***Instructions:*** *Use the table below to document a participant’s eligibility status for participation by marking “yes” or “no” 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 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 | Man or transgender woman, 18 years or older  ***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 and willing to receive HIV test results  ***Source: Site HIV rapid testing logs/Laboratory Results report*** | |  |  |
| I4 | Able and willing to provide adequate locator information  ***Source: Site-specific locator forms as specified in site SOP*** | |  |  |
| I5 | Available to return for all study visits and willing to comply with study requirements  ***Source: Screening Behavioral Eligibility Worksheet and Enrollment Behavioral Eligibility Worksheet*** | |  |  |
| I6 | In general good health  ***Source: Anorectal Exam CRF, Baseline Medical History Log CRF, Physical Exam CRF, Vital Signs CRF, Pelvic Exam Diagram and Pelvic Exam CRF*** | |  |  |
| I7 | Has a history of consensual RAI (once in the past calendar year)  ***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  ***Source: Screening Behavioral Eligibility Worksheet and Enrollment Behavioral Eligibility Worksheet*** | |  |  |
| I9 | Willing to abstain from receptive anal intercourse (RAI), receptive oral anogenital stimulation (i.e., rimming), rectal stimulation via fingers, as well as the insertion of any non-study products into the rectum for 72 hours before and after each study visit  ***Source: Screening Behavioral Eligibility Worksheet and Enrollment Behavioral Eligibility Worksheet*** | |  |  |
| ***EXCLUSION CRITERIA*** | | | ***Yes*** | ***No*** |
| E1a | | Hemoglobin Grade 1 or higher  ***Source: Laboratory Result Report*** |  |  |
| E1b | | Platelet count Grade 1 or higher  ***Source: Laboratory Result Report*** |  |  |
| E1c | | White blood count Grade 2 or higher  ***Source: Laboratory Result Report*** |  |  |
| E1d | | AST or ALT Grade 1 or higher  ***Source: Laboratory Result Report*** |  |  |
| E1e | | Serum creatinine >1.3× the site laboratory ULN  ***Source: Laboratory Result Report*** |  |  |
| E1f | | INR >1.5× the site laboratory ULN  ***Source: Laboratory Result Report*** |  |  |
| E1g | | Hepatitis C Antibody positive  ***Source: Laboratory Result Report*** |  |  |
| E1h | | Hepatitis B Surface Antigen positive  ***Source: Laboratory Result Report*** |  |  |
| E1i | | Reported history of inflammatory bowel disease  ***Source: Baseline Medical History Log CRF*** |  |  |
| E2 | | Known adverse reaction to latex or polyurethane (ever)  ***Source: Screening Behavioral Eligibility Worksheet*** |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **EXCLUSION CRITERIA** | | ***Yes*** | ***No*** |
| E3a | Anticipated use of and/or unwillingness to abstain from using anticoagulant medications  ***Source: Screening Behavioral Eligibility Worksheet and Enrollment Behavioral Eligibility Worksheet*** |  |  |
| E3b | Anticipated use of and/or unwillingness to abstain from using aspirin (greater than 81 mg/day)  ***Source: Screening Behavioral Eligibility Worksheet and Enrollment Behavioral Eligibility Worksheet*** |  |  |
| E3c | Anticipated use of and/or unwillingness to abstain from using non-steroidal anti-inflammatory drugs (NSAIDS)  ***Source: Screening Behavioral Eligibility Worksheet and Enrollment Behavioral Eligibility Worksheet*** |  |  |
| E3d | Anticipated use of and/or unwillingness to abstain from using any other drugs that are associated with increased likelihood of bleeding  ***Source: Screening Behavioral Eligibility Worksheet and Enrollment Behavioral Eligibility Worksheet*** |  |  |
| E3e | Anticipated use of and/or unwillingness to abstain from using rectally-administered medications or products containing N-9 or corticosteroids  ***Source: Screening Behavioral Eligibility Worksheet and Enrollment Behavioral Eligibility Worksheet*** |  |  |
| E3f | Anticipated use of and/or unwillingness to abstain from using CYP3A inducer(s) and/or inhibitor(s)  ***Source: Screening Behavioral Eligibility Worksheet and Enrollment Behavioral Eligibility Worksheet*** |  |  |
| E3g | Anticipated use of and/or unwillingness to abstain from using hormone-replacement therapy in tablet, injectable or gel form  ***Source: Screening Behavioral Eligibility Worksheet and Enrollment Behavioral Eligibility Worksheet*** |  |  |
| E4 | Known adverse reaction to any of the components of the study product, applicator or coital stimulation device.  ***Source: Screening Behavioral Eligibility Worksheet*** |  |  |
| E5 | Reported use of PrEP for HIV prevention within the 1 month prior to Enrollment and/or anticipated use during study participation  ***Source: Screening Behavioral Eligibility Worksheet and Enrollment Behavioral Eligibility Worksheet*** |  |  |
| E6 | Reported use of PEP for potential HIV exposure within 6 months prior to Enrollment  ***Source: Screening Behavioral Eligibility Worksheet and Enrollment Behavioral Eligibility Worksheet*** |  |  |
| E7 | Reported use or anticipated use of systemic immunomodulatory medications within the 6 months prior to Enrollment, and/or during study participation  ***Source: Screening Behavioral Eligibility Worksheet and Enrollment Behavioral Eligibility Worksheet*** |  |  |
| E8 | Engaged in RAI without a condom and/or penile-vaginal intercourse with a partner known to be HIV-positive in the past 6 months  ***Source: Screening Behavioral Eligibility Worksheet and Enrollment Behavioral Eligibility Worksheet*** |  |  |
| E9 | Non-therapeutic injection drug use in the past 12 months  ***Source: Screening Behavioral Eligibility Worksheet and Enrollment Behavioral Eligibility Worksheet*** |  |  |
| E10 | Participation in research studies involving drugs, medical devices, genital or rectal products, or vaccines (within 30 days)  ***Source: Screening Behavioral Eligibility Worksheet and Enrollment Behavioral Eligibility Worksheet*** |  |  |
| E11 | Reported treatment for an anogenital STI within the past 3 months prior to Screening  ***Source: Baseline Medical History Log CRF, Screening Behavioral Eligibility Worksheet*** |  |  |
| E12 | Diagnosed or participant reported symptoms of active anorectal or RTI requiring treatment per WHO guidelines or symptomatic UTI at Screening  ***Source: Anorectal Exam CRF, Screening Behavioral Eligibility Worksheet, Baseline Medical History Questions Log CRF, Pelvic Exam Diagram, Pelvic Exam CRF, local site-specific testing log and/or local lab results report*** |  |  |
| E13 | Diagnosed with an active anorectal or RTI requiring treatment per WHO guidelines or symptomatic UTI at Enrollment  ***Source: Anorectal Exam CRF, Baseline Medical History Log CRF, Pelvic Exam Diagram, Pelvic Exam CRF, local site-specific testing log and/or local lab results report*** |  |  |
| E14 | 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-I9) above must be “Yes” and responses to Exclusion Criteria (items E1-E14) above must be “No.”**

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

Once a participant is deemed eligible to enroll in MTN-033, complete signatures below to confirm and verify final determination of eligibility. Only staff delegated the responsibility of primary eligibility determination per the 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 CONFIRMATION**

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

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

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

**ELIGBILITY VERIFICATION**

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

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

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