**MATRIX-001 Screening and Enrollment Log**

**Protocol Version and Date**:\_\_\_\_\_\_\_\_, dated \_\_\_\_\_\_\_\_\_\_\_\_

*If you are creating a new entry, complete the first three columns and initial and date the fourth column. When enrollment or screen fail status is determined, complete the remaining columns and initial and date the last column. Include all codes for screen failure/discontinuation that apply.*

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| --- | --- | --- | --- | --- | --- | --- | --- |
| **Screening Date** | **Screening Attempt** | **PTID** | **Staff Initials/Date** | **Enrollment Date  (or N/A if not enrolled)** | **Screen Failure Date (or N/A if enrolled)** | **Screen Failure/ Discontinuation Codes (or N/A if enrolled)** | **Staff Initials/Date** |
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*\*Per protocol, only one re-screening attempt is permitted*

*^Re-screens use the same PTID*

**Screening Failure/Discontinuation Codes [*per inclusion/exclusion criteria in protocol Sections 5.2 and 5.3*]**

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **I-1** | **Not 18-50 years old** | **I-8** | **Positive pregnancy test** | **E-2** | **Currently breastfeeding** | **E-9** | **Participation in drug/device trial within last 30 days or during study** | **N-16** | **Other – No enrollment visit within 8wk window** |
| **I-2** | **Not assigned female at birth** | **I-9** | **No effective contraception** | **E-3** | **Positive HIV test** | **E-10** | **Previously received HIV vaccine/bNAb** |  |  |
| **I-3** | **Unable to provide written informed consent** | **I-10** | **No documentation of satisfactory PAP within 3 year or at screening** | **E-4** | **History of allergy to study product/topical anesthetic/cellulose based material/silver nitrate/Monsel’s solution** | **E-11** | **Use of PEP/oral PrEP in past 4 weeks/any use of long-acting systemic PrEP** |  |  |
| **I-4** | **Not in general good health** | **I-11** | **Abnormal cervicovaginal mucosa** | **E-5** | **History or current STI in past 12 months** | **E-12** | **Grade 2 or higher pelvic/lab result** |  |  |
| **I-5** | **Not had vaginal sex and no intact uterus/cervix** | **I-12** | **Unwilling/unable to comply with protocol requirements** | **E-6** | **Chronic/acute vulvar, vaginal or cervical symptoms** | **E-13** | **Use of stimulants/inhaled nitrates/illicit drug injection in past 12 months** |  |  |
| **I-6** | **Irregular/unpredictable bleeding pattern** | **I-13** | **Not in mutually monogamous relationship/partner HIV/STI positive** | **E-7** | **Known bleeding/clotting disorder/using anti-coagulants** | **E-14** | **Any other condition deemed by IoR/designee causing participation to be unsafe, complicate results or interfere with study objectives** |  |  |
| **I-7** | **HIV infected** | **E-1** | **Planning to become pregnant, breastfeed, relocate or travel away from study site during participation** | **E-8** | **Need for continued use of contraindicated medications** | **N-15** | **Other – Declines enrollment** |  |  |