

# MTN-029 Screening Behavioral Eligibility Worksheet (Page 1 of 1)

PTID: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

VISIT CODE: 1.0

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

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

1	Are you willing and able to communicate in spoken and written English during your study participation?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
2	When was the last time you gave birth? Date: _____ (dd-MMM-yy) <b>Note: participant must be at least 6 weeks postpartum at Enrollment to be eligible for the study.</b>		
3	Have you stopped breastfeeding, or do you plan to stop breastfeeding prior to Enrollment in the study?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
4	Do you agree not to provide your breast milk to your child(ren) or others for consumption after you start using the study vaginal ring? <b>Note: this does not include breast milk that has been expressed prior to Enrollment in the study.</b>	Yes <input type="checkbox"/>	No <input type="checkbox"/>
5	Are you willing and able to express breast milk at least twice a day as directed for study purposes?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
6	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 <input type="checkbox"/>	No <input type="checkbox"/>
7	If you were to join this research study, would you be willing to abstain from receptive sexual activity for 24 hours prior to each study visit? This includes penile-vaginal intercourse, anal intercourse, receptive oral intercourse, finger stimulation, and the use of sex toys.	Yes <input type="checkbox"/>	No <input type="checkbox"/>
8	If you were to join this research study, would you be willing not to insert any non-study objects into your vagina for 24 hours prior to each study visit? This includes, but is not limited to: tampons, female condoms, diaphragms, menstrual cups, and cervical caps (or any other vaginal barrier method).	Yes <input type="checkbox"/>	No <input type="checkbox"/>
9	If you were to join this research study, would you be willing not to use any vaginal products for the duration of your study participation? This includes, but is not limited to: spermicides, lubricants, contraceptive vaginal rings, douches, and vaginal medications.	Yes <input type="checkbox"/>	No <input type="checkbox"/>
10	Do you agree not to participate in other research studies involving drugs, medical devices, vaginal products, vaccines, or breast milk sampling for 30 days prior to Enrollment through the end of your study participation?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
11	Have you ever had a known adverse or bad reaction to any component of the dapivirine vaginal ring?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
12	Have you ever had a complication of lactation, such as mastitis, that required treatment?	Yes <input type="checkbox"/>	No <input type="checkbox"/>

**In order for the participant to be eligible, the responses to items 1 and 3-10 must be "Yes" at Screening, and the responses to items 11-12 must be "No" at Screening.**

\_\_\_\_\_ (Staff Initials/Date)

Version 1.0 dated 29 October 2015