|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Mother - Screening Failure/Discontinuation Codes** | | | | | | | |
| **M-I-1** | Not 18 yrs old or older | **M-I-8** | HIV infected (per 2 positive rapids or confirmation test) | **M-E-2f** | Exposed to study drug(s) during pregnancy | **M-E-7** | Diagnosed with UTI/PID/RTI/STI |
| **M-I-2** | Not between 6-12 weeks postpartum | **M-I-9** | Not willing to be randomized and use assigned product | **M-E-3** | HIV-positive test (at least 1 positive rapid) | **M-E-8** | Significant uncontrolled active or chronic disease (IoR/designee) |
| **M-I-3** | Not currently/planning to continue exclusive breastfeeding | **M-E-1** | Infant ineligible | **M-E-4** | Breast or genitourinary finding grade 2 or higher | **M-E-9** | Any other condition (IoR/designee) |
| **M-I-4** | Not using/intending to continue effective contraception | **M-E-2a** | Known study product adverse reaction | **M-E-5** | Positive pregnancy test | **M-E-10a** | Participated in drug/device/vaccine trial in past 30 days |
| **M-I-5** | Not willing to comply with study | **M-E-2b** | Known latex/polyurethane adverse reaction | **M-E-6a** | Positive HBsAG | **M-E-10b** | Participating in drug/device/vaccine trial currently |
| **M-I-6a** | No informed consent for self | **M-E-2c** | PEP use in past 6 months | **M-E-6b** | AST/ALT grade 2 or higher | **M-E-10c** | Planning to participate in drug/device/vaccine trial |
| **M-I-6b** | No informed consent for infant | **M-E-2d** | Vaginal meds/product use in previous 5 days | **M-E-6c** | Creatinine grade 1 or higher |  |  |
| **M-I-7** | Not willing to stay in area/inadequate locator info | **M-E-2e** | Injection drug use in past 12 months | **M-E-6d** | Creatinine clearance grade 2 or higher |  |  |
| **Infant – Not Enrolled Codes** | | | | | | | |
| **B-I-1** | Not exclusively breastfed | **B-I-3** | Not between 6-12 weeks old | **B-E-2a** | Birth Weight < 2000g | **B-E-2c** | Participating in drug/device/vaccine trial currently |
| **B-I-2** | Not in good health (IoR/designee) | **B-E-1** | Any other condition (IoR/designee) | **B-E-2b** | Participated in drug/device/vaccine trial in past 30 days | **B-E-2d** | Expected to participate in drug/device/ /vaccine trial |
| **Mother/Infant – Other Not Enrolled Codes** | | | | | | | |
| **N-1** | Eligible/Not Enrolled (specify reason in screen fail code column) | **N-2** | Incomplete Screening | N-3 | Other (specify reason in screen fail code column) |  | |

**\* Only 1 re-screen permitted per participant**

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| --- | --- | --- | --- | --- | --- | --- | --- |
| **Screening Date** | **Screening Attempt\*** | **PTID** | **Staff I&D** | **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 I&D** |
|  |  | Mother |  |  |  | Mother |  |
| Infant |  | Infant |  |
|  |  | Mother |  |  |  | Mother |  |
| Infant |  | Infant |  |
|  |  | Mother |  |  |  | Mother |  |
| Infant |  | Infant |  |
|  |  | Mother |  |  |  | Mother |  |
| Infant |  | Infant |  |
|  |  | Mother |  |  |  | Mother |  |
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| Infant |  | Infant |  |
|  |  | Mother |  |  |  | Mother |  |
| Infant |  | Infant |  |