***Instructions:*** *Starting at the screening 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. Add participant to Screening/Enrollment log and include in MSR.*

*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 to 50 years (inclusive) at Screening, verified per site SOP   * *Source: Demographic CRF, copy of identification card or other documents as specified in SOP* |  |  |
| I2 | Assigned female at birth   * *Source: Demographic CRF or per participant report* |  |  |
| I3 | Able and willing to provide written informed consent to be screened for and enrolled in MATRIX-001.   * *Source: Signed MATRIX-001 informed consent form and language assessed per site SOP* |  |  |
| I4 | General good health (by volunteer history) without any clinically significant systemic disease.   * *Source: Per participant report, Basic Medical and Menstrual History CRF and Pre-existing Medical Conditions CRF* |  |  |
| I5 | Has had vaginal sex and has an intact uterus and cervix.   * *Source: Per participant report and Behavior Assessment CRF* |  |  |
| I6 | Has a regular and/or predictable bleeding pattern based on the opinion of the investigator, or is oligomenorrheic or amenorrhoeic.   * *Source: Per participant report and Baseline Medical and Menstrual History CRF* |  |  |
| I7 | 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* |  |  |
| 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 | Protected from pregnancy by an effective contraceptive method as confirmed by site SOP; effective methods include:   * minimum of 3 months of use of a combined hormonal contraceptive method (except vaginal rings) * minimum of 6 months of use of a progestin only contraceptive method or copper IUD * Sterilization of participant or partner * Correct and consistent condom use (for US site only) * Abstinence from penile-vaginal intercourse (for US site only) * *Source: Chart notes or other site-specific document at Screening and Enrollment; Concomitant Medications Log CRF or other documents as specified in SOP* |  |  |
| I10 | Participants over the age of 21 (inclusive) must have documentation of a Grade 0 Pap smear within the past 3 years prior to Enrollment, 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, or Grade 1 or higher Pap smear at Screening with no treatment required.   * *Source: Local testing log, laboratory test results report or other site-specific document at Screening and Enrollment* |  |  |
| I11 | Normal cervicovaginal mucosa (as defined in MATRIX-001 Study Specific Procedures [SSP] manual) prior to randomization.   * *Source: Pelvic Exam CRF, chart notes at Screening and Enrollment or site-specific document of cervicovaginal exam* |  |  |
| I12 | Willing and able to comply with protocol requirements, including abstaining from vaginal activity and product use at specified times.   * *Source: Signed MATRIX-001 Informed Consent Form, chart notes or other site-specific document at Screening and Enrollment* |  |  |
| I13 | If in a relationship, must be in a mutually monogamous relationship with a partner who is not known to be HIV/STI positive.   * *Source: Per participant report, chart notes or other site-specific document at Screening and Enrollment* |  |  |
| ***EXCLUSION CRITERIA*** | | ***Yes No*** | |
| E1 | Per participant report, intends to do any of the following during the study participation period:   * Become pregnant. * Breastfeed. * Relocate away from the study site. * Travel away from the study site for a time period that would interfere with product resupply and/or study participation. * *Source:*  per participant report, *Chart notes or other site-specific document at Screening and Enrollment* |  |  |
| E2 | Currently breastfeeding.   * *Source: Chart notes or other site-specific document at Screening and Enrollment* |  |  |
| E3 | Positive HIV test at Screening or Enrollment.   * *Source: Local testing log, laboratory test results report or other site-specific document at Screening and Enrollment* |  |  |
| E4 | History of sensitivity/allergy to any component of the study product, topical anesthetic, cellulose based thrombogenic material, or to both silver nitrate and Monsel’s solution.   * *Source: Local testing log or other site-specific document; Baseline Medical and Menstrual History CRF; Concomitant Medication CRF; chart notes or other site-specific document at Screening and Enrollment* |  |  |
| E5 | Positive test for *Trichomonas vaginalis* (TV), *Neisseria gonorrhea* (GC), *Chlamydia trachomatis* (CT), *Treponema pallidum* (Syphilis), or Hepatitis B surface antigen (HBsAg) at Screening or (per participant report) treated for GC, CT, TV, HBsAg or syphilis in the past 12 months.   * So*urce: local lab testing; Lab Results CRF; chart notes or other site-specific document at Screening and Enrollment* |  |  |
