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

|  |  |  |  |
| --- | --- | --- | --- |
|  | Were you assigned female sex at birth? | Yes 🞎 | No 🞎 |
|  | Are you able to speak, read and write proficiently in English? | Yes 🞎 | No 🞎 |
|  | Are you available for all visits and willing and able to comply with all study procedural requirements? | Yes 🞎 | No 🞎 |
|  | Are you willing to comply with the abstinence and other protocol requirements as explained to you during the informed consent process?  | Yes 🞎 | No 🞎 |
|  | Are you willing to use male condoms for penile-vaginal intercourse and penile-rectal intercourse for the duration of study participation? | Yes 🞎 | No 🞎 |
|  | If you were to join this research study, would you be willing to use an effective form of contraception for 30 days prior to enrollment and for the duration of the study (about 13 weeks)? Effective methods include: hormonal methods (except contraceptive ring), intrauterine device (IUD), sterilization (you or your partner), having sex exclusively with individuals assigned female sex at birth; or abstinence from penile-vaginal intercourse for 90 days prior to Enrollment.  | Yes 🞎 | No 🞎 |
|  | Do you have regular menstrual cycles with at least 21 days between menses? | Yes 🞎 | No 🞎\* |
|  | Are you willing to refrain from inserting any non-study vaginal products or objects into your vagina or rectum including, but not limited to spermicides, female condoms, diaphragms, intravaginal rings, vaginal or rectal medications, menstrual cups, cervical caps, douches, lubricants, and sex toys (vibrators, dildos, etc.) for the 24 hours preceding your Enrollment Visit and for the duration of study participation?  | Yes 🞎 | No 🞎 |
|  | Do you agree not to take part in any other research studies involving drugs, medical devices, vaginal or rectal products, or vaccines after this Screening visit and for the duration of your study participation? | Yes 🞎 | No 🞎 |
|  | Are you willing to abstain from using pre-exposure prophylaxis (PrEP) (Truvada®) for HIV prevention for the during your study participation? | Yes 🞎 | No 🞎 |
|  | In the past 3 months, have you used PrEP for HIV prevention or post-exposure prophylaxis (PEP) for HIV exposure? | Yes\*\* 🞎 | No 🞎 |
|  | Are you pregnant or do you plan to become pregnant during your study participation? | Yes 🞎 | No 🞎 |
|  | Have you ever had an adverse or bad reaction to any of the study products, including polyurethane?  | Yes 🞎 | No 🞎 |
|  | Do you have chronic and/or recurrent vaginal candidiasis? | 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 🞎 |
|  | Have you been pregnant within the last 90 days (3 months)? | Yes\*\* 🞎 | No 🞎 |
|  | Have you had a gynecologic or genital procedure (e.g., tubal ligation, dilation and curettage, piercing) in the last 45 days (1.5 months)? | Yes\*\* 🞎 | No 🞎 |
|  | In the past 60 days (8 weeks) have you participated in any other research study involving drugs, medical devices, vaginal or rectal products or vaccines? | Yes\*\* 🞎 | No 🞎 |
|  | Are you breastfeeding or do you plan to begin breastfeeding during your study participation? | Yes 🞎 | No 🞎 |

**For the participant to be eligible, the responses to items 1-10 above must be “Yes.”**

\*Answer may be “no” to item 7 for participants who report using a progestin-only method of contraception at screening or participants using continuous combination oral contraceptive pills

**For the participant to be eligible, the responses to items 11-19 above must be “No.”**

**\*\*If the response to item 11, 15-18 are “Yes,” assess likelihood of eligibility by Enrollment Visit and proceed accordingly.**