***Instructions:*** *Starting at V1 Screening, use the table below to document eligibility by* ***INITIALING*** *“yes” or “no.” Items that are not applicable are blacked out. At V2 Enrollment, all criteria must be (re-)reviewed/confirmed by IoR/designee as listed on the site’s DOD Log. If any items are not conducted on the visit date recorded above, ensure the date is included with initials.*

*If determined ineligible, any items not yet completed may be left blank. If deemed eligible at V2, the checklist must be completed for all items and signed prior to randomization. At V2, complete the CONFIRMATION OF ELIGIBILITY for all participants once a participant’s eligibility status is determined.*

*→Source = the source for each criterion. When “Eligibility Checklist” is listed as the source, the participant is directly asked the criterion and their response is documented on this form and acts as the source for that criterion. [SITES: Carefully review the →source information on this form, update according to what will be source for your site, delete this note prior to finalizing]*

|  |  |  |
| --- | --- | --- |
| **INCLUSION CRITERIA** | **V1: SCREENING** | **V2: ENROLLMENT** |
| **YES** | **NO** | **YES** | **NO** |
| **I1** | **Age 18 to 45 years (inclusive) at Screening, verified per site SOP***→Source: copy of identification card, Demographic (DEM) CRF or other documents as specified in site SOP* |  |  |  |  |
| **I2** | **Assigned female sex at birth***→Source: Demographic (DEM) CRF* |  |  |  |  |
| **I3** | **Able and willing to provide written informed consent to be screened for and enrolled in MATRIX-003 in one of the study languages (as specified in site SOP)**Note: A single, combined screening and enrollment consent will be used unless otherwise determined by the IRB/IEC*→Source: Signed informed consent form(s) and Informed Consent Coversheet(s)* |  |  |  |  |
| **I4** | **Able and willing to provide adequate contact/locator information, as defined in site SOP***→Source: Site-specific locator form or other documents as specified in site SOP* |  |  |  |  |
| **I5** | **Able and willing to comply with all protocol requirements, including:***→Source: Eligibility Checklist, chart notes as applicable* |  |  |  |  |
| **I5a** | * **Abstaining from other intravaginal products or practices for the duration of the study**

Note: see protocol section 6,7; this does not include tampons or menstrual cups |  |  |  |  |
| **I5b** | * **Refraining from participation in other research studies involving drugs, medical devices, vaginal products, or vaccines starting 2 weeks before the Screening Visit and for the duration of the study, unless approved by the PSRT**

*Note: If approval from PSRT is applicable, include PSRT communication/approval in participant’s chart* |  |  |  |  |
| **I5c** | * **Reliable access to a private phone for scheduled phone contacts**
 |  |  |  |  |
| **I6** | **HIV-uninfected based on testing performed at Screening and Enrollment (per protocol algorithms in Appendix II)***→Source: Local testing log, laboratory test results report or other site-specific document at Screening and Enrollment* |  |  |  |  |
|  |  |  |  |  |  |
| **INCLUSION CRITERIA** | **V1: SCREENING** | **V2: ENROLLMENT** |
| **YES** | **NO** | **YES** | **NO** |
| **I7** | **Per participant report, must be either not currently sexually active or in a mutually monogamous relationship with only one partner who is not known to be HIV positive or to currently have a sexually transmitted infection (STI)***→Source: Eligibility Checklist, chart notes as applicable* |  |  |  |  |
| **I8** | **Negative urine pregnancy test at Screening and Enrollment***→Source: Local testing log, laboratory test results report or other site-specific document at Screening and Enrollment* |  |  |  |  |
| **I9** | **Participants over the age of 21 (inclusive) must have documentation of a Grade 0 Pap smear within the past 3 years prior to Enrollment, or a Grade 1 Pap smear at Screening with no treatment required, per the Female Genital Grading Table for Use in Microbicide Studies Addendum 1 (Dated November 2007) to the DAIDS Table for Grading Adult and Pediatric Adverse Events, Corrected Version 2.1, July 2017** [ ]  Pap smear done in past three years, report available and reviewed at Screening Visit, and verified as Grade 0  [ ]  Pap smear collected at Screening Visit [ ]  Result received and reviewed prior to Enrollment (must be Grade 0 or Grade 1 with no treatment required to be eligible)*→Source: Pap smear report* |  |  |  |  |
| **I10** | **Protected from pregnancy starting two weeks before Screening and continuing for the duration of study participation by an effective contraceptive method as confirmed by site SOP; effective methods include:*** **Hormonal methods except vaginal rings** - method: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ start/insertion date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* **Copper intrauterine device (IUD)** - insertion date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* **Sterilization of participant** **OR** [ ]  **Sterilization of monogamous partner, if applicable** - sterilization date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_
* **Correct and consistent condom use at study entry, and agrees to use site-provided condoms during the study (for US site only)** - start date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Does participant report use of condoms according to package insert? [ ]  Yes [ ]  No [must be YES to continue]Have condoms been used 100% of the time with vaginal intercourse with a male partner starting at least two weeks prior to the Screening Visit? [ ]  Yes [ ]  No [must be YES to continue]Do condoms used within the past two weeks contain spermicide? [ ]  Yes [ ]  No [ ]  Unknown → [must be NO to continue]Is participant willing to use the condoms provided by the site during study participation? [ ]  Yes [ ]  No [must be YES to continue]*Note: For participants using a hormonal method or copper IUD, document on CONCOMITANT MEDICATIONS CRF; for participants using another method, include above and any additional information in chart notes, as applicable**→Source: Eligibility Checklist*  |  |  |  |  |

