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| --- | --- | --- | --- | --- | --- | --- | --- |
| **ScreeningDate** | **Screening Attempt\*** | **PTID^** | **Staff Initials/Date** | **Enrollment Date (or N/A if not enrolled)** | **Screen Failure Date(or N/A if enrolled)** | **Screening Failure Codes** **(or N/A if enrolled)** | **Staff Initials/Date** |
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| **\*Per protocol, only one re-screening attempt is permitted****^Assign new PTID with each screen attempt** |
| **I-1** | **Not 18 -45 y/o at Screening** | **I-6** | **HIV +** | **E-1c** | **Intends to relocate from study site** | **E-6b** | **Use of diaphragm, NuvaRing, or spermicide in two weeks prior to screening** | **E-7a** | **Grade 2 or higher AST** |
| **I-2** | **Not assigned female sex at birth** | **I-7** | **Not in monogamous relationship/partner with HIV or STI** | **E-1d** | **Intends to travel during study period and would interfere**  | **E-6c** | **Use of non-therapeutic drugs in past 12 months as defined in the protocol**  | **E-7b** | **Grade 2 or higher ALT** |
| **I-3** | **Did not provide consent** | **I-8** | **Positive pregnancy test at Screening or Enrollment** | **E-2** | **HIV +** | **E-6d** | **Prior use of PEP or PrEP in past 4 weeks; any use of long-acting systemic PrEP ever** | **E-7c** | **Grade 2 or higher creatinine** |
| **I-4** | **Inadequate locator info** | **I-9** | **Abnormal Pap** | **E-3** | **STI at screening and in the past 12 months** | **E-6e** | **Antibiotic, steroid or antifungal (oral or intravaginal) within 14 days of enrollment** | **E-7d** | **Grade 2 or higher hemoglobin** |
| **I-5a** | **Unable/not willing to abstain from vaginal products or practices (see protocol section 6.7)** | **I-10** | **Not protected from pregnancy/not on an effective contraception** | **E-4** | **UTI, PID or RTI at enrollment**  | **E-6f** | **Hysterectomy** | **E-8** | **Other condition per IoR** |
| **I-5b** | **Unable/not willing to refrain from participation in other studies** | **E-1a** | **Intends to become pregnant** | **E-5** | **Grade 2 or higher pelvic exam finding at enrollment** | **E-6g** | **Gynecologic or genital procedure within 21 days of Enrollment** | **N-1** | **Other – Declines enrollment** |
| **I-5c** | **Does not have reliable access to a private phone** |
| **I-5e** | **Unable/not willing to respond to phone/SMS contacts** | **E-1b** | **Intends to breastfeed** | **E-6a** | **Known adverse reaction to silicone** | **E-6h** | **Significant uncontrolled active or chronic issue at screening or enrollment as determined by IoR/Designee** | **N-2** | **Other – Not enrolled visit within 45-day window** |