**Instructions:** Use the table below to document a woman participant's eligibility status for MTN-011 study participation. Initial and date below each set of "yes/no" checkboxes upon assessment of each eligibility criterion. Once ineligibility status is determined, the form may be stopped and the remaining questions may be left blank.

| **Inclusion Criteria** | **Screening Visit** | | **Enrollment Visit** | |
|---|---|---|---|---|
| | ***Yes*** | ***No*** | ***Yes*** | ***No*** |
| **1.** *a.* Able and willing to provide written informed consent to be screened for and take part in the study | ☐ _____ | ☐ | *not required* | |
| *b.* Able and willing to provide adequate locator information, as defined by the site SOPs. | *review and proceed accordingly* | | ☐ _____ | ☐ |
| **2.** *a.* Per participant report, no STIs in the 6 months prior to Screening | ☐ _____ | ☐ | *not required* | |
| *b.* Per participant report, no non-therapeutic intravenous drug use in the 18 months prior to Screening | ☐ _____ | ☐ | *not required* | |
| *c.* Per participant report, in a mutually monogamous relationship with a partner of the opposite sex for 6 months prior to Screening and the intent to stay in this relationship for the duration of study participation. | ☐ _____ | ☐ | *not required* | |
| **3.** At Screening and Enrollment, both partners independently report not using barrier contraception and/or barrier protection as part of the normal coital routine and report the intent to continue said sexual practice for the duration of study participation. | ☐ _____ | ☐ | ☐ _____ | ☐ |
| **4.** HIV-uninfected, based on testing performed by study staff at Screening (per algorithm in protocol appendix III) | ☐ _____ | ☐ | *not required* | |
| **5.** Agrees not to participate in other research studies involving drugs, medical devices, genital or rectal products, or large blood draw studies during study participation. | ☐ _____ | ☐ | ☐ _____ | ☐ |

***Note: In order for the participant to be <u>eligible,</u> all of the responses to items* 1-5 *above <u>must be "yes"</u>.***

| **Inclusion Criteria – cont'd** | **Screening Visit** | **Enrollment Visit** |
|---|---|---|
| | ***Yes*** ***No*** | ***Yes*** ***No*** |
| **6.** *a.* Age 21 through 46 years (inclusive) at Screening, verified per site SOPs. | ☐ ☐ | *not required* |
| *b.* Pap results in the 12 calendar months prior to Screening consistent with Grade 0 according to the FGGT* or satisfactory evaluation with no treatment required of non-Grade 0 Pap result per American Society for Colposcopy and Cervical Pathology (ASCCP) guidelines in the 12 calendar months prior to the Screening Visit | ☐ ☐ | *not required* |
| ***Note****: Women with a documented normal results with the 12 months prior to screening need not have a Pap smear during the Screening period. Women with abnormal Pap smears can be enrolled upon completion of the initial phase of evaluation if no current treatment is indicated (baed on local standard ofcare for management of abnormal cervical cytology). Need for a repeat Pap within 6 months does not preclude enrollment prior to that result becoming available.* | | |
| *c.* Must be currently using effective non-barrier contraception, other than a contraceptive vaginal ring, for at least three months prior to Screening (i.e. oral contraceptive, patch, injectable hormones, subdermal implants, intrauterine device, female or male sterilization) and intending to use this method for the course of the study. | ☐ ☐ | ☐ ☐ |
| *d.* Per participant report, regular menstrual cycles with at least 21 days between menses (does not apply to participants who report using a progestin-only method of contraception at screening, e.g., Depo-Provera) | ☐ ☐ | *not required* |
| **Note:** *This criterion is not applicable to participants using continuous combination oral contraceptive pills, as the absence of regular menstrual cycles is an expected, normal consequence in the context* | | |
| *e.* Anatomy sufficient for performing pelvic examinations and for collecting vaginal and cervical specimens. | ☐ ☐ | *not required* |
| *f.* Must also agree to abstain from intercourse (oral, anal, or penile-vaginal) and other vaginal practices (e.g. masturbation, douching, tampon use, application of lubricants/spermicides or other related practices) 72 hours prior to each follow-up visit. Group 2 participants must agree to also abstain from the aforementioned practices throughout the at-home gel use period. | ☐ ☐ | ☐ ☐ |

***Note: In order for the participant to be <u>eligible,</u> all of the responses to items* 6 *above <u>must be "yes"</u>.***

