***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*** |
| I-1 | Age 18 through 40 years (inclusive) at Enrollment   * *Source: copy of identification card or other documents as specified in SOP* |  |  |
| I-2 | Evidence of a viable, intrauterine, singleton pregnancy with sonographic confirmation, including for gestational age assessment at Enrollment   * *Source: Ultrasound report; Pregnancy Assessment CRF; medical records; chart notes or other site-specific documentation as listed in SOP* |  |  |
| I-3 | Pregnancy within gestational age limits of the currently enrolling cohort at Enrollment   * *Source: Ultrasound report; Pregnancy Assessment CRF; medical records; chart notes or other site-specific documentation as listed in SOP* |  |  |
| I-4 | HIV-uninfected   * *Source: Local testing log, laboratory test results report or other sites-specific document at Screening and Enrollment* |  |  |
| I-5 | Intending to continue her pregnancy until delivery.   * *Source: Screening Behavioral Eligibility Worksheet Item 1; Enrollment Behavioral Eligibility Worksheet Item 1* |  |  |
| I-6 | Intending to deliver at a health center or hospital where adequate records may be obtained   * *Source: Screening Behavioral Eligibility Worksheet Item 2; Enrollment Behavioral Eligibility Worksheet Item 2* |  |  |
| I-7 | At Screening and Enrollment, willing to be randomized at time of enrollment to either of the two study arms, and to continue study product use until delivery.   * *Source: Screening Behavioral Eligibility Worksheet Item 3; Enrollment Behavioral Eligibility Worksheet Item 3* |  |  |
| I-8 | Able and willing to comply with all study requirements and complete all study procedures   * *Source: Screening Behavioral Eligibility Worksheet Item 4; Enrollment Behavioral Eligibility Worksheet Item 4* |  |  |
| I-9a | Able and willing to provide Informed consent for her and her infant to be screened for and to enroll in MTN-042   * *Source: Signed informed consent form for mother, and either signed infant IC (if consent obtained prior to Mother enrollment) or confirmation of intention/willingness to provide IC after birth as documented on the screening visit checklist (if consent to be obtained after Mother Enrollment) or chart notes* |  |  |
| I-9b | Able and willing to provide adequate locator information   * *Source: Site specific locator form as listed in SOP* |  |  |
| I-9c | Able and willing to provide adequate documentation of registration for antenatal care, as defined in site SOPs.   * *Source: Antenatal care records; other site-specific documentation as listed in SOP* |  |  |
| I-9d | Able and willing to provide permission to contact participant’s antenatal and postpartum care provider(s) and to obtain copies of antenatal and postpartum care records.   * *Source: Screening Behavioral Eligibility Worksheet Item 5; Enrollment Behavioral Eligibility Worksheet Item 5; other site-specific documentation (e.g. medical records release) as listed in SOP* |  |  |
| ***INCLUSION CRITERIA*** | | ***Enrollment Visit Date*** | |
|  | |
| ***Yes*** | ***No*** |
| I-10 | 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, unless approved by the PSRT.   * *Source: Screening Behavioral Eligibility Worksheet Item 6; Enrollment Behavioral Eligibility Worksheet Item 6* |  |  |
| E-1a | Per participant report, intends to use oral PrEP outside the context of study participation.   * *Source: Screening Behavioral Eligibility Worksheet Item 7; Enrollment Behavioral Eligibility Worksheet Item 7* |  |  |
| E-1b | Per participant report, intends to relocate away from the study site.   * *Source: Screening Behavioral Eligibility Worksheet Item 8; Enrollment Behavioral Eligibility Worksheet Item 8* |  |  |
| E-1c | Per participant report, intends to travel away from the study site for a time period that would interfere with study participation.   * *Source: Screening Behavioral Eligibility Worksheet Item 9; Enrollment Behavioral Eligibility Worksheet Item 9* |  |  |
| E-2 | Positive HIV test   * *Source: Local testing log, laboratory test results report or other site-specific document at Screening and Enrollment* |  |  |
| E-3 | Diagnosed with urinary tract infection (UTI), cervicitis, STI or reproductive tract infection (RTI) requiring treatment per WHO guidelines.   * *Source:* *Local testing log, laboratory test results report or other site-specific document; Baseline Medical History CRF; Pelvic Exam Diagram; chart notes* |  |  |
| E-4 | Has a clinically apparent Grade 2 or higher pelvic exam finding   * *Source: Pelvic Exam Diagrams, Baseline Medical History Log* |  |  |
| E-5a | Currently breastfeeding at Enrollment   * *Source: Screening Behavioral Eligibility Worksheet Item 10; Enrollment Behavioral Eligibility Worksheet Item 10;* |  |  |
| E-5b | Known adverse reaction to any of the study products (ever)   * *Source: Screening Behavioral Eligibility Worksheet Item 11* |  |  |
| E-5c | Known adverse reaction to latex and polyurethane (ever)   * *Source: Screening Behavioral Eligibility Worksheet Item 12* |  |  |
