***Instructions:*** *At the enrollment visit, use the table below to document a participant’s eligibility status for participation by marking “yes” or “no.” If the participant is deemed ineligible, 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*** |
| 11 | Age 18 years (inclusive) or older* *Source: copy of ID card/driver’s license or other documents as specified in SOP*
 |  |  |
| I2 | Able and willing to provide written informed consent* *Source: Signed consent forms*
 |  |  |
| I3 | HIV uninfected and willing to receive HIV test results* *Source: Local testing log, laboratory test results report or other site-specific document*
 |  |  |
| I4 | Able and willing to provide adequate locator information* *Source: Site specific locator form as listed in SOP*
 |  |  |
| I5 | Available for all visits and able to comply with all study procedural requirements* *Source: Screening Behavioral Eligibility Worksheet item #4; Enrollment Behavioral Eligibility Worksheet item #3*
 |  |  |
| I6 | In general good health by as determined by IoR/designee* *Source: Baseline Medical History CRF; Physical Exam CRF, Pelvic Exam Diagram CRF, Vital Signs CRF, Anorectal Exam CRF; chart notes at Screening and Enrollment*
 |  |  |
| I7 | Reports a history of at least one consensual RAI participant’s in lifetime* *Source: Screening Behavioral Eligibility Worksheet item #2*
 |  |  |
| I8 | Agrees not to participate in other research studies drugs, medical devices, genital or rectal products, or vaccines after Screening and for the duration of study participation* *Source: Screening Behavioral Eligibility Worksheet item #3; Enrollment Behavioral Eligibility Worksheet item #2*
 |  |  |
| I9 | Willing to follow abstinence requirements for the duration of study participation* *Source: Screening Behavioral Eligibility Worksheet item #5; Enrollment Behavioral Eligibility Worksheet item #4*
 |  |  |
| I10 | FOR PARTICIPANTS OF CHILDBEARING POTENTIAL: Negative pregnancy test* *Source: Local testing log, laboratory test results report or other sites-specific document*
 |  |  |
| I11 | FOR PARTICIPANTS OF CHILDBEARING POTENTIAL: Using an effective contraception method, and intending to continue use for the duration of study participation* *Source: Screening Behavioral Eligibility Worksheet item #1; Enrollment Behavioral Eligibility Worksheet item #1*
 |  |  |
| ***EXCLUSION CRITERIA*** | ***Yes*** | ***No*** |
| 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 | White blood count Grade 2 or higher* *Source:*  *Laboratory test results report or other site-specific document*
 |  |  |
| E1d | AST or ALT Grade 1 or higher* *Source:*  *Laboratory test results report or other site-specific document*
 |  |  |
| E1e | Serum creatinine >1.3× the site laboratory upper limit of normal (ULN) * *Source:*  *Laboratory test results report or other site-specific document*
 |  |  |
| E1f | International normalized ratio (INR) >1.5× the site laboratory ULN * *Source:*  *Laboratory test results report or other site-specific document*
 |  |  |
| E1g | Reports history of inflammatory bowel disease* *Source:*  *Chart notes, Baseline Medical History CRF*
 |  |  |
| E2 | Has a known adverse reaction to latex or polyurethane (ever)* *Source: Screening Behavioral Eligibility Worksheet item #13*
 |  |  |
| E3 | Anticipated use of and/or unwillingness to abstain from anticoagulant medications or rectally-administered medications during study participation* *Source: Screening Behavioral Eligibility Worksheet item #6; Enrollment Behavioral Eligibility Worksheet item #6*
 |  |  |
| E4 | Known adverse reaction to any of the study product components* *Source: Screening Behavioral Eligibility Worksheet item #12*
 |  |  |
| E5 | Reports use of PrEP for HIV prevention within 1 month prior to Enrollment, and/or anticipated use and/or unwillingness to abstain from use during study participation* *Source: Screening Behavioral Eligibility Worksheet items #7, #8; Enrollment Behavioral Eligibility Worksheet items #5, #8; Concomitant Medications Log CRF*
 |  |  |
| E6 | Reports use of PEP for potential HIV exposure within 3 months prior to Enrollment.* *Source: Screening Behavioral Eligibility Worksheet item #9; Enrollment Behavioral Eligibility Worksheet item #9*
 |  |  |
| E7 | Reports 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 item #14; Enrollment Behavioral Eligibility Worksheet item #7*
 |  |  |
| E8 | Reports non-therapeutic injection drug use in the 12 months prior to Enrollment* *Source: of the Screening Behavioral Eligibility #15; Enrollment Behavioral Eligibility Worksheet item #11*
 |  |  |
| E9 | Participation in any other research study involving drugs, medical devices, genital or rectal products, or vaccines within 30 days prior to Enrollment* *Source: Screening Behavioral Eligibility Worksheet item #16; Enrollment Behavioral Eligibility Worksheet item #12*
 |  |  |
| E10 | Has had a gynecologic, genital, or rectal procedure (e.g., tubal ligation, dilation and curettage, piercing, hemorrhoidal resection, polyp removal) within 60 days prior to Enrollment, or rectal biopsy, within 7 days prior to Enrollment* *Source: Baseline Medical History CRF; Screening Behavioral Eligibility Worksheet item #18; Enrollment Behavioral Eligibility Worksheet item #13*
 |  |  |
| E11a | Diagnosis or treatment of any anogenital STI in the past 3 months* *Source: Baseline Medical History Questionnaire; Screening Behavioral Eligibility Worksheet item #17; Enrollment Behavioral Eligibility Worksheet #14; chart notes*
 |  |  |
| E11b | Currently symptomatic of a UTI* *Source: Baseline Medical History Questions Form; local testing log, laboratory test results report other site-specific document; Pelvic Exam Diagram; chart notes*
 |  |  |
| E11c | Symptomatic, clinically or laboratory diagnosis of active pharyngeal infection, anorectal infection or RTI requiring treatment* *Source: Laboratory test results report or other site-specific document; Baseline Medical History Questions Form; Pelvic Exam Diagram CRF, Pelvic Exam CRF, Anorectal Exam CRF, chart notes*
 |  |  |
| E12a | Reports being pregnant or breastfeeding or plans to become pregnant or begin breastfeeding during study participation* *Source: Screening Behavioral Eligibility Worksheet item #10; Enrollment Behavioral Eligibility Worksheet item #10; local testing log or other site-specific document; Chart notes at Screening and Enrollment*
 |  |  |
| E12b | Per participant report, had last pregnancy outcome within 90 days prior to Screening* *Source: Screening Behavioral Eligibility Worksheet item #11*
 |  |  |
| 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 this checklist*
 |  |  |

**For the participant to be eligible, all responses to Inclusion Criteria (items I1-I11) above must be “Yes” and responses to Exclusion Criteria (items E1-E13) above must be “No”.**

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

Once a participant is deemed eligible to enroll in MTN-037, complete signatures below to confirm and verify final determination of eligibility. Only staff delegated the responsibility of primary eligibility determination per site DoA may complete the first signature line; only staff delegated the responsibility of secondary/verification of eligibility may complete the second signature line.

**ELIGBILITY VERIFICATION**

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

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

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

**INITIAL ELIGIBILTY CONFIRMATION**

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

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

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