**MTN-028 Enrollment Behavioral Eligibility Worksheet**

PTID: \_\_\_ \_\_\_ \_\_\_- \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_\_- \_\_\_ VISIT CODE: 2. 0

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

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

|  |  |  |  |
| --- | --- | --- | --- |
| 1 | If you were to join this research study, would you be willing to use an effective method of contraception at Enrollment and continue the use of an effective method during study participation?  Effective methods include: hormonal methods other than vaginal rings, IUD inserted at least 28 days (4 weeks) before Enrollment, sterilization of you or partner, you self-identify as a woman who has sex with women exclusively, you have been sexually abstinent (no sex) for at least 90 days before enrollment. | Yes 🞎 | No 🞎 |
| 2 | Do you agree that you will not take part in other research studies involving drugs, medical devices, or vaginal products for the duration of study participation? | Yes 🞎 | No 🞎 |

**In order for the participant to be eligible, the response to items 1-2 above must be ‘YES’.**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 3 | 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 🞎 |
| 4 | In the past 6 months, have you used Post-exposure prophylaxis (PEP) for HIV exposure or Pre-exposure prophylaxis (PrEP) for HIV prevention? | Yes 🞎 | | No 🞎 |
| 5 | Do you regularly use of do you anticipate using CYP3A inducer(s) and/or inhibitor(s) during study participation? *[Note to interviewer: ensure list of CYP3A inducers/inhibitors is reviewed with participants]* | Yes 🞎 | | No 🞎 |
| 6 | Are you using or do you plan to use female-to-male transition therapy during the period of study participation? | Yes 🞎 | | No 🞎 |
| 7 | In the past 6 months, have you been diagnosed with gonorrhea, chlamydia or syphilis? | Yes 🞎 | | No 🞎 |
| 8 | Are you breastfeeding now? | Yes 🞎 | | No 🞎 |
| 9 | Do you intend to become pregnant in the next 3 months? | Yes 🞎 | | No 🞎 |
| 10 | Do you plan to move away from the study site area in the next 3 months? | Yes 🞎 | | No 🞎 |
| 11 | If you currently have a sexual partner, is your partner known to be HIV-positive? | NA 🞎 | Yes 🞎 | No 🞎 |
| 12 | In the past 60 days (8 weeks) have you participated in any other research study involving drugs, medical devices, or vaginal products? | Yes 🞎 | | No 🞎 |

**In order for the participant to be eligible, all of the responses to items 3-12 above must be ‘No’ or “NA”**

Staff Initials/Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Version 1.0 dated 23 February 2015