***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*** | ***Enrollment Visit Date******­­\_\_\_\_\_\_\_\_\_\_\_*** |
| ***Yes*** | ***No*** |
| I1 | 18 years of age or older at Screening* *Source: copy of identification card or other documents as specified in SOP*
 |  |  |
| I2 | Able and willing to provide written informed consent to be screened for and enrolled in MTN-039* *Source: Signed informed consent form*
 |  |  |
| I3 | HIV 1/2 uninfected at Screening and Enrollment (per algorithm) and willing to receive HIV test results* *Source: Local testing log, laboratory test results report or other sites-specific document at Screening and Enrollment*
 |  |  |
| I4 | Able and willing to provide adequate locator information* *Source: Site-specific locator form or other documents as specified in SOP*
 |  |  |
| I5 | Able to communicate in spoken and written English* *Source: N/A, assessed per site SOP*
 |  |  |
| I6 | Per participant report, available for all visits and able and willing to comply with all study procedural requirements* *Source: Screening Behavioral Eligibility Worksheet; Enrollment Behavioral Eligibility Worksheet*
 |  |  |
| I7 | In general good health at Screening and Enrollment* *Source: Medical History Log CRF; local testing log, laboratory test results report or other site-specific document; Physical Exam CRF, Anorectal Exam CRF; Pelvic Exam CRF; Pelvic Exam Diagram; chart notes*
 |  |  |
| I8 | Per participant report, has a history of consensual RAI at least once in lifetime at Screening* *Source: Screening Behavioral Eligibility Worksheet*
 |  |  |
| I9 | Per participant report, willing not to take part in other research studies involving drugs, medical devices, genital or rectal products, or vaccines for the duration of study participation (including the time between Screening and Enrollment)* *Source: Screening Behavioral Eligibility Worksheet; Enrollment Behavioral Eligibility Worksheet*
 |  |  |
| I10 | Per participant report, willing to comply with abstinence and other protocol requirements as outlined in MTN-039 protocol (*refrain from using strong/moderate CYP3As; abstain from using aspirin (greater than 81 mg), NSAIDS, anticoagulants or blood thinners, inserting non-study rectal products or objects (such as sex toys, fingers, etc.) into the rectum for 72 hours before and after study visits, engaging in receptive oral and anal intercourse; abstain from vaginal intercourse and inserting anything into the vagina for 72 hours prior to each study visit*). * *Source: Screening Behavioral Eligibility Worksheet; Enrollment Behavioral Eligibility Worksheet*
 |  |  |
| I11 | Negative pregnancy test at Screening and Enrollment * *Source: Local testing log or other site-specific document at Screening and Enrollment*
 |  |  |
| ***INCLUSION CRITERIA*** | ***Enrollment Visit Date******­­\_\_\_\_\_\_\_\_\_\_\_*** |
| I12 | Per participant report, using an effective contraception method for at least 30 days prior to Enrollment, and intending to continue use for the duration of study participation* *Source: Screening Behavioral Eligibility Worksheet; Enrollment Behavioral Eligibility Worksheet; Concomitant Medications Log CRF*
 |  |  |
| ***EXCLUSION CRITERIA*** | ***Enrollment Visit Date******­­\_\_\_\_\_\_\_\_\_\_\_*** |
| E1a | Hemoglobin Grade 1 or higher* *Source:*  *Laboratory test results report or other site-specific document*
 |  |  |
| E1b | Platelet count Grade 1 or higher* *Source:*  *Laboratory test results report or other site-specific document*
 |  |  |
| E1c | AST or ALT Grade 1 or higher* *Source:*  *Laboratory test results report or other site-specific document*
 |  |  |
| E1d | Serum creatinine >1.3 × site laboratory upper limit of normal (ULN) * *Source:*  *Laboratory test results report or other site-specific document*
 |  |  |
| E1e | International normalized ratio (INR) >1.5 × site laboratory ULN * *Source:*  *Laboratory test results report or other site-specific document*
 |  |  |
| E1f | Per participant report, has a history of inflammatory bowel disease* *Source:*  *Chart notes; Medical History Log CRF*
 |  |  |
| E1g | Positive hepatitis B surface antigen* *Source:*  *Laboratory test results report or other site-specific document*
 |  |  |
| E2 | Per participant report, anticipated use of and/or unwillingness to abstain from anticoagulant medications or non-study rectally-administered medications and any products containing N-9 during study participation* *Source: Screening Behavioral Eligibility Worksheet; Enrollment Behavioral Eligibility Worksheet*
 |  |  |
| E3 | Per participant report, has a known adverse reaction to any of the components of the study product * *Source: Screening Behavioral Eligibility Worksheet*
 |  |  |
| E4 | Per participant report, use of approved or other investigational 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; Enrollment Behavioral Eligibility Worksheet; Concomitant Medications Log CRF*
 |  |  |
| E5 | Per participant report, use of PEP for potential HIV exposure within 6 months prior to Enrollment* *Source: Screening Behavioral Eligibility Worksheet; Enrollment Behavioral Eligibility Worksheet*
 |  |  |
| E6 | Per participant report, engagement in condomless RAI and/or penile-vaginal intercourse with a partner known to be HIV-positive or whose status is unknown within 6 months prior to Enrollment* *Source: Screening Behavioral Eligibility Worksheet; Enrollment Behavioral Eligibility Worksheet*
 |  |  |
| E7 | Per participant report, reports a history of transactional sex in the 12 months prior to Enrollment* *Source: Screening Behavioral Eligibility Worksheet; Enrollment Behavioral Eligibility Worksheet*
 |  |  |
| E8 | Per participant report, use of non-therapeutic, non-injection stimulant drug use in the 12 months prior to Enrollment* *Source: of the Screening Behavioral Eligibility; Enrollment Behavioral Eligibility Worksheet*
 |  |  |

