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

|  |  |  |  |
| --- | --- | --- | --- |
| All Participants | | | |
| 1 | If you were to join this research study, are you able and willing to return for all study visits and comply with study participation requirements? | Yes 🞎 | No 🞎 |
| 2 | If you were to join this research study, are you willing to not take part in other research studies involving drugs, medical devices, genital or rectal products, or vaccines for the duration of study participation? | Yes 🞎 | No 🞎 |
| 3 | Have you had consensual receptive anal intercourse at least once in the past year? | Yes 🞎 | No 🞎 |
| 4 | If you were to join this research study, would you be willing to be sexually abstinent for 72 hours prior to each study visit, during the study product use periods and if male, 72 hours after biopsy collection? | Yes 🞎 | No 🞎 |
| 5 | If you were to join this research study, would you be willing to abstain from inserting any non-study products into the rectum for 72 hours prior to each study visit, during the study product use periods and if male, 72 hours after biopsy collection? | Yes 🞎 | No 🞎 |
| Additional Criteria for Female Participants Listed Below. **Mark here if not female: 🞏 N/A** | | | |
| 6 | If you were to join this research study, would you be willing to use an effective method of contraception at least 30 days prior to Enrollment and continue the use of an effective method for the duration of study participation?  Effective methods include: hormonal methods other than vaginal rings, IUD, sterilization of you or your partner or you have been sexually abstinent (no sex) for the past 90 days. | Yes 🞎 | No 🞎 |
| 7 | If you were to join this research study, would you be willing to abstain from inserting any non-study products into the vagina for 72 hours prior to each study visit, during the study product use periods and for 7 days after biopsy collection? | Yes 🞎 | No 🞎 |
| 8 | If you were to join this research study, would you be willing to be sexually abstinent for 72 hours prior to each study visit, during the study product use periods and for 7 days after biopsy collection? | Yes 🞎 | No 🞎 |

**In order for the participant to be eligible, the responses to items 1-5, and for female participants’ items 6-8, above must be ‘YES’ at Screening.**

Staff Initials/Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

|  |  |  |  |
| --- | --- | --- | --- |
| All Participants | | | |
| 9 | Have you ever had a known adverse or bad reaction to any of the components of the study products? | Yes 🞎 | No 🞎 |
| 10 | Do you anticipate using and are you not willing to abstain from using prohibited medications and medications that are associated with the increased likelihood of bleeding during study participation? These medications include NSAIDS, aspirin (greater than 81mg), CYP3A inducer(s) and/or inhibitor(s), hormone-replacement therapy. *[Note to interviewer: ensure list of prohibited medications, CYP3A inducers/inhibitors is reviewed with participant]* | Yes 🞎 | No 🞎 |
| 11 | 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 🞎 |
| 12 | In the past 3 months, have you been treated for an anogenital STI? | Yes 🞎 | No 🞎 |
| 13 | In the past 6 months, have you had receptive anal intercourse, without a condom, or penile-vaginal intercourse with a partner known to be HIV-positive? | Yes 🞎 | No 🞎 |
| 14 | In the past 6 months, have you used Post-exposure prophylaxis (PEP) for HIV exposure? | Yes 🞎\* | No 🞎 |
| 15 | In the past 6 months, have you used Pre-exposure prophylaxis (PrEP) for HIV prevention or do you anticipate using PrEP during study participation? | Yes 🞎\* | No 🞎 |
| 16 | In the past 6 months, have you used or do you anticipate using systemic immunomodulatory medications during study participation? | Yes 🞎\* | No 🞎 |
| 17 | In the past 45 days (about 7 weeks), have you participated in any other research study involving drugs, medical devices, genital or rectal products or vaccines? | Yes 🞎\* | No 🞎 |
| Additional Criteria for Female Participants Listed Below. **Mark here if not female: 🞏 N/A** | | | |
| 18 | In the past 3 months (90 days), have you been pregnant, given birth (including stillbirth) or had a pregnancy terminated? | Yes 🞎 | No 🞎 |
| 19 | Are you currently breastfeeding? | Yes 🞎 | No 🞎 |
| 20 | Have you had a hysterectomy? | Yes 🞎 | No 🞎 |

**In order for the participant to be eligible, the responses to items 9-13 and 18-20 above must be ‘NO’ or NA.**

**\*If the responses to any of items 14-17 ‘YES’, assess likelihood of eligibility by enrollment visit and proceed accordingly.**

Staff Initials/Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_