MTN-030/IPM 041 Eligibility Checklist **PTID:** _____

Instructions: *Use the table below to document a participant's eligibility status for participation in the study. Please mark "yes" or "no" and initial and date (as needed) upon assessment of each eligibility criterion. If the same person assesses multiple criteria, brackets can be used. Once ineligibility status is determined, the form may be stopped and the remaining questions may be left blank; chart note why items of the checklist were left blank. Complete the Eligibility Criteria CRF and Inclusion Criteria CRF and/or Exclusion Criteria CRF (if applicable) for all screened participants once the participant's eligibility/enrollment status is determined. The study eligibility criteria are abbreviated in this checklist; refer to protocol Sections 5.2 and 5.3 for a complete description of the criteria.*

ELIGIBILITY CRITERIA		*Enrollment Date* __ __/__ __ __/__ __		
INCLUSION CRITERIA		*Yes*	*No*	*Staff Initials (Date, if different from above)*
1	Age 18 – 45 years (inclusive)			
2	Able and willing to provide written informed consent			
3	Able and willing to provide adequate locator information			
4	Able to communicate in spoken and written English			
5	Available for all study visits and able and willing to comply with study procedural requirements including SMS requirements			
6	Willing to abstain from receptive intercourse (vaginal, oral and finger stimulation) for 24 hours preceding the Enrollment visit and for the duration of study participation			
7	Using an effective, non-hormonal method of contraception and intending to continue the use of an effective, non-hormonal method for the duration of study participation			
8	In general good health as determined by IoR/designee			
9	HIV uninfected			
10	Has regular menstrual cycles of approximately 21 to 35 days' duration			
11	Has an intact uterus with at least one ovary			
12	Willing to refrain from inserting any non-study vaginal products or objects into the vagina for 24 hours prior to enrollment and for the duration of study participation			
13	If over the age of 21 (inclusive), has documentation of a satisfactory Pap within the past 3 years prior to Enrollment consistent with Grade 0 or satisfactory evaluation with no treatment required of Grade 1 or higher Pap result			
14	Willing not to participate in other research studies involving drugs, medical devices, vaginal products or vaccines after Screening and for the duration of study participation			
EXCLUSION CRITERIA		*Yes*	*No*	*Staff Initials/Date (if different from above)*
15	Has a Body Mass Index (BMI) greater than 35 kg/m^2 at Screening			
16	Is pregnant or has plans to become pregnant			
17	Diagnosed with a urinary tract infection (UTI) or reproductive tract infection (RTI)*			
18	Diagnosed with an acute sexually transmitted infection requiring treatment such as gonorrhea, chlamydia, trichomonas, pelvic inflammatory disease, and/or syphilis			

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ELIGIBILITY CRITERIA			*Enrollment Date* __ __/__ __ __/__ __		
EXCLUSION CRITERIA			*Yes*	*No*	*Staff Initials/Date (if different from above)*
19	Has a clinically apparent Grade 2 or higher pelvic examination finding**				
20	Has a known adverse reaction to any of the study products (ever)				
21	Reported chronic and/or recurrent vaginal candidiasis				
22	Has a contraindication to progestin-only contraceptive method as defined by a category 3 or 4 CDC U.S. Medical Eligibility Criteria for Contraceptive Use, 2016 condition				
23	Reported use of hormonal contraception, including hormonal IUD within the 28 days prior to Enrollment				
24	Reported current use or planned use of CYP3A inhibitors and inducers				
25	Reported current use or planned use of antibiotics and/or corticosteroids that interact with levonorgestrel				
26	Reported use of depot medroxyprogesterone acetate (DMPA) use in the 6 months prior to Enrollment				
27	Reported non-therapeutic injection drug use in the 12 months prior to Enrollment				
28	Reported use of PEP for potential HIV exposure within 6 months prior to Enrollment				
29	Reported use of PrEP for HIV prevention within 6 months prior to Enrollment				
30	Reported last pregnancy outcome within 90 days prior to enrollment				
31	Had gynecologic or genital procedure (e.g., tubal ligation, dilation and curettage, piercing) 60 days or less prior to Enrollment				
32	Currently breastfeeding or planning to breastfeed during the course of the study				
33	Participation in research studies involving drugs, medical devices, genital products, or vaccines within 60 days prior to Enrollment				
34	Hemoglobin Grade 1 or higher***	Per the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events Version 2.0. [November 2014]			
35	AST or ALT Grade 1 or higher***				
36	Serum creatinine Grade 1 or higher***				
37	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				

**Otherwise eligible participants diagnosed with UTI/RTI during screening will be offered treatment. If treatment is completed and symptoms have resolved within the 60-day screening window, otherwise eligible participants may be enrolled.*

***Otherwise eligible participants with exclusionary pelvic examination findings may be enrolled/randomized after the findings have improved to a non-exclusionary severity grading or resolved within 60 days of providing informed consent for screening.*

****Otherwise eligible participants with an exclusionary laboratory result may be retested and may be enrolled/randomized after the findings have improved to a non-exclusionary severity grading or resolved within 60 days of providing informed consent for screening. Results of safety laboratory testing performed at the Enrollment Visit are expected to be received after the Enrollment Visit, and thus will not be exclusionary.*

In order for the participant to be eligible, all of the responses to items 1-14 above must be "Yes" and responses to items 15-37 above must be "No".

Once a participant is deemed eligible to enroll in MTN-030/IPM 041, the IoR (or designee) and a second staff member should complete signatures below to confirm and verify final determination of eligibility. Only staff delegated the responsibility of primary eligibility determination per site delegation of duties (DOA)/staff roster should complete the applicable signature lines.

Eligible for enrollment? ☐ **Yes** ☐ **No**

Staff Signature: _____

Date: ___ ___ / ___ ___ ___/ ___ ___

Time: ___ ___: ___ ___

Eligible for enrollment? ☐ **Yes** ☐ **No**

IoR (or designee) Signature: _____

Date: ___ ___ / ___ ___ ___/ ___ ___

Time: ___ ___: ___ ___