**MTN-024/IPM 031 Enrollment Behavioral Eligibility Worksheet**

PTID: \_\_\_ \_\_\_ \_\_\_- \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_\_- \_\_\_ VISIT CODE: 02. 0

VISIT DATE: \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_

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

|  |  |  |  |
| --- | --- | --- | --- |
| 1 | Are you willing to comply with all study procedural requirements? (Including, clinical and laboratory assessments, vaginal examinations, urine and blood testing, as well as attendance at all scheduled study visits) | Yes 🞎 | No 🞎 |
| 2 | If you were to join this research study, would you be willing to use only study provided or approved vaginal products for the duration of the study? | Yes 🞎 | No 🞎 |
| 3 | If you were to join this research study, would you agree to use male latex condoms for sexual intercourse? | Yes 🞎 | No 🞎 |
| 4 | Are you willing to not insert any non-study vaginal products or objects into the vagina for the duration of the study? Including, but not limited to, spermicides, female condoms, diaphragms, topical or systemic hormone replacement therapy, including vaginal estrogens, and/or hormonal contraceptives, vaginal medications, menstrual cups, cervical caps (or any other vaginal barrier method), vaginal douches, lubricants and moisturizers, sex toys (vibrators, dildos, etc.) | Yes 🞎 | No 🞎 |
| 5 | Do you agree that you will not take part in other research studies involving drugs, medical devices, or vaginal products, or vaccines for the duration of study participation? | Yes 🞎 | No 🞎 |
| 6 | Are you willing to not insert study approved lubricant into the vagina for 72 hours prior to each visit? | Yes 🞎 | No 🞎 |
| 7 | Are you willing to not have vaginal intercourse for 72 hours prior to each visit? | Yes 🞎 | No 🞎 |

**In order for the participant to be eligible, all of the responses to items 1-7 above must be ‘YES’.**

|  |  |  |  |
| --- | --- | --- | --- |
| 8 | Have you had chronic and/or recurrent vaginal candidiasis? (4 or more treated episodes in the past year) | Yes 🞎 | No 🞎 |
| 9 | In the past year, have you used a needle to inject drugs that were not prescribed to you by a medical professional? | Yes 🞎 | No 🞎 |
| 10 | In the past 6 months, have you used topical or systemic hormone replacement therapy and/or hormonal contraception? | Yes 🞎 | No 🞎 |
| 11 | In the past 6 months, have you used Post-exposure prophylaxis (PEP) or Pre-exposure prophylaxis (PrEP)? | Yes 🞎 | No 🞎 |
| 12 | In the past 6 months, have you been pregnant, given birth (including stillbirth) or had a pregnancy terminated? | Yes 🞎 | No 🞎 |
| 13 | Are you breastfeeding now? | Yes 🞎 | No 🞎 |
| 14 | In the past 45 days have you participated in any other research study involving drugs, medical devices, vaginal products, or vaccines? | Yes 🞎 | No 🞎 |

**In order for the participant to be eligible, all of the responses to items 8-14 above must be ‘NO’.**