Instructions: Use the table below to document a participant's eligibility status for MTN-011 study participation. Initial and date below each set of "yes/no" checkboxes upon assessment of each eligibility criterion. Once ineligibility status is determined, the form may be stopped and the remaining questions may be left blank.

Inclusion Criteria	**Screening Visit**		**Enrollment Visit**	
	Yes	***No***	***Yes***	***No***
1. *a.* Able and willing to provide written informed consent to be screened for and take part in the study	☐ _____	☐	*not required*	
b. Able and willing to provide adequate locator information, as defined by the site SOPs.	*review and proceed accordingly*		☐ _____	☐
2. *a.* Per participant report, no STIs in the 6 months prior to Screening	☐ _____	☐	*not required*	
b. Per participant report, no non-therapeutic intravenous drug use in the 18 months prior to Screening	☐ _____	☐	*not required*	
c. Per participant report, in a mutually monogamous relationship with a partner of the opposite sex for 6 months prior to Screening and the intent to stay in this relationship for the next 4 months.	☐ _____	☐	*not required*	
3. At Screening and Enrollment, both partners independently report not using barrier contraception and/or barrier protection as part of the normal coitus routine and report the intent to continue said sexual practice for the duration of study participation.	☐ _____	☐	☐ _____	☐
4. HIV-uninfected, based on testing performed by study staff at Screening (per algorithm in protocol appendix III)	☐ _____	☐	*not required*	
5. Agrees not to participate in other research studies involving drugs, medical devices, genital or rectal products, or large blood draw studies during study participation.	☐ _____	☐	☐ _____	☐

Note: In order for the participant to be <u>eligible,</u> all of the responses to items* 1-5 *above <u>must be "yes"</u>.

Inclusion Criteria cont'd	**Screening Visit**		**Enrollment Visit**	
	Yes	***No***	***Yes***	***No***
6. *a.* Age 21 or older at Screening, verified by site SOPs	☐	☐	*not required*	
b. Agree to abstain from intercourse (oral, anal, or penile-vaginal) and other penile practices (e.g. masturbation, application of lubricants/spermicides or other related practices) 72 hours prior to each follow-up visit. Group 2 participants must also agree to refrain from intercourse (oral, anal, or penile-vaginal) throughout their partner's at-home gel use period	☐	☐	☐	☐

Note: In order for the participant to be <u>eligible,</u> all of the responses to items* 6 *above <u>must be "yes"</u>.

Exclusion Criteria	**Screening Visit**		**Enrollment Visit**	
	Yes	***No***	***Yes***	***No***
Participant report of any of the following: **1.** Known allergy to study product (ever)	☐	☐	*not required*	
b. Post-exposure prophylaxis (PEP) for HIV exposure within 6 months prior to Screening	☐	☐	*not required*	
c. Participation in any other research study involving drugs, medical devices, or genital products 30 days or less prior to Enrollment	*review and proceed accordingly*		☐	☐
d. Plans to relocate away from the study site in the next 4 months.	☐	☐	*not required*	
e. History of domestic violence with current partner (ever)	☐	☐	*not required*	
f. Systemic or topical antimicrobials within the last 7 days prior to Enrollment	*review and proceed accordingly*		☐	☐
g. Currently using or planning to use pharmacologic immune modulator(s)	☐	☐	☐	☐
2. At Screening or Enrollment, symptomatic urinary tract infection (UTI)	☐	☐	☐	☐
Note: *Otherwise eligible participants diagnosed with UTI during screening are offered treatment and may be enrolled after completing treatment and all symptoms have resolved as long as treatment is completed and all symptoms have resolved with 30 days of obtaining informed consent for Screening/Enrollment.*				
3. At Screening, has a positive hepatitis B surface antigen (HbsAg) test result	☐	☐	*Not required*	

Note: In order for the participant to be <u>eligible,</u> all of the responses to items* 1a-3 *above <u>must be "no"</u>.

Exclusion Criteria cont'd	**Screening Visit**		**Enrollment Visit**	
	Yes	***No***	***Yes***	***No***
4. At Screening and Enrollment, has an STI or reproductive tract infection (RTI) requiring treatment per current CDC guidelines	☐	☐	☐	☐
5. Genital signs and/or symptoms of Grade 2 or higher	☐	☐	☐	☐
Note: *Otherwise eligible participants with exclusionary genital findings may be enrolled after the findings have improved to a non-exclusionary severity grading or resolved as long as treatment is completed and all symptoms have resolved within 30 days of obtaining informed consent for Screening/Enrollment.*				
6. Has any other condition that, in the opinion of the IoR/designee, would preclude informed consent, make study participation unsafe, complicate interpretation of study outcome data, or otherwise interfere with achieving study objectives	☐	☐	☐	☐
7. *a*. Participant report of penile procedures (e.g. biopsy, circumcision) with 42 days prior to Enrollment	*review and proceed accordingly*		☐	☐
b. For uncircumcised men, per participant report, treatment of candidal balanoposthitis/balanitis within 30 days to Enrollment	*review and proceed accordingly*		☐	☐

Note: In order for the participant to be <u>eligible,</u> all of the responses to items* 4-7b *above <u>must be "no"</u>.

At enrollment visit, participant is found to meet all eligibility criteria:

_____ _____ _____ _____

Signature of staff member *Date* *Signature of Investigator of Record (or designee)* *Date*