MTN-013/IPM 026 Eligibility Checklist

PTID: _____

Instructions: Use the table below to document a participant's eligibility for MTN-013/IPM 026 study participation. By writing your initials and date, you are documenting that the participant is eligible with regard to the inclusion/exclusion criterion listed on that row. Note that you may need to reference other source documents (i.e. Screening Behavioral Eligibility (non-DataFax) form, Enrollment Behavioral Eligibility (non-DataFax) form, Medical History Log, laboratory results, etc.) in order to assess the item.

Inclusion Criteria	**Screening Visit Staff Init/Date**	**Enrollment Visit Staff Init/Date**
Age 18 through 40 years (inclusive) at screening, verified per site SOPs		
Able and willing to provide written informed consent to be screened for and take part in the study		
Able and willing to provide adequate locator information, as defined by the site SOPs		
HIV-uninfected, based on testing performed by study staff at Screening and Enrollment (per applicable algorithm in Appendix II)		
In general good health at Screening and Enrollment, as determined by the site IoR or designee		
At Screening, participant states willingness to abstain from receptive sexual activity (including oral, vaginal and anal intercourse) for the 14 days prior to enrollment and for the duration of study participation		
Per participant report, using an effective method of contraception at Enrollment, and intending to continue use of an effective method for the duration of study participation. Effective methods include hormonal methods (except contraceptive vaginal rings), intrauterine device (IUD) inserted at least 28 days prior to enrollment, being a woman who identifies as a woman who has sex with women exclusively, sterilization, and/or sexually abstinent for the past 90 days		
Satisfactory Pap result in the 12 calendar months prior to Enrollment consistent with Grade 0 according to the Female Genital Grading Table for Use in Microbicide Studies Addendum 1 to the DAIDS Table for Grading Adult and Pediatric Adverse Events, Version 1.0, December 2004 (Clarification dated August 2009), or satisfactory evaluation with no treatment required of Grade 1 or higher Pap result per American Society for Colposcopy and Cervical Pathology (ASCCP) guidelines in the 12 calendar months prior to Enrollment.		
Per participant report at Screening and Enrollment, agrees not to participate in other research studies involving drugs, medical devices, or vaginal products for the duration of study participation		
Per participant report at Screening, regular menstrual cycles with at least 21 days between menses (does not apply to participants who report using a progestin-only method of contraception at screening, e.g., Depo-Provera or levonorgestrel-releasing IUD)		
At Screening and Enrollment, participant states a willingness to refrain from inserting any non-study vaginal products or objects into the vagina, including but not limited to, spermicides, female condoms, diaphragms, contraceptive vaginal rings, vaginal medications, menstrual cups, cervical caps (or any other vaginal barrier method), douches, lubricants, sex toys (vibrators, dildos, etc.), and tampons for the 5 days prior to enrollment throughout the duration of study participation. *Note: At the Screening visit participant also agrees to refrain from the practices listed above for at least 5 days prior to enrollment.*		

Exclusion Criteria	**Screening Visit Staff Init/Date**	**Enrollment Visit Staff Init/Date**
Participant report of any of the following at Screening: a. Known adverse reaction to silicone, titanium dioxide, or to any of the components of the study products b. Use and/or anticipated use during the period of study participation of CYP3A inducer(s) and/or inhibitor(s) c. Chronic and/or recurrent candidiasis d. Non-therapeutic injection drug use in the 12 months prior to screening e. Post-exposure prophylaxis for HIV exposure within 6 months prior to screening f. Last pregnancy outcome 90 days or less prior to screening g. Currently breastfeeding h. Hysterectomy i. Intends to become pregnant within the next 4 months j. Has plans to relocate away from the study site area in the next 4 months		[redacted]
Reports participating in any other research study involving drugs, medical devices, or vaginal products 60 days or less prior to enrollment		
At Screening or Enrollment, as determined by the IoR/designee, any significant uncontrolled active or chronic cardiovascular, renal, liver, hematologic, neurologic, gastrointestinal, psychiatric, endocrine, respiratory, immunologic disorder or infectious disease, or at increased risk of cardiovascular events		
Has any of the following laboratory abnormalities at Screening: a. Aspartate aminotransferase (AST) or alanine transaminase (ALT) Grade 1 or higher as per the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events Version 1.0, December, 2004 (Clarification dated August 2009) b. Calculated creatinine clearance less than 60 mL/min by the Cockcroft-Gault formula, where creatinine clearance (female) in mL/min = (140 – age in years) x (weight in kg) x (0.85)/72 x (creatinine in mg/dL) c. Hemoglobin Grade 1 or higher as per the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events Version 1.0, December, 2004 (Clarification dated August 2009) d. Platelet count Grade 1 or higher as per the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events Version 1.0, December, 2004 (Clarification dated August 2009) *Note: Otherwise eligible participants with an exclusionary test result may be re-tested during the screening process. If a participant is re-tested and a non-exclusionary result is documented within 45 days of providing informed consent for screening, the participant may be enrolled.*		[redacted]
At Screening or Enrollment, is pregnant		
Diagnosed with urinary tract infection (UTI) at Screening or Enrollment[3] *Note: Otherwise eligible participants diagnosed with UTI during screening will be offered treatment and may be enrolled after completing treatment and all symptoms have resolved. If treatment is completed and symptoms have resolved within 45 days of obtaining informed consent for screening, the participant may be enrolled.*		

Exclusion Criteria - *continued*	**Screening Visit Staff Init/Date**	**Enrollment Visit Staff Init/Date**
Diagnosed with pelvic inflammatory disease, a sexually transmitted infection (STI) or reproductive tract infection (RTI) requiring treatment per current Centers for Disease Control and Prevention (CDC) guidelines (http://www.cdc.gov/std/treatment/) at Screening or Enrollment *Note: Otherwise eligible participants diagnosed with STI or RTI during screening will be offered treatment and may be enrolled after completing treatment and all symptoms have resolved. If treatment is completed and symptoms have resolved within 45 days of obtaining informed consent for screening, the participant may be enrolled.*		
At Screening or Enrollment, has a clinically apparent Grade 1 or higher pelvic exam finding (observed by study clinician or designee) per the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, Version 1.0, December 2004 (Clarification dated August 2009), Addendum 1, Female Genital Grading Table for Use in Microbicide Studies *Note: Cervical friability bleeding associated with speculum insertion and/or specimen collection judged to be within the range of normal according to the clinical judgment of the IoR/designee is considered expected non-menstrual bleeding and is not exclusionary.*		
At Screening, severe pelvic relaxation such that either the vaginal walls or the uterine cervix descend beyond the vaginal introitus with valsalva maneuver		
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		