***Instructions:*** *Starting at the enrollment visit, use the table below to document a participant’s eligibility status for participation by marking “yes” or “no.” If ineligibility status is determined, any items not yet completed may be left blank. For an eligible participant, the checklist must be completed for all items and have staff sign-off at the end of the form to confirm and verify eligibility. Complete the Inclusion/Exclusion Criteria CRF for all screened participants once a participant’s eligibility/enrollment status is determined.*

*Note: The study eligibility criteria are abbreviated in this checklist; refer to Protocol Sections 5.2 and 5.3 for a complete description of the criteria.*

|  |  |  |  |
| --- | --- | --- | --- |
| **INCLUSION CRITERIA** | | ***Yes*** | ***No*** |
| I-1 | Assigned female sex at birth   * *Source: Screening Behavioral Eligibility Worksheet item 1* |  |  |
| I-2 | Age 18 through 45 years (inclusive) at Screening   * *Source: copy of ID card/driver’s license or other documents as specified in SOP* |  |  |
| I-3 | Able and willing to provide written informed consent   * *Source: Signed consent forms(s)* |  |  |
| I-4 | Able and willing to provide adequate locator information   * *Source: Site specific locator form as listed in site SOP* |  |  |
| I-5 | Able to communicate in spoken and written English   * *Source: Screening Behavioral Eligibility Worksheet item 2* |  |  |
| I-6 | Available for all visits and able to comply with all study procedural requirements   * *Source: Screening Behavioral Eligibility Worksheet item 3; Enrollment Behavioral Eligibility Worksheet item 1* |  |  |
| I-7 | Willing to follow abstinence requirements and other protocol requirements as outlined in Sections 6.6 and 6.7   * *Source: Screening Behavioral Eligibility Worksheet item 4; Enrollment Behavioral Eligibility Worksheet item 2* |  |  |
| I-8 | Willing to use male condoms for penile-vaginal intercourse and penile-rectal intercourse for the duration of study participation   * *Source: Screening Behavioral Eligibility Worksheet item 5; Enrollment Behavioral Eligibility Worksheet item 3* |  |  |
| I-9 | Reports using an effective contraception method (as defined in the MTN-038 Protocol) for 30 days prior to Enrollment, and intending to continue use for the duration of study participation.   * *Source: Screening Behavioral Eligibility Worksheet item 6; Enrollment Behavioral Eligibility Worksheet item 4* |  |  |
| I-10 | In general good health as determined by IoR/designee   * *Source: Medical History CRF; Pelvic Exam Diagram; Pelvic Exam CRF; chart notes at Screening and Enrollment* |  |  |
| I-11 | HIV uninfected   * *Source: Local testing log, laboratory test results report or other sites-specific document at Screening and Enrollment* |  |  |
| I-12 | Reports having regular menstrual cycles at screening with at least 21 days between menses   * *Source: Screening Behavioral Eligibility Worksheet item 7* |  |  |
| I-13 | Willing to refrain from inserting any non-study vaginal or rectal products or objects into the vagina or rectum for the 24 hours preceding the Enrollment Visit and for the duration of study participation   * *Source: Screening Behavioral Eligibility Worksheet item 8; Enrollment Behavioral Eligibility Worksheet item 5* |  |  |
| I-14 | If over age 21 (inclusive), documentation of a satisfactory Pap within past 3 years prior to Enrollment either consistent with Grade 0 or satisfactory evaluation with no treatment required of Grade 1 or higher Pap result. Record as “N/A” if participant is <21.   * *Source:* *Laboratory test results report* |  |  |
| I-15 | Agrees not to participate in other research studies involving drugs, medical devices, vaginal or rectal products, or vaccines after Screening and for the duration of study participation   * *Source: Screening Behavioral Eligibility Worksheet item 9; Enrollment Behavioral Eligibility Worksheet item 6* |  |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| ***EXCLUSION CRITERIA*** | | ***Yes*** | ***No*** | |
| E-1 | Pregnant or plans to become pregnant during study participation   * *Source: Local testing log, laboratory test results report or other sites-specific document; Screening Behavioral Eligibility Worksheet item 12; Enrollment Behavioral Eligibility Worksheet item 9* |  |  |