|  |  |  |
| --- | --- | --- |
| **EXCLUSION CRITERIA** | **V1: SCREENING** | **V2: ENROLLMENT** |
| **YES** | **NO** | **YES** | **NO** |
| **E1** | **Per participant report at Screening and Enrollment, intends to do any of the following during the study participation period:***→Source:*  *Eligibility Checklist, chart notes as applicable* |  |  |  |  |
| **E1a** | * **Become pregnant**
 |  |  |  |  |
| **E1b** | * **Breastfeed**
 |  |  |  |  |
| **E1c** | * **Relocate away from the study site**
 |  |  |  |  |
| **E1d** | * **Travel away from the study site for a time period that would interfere with product resupply and/or study participation**
 |  |  |  |  |
| **E2** | **Positive HIV test at Screening or Enrollment***→Source: Local testing log, laboratory test results report or other site-specific document at Screening and Enrollment* |  |  |  |  |
| **E3** | **Positive test for *Trichomonas vaginalis* (TV), *Neisseria gonorrhea* (GC), *Chlamydia trachomatis* (CT), or *Treponema pallidum* (Syphilis) at Screening AND (per participant report) treated for potential STI within past 12 months**→So*urce for testing: Local testing log, laboratory test results report or other site-specific document at Screening*→So*urce for history: Eligibility Checklist, chart notes as applicable* |  |  |  |  |
| **E4** | **Diagnosed with urinary tract infection (UTI), pelvic inflammatory disease (PID), or reproductive tract infection (RTI) requiring treatment per WHO guidelines at Enrollment***Note: Otherwise eligible participants diagnosed during screening with a UTI, symptomatic yeast infection or symptomatic BV infection are offered treatment consistent with WHO recommendations. If treatment is completed and symptoms have resolved within 45 days of obtaining informed consent for screening, the participant may be enrolled.* *→Source: Laboratory test results report or other site-specific document; Updated Medical and Menstrual History CRF; Pelvic Exam CRF, Physical Exam CRF, chart notes as applicable* |  |  |  |  |
| **E5** | **Clinically apparent Grade 2 or higher pelvic exam finding per the DAIDS Table for Grading Adult and Pediatric Adverse Events, Corrected Version 2.1, July 2017 and/or Addenda 1 (Female Genital Grading Table for Use in Microbicide Studies [Dated November 2007]) at Enrollment***Note: Otherwise eligible participants with exclusionary pelvic exam findings at Screening may be enrolled/randomized if treatment is completed at least 7 days prior to enrollment and findings have improved to a non-exclusionary severity grading or resolved by the time of enrollment.* *Spotting/bleeding will be considered exclusionary only if greater than what would be expected from contraceptive use.**→Source: Pelvic Exam CRF; chart notes as applicable* |  |  |  |  |
| **E6** | **Participant report and/or clinical evidence of any of the following:***→Source: Eligibility Checklist unless otherwise specified* |  |  |  |  |
| **E6a** | * **Known adverse reaction to silicone (ever)**
 |  |  |  |  |
| **E6b** | * **Use of diaphragm, NuvaRing, or spermicide for contraception starting 2 weeks prior to Screening through Enrollment**
 |  |  |  |  |
| **E6c** | * **Use of any of the following in the past 12 months: stimulants (cocaine [including crack], methamphetamine, or non-physician prescribed pharmaceutical-grade stimulants), or inhaled nitrates, or illicit injection drug use of any kind**
 |  |  |  |  |
| **E6d** | * **Prior use of post-exposure prophylaxis (PEP) or oral pre-exposure prophylaxis (PrEP) (including FTC/TDF) in the past 4 weeks or any prior use of long-acting systemic PrEP (including cabotegravir or islatravir)**
 |  |  |  |  |
| **E6e** | * **Antibiotic, steroid, or antifungal (oral or intravaginal) therapy within 14 days of Enrollment**
 |  |  |  |  |
| **E6f** | * **Hysterectomy**
 |  |  |  |  |
| **E6g** | * **Gynecologic or genital procedure (e.g., tubal ligation, dilation and curettage, piercing, IUD insertion or removal, colposcopy) within 21 days prior to Enrollment**
 |  |  |  |  |
| **E6h** | * **At Screening or Enrollment, as determined by the Investigator of Record (IoR)/designee, has any significant uncontrolled active or chronic cardiovascular, renal, liver, hematologic, neurologic, gastrointestinal, psychiatric, endocrine, respiratory, immunologic disorder or infectious disease**