| E-5d | Symptoms suggestive of acute HIV infection at Screening or Enrollment   * *Source: Chart notes; Physical Exam CRF; Baseline Medical History CRF* |  |  |
| E-5e | Non-therapeutic injection drug use in the 12 months prior to Enrollment   * *Source: Screening Behavioral Eligibility Worksheet Item 13; Enrollment Behavioral Eligibility Worksheet Item 11* |  |  |
| E-5f | Use of HIV post-exposure prophylaxis (PEP) and/or PrEP during the current pregnancy   * *Source: Screening Behavioral Eligibility Worksheet Item 14; Enrollment Behavioral Eligibility Worksheet Item 12; antenatal/medical care record* |  |  |
| E-5g | Participation in any other research study involving drugs, medical devices, vaginal products, or vaccines during the current pregnancy   * *Source: Screening Behavioral Eligibility Worksheet Item 15; Enrollment Behavioral Eligibility Worksheet Item 13; antenatal/medical care record* |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| ***EXCLUSION CRITERIA*** | | ***Enrollment Visit Date*** | |
|  | |
| ***Yes*** | ***No*** |
| E-5h | Has any of the following during the current pregnancy: Multiple gestation, Placenta previa, Cervical cerclage, Abnormal fetal anatomy (in the opinion of the IoR or designee), Intrauterine growth restriction, Pre-existing or gestational diabetes, Hypertensive disorder of pregnancy, Severe malaria, Treatment for preterm labor, Abnormal quantity of amniotic fluid (oligohydramnios or polyhydramnios)   * *Source: Ultrasound report; Obstetric Abdominal Exam CRF; Physical Exam CRF; Pelvic Exam Diagram; Baseline Medical History CRF; antenatal/medical care records; records or other site-specific documentation*   *NOTE: Per LoA#1, PROM (term or preterm) and placental abnormalities (e.g., persistent placenta previa, vasa previa) are also exclusionary for the current pregnancy.* |  |  |
| E-5i | Has had any of the following in a previous pregnancy: Intrauterine growth restriction, Gestational diabetes, Hypertensive disorder of pregnancy, Intrauterine fetal demise, delivery prior to 37 0/7 weeks  *Source: Pregnancy History CRF; Baseline Medical History CRF; antenatal/medical records* |  |  |
| E-5j | At Enrollment, as determined by the IoR/designee, has any significant obstetrical complication (e.g., premature rupture of membranes, any abnormal placentation) or uncontrolled active or chronic cardiovascular, renal, liver, hematologic, neurologic, gastrointestinal, psychiatric, endocrine, respiratory, immunologic disorder or infectious disease that would make study participation unsafe   * *Source: Local testing log, laboratory test results report or other site-specific document; Physical Exam CRF; Obstetric Abdominal Exam CRF; Baseline Medical History CRF; Chart notes* |  |  |
| E-6a | Positive for hepatitis B surface antigen (HBsAg) at Screening.   * *Source: Local testing log, laboratory test results report or other site-specific document* |  |  |
| E-6b | Aspartate aminotransferase (AST) or alanine transaminase (ALT) ≥ Grade 1   * *Source:*  *Local testing log, laboratory test results report or other site-specific document* |  |  |
| E-6c | Hemoglobin ≥ Grade 2   * *Source: Local testing log, laboratory test results report or other site-specific document* |  |  |
| E-6d | Platelet count ≥ Grade 1   * *Source: Local testing log, laboratory test results report or other site-specific document* |  |  |
| E-6e | Creatinine ≥ Grade 1   * *Source: Local testing log, laboratory test results report or other site-specific document* |  |  |
| E-6f | Estimated creatinine clearance ≥ Grade 2(Cockcroft Gault formula)   * *Source: Local testing log, laboratory test results report or other site-specific document* |  |  |
| E-6g | Glycosuria ≥ Grade 2   * *Source: Local testing log, laboratory test results report or other site-specific document* |  |  |
| E-6h | Proteinuria ≥ Grade 2   * *Source: Local testing log, laboratory test results report or other site-specific document* |  |  |
| E-7 | Has any 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 and this checklist* |  |  |

**For the participant to be eligible, all responses to Inclusion Criteria (items I-1 to I-10) above must be “Yes” and responses to Exclusion Criteria (items E-1 to E-7) above must be “No.”**

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

Once a participant is deemed eligible to enroll in MTN-042, have two different staff complete signatures below to confirm and verify final determination of eligibility. Only staff delegated per site DoD may sign for Eligibility Confirmation or Eligibility Verification.

**ELIGIBILITY CONFIRMATION**

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

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

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

**ELIGIBILITY VERIFICATION**

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

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

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