|  |  |
| --- | --- |
| ***EXCLUSION CRITERIA*** | ***Enrollment Visit Date******­­\_\_\_\_\_\_\_\_\_\_\_*** |
| E9 | Per participant report, participation in another research study involving drugs, medical devices, genital or rectal products, or vaccines within 30 days prior to Enrollment* *Source: Enrollment Behavioral Eligibility Worksheet*
 |  |  |
| E10a | Per participant report, diagnosis of or treatment for any anogenital STI in the past 3 months within Enrollment* *Source: Medical History Log CRF; Screening Behavioral Eligibility Worksheet; Enrollment Behavioral Eligibility Worksheet; chart notes*
 |  |  |
| E10b | Symptomatic of or clinically or laboratory diagnosed with an active pharyngeal infection, anorectal infection or RTI requiring treatment *at Screening and Enrollment** *Source: Laboratory test results report or other site-specific document; Medical History Log CRF; Pelvic Exam Diagram form, Pelvic Exam CRF, Physical Exam; Anorectal Exam CRF, chart notes*
 |  |  |
| E10c | Has a symptoms indicative of a urinary tract infection (UTI)* *Source: Laboratory test results report or other site-specific document; Medical History Log CRF; Physical Exam CRF; chart notes*
 |  |  |
| E11 | Pregnant or breastfeeding or plans to become pregnant or begin breastfeeding during study participation* *Source: Screening Behavioral Eligibility Worksheet; Enrollment Behavioral Eligibility Worksheet; local testing log or other site-specific document; chart notes at Screening and Enrollment*
 |  |  |
| E12 | Per participant report, last pregnancy outcome within 90 days prior to Screening* *Source: Screening Behavioral Eligibility Worksheet*
 |  |  |
| 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* *Chart notes, Eligibility checklist*
 |  |  |

**For the participant to be eligible, all responses to Inclusion Criteria (items I1-12) above must be “Yes” and responses to Exclusion Criteria (items E1-13) above must be “No.”**

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

Once a participant is deemed eligible to enroll in MTN-039, complete signatures below to confirm and verify final determination of eligibility. Only staff delegated the responsibility of eligibility determination per site Delegation of Duties Log may sign for eligibility confirmation and verification.

**ELIGBILITY VERIFICATION**

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

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

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

**ELIGBILITY CONFIRMATION**

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

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

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