*→Source: Baseline Medical History Review Guide, PHysical Exam, Pelvic Exam, lab results, chart notes as applicable* |  |  |  |  |
| **E7** | **Has any of the following laboratory abnormalities at Screening per the DAIDS Table for Grading Adult and Pediatric Adverse Events, Corrected Version 2.1, July 2017***→Source: Laboratory test results report or other site-specific document* |  |  |  |  |
| **E7a** | * **Grade 2 or higher aspartate aminotransferase (AST)**
 |  |  |  |  |
| **E7b** | * **Grade 2 or higher alanine transaminase (ALT)**
 |  |  |  |  |
| **E7c** | * **Grade 2 or higher creatinine**
 |  |  |  |  |
| **E7d** | * **Grade 2 or higher hemoglobin**
 |  |  |  |  |
| **E8** | **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 the study objectives***→Source: Relevant study document (specify below), chart notes as applicable**Brief description if ineligible:*  |  |  |  |  |

**REVIEW OF Screening Eligibility\***

*Note: Only to be reviewed and signed after all applicable screening eligibility on pages 1-4 have been assessed/obtained****.***

□ Screen Failure → Complete PARTICIPANT DISPOSITION

□ Able to proceed with Enrollment Visit based on review of above Screening Criteria

**IoR/Designee Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_ \_\_\_ / \_\_\_ \_\_\_ / \_\_\_ \_\_\_ \_\_\_ \_\_\_**

**FINAL DETERMINATION OF ELIGIBILITY AT ENROLLMENT AND PRIOR TO RANDOMIZATION\***

*Note: For the participant to be eligible, all responses to Inclusion Criteria above must be “Yes” and responses to Exclusion Criteria above must be “No.”*

**Is participant eligible to enroll based on above Eligibility Criteria reviewed and documented on pages 1-4?** □ YES □ NO

**IoR/Designee Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_ \_\_\_ / \_\_\_ \_\_\_ / \_\_\_ \_\_\_ \_\_\_ \_\_\_ Time: \_\_\_ \_\_\_: \_\_\_ \_\_\_**

\*To be completed and signed by IoR or staff delegated the responsibility of eligibility determination per site Delegation of Duties Log.