**Instructions:** Use the table below to document a participant’s eligibility status for MTN-025 study participation at the enrollment visit. Initial and date the bottom of each page. For each item, the reference/source document is listed. If ineligibility status is determined, the form may be stopped and the remaining questions may be left blank. If the participant is confirmed eligible, the IoR (or designee) should sign and date this checklist and a second staff member should sign to verify eligibility. **The act of completing this checklist and final sign-off by designated staff is the act of enrollment into MTN-025.** Complete the Eligibility Criteria CRF for all screened participants once the participant’s eligibility/enrollment status is determined.

|  |  |
| --- | --- |
| **Inclusion Criteria** | ***Yes No*** |
| **I1. Previously enrolled in MTN-020 (ASPIRE)**  *Source: site-specific identification/co-enrollment procedures, as outlined and documented per site SOPs (sites to modify to make specific)* |  |
| **I2. Able and willing to provide written informed consent to be screened for and take part in the study**  *Source: signed/marked Screening and Enrollment consent forms* |  |
| **I3. Able and willing to provide adequate locator information, as defined by the site SOPs**  *Source: locator forms as listed in SOP* |  |
| **I4. HIV-uninfected, based on testing performed by study staff at Screening and Enrollment (per applicable algorithm in Appendix II)**  *Source: rapid HIV testing logs* |  |
| **I5. Using an effective method of contraception at enrollment and intending to use of an effective method for the duration of study participation; effective methods include hormonal methods (except contraceptive ring), intrauterine contraceptive device (IUCD), and sterilization, (of participant, as defined in site SOPs)**  *Source: Listed Family Planning/Contraception Methods on Family Planning Log CRF and Item 1 of Enrollment Behavioral Eligibility Worksheet* |  |
| **I6. At Screening and Enrollment, agrees not to participate in other research studies involving drugs, medical devices, vaginal products, or vaccines for the duration of study participation.**  *Source: Item 2 of Screening Behavioral Eligibility Worksheet, Item 2 of Enrollment Behavioral Eligibility Worksheet* |  |
| ***Note: In order for the participant to be eligible, all of the responses to items* I1- I6 *above must be “yes”*** | |
| **Exclusion Criteria** | ***Yes No*** |
| **E1. Study product use permanently discontinued in response to an AE or safety related concern while taking part in the MTN-020 (ASPIRE) trial.**  *Source: site-specific recruitment lists generated by SDMC* |  |
| **E2. Per participant report at Screening:**   1. **Plans to relocate away from the study site during study participation**   *Source: Item 3 of Screening Behavioral Eligibility Worksheet* |  |
| 1. **Plans to travel away from the study site for more than 3 consecutive months during study participation**   *Source: Item 4 of Screening Behavioral Eligibility Worksheet* |  |
| **E3. Per participant report at Enrollment, currently taking Post-Exposure Prophylaxis (PEP)**  *Source: Item 3 of Enrollment Behavioral Eligibility Worksheet* |  |
| ***Note:*** *PEP use at Screening is not exclusionary. Participants may be enrolled after the PEP regimen is complete and a negative HIV test is documented within 56 days of providing informed consent for Screening.* | |
| **Exclusion Criteria** | ***Yes No*** |
| **E4. With the exception of MTN-020 (ASPIRE), participation in any other research study involving drugs, medical devices, vaginal products, or vaccines, within 60 days of enrollment**  *Source: Item 6 of Enrollment Behavioral Eligibility Worksheet, Site-specific co-enrollment check as outlined and documented in site SOPs* |  |
| ***Note:*** *Participation in the ‘Decliner Population’ does not preclude MTN-025 full study participation in the future.* | |
| **E5. Is pregnant at screening or enrollment, or planning to become pregnant in the participant’s anticipated study participation period.**  *Source: pregnancy result on testing logs or chart note documenting self-reported pregnancy; pregnancy intentions documented in item 6 of Screening Behavioral Eligibility Worksheet and Item 4 of Enrollment Behavioral Eligibility Worksheet* |  |
| ***Note:*** *A documented negative pregnancy test performed by study staff is required for inclusion; however a self-reported pregnancy is adequate for exclusion from screening/enrollment into the study.* | |
| **E6. Currently breastfeeding**  *Source: Item 7 of Screening Behavioral Eligibility Worksheet, Item 5 of Enrollment Behavioral Eligibility Worksheet* |  |
| **E7. Diagnosed with urinary tract infection (UTI), pelvic inflammatory disease (PID), STI or reproductive tract infection (RTI) requiring treatment per WHO guidelines.**  *Source: Baseline Medical History Questions, Baseline Medical History Log CRF, Pelvic Exam Diagrams, STI and RTI laboratory results, STI Test Results CRF* |  |
| ***Note:*** *Otherwise eligible participants diagnosed during screening with a UTI, PID or STI/RTI requiring treatment per WHO guidelines — other than asymptomatic BV and asymptomatic candidiasis — are offered treatment consistent with WHO recommendations and may be enrolled after completing treatment if all symptoms have resolved. If treatment is completed and symptoms have resolved within 56 days of obtaining informed consent for screening, the participant may be enrolled. Genital warts requiring treatment also must be treated prior to enrollment. Genital warts requiring therapy are defined as those that cause undue burden or discomfort to the participant, including bulky size, unacceptable appearance, or physical discomfort.* | |
| **E8. At Screening, has a clinically apparent Grade 3 pelvic exam finding (observed by study staff) per the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, Version 2.0, November 2014, Addendum 1, Female Genital Grading Table for Use in Microbicide Studies**  *Source: Pelvic Exam Diagrams, Baseline Medical History Log CRF* |  |
| ***Note****: Otherwise eligible participants with exclusionary pelvic exam findings may be enrolled after the findings have improved to a non-exclusionary severity grading or resolved. If improvement to a non-exclusionary grade or resolution is documented within 56 days of providing informed consent for screening, the participant may be enrolled.* | |
| **E9. Has any of the following laboratory abnormalities at Screening Visit per the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events Version 2.0, November 2014:**  *Source for E9a-E9e: laboratory test results reports* |  |
| 1. **Aspartate aminotransferase (AST) or alanine transaminase (ALT) Grade 3 or higher** |  |
| 1. **Creatinine Grade 3 or higher** |  |
| 1. **Hemoglobin Grade 3 or higher** |  |
| 1. **Platelet count Grade 3 or higher** |  |
| 1. **Pap result Grade 3 or higher according to the Female Genital Grading Table for Use in Microbicide Studies, Addendum 1** |  |
| ***Note:*** *Otherwise eligible participants with an exclusionary test result may be re-tested during the screening process.*  ***Note:*** *Women with a documented normal result Pap result within the 12 months prior to enrollment need not have Pap smear during the screening period. Need for a repeat Pap within 6 months does not preclude enrollment prior to that result becoming available.* | |
| **Exclusion Criteria** | ***Yes No*** |
| **E10. Has any significant medical condition or 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 the study objectives**  *Source: Chart notes or this checklist* |  |

***Note: In order for the participant to be eligible, all of the responses to items* E1- E10 *above must be “no”.***

***Complete Eligibility Criteria CRF for each participant screened for the study, regardless of enrollment.***

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

*FOR PARTICIPANTS DETERMINED TO BE ELIGIBLE TO ENROLL IN MTN-025, 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.*

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*Signature of Investigator of Record (or designee) Date*

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*Signature of second staff member verifying eligibility Date*

**The act of completing this checklist and final sign-off by designated staff is the act of enrollment into MTN-025.**