**To confirm your eligibility for the study, I need to ask you a few more questions:**

|  |  |  |  |
| --- | --- | --- | --- |
| All Participants | | | |
| 1 | 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 🞎 |
| 2 | 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 🞎 |
| 3 | 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 🞎 |
| 4 | 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** | | | |
| 5 | Have you been using an effective method of contraception for at least the past 30 days and are you willing to continue use of this method for the duration of study participation?  Effective methods include: hormonal methods other than vaginal rings, IUD, sterilization of you or partner, or you have been sexually abstinent (no sex) for the past 90 days. | Yes 🞎 | No 🞎 |
| 6 | 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 🞎 |
| 7 | 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, all the response to items 1-7 above must be ‘YES’ or NA.**

|  |  |  |  |
| --- | --- | --- | --- |
| All Participants | | | |
| 8 | 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 🞎 |
| 9 | In the past 6 months have you used Post-exposure prophylaxis (PEP) for HIV exposure? | Yes 🞎 | No 🞎 |
| 10 | 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 🞎 |
| 11 | 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 🞎 |
| 12 | In the past 6 months, have you had receptive anal or vaginal intercourse, without a condom, with a partner known to be HIV-positive? | Yes 🞎 | No 🞎 |
| 13 | In the past 6 months, have you used or do you anticipate using systemic immunomodulatory medications during study participation? | Yes 🞎 | No 🞎 |
| 14 | 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** | | | |
| 15 | Are you currently breastfeeding? | Yes 🞎 | No 🞎 |

**In order for the participant to be eligible, all of the responses to items 8-15 above must be ‘No’ or NA.**

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