|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Screening Date** | | **Screening Attempt** | | **PTID** | | **Staff Initials/Date** | | **Enrollment Date  (or N/A if not enrolled)** | | **Screen Failure Date (or N/A if enrolled)** | | **Screening Failure/ Discontinuation Codes**  **(or N/A if enrolled)** | | | **Staff Initials/Date** |
|  | |  | |  | |  | |  | |  | |  | | |  |
|  | |  | |  | |  | |  | |  | |  | | |  |
|  | |  | |  | |  | |  | |  | |  | | |  |
|  | |  | |  | |  | |  | |  | |  | | |  |
|  | |  | |  | |  | |  | |  | |  | | |  |
|  | |  | |  | |  | |  | |  | |  | | |  |
|  | |  | |  | |  | |  | |  | |  | | |  |
|  | |  | |  | |  | |  | |  | |  | | |  |
| **Screening Failure/Discontinuation Codes** | | | | | | | | | | | | | | | |
| **I-1** | **Not 18 yrs or older** | | **I-8** | | **No history of RAI once in lifetime** | | **E-1c** | **AST/ALT Grade 1 or higher** | **E-4** | | **Use of PrEP w/n 3 months/unwilling to not use in study** | | **E-10b** | **Symptoms/diagnosis of active pharyngeal anorectal infection or RTI** | |
| **I-2** | **No informed consent** | | **I-9** | | **Unwilling to refrain from other studies** | | **E-1d** | **Serum creatinine>1.3 X site ULN** | **E-5** | | **Use of PEP w/n 6 months** | | **E-10c** | **Current symptomatic UTI** | |
| **I-3** | **HIV 1/2 infected** | | **I-10** | | **Not able/willing to comply w/abstinence/protocol requirements** | | **E-1e** | **INR>1.5 X site ULN** | **E-6** | | **Condomless RAI/penile-vaginal sex with partner who is HIV-positive or of unknown status w/n 6 months** | | **E-11** | **Pregnant/Breastfeeding** | |
| **I-4** | **Inadequate locator** | | **I-11** | | **Positive pregnancy test** | | **E-1f** | **History of inflammatory bowel disease** | **E-7** | | **History of transactional sex w/n 12 months** | | **E-12** | **Pregnancy outcome w/n 90 days** | |
| **I-5** | **Unable to speak/write English** | | **I-12** | | **No effective contraception** | | **E-1g** | **Positive HBsAg** | **E-8** | | **Non-therapeutic, non-injection stimulant**  **drugs w/n 12 months** | | **E-13** | **Any other condition (IoR/designee)** | |
| **I-6** | **Not able/willing to comply w/ visit/procedural requirements** | | **E-1a** | | **Hemoglobin Grade 1 or higher** | | **E-2** | **Unwilling to refrain from anticoagulant/rectally-administered meds/N-9** | **E-9** | | **Participation in drug/device/genital or rectal product/vaccine trial w/n 30 days** | | **N-14** | **Other – Declines enrollment** | |
| **I-7** | **Not in general good health** | | **E-1b** | | **Platelet count Grade 1 or higher** | | **E-3** | **Known study product adverse reaction** | **E-10a** | | **Diagnosed with anogenital STI in past 3 months** | | **N-15** | **Other – No enrollment visit within 45-day window** | |