***Instructions:***At Enrollment, use the table below to document the participant’s eligibility status for participation by placing a check mark or an “X” in the “Yes” or “No” column for each listed eligibility criterion. If ineligibility status is determined, any items not yet completed may be left blank; chart note why items of the checklist were left blank if not self-explanatory. For an eligible participant, the checklist must be completed for all items and staff must 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 here; refer to Protocol Sections 5.2 and 5.3 for a complete description of the criteria.*

|  |  |  |  |
| --- | --- | --- | --- |
| **INCLUSION CRITERIA** | | ***Yes*** | ***No*** |
| I1 | Men (cis or transgender) and transgender female, age 18 – 35 years (inclusive) at Screening  ***Source: copy of identification card or other documents as specified in site SOP*** |  |  |
| I2 | Able and willing to provide written informed consent  ***Source: Signed/Marked Screening and Enrollment Consent Form*** |  |  |
| I3 | HIV-1/2 uninfected at Screening and Enrollment, and willing to receive HIV test results  ***Source: In-clinic testing results on testing log or laboratory results report*** |  |  |
| I4 | Able and willing to provide adequate locator information  ***Source: Site-specific locator form as specified in site SOP*** |  |  |
| I5 | Available to return for all study visits and willing to comply with study participation requirements  ***Source: Screening Behavioral Eligibility Worksheet and Enrollment Behavioral Eligibility Worksheet*** |  |  |
| I6 | In good general health at Screening and Enrollment, as determined by the site Investigator of Record (IoR) or designee  ***Source: Anorectal Exam CRF, Medical History Log CRF, Physical Exam CRF, Vital Signs CRF. If applicable, Pelvic Exam Diagram Form, Genital Exam CRF, Pelvic Exam CRF*** |  |  |
| I7 | Has a history of consensual RAI at least three times in the past three months and expecting to maintain at least this frequency during study participation  ***Source: Screening Behavioral Eligibility Worksheet*** |  |  |
| I8 | Willing to not participate in other research studies involving drugs, medical devices, genital or rectal products or vaccines for the duration of study participation (including between Screening and Enrollment)  ***Source: Screening Behavioral Eligibility Worksheet and Enrollment Behavioral Eligibility Worksheet*** |  |  |
| ***Criteria I9-I10 for individuals who can get pregnant (mark N/A if cis-male or transgender female)*** | | ***□ N/A*** | |
| I9 | Has a negative pregnancy test at Screening and Enrollment  ***Source: In-clinic testing results on testing log or laboratory results report*** |  |  |
| I10 | Willing to use an effective method of contraception for at least 30 days (inclusive) prior to Enrollment and intending to continue to use an effective method of contraception during study duration  ***Source: Screening Behavioral Eligibility Worksheet, Enrollment Behavioral Eligibility Worksheet*** |  |  |
| ***EXCLUSION CRITERIA*** | | ***Yes*** | ***No*** |
| E1a | At Screening, has a history of inflammatory bowel disease  ***Source: Medical History Log CRF*** |  |  |
| E1b | At Screening, has a current anorectal condition that would impede product placement or assessment of tolerability by participant report or exam  ***Source: Anorectal Exam CRF, Medical History Log CRF*** |  |  |
| E2 | Anticipated use of and/or unwilling to abstain from using non-study, rectally administered medications and products during study participation, including personal lubricants containing N-9  ***Source: Screening Behavioral Eligibility Worksheet and Enrollment Behavioral Eligibility Worksheet*** |  |  |
| E3 | Known adverse reaction to any of the components of the study products  ***Source: Screening Behavioral Eligibility Worksheet, Medical History Log CRF*** |  |  |
| E4 | Participation in research studies involving drugs, medical devices, genital products, or vaccines within 30 days of Enrollment  ***Source: Screening Behavioral Eligibility Worksheet and Enrollment Behavioral Eligibility Worksheet*** |  |  |
| E5 | Participation in research studies involving rectal products (ever)  ***Source: Screening Behavioral Eligibility Worksheet and Enrollment Behavioral Eligibility Worksheet*** |  |  |
| E6 | Reported use of post-exposure prophylaxis (PEP) for potential HIV exposure within 3 months prior to Enrollment  ***Source: Screening Behavioral Eligibility Worksheet and Enrollment Behavioral Eligibility Worksheet*** |  |  |
| E7 | Reported engagement in receptive anal or vaginal sex without a condom while not on PrEP, with a HIV-positive partner, and either not on antiretroviral therapy (ART) or of unknown ART use status, within 3 months prior to Enrollment  ***Source: Screening Behavioral Eligibility Worksheet and Enrollment Behavioral Eligibility Worksheet*** |  |  |
| E8 | Reported engagement in receptive anal or vaginal sex without a condom while not on PrEP with a partner who is of unknown HIV status, and unknown PrEP/ART use status, within 1 month prior to Enrollment  ***Source: Screening Behavioral Eligibility Worksheet and Enrollment Behavioral Eligibility Worksheet*** |  |  |
| E9 | Non-therapeutic injection drug use in the 12 months prior to Enrollment  ***Source: Screening Behavioral Eligibility Worksheet and Enrollment Behavioral Eligibility Worksheet*** |  |  |
| E10 | At Screening and Enrollment, diagnosis and/or participant-reported symptoms indicative of an active anorectal or reproductive tract infection requiring treatment per WHO guidelines, or symptomatic UTI  ***Source: Anorectal Exam CRF, In-clinic testing results on testing log or laboratory results report, Medical History Log CRF. If applicable, Pelvic Exam Diagram Form, Genital Exam CRF, Pelvic Exam CRF*** |  |  |
| ***Criteria E11-E12 for individuals who can get pregnant (mark N/A if cis-male or transgender female)*** | | ***□ N/A*** | |
| E11 | At Screening or Enrollment, pregnant or breastfeeding or intends to become pregnant during study participation  ***Source: Screening Behavioral Eligibility Worksheet and Enrollment Behavioral Eligibility Worksheet, in-clinic testing log*** |  |  |
| E12 | Last pregnancy outcome less than 90 days (inclusive) prior to Screening  ***Source: Screening Behavioral Eligibility Worksheet*** |  |  |
| ***Criteria E13 for all potential study participants*** | | | |
| E13 | 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 other site-specific forms*** |  |  |

**For the participant to be eligible, all responses to Inclusion Criteria (items I1-I8) above must be “Yes” and responses to Exclusion Criteria (items E1-E10, and E13) above must be “No.” For individuals who can get pregnant, responses to I9 and I10 must be “YES” and responses to E11 and E12 above must be “No.”**

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

Once a participant is deemed eligible to enroll in MTN-035, complete signatures below to confirm and verify final determination of eligibility. Only staff delegated the responsibility of primary eligibility determination per site Delegation of Authority/Staff Roster 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: \_\_\_ \_\_\_: \_\_\_ \_\_\_**