| E-2 | Diagnosed with a symptomatic urinary tract infection (UTI) or reproductive tract infection (RTI)   * *Source:* *Local testing log, laboratory test results report or other site-specific document; Medical History CRF; Pelvic Exam Diagram; Chart notes*   Note: If treatment is complete and symptoms have resolved within the 45 day screening window, eligible participants may be enrolled. |  |  |
| E-3 | Diagnosed with an acute STI requiring treatment per current CDC guidelines   * *Source:* *Local testing log, laboratory test results report or other site-specific document at Screening and Enrollment; Medical History CRF* |  |  |
| E-4 | Has a clinically apparent Grade 2 or higher pelvic examination finding   * *Source: Pelvic Exam Diagrams; Pelvic Exam CRF; Medical History CRF* |  |  |
| E-5a | Known adverse reaction to study product (ever)   * *Source: Screening Behavioral Eligibility Worksheet item 13* |  |  |
| E-5b | Reports chronic and/or recurrent vaginal candidiasis   * *Source: Screening Behavioral Eligibility Worksheet item 14; Medical History CRF* |  |  |
| E-5c | Reports non-therapeutic injection drug use in the 12 months prior to Enrollment   * *Source: Screening Behavioral Eligibility Worksheet item 15; Enrollment Behavioral Eligibility Worksheet item 10* |  |  |
| E-5d | Reported last pregnancy outcome within 90 days prior to Enrollment   * *Source: Screening Behavioral Eligibility Worksheet item 16; Enrollment Behavioral Eligibility Worksheet item 11* |  |  |
| E-5e | Has had a gynecologic or genital procedure (e.g., tubal ligation, dilation and curettage, piercing) 45 days or less prior to Enrollment   * *Source: Chart notes; Medical History CRF; Screening Behavioral Eligibility Worksheet item 17; Enrollment Behavioral Eligibility Worksheet item 12* |  |  |
| E-5f | Currently breastfeeding or plans to begin breastfeeding during study participation   * *Source: Screening Behavioral Eligibility Worksheet item 19; Enrollment Behavioral Eligibility Worksheet item 13* |  |  |
| E-5g | Participation in any other research study involving drugs, medical devices, vaginal products, or vaccines within 60 days prior to Enrollment   * *Source: Screening Behavioral Eligibility Worksheet item 18; Enrollment Behavioral Eligibility Worksheet item 6* |  |  |
| E-6 | Reports use of PEP for potential HIV exposure or PrEP for HIV prevention within 3 months prior to Enrollment, and/or anticipated use and/or unwillingness to abstain from use during study participation   * *Source: Screening Behavioral Eligibility Worksheet item 10 & 11; Enrollment Behavioral Eligibility Worksheet item 7 & 8* |  |  |
| E-7a | AST or ALT Grade 1 or higher   * *Source:*  *Laboratory test results report or other sites-specific document* |  |  |
| E-7b | Hemoglobin Grade 1 or higher   * *Source:*  *Laboratory test results report or other sites-specific document* |  |  |
| E-7c | Calculated creatinine clearance less than 60 mL/min by the Cockcroft-Gault formula   * *Source:*  *Laboratory test results report or other sites-specific document* |  |  |
| E-7d | Positive Hepatitis B surface antigen result   * *Source:*  *Laboratory test results report or other sites-specific document* |  |  |
| E-8 | 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   * *Source: Chart notes and this checklist* |  |  |

**For the participant to be eligible, all responses to Inclusion Criteria (items I1-I15) above must be “Yes” and responses to Exclusion Criteria (items E1-E8) above must be “No.”**

**Final Sign-off of Participant Eligibility to Enroll:**

Once a participant is deemed eligible to enroll in MTN-038, complete signatures below to confirm and verify final determination of eligibility. Only staff delegated the responsibility of eligibility determination per site DoA may sign for Eligibility Confirmation and Eligibility Verification; sign-off from two different delegated study staff is required.

**ELIGBILITY VERIFICATION**

**IoR (or designee) Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Date: \_\_\_ \_\_\_ / \_\_\_ \_\_\_ \_\_\_/ \_\_\_ \_\_\_**

**Time: \_\_\_ \_\_\_: \_\_\_ \_\_\_**

**ELIGBILITY CONFIRMATION**

**Staff Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Date: \_\_\_ \_\_\_ / \_\_\_ \_\_\_ \_\_\_/ \_\_\_ \_\_\_**

**Time: \_\_\_ \_\_\_: \_\_\_ \_\_\_**