**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 but please remember that we do not have your name on these papers. All of your answers will be kept confidential.”

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

|  |  |  |  |
| --- | --- | --- | --- |
|  | If you were to join this research study, are you available for all visits and willing and able to comply with all study procedural 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 once in your lifetime? | 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 can last between 6 to 13 weeks? | Yes 🞎 | No 🞎 |
|  | If you were to join this research study, are you willing to comply with the abstinence and other requirements which will be reviewed with you by study staff?  *This includes refraining from using prohibited medications such as strong or moderate CYP3As (staff will review what these are and examples of these types of products). You must also be willing to abstain from having receptive anal/oral sex and inserting any non-study products (such as fingers, sex toys, lubricants, enemas/douches, medications) in your rectum for 3 days before and after your visits to the clinic. If applicable, you must also be willing to abstain from vaginal sex as well as from inserting anything into your vagina (such as fingers, spermicides, medications, lubricants, moisturizers and sex toys) for 3 days before your visits to the clinic.* | Yes 🞎 | No 🞎 |
|  | ***Note: To be asked of those that are of childbearing potential.*** 🞎 Not applicable  If you were to join this research study, would you be willing to use an effective method of contraception starting at least 30 days prior to your Enrollment visit and for the duration of your study participation, which can last between 6 to 13 weeks?  *Effective methods include hormonal methods (such as oral contraceptive pills, contraceptive injections or implants, the intrauterine contraceptive device (IUD)); sterilization (yourself or your partner); or being sexually abstinent (defined as either abstaining from or not engaging in penile-vaginal intercourse) for at least 90 days (3 months) prior to Enrollment.* | Yes\* 🞎 | No 🞎 |
|  | If you were to join this research study, do you plan to use or are you unwilling to abstain from using anticoagulant medications or blood-thinners *(for example, heparin, Lovenox, Plavix, Warfarin)* and non-study rectally administered medications and any products containing N-9? | Yes 🞎 | No 🞎 |
|  | Have you ever had an adverse or bad reaction to any component of the study products? | Yes 🞎 | No 🞎 |
|  | In the past 3 months, have you used approved or other investigational pre-exposure prophylaxis (PrEP) for HIV prevention or do you plan to access or use approved or other investigational PrEP during your study participation? | Yes\*\*🞎 | No 🞎 |
|  | In the past 6 months, have you used post-exposure prophylaxis (PEP) for possible HIV exposure? | Yes\*\*🞎 | No 🞎 |
|  | In the past 6 months, have you had unprotected (without the use of a condom) receptive anal or penile-vaginal intercourse with a partner whose HIV status you do not know or who is HIV positive? | Yes\*\*🞎 | No 🞎 |
|  | In the past 12 months, have you engaged in sexual activity with someone (a partner or lover) in exchange for material support (money, for example) or other goods or benefits? | 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 🞎 |
|  | In the past 3 months, have you been diagnosed (or tested positive) for an anogenital (anus or genital areas) sexually transmitted infection/disease (STI/STD)? | Yes\*\*🞎 | No 🞎 |
|  | ***Note: To be asked of those that are of childbearing potential.*** 🞎 Not applicable  Are you currently pregnant or breastfeeding or do you have any plans to become pregnant during your study participation? | Yes 🞎 | No 🞎 |
|  | ***Note: To be asked of those that are of childbearing potential.*** 🞎 Not applicable  Have you been pregnant within the last 90 days (3 months)? | Yes\*\*🞎 | No 🞎 |

**For the participant to be eligible, the responses to items 1-5 above must be “Yes.”**

\*If the response to items 5 is “No,” assess likelihood of eligibility by Enrollment visit and proceed accordingly.

**For the participant to be eligible, the responses to items 6-15 above must be “No.”**

\*\*If the response to item 8-13, and 15 are “Yes,” assess likelihood of eligibility by Enrollment Visit and proceed accordingly.