**MTN-029 Enrollment Behavioral Eligibility Worksheet (Page 1 of 1)**

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

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

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

|  |  |  |  |
| --- | --- | --- | --- |
| 1 | Was the last time you gave birth at least 6 weeks ago? |  Yes 🞎 | No 🞎 |
| 2 | Have you stopped breastfeeding?  |  Yes 🞎 | No 🞎 |
| 3 | 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 for the duration of your 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, or you have been sexually abstinent (no sex) for at least 90 days before Enrollment. | Yes 🞎 | No 🞎 |
| 4 | Do you agree not to participate in other research studies involving drugs, medical devices, vaginal products, vaccines, or breast milk sampling for the duration of your study participation? |  Yes 🞎 | No 🞎 |

**In order for the participant to be eligible, the responses to items 1-4 above must be “Yes”.**

|  |  |  |  |
| --- | --- | --- | --- |
| 5 | In the last 30 days, have you participated in any other research study involving drugs or medical devices? |  Yes 🞎 | No 🞎 |
| 6 | In the last 5 days, have you used any vaginal medication(s)? |  Yes 🞎 | No 🞎 |
| 7 | In the last 5 days, have you used any oral or vaginal antibiotic or antifungal medications?  | Yes 🞎 | No 🞎 |
| 8 | Have you ever had a complication of lactation, such as mastitis, that required treatment? | Yes 🞎 | No 🞎 |

**In order for the participant to be eligible, the responses to items 5-8 above must be “No”.**

\_\_\_\_\_\_\_\_\_\_\_ (Staff Initials/Date) Version 1.0 dated 29 October 2015