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

PTID: \_\_\_ \_\_\_ \_\_\_- \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_\_- \_\_\_ VISIT CODE: 1. 0

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

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

|  |  |  |  |
| --- | --- | --- | --- |
| 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 🞎 |
| 8 | Are you willing to not insert anything into the vagina for 72 hours after the collection of tissue samples? | Yes 🞎 | No 🞎 |
| 9 | Are you willing to not have vaginal intercourse for 72 hours after the collection of tissue samples? | Yes 🞎 | No 🞎 |

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

**Biopsy Subset only- In order for the participant to be eligible, the responses to items 8 and 9 above also must be ‘YES’.**

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PTID: \_\_\_ \_\_\_ \_\_\_- \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_\_- \_\_\_ VISIT CODE: 1. 0

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

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

|  |  |  |  |
| --- | --- | --- | --- |
| 10 | Do you plan to relocate away from the study site during your participation on the study? | Yes 🞎 | No 🞎 |
| 11 | Do you plan to travel away from the study site for more than 4 weeks in a row during your participation on the study? | Yes 🞎 | No 🞎 |
| 12 | Have you ever had a known adverse or bad reaction to dapivirine? | Yes 🞎 | No 🞎 |
| 13 | Have you ever had a known adverse or bad reaction to silicone? | Yes 🞎 | No 🞎 |
| 14 | Have you ever had a known adverse or bad reaction to latex, such as latex condoms or latex gloves? | Yes 🞎 | No 🞎 |
| 15 | Have you had chronic and/or recurrent vaginal candidiasis? (4 or more treated episodes in the past year) | Yes 🞎\* | No 🞎 |
| 16 | In the past year, have you used a needle to inject drugs that were not prescribed to you by a medical professional? | Yes 🞎\* | No 🞎 |
| 17 | In the past 6 months, have you used topical or systemic hormone replacement therapy and/or hormonal contraception? | Yes 🞎\* | No 🞎 |
| 18 | In the past 6 months, have you used Post-exposure prophylaxis (PEP) or Pre-exposure prophylaxis (PrEP)? | Yes 🞎\* | No 🞎 |
| 19 | In the past 6 months, have you been pregnant, given birth (including stillbirth) or had a pregnancy terminated? | Yes 🞎\* | No 🞎 |
| 20 | Are you breastfeeding now? | Yes 🞎\* | No 🞎 |
| 21 | In the past 45 days have you participated in any other research study involving drugs, medical devices, vaginal products, or vaccines? | Yes 🞎\* | No 🞎 |
|  | | | |
| **All questions for the participant have been completed. The following question is to be completed by the interviewer.** | | | |
| 22 | Is the participant able to communicate in spoken and written English? | Yes 🞎\*\* | No 🞎 |

**In order for the participant to be eligible, the responses to items 10 through 14 above must be ‘NO’.**

**\*If the responses to any of items 15 through 21 are ‘YES’, assess likelihood of eligibility by enrollment visit and proceed accordingly.**

**\*\*In order for the participant to be eligible, the responses to item 22 above must be ‘YES’.**