Participant Disposition

01	Date of study exit:	__ __ / __ __ / __ __ __ __ (dd/mm/yyyy)
02	Primary reason for completion/discontinuation:	☐ Scheduled exit visit/end of study *(answer 02a)* ☐ Participant did not meet all eligibility criteria *(answer if Screen failure below & 02b)* ↳ ☐ *Yes, PTID is a Screen failure* ⓘ *Response required in REDCap. If this is not accurate, revise the primary reason for study discontinuation.* ☐ Participant did not enroll within 45 days of screening *(answer if Screen failure below & 02c)* ↳ ☐ *Yes, PTID is a Screen failure* ⓘ *Response required in REDCap. If this is not accurate, revise the primary reason for study discontinuation.* ☐ Participant refused further participation/Participant is unwilling or unable to comply with required study procedures *(answer 02a)* ☐ Participant refused further study product use *(answer 02a)* ☐ Lost to follow-up *(answer 02a)* ☐ Investigator decision *(answer 02a)* ☐ Early study closure *(answer 02a)* ☐ Study terminated by sponsor *(answer 02a)* ☐ Protocol deviation *(answer 02a)* ☐ AE/SAE *(answer 02d)* ☐ Product Hold/Discontinuation (reason documented on that form) *(answer 02a)* ☐ Other *(answer 02e)*

ⓘ *02a. Complete if primary reason for completion/discontinuation is marked for any value EXCEPT "Participant did not meet all eligibility criteria" or "Participant did not enroll within 45 days of screening" or "AE/SAE" or "Other":*

Is this participant evaluable? ⓘ *Per protocol, "evaluable" is defined as having completed V6.*	☐ Yes ☐ No

ⓘ *02b. Complete if primary reason for completion/discontinuation is "Participant did not meet all eligibility criteria":*

Which eligibility criteria prevented the participant from enrolling? ⓘ *Mark all that apply.*	☐ Inclusion criteria *(answer 02b-1)* ☐ Exclusion criteria *(answer 02b-2)*

ⓘ *02b-1. Complete if the eligibility criteria that prevented the participant from enrolling was "Inclusion criteria":*

Mark the primary reason the participant did not meet the inclusion criteria:

ⓘ *Based on Protocol v1.0 dated 24MAY2023..*

☐ Not aged 18-45 y/o
☐ Not assigned female sex at birth
☐ Did not provide consent
☐ Inadequate locator information
☐ Not able/willing to comply with protocol requirement: sex and vaginal product restrictions in month 1
☐ Not able/willing to refrain from participation in other research studies for the duration of the study
☐ Not able/wiling to respond to scheduled phone/short message service contacts, or attend all clinic follow-up visits.
☐ Not HIV-uninfected
☐ Not in monogamous relationship, or has a partner with HIV or STI
☐ Positive urine pregnancy test
☐ Could not provide documentation of a Grade 0 Pap smear within the past 3 years (if over age 21), or required treatment for pap smear at screening
☐ Not protected from pregnancy, or not on an effective contraceptive method

If there is a secondary reason the participant did not meet inclusion criteria, specify:	_____

Participant Disposition (continued)

02b-2. Complete if the eligibility criteria that prevented the participant from enrolling was "Exclusion criteria":

Mark the primary reason the participant did not meet the exclusion criteria:

Based on Protocol v1.0 dated 24MAY2023.

- ☐ Participant intends to become pregnant
- ☐ Participant intends to breastfeed
- ☐ Participant intends to relocate from study site
- ☐ Participant intends to travel during study period and would interfere with participation
- ☐ HIV + at screen or enrollment
- ☐ STI at screening or past 12 months
- ☐ UTI, PID, or RTI at enrollment
- ☐ Grade 2 or higher pelvic exam finding at enrollment
- ☐ Spotting/bleeding greater than what is expected from contraceptive use
- ☐ Known study product adverse reaction
- ☐ Hysterectomy
- ☐ Pelvic surgical procedures within 30 days of enrollment
- ☐ Use of diaphragm, NuvaRing, or spermicide in two weeks prior to screening
- ☐ Antibiotic or antifungal (oral or intravaginal) therapy within 7 days of Enrollment
- ☐ Prior use of PEP or PrEP in the 4 weeks, or any prior use of long-acting systemic PrEP ever
- ☐ Use of non-therapuetic drugs in past 12 months as defined in the protocol
- ☐ Significant uncontrolled active or chronic issue at screening or enrollment as determined by IoR/Desginee
- ☐ Grade 2 or higher AST
- ☐ Grade 2 or higher ALT
- ☐ Grade 2 or higher Creatinine
- ☐ Grade 2 or higher hemoglobin
- ☐ Any other condition per IoR precluding informed consent or safe study participation

If there is a secondary reason the participant did not meet exclusion criteria, specify:	_____

02d. Complete if primary reason for completion/discontinuation is "AE/SAE":

If "AE/SAE" indicate applicable adverse event term/description:	_____
Is this participant evaluable? *Per protocol, "evaluable" is defined as having completed V6.*	☐ Yes ☐ No

02e. Complete if primary reason for completion/discontinuation is "Other":

If "Other" specify:	_____
Is this participant evaluable? *Per protocol, "evaluable" is defined as having completed V6.*	☐ Yes ☐ No

03	Document additional relevant details:

CRF Completed By: _____ (initials)

CRF Completion Date: __ __ / __ __ / __ __ __ __ (dd/mm/yyyy)