****Female Genital Grading Table for Use in Microbicide Studies Addendum 1 to the DAIDS Table for Grading Adult and Pediatric Adverse Events, Version 1.0, December 2004 (Clarification dated August 2009).***

| **Exclusion Criteria** | **Screening Visit** | | **Enrollment Visit** | |
|---|---|---|---|---|
| | ***Yes*** | ***No*** | ***Yes*** | ***No*** |
| **Participant report of any of the following:**<br>**1.**<br>*a.* Known allergy to study product (ever) | ☐ | ☐ | *not required* | |
| *b.* Post-exposure prophylaxis (PEP) for HIV exposure within 6 months prior to Screening | ☐ | ☐ | *not required* | |
| *c.* Pre-exposure prophylaxis (PrEP) for HIV prevention within 6 months prior to Screening | ☐ | ☐ | *not required* | |
| *d.* Participation in any other research study involving drugs, medical devices, or genital products 30 days or less prior to Enrollment | *review and proceed accordingly* | | ☐ | ☐ |
| *e.* Plans to relocate away from the study site for the duration of the study | ☐ | ☐ | *not required* | |
| *f.* History of domestic violence with current partner (ever) | ☐ | ☐ | *not required* | |
| *g.* Systemic or topical antimicrobials within the last 7 days prior to Enrollment | *review and proceed accordingly* | | ☐ | ☐ |
| **2.** At Screening or Enrollment, symptomatic urinary tract infection (UTI) | ☐ | ☐ | ☐ | ☐ |
| ***Note**: Otherwise eligible participants diagnosed with UTI during screening are offered treatment and may be enrolled after completing treatment and all symptoms have resolved as long as treatment is completed and all symptoms have resolved with 30 days of obtaining informed consent for Screening/Enrollment.* | | | | |

***Note: In order for the participant to be <u>eligible,</u> all of the responses to items 1-2 above <u>must be "no"</u>.***

| **Exclusion Criteria cont'd** | **Screening Visit** | | **Enrollment Visit** | |
|---|---|---|---|---|
| | ***Yes*** | ***No*** | ***Yes*** | ***No*** |
| **3.** At Screening, has a positive hepatitis B surface antigen (HbsAg) test result | ☐ | ☐ | *not required* | |
| **4.** At Screening and Enrollment, has an STI or reproductive tract infection (RTI) requiring treatment per current CDC guidelines | ☐ | ☐ | ☐ | ☐ |
| **5.** Genital signs and/or symptoms of Grade 2 or higher | ☐ | ☐ | ☐ | ☐ |
| ***Note:*** *For female participants, cervical bleeding associated with speculum insertion and/or specimen collection judged to be within the range of normal according to the clinical judgment of the IoR/designee is considered expected non-menstrual bleeding and is not exclusionary.* *Note: Otherwise eligible participants with exclusionary genital findings may be enrolled after the findings have improved to a non-exclusionary severity grading or resolved as long as treatment is completed and all symptoms have resolved within 30 days of obtaining informed consent for Screening/Enrollment.* | | | | |
| **6.** Has any other condition that, in the opinion of the IoR/designee, would preclude informed consent, make study participation unsafe, complicate interpretation of study outcome data, or otherwise interfere with achieving study objectives | ☐ | ☐ | ☐ | ☐ |
| **7. a.** Participant report (or clinical finding) of the following: *i.* Last pregnancy outcome 90 days or less prior to Enrollment | *review and proceed accordingly* | | ☐ | ☐ |
| *ii.* Currently pregnant | ☐ | ☐ | ☐ | ☐ |
| ***Note:*** *Self-reported pregnancy is adequate for exclusion from the study. A documented negative pregnancy test performed by study staff is required for inclusion.* | | | | |
| *iii.* Currently breastfeeding | ☐ | ☐ | ☐ | ☐ |
| *iv.* Intends to become pregnant for the duration of the study | *review and proceed accordingly* | | ☐ | ☐ |

***Note: In order for the participant to be <u>eligible,</u> all of the responses to items* 3- 7a(iv) *above <u>must be "no"</u>.***

| **Exclusion Criteria cont'd** | **Screening Visit** | | **Enrollment Visit** | |
|---|---|---|---|---|
| | ***Yes*** | ***No*** | ***Yes*** | ***No*** |
| *v.* Gynecologic or genital procedure (e.g. tubal ligation, dilation and curettage) within the prior 30 days to Enrollment | *review and proceed accordingly* | | ☐ _____ | ☐ |
| ***Note:*** *This does not include biopsy for the evaluation of an abnormal pap results or endometrial biopsy that occurred more than 7 days prior to Enrollment.* | | | | |
| *vi.* Currently using or planning to use systemic immune modulator(s) for the duration of the study | ☐ _____ | ☐ | ☐ _____ | ☐ |
| **7. b.** Any of the following laboratory abnormalities at Screening:<br>*i.* Hemoglobin less than 10.0 g/dl | ☐ _____ | ☐ | *review and proceed accordingly* | |
| *ii.* Platelet count less than 100,000/$mm^3$ | ☐ _____ | ☐ | *review and proceed accordingly* | |
| ***Note:*** *Otherwise eligible participants with an exclusionary test may be re-tested during the screening process.* | | | | |
| **7. c.** Use of a vaginal douche or other intravaginal products (excluding tampon use) in the 30 days prior to Enrollment | *review and proceed accordingly* | | ☐ _____ | ☐ |
| **7. d.** Currently menopausal or perimenopausal | ☐ _____ | ☐ | ☐ _____ | ☐ |

***Note: In order for the participant to be <u>eligible,</u> all of the responses to items* 7a(*v*)-7d *above <u>must be "no"</u>.***

At enrollment visit, participant is found to meet all eligibility criteria:

_____ _____ _____ _____

*Signature of staff member* *Date* *Signature of Investigator of Record (or designee)* *Date*