**Read the following statement to the participant before administering the Eligibility Worksheet:**

*“I am now going to ask you some questions about yourself. Some of these questions are personal and sensitive. All of your answers will be kept confidential.”*

**To confirm eligibility for the study, ask the participant the following questions and mark the responses accordingly.**

|  |  |  |  |
| --- | --- | --- | --- |
|  | Are you available to return for all visits and willing to comply with all study participation requirements? | Yes 🞎 | No 🞎 |
|  | Have you had consensual receptive anal intercourse (meaning, you are the person who is penetrated during anal sex, or is known as the ‘bottom’) at least 3 times in the past 3 months (90 days) and are you planning to continue having RAI at this frequency during study participation? | Yes 🞎 | No 🞎 |
|  | If you were to join this research study, do you agree to not take part in any other research studies involving drugs, medical devices, genital or rectal products, or vaccines for the duration of your participation, which is expected to be about 3.5 months? | Yes 🞎 | No 🞎 |
|  | Are you willing to avoid inserting any non-study medications or products rectally during study participation? This includes personal lubricants containing nonoxynol-9 (N-9). | Yes 🞎 | No 🞎 |
|  | Have you ever had an adverse or bad reaction to any component of the study products? | Yes 🞎 | No 🞎 |
|  | Have you recently participated or are you currently participating in a research study involving drugs, medical devices, genital products, or vaccines? | Yes 🞎 | No 🞎 |
|  | Have you ever participated in a research study involving the use of a rectal product? | Yes 🞎 | No 🞎 |
|  | In the past 3 months, have you used post-exposure prophylaxis (PEP) for HIV exposure? | Yes 🞎 | No 🞎 |
|  | In the past 3 months, have you had receptive anal or vaginal intercourse without the use of a condom and while not using PrEP with a partner who is HIV-positive and either not on antiretroviral therapy (ART) or whose ART use status you do not know? | Yes 🞎 | No 🞎 |
|  | Have you recently or are you currently having receptive anal or vaginal intercourse without the use of a condom and while not using PrEP with a partner whose HIV and PrEP/ ART use status you do not know? | Yes 🞎 | No 🞎 |
|  | In the past 12 months, have you used a needle to inject drugs that were not prescribed to you by a medical professional? | Yes 🞎 | No 🞎 |
| ***For those that can get pregnant, ask questions 12-16. Mark “N/A” for cis-males or transgender females*** | | | N/A 🞎 |
|  | Have you been pregnant within the last 90 days (3 months)? | Yes 🞎 | No 🞎 |
|  | Are you currently pregnant? | Yes 🞎 | No 🞎 |
|  | Are you currently breastfeeding? | Yes 🞎 | No 🞎 |
|  | Do you plan to become pregnant in the next 4 months? | Yes 🞎 | No 🞎 |
|  | If you were to join this research study, are you willing to use an effective method of contraception for at least 30 days prior to Enrollment and continue using an effective method for the duration of your study participation, which is expected to be about 3.5 months?  *Effective methods include hormonal methods such as oral contraceptive pills, contraceptive injections or implants; an intrauterine contraceptive device (IUD), sterilization (yourself or if you are in a monogamous relationship, of your partner); or you abstain from engaging in receptive vaginal intercourse (when someone places their penis inside into the vagina). If abstinent, you must refrain from penile-vaginal sex for at least 3 months (90 days) prior to Enrollment and intend to remain abstinent for the duration of study participation.* | Yes 🞎 | No 🞎 |

**For the participant to be eligible, responses to items 1-4 and 16 above must be “Yes” and responses to items 5-15 must be “No” or “N/A.”**