MTN-030/IPM 041
Enrollment Behavioral Eligibility Worksheet

PTID: _____ VISIT CODE: 2. 0

VISIT DATE: __ __ /__ __ __ / __ __

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

1	Are you available for all visits and willing and able to comply with all study procedural requirements, including SMS (that is, phone text message) requirements?	Yes ☐	No ☐
2	Are you willing to abstain from receptive intercourse (including vaginal, oral and finger stimulation) for 24 hours before your Enrollment Visit and for the duration of your study participation?	Yes ☐	No ☐
3	Are you willing to use an effective, non-hormonal method of contraception at Enrollment and continue the use of an effective method for the duration of your study participation? Effective non-hormonal methods include sterilization (self or partner), non-hormonal (e.g., copper) intrauterine device (IUD) inserted at least 28 days prior to Enrollment, sex exclusively with women, and/or sexual abstinence for the past 90 days with plans to remain abstinent for the duration of study participation (that is, until your study exit visit).	Yes ☐	No ☐
4	Do you have a regular menstrual cycle of approximately 21 to 35 days' duration? *Note: Have the participant count the first day of her last period to the first day of the next period.*	Yes ☐	No ☐
5	Are you willing to avoid inserting any non-study vaginal products or objects into your vagina for 24 hours prior to enrollment and for the duration of your study participation? The "vaginal products or objects" include, but are not limited to, tampons, spermicides, female condoms, diaphragms, contraceptive vaginal rings, vaginal medications, menstrual cups, cervical caps (or any other vaginally applied barrier method), vaginal douches, lubricants and moisturizers, and sex toys (vibrators, dildos, etc.).	Yes ☐	No ☐
6	Do you agree that you will not take part in other research studies involving drugs, medical devices, vaginal products, or vaccines after your Screening Visit and for the duration of your study participation?	Yes ☐	No ☐
7	Do you plan to become pregnant during your participation in the study?	Yes ☐	No ☐
8	In the past year (12 months), have you had four or more yeast infections?	Yes ☐	No ☐
9	In the last 28 days, have you used a hormonal contraception, including an intrauterine device (IUD) such as Mirena, the pill or the patch?	Yes ☐	No ☐
10	Do you use or do you plan to use CYP3A inducer(s) and/or inhibitor(s)during study participation? *(Note: Staff to review list of prohibited medications with participant)*	Yes ☐	No ☐
11	Do you use or do you plan to use antibiotics or corticosteroids during your study participation? *(Note: Review list of prohibited medications with participant)*	Yes ☐	No ☐
12	In the past 6 months, have you used depot medroxyprogesterone acetate (DMPA) also known as Depo-Provera®?	Yes ☐	No ☐
13	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 ☐

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

14	In the past 6 months, have you used post-exposure prophylaxis (PEP) for HIV exposure?	Yes ☐	No ☐
15	In the past 6 months, have you used pre-exposure prophylaxis (PrEP) (Truvada®) for HIV prevention?	Yes ☐	No ☐
16	In the past 3 months (90 days), have you been pregnant, given birth (including stillbirth), or had a pregnancy terminated?	Yes ☐	No ☐
17	In the past 60 days, have you had any gynecologic or genital procedure such as tubal ligation, dilation and curettage, or piercing?	Yes ☐	No ☐
18	Are you breastfeeding now or planning to breastfeed during your study participation?	Yes ☐	No ☐
19	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, the responses to items 1-6 above must be "Yes." Responses 7-19 must be "No" in order for the participant to be eligible for study participation.

Staff Initials: _____

Staff Date: _____

Version 2.0 dated 11 January 2017