Instructions: Use the table below to document a participant's eligibility status for MTN-024/IPM 031 study participation. Initial and date below each set of "yes/no" checkboxes upon assessment of each eligibility criterion. For each item, the reference/source document is listed. Once ineligibility status is determined, the form may be stopped and the remaining questions may be left blank. Include an entry in the chart notes as to why items of the checklist are left blank. Note: A staff member and the IoR/designee must review and sign/date below to document the participants eligilbity status is confirmed prior to enrollment/randomization. Complete the Eligibility Criteria CRF for all screened participants once the participant's eligibility/enrollment status is determined.

Inclusion Criteria	**Screening Visit**	**Enrollment Visit**
	Yes No	**Yes No**
1. Age 45 through 65 years (inclusive) at Screening, verified per site SOPs *Source: copy of identification card or other documents as specified in SOP*	☐ ☐ _____	*not required*
2. Per participant report, postmenopausal at Screening, defined as amenorrheaic for the past 12 months (minimum) or at least 6 months status post-bilateral oophorectomy *Source: Screening Menstrual History Worksheet*	☐ ☐ _____	*not required*
3. Follicle-stimulating hormone (FSH) level at 40 mIU/ml or higher at Screening *Source: laboratory test results report*	☐ ☐ _____	*not required*
4. Able and willing to provide written informed consent to be screened for and enrolled in study *Source: signed/marked Screening/Enrollment consent form*	☐ ☐ _____	*not required*
5. Able to communicate in spoken and written English *Source: Screening Behavioral Eligibility Worksheet*	☐ ☐ _____	*not required*
6. Able and willing to comply with all study procedural requirements *Source: Screening Behavioral Eligibility Worksheet, Enrollment Behavioral Eligibility Worksheet*	Review and proceed accordingly	☐ ☐ _____
7. Willing to only use study provided and/or approved vaginal products throughout the duration of study participation *Source: Screening Behavioral Eligibility Worksheet, Enrollment Behavioral Eligibility Worksheet*	Review and proceed accordingly	☐ ☐ _____
8. Willing to abstain from inserting study approved lubricant into the vagina for 72 hours prior to each visit *Source: Screening Behavioral Eligibility Worksheet, Enrollment Behavioral Eligibility Worksheet*	Review and proceed accordingly	☐ ☐ _____
9. Willing to abstain from vaginal intercourse for 72 hours prior to each visit *Source: Screening Behavioral Eligibility Worksheet, Enrollment Behavioral Eligibility Worksheet*	Review and proceed accordingly	☐ ☐ _____

Note: In order for the participant to be eligible , all of the responses to items 1-9 above must be 'yes'.

Inclusion Criteria	Screening Visit Yes	Screening Visit No	Enrollment Visit Yes	Enrollment Visit No
10. In general good health as determined by the Investigator of Record (IoR)/designee at Screening and Enrollment *Source: Physical Exam CRF, Baseline Medical History Questions Sheet, Pelvic Exam Diagram, Pelvic Exam CRF*	☐	☐	☐	☐
11. Able and willing to provide adequate locator information, as defined in site SOPs *Source: Site specific locator forms as specified in site SOP*	☐	☐	☐	☐
12. HIV-uninfected based on testing performed at Screening *Source: site HIV testing logs*	☐	☐	*not required*	
13. Per participant report at Screening and Enrollment, agrees to use male latex condoms for sexual intercourse *Source: Screening Behavioral Eligibility Worksheet, Enrollment Behavioral Eligibility Worksheet*	☐	☐	☐	☐
14. Per participant report at Screening and Enrollment, 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, topical or systemic hormone replacement therapy, including vaginal estrogens, and/or hormonal contraceptives, vaginal medications, menstrual cups, cervical caps (or any other vaginal barrier method), vaginal douches, lubricants and moisturizers, sex toys (vibrators, dildos, etc.), for the duration of the study participation. *Note: Use of study approved lubricant is permitted.* *Source: Screening Behavioral Eligibility Worksheet, Enrollment Behavioral Eligibility Worksheet*	☐	☐	☐	☐
15. At Screening and Enrollment, agrees not to participate in other research studies involving drugs, medical devices, vaginal products, or vaccines for the duration of study participation *Source: Screening Behavioral Eligibility Worksheet, Enrollment Behavioral Eligibility Worksheet*	☐	☐	☐	☐
Participants in the biopsy subset must also meet the following criteria at Screening to be eligible for inclusion:				
16. Willing to abstain from inserting anything into the vagina for 72 hours following the collection of biopsies, including abstaining from vaginal intercourse *Source: Screening Behavioral Eligibility Worksheet*	☐	☐	*not required*	
17. Anatomy sufficient for the collection of cervical biopsies *Source: Screening Menstrual History formBaseline Medical History Questions Sheet, Pelvic Exam Diagram*	☐	☐	*not required*	

Note: In order for the participant to be eligible , all of the responses to items 10-15 above must be 'yes'.
In order for the participant to be eligible for the biopsy subset, responses to items 16 and 17 must be 'yes'.

