



Rennie et al. • The Essential Need for Trust When Transmission Risk Cannot Be Eliminated in HIV-Remission Trials

Appendix 1. HIV-Transmission Risk to Sexual Partners

Model language for enhancing trust to reduce the risk of HIV transmission in trials that include analytic treatment interruption

[The content below is focused on HIV transmission risk and should be added to educational materials with more general information about remission trials and treatment interruption, including information on risk to the participant.]

You have been invited to join an HIV remission trial. During the trial you would stop your antiretroviral therapy (ART) for a period of time while under the careful watch of the trial team. This is done even if your ART has been working well and keeping your viral load at a low or undetectable level.

Stopping ART during a trial is often called analytic treatment interruption (ATI). This allows the clinical trial team to tell whether the experimental drug works. Later in the trial you would restart your ART based on cut offs set by the clinical trial team.

If you stop taking your ART during a clinical trial, your viral load is very likely to increase. An increase in viral load may lead to two risks:

1. Risk to your own health. That risk is described [elsewhere].
2. Risk to your sexual partners.

While you are off ART, you have a high chance of giving your sexual partners HIV if you have unprotected sex. If you are like most other people with HIV who stop ART, your viral load will go up and you will no longer be undetectable. In other words, stopping ART during the trial will ‘break’ U=U. When that happens, you can transmit HIV to your sexual partner(s).

Protecting sexual partners is a team effort. If you join the trial, you will have to help the researchers protect your partners.



Joining a trial is up to you. If you decide to join a remission trial and stop ART during the trial, you can still protect your sexual partners. There are several reliable ways to prevent transmission to partners while you are in the trial.

Why does the research team need your help?

The research team cannot know what participants do every day. Though they will talk to you at study visits about safe sex, they have to trust research participants to keep their partners safe.

Here is how you can count on the study team:

- To help you understand the requirements for the study.
- To tell you how to prevent HIV transmission to sexual partners during the remission trial.
- To monitor your safety during the trial, especially when you are off ART.
- To tell you when to restart ART.
- To do everything in their power to help you become undetectable again after the study.

You can count on the research team to protect you the same way the research team is counting on you to protect your sexual partner(s).

Here is how the research team counts on you:

- To follow the study requirements. The requirements are different for each trial.
- To tell the research team if you cannot follow the requirements **before** you put any sexual partner(s) at risk.

Your sexual partner(s) will count on you to prevent transmission of HIV.

If you decide to join, most trials give you choices about how to protect your partner(s). Here are some choices you may have:

1. Do not have sex with penetration during the time you are off ART and until your viral load goes back to undetectable. Or:



2. Use condoms consistently, every single time you have sex while off ART and until your viral load goes back to undetectable, and
3. Protect partners by encouraging them to use PrEP.

Is one of these choices possible and acceptable to you?

Your partners and the research team are counting on you to choose one of these options and follow through the entire time you are in the trial.

Here are other things you can do to help keep your partners safe.

- Tell your partner(s) that you have HIV. If your partner(s) do not know about your HIV, they will not know they need to protect themselves.
- Tell your partner(s) that you are volunteering for research to find a cure, but that the research has some risks. One risk is that the amount of virus in your body may increase, and they can get HIV if you do not follow safe sex.
- Tell your sexual partner(s), every time, that they need to use PrEP and that you also need to use a condom.

Trial participants, researchers, and sexual partners rely on each other to ensure that HIV remission trials gain important new information without putting sexual partners at risk. Clinical trials require us to work together to prevent HIV transmission to others.
