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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)** | | | **Screening Failure/ Discontinuation Codes**  **(or N/A if enrolled)** | | | **Staff Initials/Date** |
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| **Screening Failure/Discontinuation Codes** | | | | | | | | | | | | | | | |
| **I1** | Not 18 yrs old or older | | **I19** | Not willing to follow abstinent requirements | | **E1f** | INR >1.5 x site ULN | | | **E8** | IDU w/in 12 months | | **E13** | Any other condition (IoR/designee) | |
| **I2** | No informed consent | | **I10** | Positive pregnancy test | | **E1g** | History of inflammatory bowel disease | | | **E9** | Participation in drug/device/genital or rectal product/vaccine trial w/in 30 days | | **O1** | Other – Declines enrollment | |
| **I3** | HIV infected/unwilling to receive HIV test results | | **I11** | No effective contraceptive | | **E2** | Known latex/polyurethane adverse reaction | | | **E10** | Gyno/genital/rectal procedure w/in 60 days prior or rectal biopsy w/in 7 days | | **O2** | Other – No enrollment visit within 45-day window | |
| **I4** | Inadequate locator | | **E1a** | Hemoglobin Grade 1 or higher | | **E3** | Unwilling to refrain from anticoagulant/ rectally-administered meds | | | **E11a** | Diagnosed with STI in past 3 months | | **O3** | Other: [Explain] | |
| **I5** | Not willing to comply with study | | **E1b** | Platelet count Grade 1 or higher | | **E4** | Known study product adverse reaction | | | **E11b** | Symptoms/ diagnosis of active pharyngeal anorectal infection or RTI | |
| **I6** | Not in general good health (IoR/designee) | | **E1c** | WBC Grade 2 or higher | | **E5** | Use of PrEP w/in 1 month /unwilling to not use in study | | | **E11c** | Current symptomatic UTI | |  |  | |
| **I7** | No history of consensual RAI in lifetime | | **E1d** | AST/ALT Grade 1 or higher | | **E6** | Use of PEP w/in 3 months | | | **E12a** | Pregnant/ Breastfeeding | |  |  | |
| **I8** | Not willing to refrain from other studies | | **E1e** | Creatinine >1.3x site ULN | | **E7** | Condomless RAI/penile-vaginal with partner of HIV-positive or unknown status w/in 6 months | | | **E12b** | Pregnancy outcome w/in 90 days | |  |  | |