**MTN-023/IPM 030 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 procedure requirements, including clinical and laboratory assessments, vaginal examinations, urine and blood testing, as well as attendance at all scheduled study visits? | Yes 🞎 | No 🞎 |
| 2 | Do you agree to not take part in other research studies involving drugs, medical devices, vaginal products, or vaccines for the duration of study participation? | Yes 🞎 | No 🞎 |
| 3 | If you were to join this research study, would you agree to use condoms for sexual intercourse? | Yes 🞎 | No 🞎 |
| 4 | Are you currently using an effective method of contraception, and do you intend to continue using this method during your participation in this study? Effective methods include hormonal methods (except contraceptive rings), intrauterine device (IUD), and sterilization. | Yes 🞎 | No 🞎\* |
| 5 | Are you willing to not insert any non-study vaginal products and/or objects into the vagina for the 5 days prior to your enrollment and throughout the duration of the study? These include spermicides, diaphragms, contraceptive vaginal rings, menstrual cups, cervical caps (or any other vaginal barrier method), douches, and lubricants. | Yes 🞎 | No 🞎 |
| 6 | Have you had sexual intercourse\* at least once time in your lifetime? | Yes 🞎 | No 🞎 |
| 7 | Are you willing not to insert anything into the vagina for 72 hours prior to each follow-up visit? | Yes 🞎 | No 🞎 |
| 8 | Are you willing not to have penile-vaginal intercourse for 72 hours prior to each follow-up visit? | Yes 🞎 | No 🞎 |

**\*Sexual intercourse is defined as one episode of penile-vaginal intercourse**

***Note:* In order for the participant to be eligible, the responses to items 1-8 above must be ‘Yes.’**

**\*If the response to item 4 is ‘No,’ assess likelihood of eligibility by enrollment visit and proceed accordingly.**

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

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

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 9 | Do you plan to relocate away from the study site during your participation in the study? | Yes 🞎 | No 🞎 | |
| 10 | Do you plan to travel away from the study site for more than 4 weeks during your participation in the study? | Yes 🞎 | No 🞎 | |
| 11 | Do you plan to become pregnant during your participation in 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 | Are you currently with a known HIV-infected partner? | Yes 🞎 | No 🞎 | |
| 15 | In the past year, have you used a needle to inject drugs that were not prescribed to you by a medical professional? | Yes 🞎 | No 🞎 | |
| 16 | In the past 6 months, have you used HIV Post-exposure prophylaxis (PEP) and/or Pre-exposure prophylaxis (PrEP)? | Yes 🞎\* | No 🞎 | |
| 17 | In the past 3 months (90 days), have you been pregnant, given birth (including stillbirth) or had a pregnancy terminated? | Yes 🞎 | No 🞎 | |
| 18 | Are you currently breastfeeding? | Yes 🞎 | No 🞎 | |
| 19 | In the past 60 days, have you participated in any other research study involving drugs, medical devices, vaginal products, or vaccines? | Yes 🞎 | No 🞎 | |
| 20 | In the past month, how many sexual partners (penile-vaginal intercourse) have you had? | \_\_\_ # if ≥ 3, **not** eligible. | | |
| ***Note:* In order for the participant to be eligible, the responses to items 9-15, and 17-19 above must be ‘No’ and the response to item 20 must be 0, 1, or 2.**  **\*If the response to item 16 is ‘Yes,’ assess likelihood of eligibility by enrollment visit and proceed accordingly.** | | | |
| **All interviewer-administered questions have been completed. The following question must be completed by the interviewer.** | | | |
| 21 | Is the participant able to communicate in spoken and written English? | Yes 🞎 | No 🞎 | |

***Note:* In order for the participant to be eligible, the response to item 21 above must be ‘Yes.’**