| E6 | Chronic or acute vulvar, vaginal or cervical symptoms (pain, irritation, spotting/bleeding other than what would be expected from contraceptive use, discharge, etc.).   * *Source: Local testing log or other site-specific document; Baseline Medical and Menstrual History CRF; Concomitant Medication CRF; chart notes at Screening and Enrollment* |  |  |
| E7 | Known bleeding/clotting disorder, including use of anti-coagulation.   * *Source: Local testing log or other site-specific document; Baseline Medical and Menstrual History CRF; Concomitant Medication CRF; chart notes at Screening and Enrollment* |  |  |
| E8 | Need for continued use of any contraindicated concomitant medications (as listed in Appendix III).     * *Baseline Medical and Menstrual History CRF; Concomitant Medication CRF; chart notes at Screening and Enrollment* |  |  |
| E9 | Participation in any other trial with use of an investigational drug/device within the last 30 days or planned participation in any other investigational trial with use of a drug/device during the study.   * *Source: Baseline Medical and Menstrual History CRF; Concomitant Medication CRF; chart notes at Screening and Enrollment* |  |  |
| E10 | Participants who previously received an HIV vaccine or HIV broadly neutralizing antibody (bNAb) are not eligible. Individuals may be eligible if they participated in an HIV vaccine or bNAb study but have documentation that they did not receive active product (e.g., placebo recipients).   * *Source: Local testing log or other site-specific document; Baseline Medical and Menstrual History CRF; Concomitant Medication CRF; chart notes at Screening and Enrollment* |  |  |
| E11 | Prior use of PEP or oral PrEP (including FTC/TDF) in the past 4 weeks or any prior use of long-acting systemic PrEP (including cabotegravir or islatravir).   * *Source: Local testing log or other site-specific document; Baseline Medical and Menstrual History CRF; Concomitant Medication CRF; chart notes at Screening and Enrollment* |  |  |
| E12 | Grade 2 or higher pelvic finding or laboratory abnormality, per the DAIDS Table for Grading Adult and Pediatric Adverse Events, Corrected Version 2.1, July 2017 and/or Addenda 1 (Female Genital Grading Tables for Use in Microbicide Studies [Dated November 2007] or clinically significant laboratory abnormality as determined by the clinician.   * *Source: Laboratory test results report or other site-specific document; Pelvic Exam CRF, Vital Signs and Physical Exam CRF, Lab Results CRF; chart notes* |  |  |
| E13 | 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.   * *Source: Local testing log or other site-specific document; Baseline Medical and Menstrual History CRF; Concomitant Medication CRF; chart notes at Screening and Enrollment* |  |  |
| E14 | Has any other condition that, based on the opinion of the Investigator of Record or designee, would preclude provision of informed consent, make participation in the study unsafe, complicate interpretation of study outcome data, or otherwise interfere with achieving the study objectives.   * *Source: Basic Medical and Menstrual History CRF, Vital Signs and Physical Exam CRF; Chart notes, Eligibility Checklist and CRF* |  |  |

Add comment section

**For the participant to be eligible, all responses to Inclusion Criteria (items I1-13) above must be “Yes” and responses to Exclusion Criteria (items E1-14) above must be “No.”**

**Is the participant ELIGIBLE for participant in this Study?  *Yes***  ***No → SCREEN FAIL: IoR (or designee) Signature:***

***\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_***

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

**Final Sign-off of Participant Eligibility to Enroll:  *N/A***

Once a participant is deemed eligible to enroll in MATRIX-001, complete signatures below to confirm and verify final determination of eligibility. Only staff delegated the responsibility of eligibility determination per site Delegation of Duties Log may sign for eligibility confirmation and verification.

**ELIGBILITY VERIFICATION**

**Staff Signature:**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

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

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

**ELIGBILITY CONFIRMATION**

**IoR (or designee) Signature:**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

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

**e: \_\_\_ \_\_\_: \_\_\_ \_\_\_**