***Instructions:*** *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 Eligibility 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*** |
| I1 | Age 16 – 21 years (inclusive) at Enrollment   * *Source: copy of identification card or other documents as specified in SOP* |  |  |
| I2 | Able and willing to provide written informed consent or assent/ parental permission (if age 16-17 years)   * *Source: Signed assent, consent and/or parental/guardian permission form(s)* |  |  |
| I3 | Able and willing to provide adequate locator information   * *Source: Site specific locator form as listed in SOP* |  |  |
| I4 | Able to comply with all study procedural requirements   * *Source: Screening Behavioral Eligibility Worksheet Item 5; Enrollment Behavioral Eligibility Worksheet item 3* |  |  |
| I5 | Per participant report at Screening, post-menarche   * *Source: Screening Behavioral Eligibility Worksheet Item 2* |  |  |
| I6 | HIV uninfected   * *Source: Local testing log, laboratory test results report or other sites-specific document at Screening and Enrollment* |  |  |
| I7 | Per participant report at Screening, has a history of at least one episode of sexual intercourse   * *Source: Screening Behavioral Eligibility Worksheet Item 3* |  |  |
| I8 | Negative pregnancy test   * *Source: Local testing log or other site-specific document at Screening and Enrollment* |  |  |
| I9 | Per participant report, using an effective contraception method consistently for two months prior to Enrollment, and intending to continue use for the duration of study participation   * *Source: Screening Behavioral Eligibility Worksheet Item 1; Enrollment Behavioral Eligibility Worksheet Item 1, hormonal contraceptives listed on Family Planning Log CRF* |  |  |
| I10 | Per participant report, agrees to abstain from inserting any non-study vaginal products or objects into the vagina, including engaging in receptive intercourse, for 72 hours prior to each study visit. Note: Tampon use permitted   * *Source: Screening Behavioral Eligibility Worksheet Item 6* |  |  |
| I11 | Per participant report, agrees not to participate in other research studies involving drugs, medical devices, vaginal products or vaccines after Screening and for the duration of study participation  *Source: Screening Behavioral Eligibility Worksheet Item 4; Enrollment Behavioral Eligibility Worksheet Item 2* |  |  |
| ***EXCLUSION CRITERIA*** | | ***Yes*** | ***No*** |
| E1a | Per participant report, plans to become pregnant   * *Source: Screening Behavioral Eligibility Worksheet Item 11; Enrollment Behavioral Eligibility Worksheet Item 8* |  |  |
| E1b | Per participant report, plans to access or use oral PrEP outside of study participation context   * *Source: Screening Behavioral Eligibility Worksheet Item 17; Enrollment Behavioral Eligibility Worksheet Item 12* |  |  |
| E1c | Per participant report, plans to relocate away from the study site   * *Source: Screening Behavioral Eligibility Worksheet Item 7; Enrollment Behavioral Eligibility Worksheet Item 4* |  |  |
| E1d | Per participant report, plans to travel away for a time period that would interfere with study resupply and study participation   * *Source: Screening Behavioral Eligibility Worksheet Item 8; Enrollment Behavioral Eligibility Worksheet Item 5* |  |  |
| E2 | Positive HIV test   * *Source: Local testing log, laboratory test results report or other site-specific document at Screening and Enrollment* |  |  |
| E3 | Diagnosed with a urinary tract infection (UTI), Pelvic Inflammatory Disease (PID), sexually transmitted disease (STI), or reproductive tract infection (RTI)   * *Source:* *Local testing log, laboratory test results report or other site-specific document; Baseline Medical History CRF; Pelvic Exam Diagram; chart notes* |  |  |
| E4 | Has a clinically apparent Grade 2 or higher pelvic examination finding   * *Source: Pelvic Exam Diagrams, Baseline Medical History Log* |  |  |
| E5a | Has a known adverse reaction to any of the study products (ever)   * *Source: Screening Behavioral Eligibility Worksheet Item 12* |  |  |
| E5b | Has a known adverse reaction to latex or polyurethane (ever)   * *Source: Screening Behavioral Eligibility Worksheet Item 13* |  |  |
| E5c | Has symptoms suggestive of acute HIV infection   * *Source: Chart notes; Physical Exam CRF; Baseline Medical History CRF* |  |  |
| E5d | Reported non-therapeutic injection drug use in the 12 months prior to Enrollment   * *Source: Screening Behavioral Eligibility Item 14; Enrollment Behavioral Eligibility Worksheet Item 9* |  |  |
| E5e | Reported use of PEP for potential HIV exposure or PrEP for HIV prevention within 3 months prior to Enrollment   * *Source: Screening Behavioral Eligibility Worksheet Items 15 and 16; Enrollment Behavioral Eligibility Worksheet Items 10 and 11* |  |  |
| E5f | Currently breastfeeding   * *Source: Screening Behavioral Eligibility Worksheet Item 10; of the Enrollment Behavioral Eligibility Worksheet Item 7* |  |  |
| E5g | Per participant report, had last pregnancy outcome within 8 weeks prior to Enrollment   * *Source: Screening Behavioral Eligibility Worksheet Item 9; Enrollment Behavioral Eligibility Worksheet Item 6* |  |  |
| E5h | Participation in any other research study involving drugs, medical devices, vaginal products or vaccines within 60 days of Enrollment   * *Source: Screening Behavioral Eligibility Worksheet Item 18; Enrollment Behavioral Eligibility Worksheet Item 13* |  |  |
| E5i | Determined at Enrollment by the IoR/designee to have any significant uncontrolled active or chronic cardiovascular, renal, liver, hematologic, neurologic, gastrointestinal, psychiatric, endocrine, respiratory, immunologic disorder or infectious disease.   * *Source: Local testing log, laboratory test results report or other site-specific document; Physical Exam CRF; Baseline Medical History CRF; Chart notes* |  |  |
| E6a | Positive for hepatitis B surface antigen (HBsAG)   * *Source: Local testing log, laboratory test results report or other site-specific document* |  |  |
| E6b | Hemoglobin Grade 2 or higher   * *Source:*  *Local testing log, laboratory test results report or other sites-specific document* |  |  |
| E6c | Calculated creatinine clearance less than 60 mL/min   * *Source:*  *Local testing log, laboratory test results report or other sites-specific document; Safety Lab Calculator Form* |  |  |
| E7 | Has any other condition that, in the opinion of the IoR/designee, would preclude informed consent or assent, make study participation unsafe, complicate interpretation of study outcome data, or otherwise interfere with achieving study objectives   * *Chart notes and this checklist* |  |  |

**For the participant to be eligible, all responses to Inclusion Criteria (items I1-11) above must be “Yes” and responses to Exclusion Criteria (items E1-7) above must be “No.”**

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

Once a participant is deemed eligible to enroll in MTN-034, complete signatures below to confirm and verify final determination of eligibility. Only staff delegated the responsibility of primary eligibility determination per site DoA may sign for Eligibility Confirmation; only staff delegated the responsibility of secondary/verification of eligibility may sign for Eligibility Verification.

**ELIGBILITY VERIFICATION**

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

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

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

**ELIGBILITY CONFIRMATION**

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

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

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