The second is the **PrEP for Partners** information sheet. This resource has information for your partners regarding how they can access PrEP. As we discussed, PrEP is a medication taken by mouth that can prevent HIV in individuals without HIV who are exposed to HIV. We recommend that your sex partner(s) without HIV consider using PrEP, particularly during the time when you are off HIV treatment. This will significantly decrease the risk of your sex partner(s) acquiring HIV.*

- *Because prescription drug coverage is complicated, the best place for your sex partner(s) to start is with their primary care doctor, if they have one. This is because sometimes PrEP can only be obtained through a person’s primary care clinic.*
- *Our research team/site has relationships with PrEP providers here in our local area and can help connect you/your partner(s) to them. Here is the current list.*
- *The **PrEP for Partners** information sheet reviews other resources as well.*

“If you have partners outside the area or who do not have a regular doctor, they can use the website www.PleasePrEPMe.org to find a PrEP provider in their area. This website also offers a live chat to help navigate individuals to clinics where they can obtain PrEP. Let’s take a moment to review the sheet.”

<pause to review **PrEP for Partners** sheet>

[For cisgender female partners] *“Finally, you mentioned that you have one or more cisgender female partners. We also have a sheet to provide information to these partners.”*

<pause to review **Special Considerations for Cisgender Female Partners**>

“We are happy to discuss the reasons why we recommend PrEP for partners of the volunteers in our study with you or your partners at any time. Please just make us aware that you wish to discuss PrEP and one of the study doctors will be available. We are also happy to review PrEP resources with your partners if they wish to come into the study center. While we cannot prescribe PrEP for them, we are ready, willing and able to help them to figure out how to access PrEP.”

“I am happy to answer any questions you may have at this point.”

<pause>

“How do you think you will proceed? Do you prefer to discuss these issues with your partners yourself, or would it be helpful to have our team’s assistance in figuring out how to access PrEP? Or other prevention measures we discussed today?”