***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 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 18 – 45 years (inclusive)***Source: copy of identification card or other documents as specified in the site SOP*** |  |  |
| I2 | Able and willing to provide written informed consent***Source: Signed/Marked Screening and Enrollment Consent Form*** |  |  |
| I3 | HIV-1/2 uninfected ***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 and Sigmoidoscopy CRF, Baseline Medical History Questions, Baseline Medical History Log CRF, Physical Exam CRF, Vital Signs CRF, Pelvic Exam Diagram Form and Pelvic Exam CRF*** |  |  |
| I7 | Has a history of consensual RAI (once in the past calendar year)***Source: Screening Behavioral Eligibility Worksheet***  |  |  |
| I8 | Willing not to 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 be sexually abstinent for 72 hours prior to each study visit, during the study product use periods and for 72 hours after biopsy collection***Source: Screening Behavioral Eligibility Worksheet and Enrollment Behavioral Eligibility Worksheet*** |  |  |
| I10 | Willing to abstain from inserting any non-study products into the rectum for 72 hours prior to each study visit and during the study product use periods***Source: Screening Behavioral Eligibility Worksheet and Enrollment Behavioral Eligibility Worksheet*** |  |  |
| ***Criteria I11-I14 for female participants only.***  |
| I11 | Women ≥ 21 years of age with a satisfactory Pap result (Grade 0 or Grade 1 or higher with no treatment) within the past 3 years***Source: Laboratory Results report***  |  |  |
| I12 | Willing to be sexually abstinent for 72 hours prior to each study visit and during the study product use periods and for 7 days after biopsy collection***Source: Screening Behavioral Eligibility Worksheet and Enrollment Behavioral Eligibility Worksheet*** |  |  |
| I13 | Willing to abstain from inserting any non-study products into the vagina for 72 hours prior to each study visit, during the study product use periods and for 7 days after biopsy collection***Source: Screening Behavioral Eligibility Worksheet and Enrollment Behavioral Eligibility Worksheet*** |  |  |
| I14 | Using an effective method of contraception for at least 30 days (inclusive) prior to Enrollment and intending to continue during study duration***Source: Screening Behavioral Eligibility Worksheet and Enrollment Behavioral Eligibility Worksheet, Contraceptive Counseling Worksheet*** |  |  |

|  |  |  |
| --- | --- | --- |
| ***EXCLUSION CRITERIA*** | ***Yes*** | ***No*** |
| E1i | Hemoglobin Grade 1 or higher***Source: Laboratory Result Report*** |  |  |
| E1ii | Platelet count Grade 1 or higher***Source: Laboratory Result Report*** |  |  |
| E1iii | White blood count Grade 2 or higher***Source: Laboratory Result Report*** |  |  |
| E1v | Serum creatinine >1.3× the site laboratory ULN***Source: Laboratory Result Report*** |  |  |
| E1v | INR >1.5× the site laboratory ULN***Source: Laboratory Result Report*** |  |  |
| E1vi | AST or ALT Grade 1 or higher***Source: Laboratory Result Report*** |  |  |
| E1vii | Hepatitis C Antibody positive***Source: Laboratory Result Report*** |  |  |
| E1viii | Hepatitis B Surface Antigen positive***Source: Laboratory Result Report*** |  |  |
| E1ix | Reported history of inflammatory bowel disease***Source: Baseline Medical History Questions Form*** |  |  |
| E2 | Anticipated use of and/or unwillingness to abstain from using prohibited medications during study participation***Source: Screening Behavioral Eligibility Worksheet and Enrollment Behavioral Eligibility Worksheet*** |  |  |
| E3 | Known adverse reaction to any of the components of the study products (dapivirine, hydroxylethyl cellulose, polycarbophil, propylene glycol, methylparaben, prophyparaben, sodium hydroxide, sodium chloride, and sorbic acid)***Source: Screening Behavioral Eligibility Worksheet***  |  |  |
| E4 | Reported use of PEP for potential HIV exposure within 6 months prior to Enrollment***Source: Screening Behavioral Eligibility Worksheet and Enrollment Behavioral Eligibility Worksheet*** |  |  |
| E5 | Reported use or anticipated use of PrEP for HIV prevention within the 6 prior to Enrollment months and/or during study participation***Source: Screening Behavioral Eligibility Worksheet and Enrollment Behavioral Eligibility Worksheet*** |  |  |
| E6 | 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*** |  |  |
| E7 | 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*** |  |  |
| E8 | Non-therapeutic injection drug use in the past 12 months***Source: Screening Behavioral Eligibility Worksheet and Enrollment Behavioral Eligibility Worksheet*** |  |  |
| E9 | Participation in research studies involving drugs, medical devices, genital or rectal products, or vaccines (within 45 days)***Source: Screening Behavioral Eligibility Worksheet and Enrollment Behavioral Eligibility Worksheet*** |  |  |
| E10 | Reported treatment for an anogenital STI within the past 3 months***Source: Baseline Medical History Questions Sheet, Screening Behavioral Eligibility Worksheet*** |  |  |
| ***EXCLUSION CRITERIA*** | ***Yes*** | ***No*** |
| E11 | Diagnosed or participant reported symptoms of active anorectal or RTI requiring treatment per WHO guidelines or symptomatic UTI***Source: Anorectal Exam and Sigmoidoscopy CRF, Screening Behavioral Eligibility Worksheet, Baseline Medical History Questions Sheet, Pelvic Exam Diagrams, Pelvic Exam CRF, local site specific testing log and/or local lab results report*** |  |  |
| E12 | Diagnosed with an active anorectal or RTI requiring treatment per WHO guidelines or symptomatic UTI***Source: Anorectal Exam and Sigmoidoscopy CRF, Baseline Medical History Questions Sheet, Pelvic Exam Diagrams Form, Pelvic Exam CRF, local site specific testing log and/or local lab results report*** |  |  |
| 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*** |  |  |
| ***Criteria E14-E17 for female participants only.***  |
| E14 | Pregnant or breastfeeding or intends to become pregnant or start breastfeeding during study participation***Source: Screening Behavioral Eligibility Worksheet and Enrollment Behavioral Eligibility Worksheet, Laboratory results report*** |  |  |
| E15 | Last pregnancy outcome less than 90 days***Source: Screening Behavioral Eligibility Worksheet*** |  |  |
| E16 | Has had a hysterectomy ***Source: Screening Behavioral Eligibility Worksheet, Baseline Medical History Questions, Pelvic Exam Diagramsform and Pelvic Exam CRF*** |  |  |
| E17 | Clinically apparent Grade 1 or higher pelvic exam finding***Source: Pelvic Exam Diagrams form, Pelvic Exam CRF and Baseline Medical History Log CRF*** |  |  |

**For the participant to be eligible, all responses to Inclusion Criteria (items I1-I14) above must be “Yes” and responses to Exclusion Criteria (items E1-E17) above must be “No.”**

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

Once a participant is deemed eligible to enroll in MTN-026, 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 CONFIRMATION**

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

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

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

**ELIGBILITY VERIFICATION**

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

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

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