Exclusion Criteria	**Screening Visit** Yes No	**Enrollment Visit** Yes No
1. Per participant report at screening: a) Plans to relocate away from the study site during study participation *Source: Screening Behavioral Eligibility Worksheet*	☐ ☐	*not required*
b) Plans to travel away from the study site for more than 4 consecutive weeks during study participation *Source: Screening Behavioral Eligibility Worksheet*	☐ ☐	*not required*
2. Pregnant at screening *Source: pregnancy test logs*	☐ ☐	*not required*
Note: *A documented negative pregnancy test performed by study staff is required for inclusion; however a self-reported pregnancy is adequate for exclusion from the study.*		
3. Diagnosed with urinary tract infection (UTI) at Screening or Enrollment *Source: urine culture if done , Baseline Medical History Questions Sheet, Pre-existing Conditions CRF*	☐ ☐	☐ ☐
Note: *Otherwise eligible participants diagnosed with UTI during screening are 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.*		
4. Diagnosed with pelvic inflammatory disease, an STI or reproductive tract infection (RTI) requiring treatment per current Centers for Disease Control and Prevention (CDC) guidelines at Screening or Enrollment *Source: Baseline Medical History Questions Sheet, Pelvic Exam Diagram, Pelvic Exam CRF, Pre-existing Conditions CRF, laboratory test results report*	☐ ☐	☐ ☐
Note: *Otherwise eligible participants diagnosed during screening with pelvic inflammatory disease or STI/RTI requiring treatment per CDC guidelines — other than asymptomatic bacterial vaginosis (BV) and asymptomatic candidiasis — are 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. Genital warts requiring treatment also must be treated prior to Enrollment. Genital warts requiring therapy as defined as those that cause undue burden or discomfort to the participant, including bulky size, unacceptable appearance, or physical discomfort.*		
5. Has a clinically apparent Grade 2 or higher pelvic exam finding (observed by study staff) at Screening or Enrollment, 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), Addendum 1-Female Genital Grading Table for Use in Microbicide Studies *Source: Pelvic Exam Diagram, Pelvic Exam CRF, Pre-existing Conditions CRF*	☐ ☐	☐ ☐
Note: *Cervical bleeding associated with speculum insertion and/or specimen collection judged to be within the range of normal according to the clinical judgment of the Investigator of Record (IoR)/designee is considered expected non-menstrual bleeding and is not exclusionary.* ***Note:*** *Otherwise eligible participants with exclusionary pelvic exam findings may be enrolled/randomized after the findings have improved to a non-exclusionary severity grading or resolved. If improvement to a non-exclusionary grade or resolution is documented within 45 days of providing informed consent for screening, the participant may be enrolled.*		

Note: In order for the participant to be <u>eligible</u> , all of the responses to items 1-5 above <u>must be 'no'.</u>

Exclusion Criteria	Screening Visit	Enrollment Visit
	Yes No	Yes No
6. Participant report and/or clinical evidence of any of the following: a) Known adverse reaction to any of the study products (ever) *Source: Baseline Medical History Questions Shee t; Screening Behavioral Eligibility Worksheet*	☐ ☐ _____	*not required*
b) Known adverse reaction to latex (ever) *Source: Baseline Medical History Questions Sheet; Screening Behavioral Eligibility Worksheet*	☐ ☐ _____	*not required*
c) Chronic and/or recurrent vaginal candidiasis *Source: Screening Behavioral Eligibility Worksheet, Enrollment Behavioral Eligibility Worksheet*	Review and proceed accordingly	☐ ☐ _____
d) Topical or systemic hormone replacement therapy and/or hormonal contraception within the 6 months prior to Enrollment *Source: Screening Behavioral Eligibility Worksheet, Enrollment Behavioral Eligibility Worksheet*	Review and proceed accordingly	☐ ☐ _____
e) Non-therapeutic injection drug use in the 12 months prior to Enrollment *Source: Screening Behavioral Eligibility Worksheet, Enrollment Behavioral Eligibility Worksheet*	Review and proceed accordingly	☐ ☐ _____
f) Post-exposure prophylaxis (PEP) for HIV exposure within the 6 months prior to Enrollment *Source: Screening Behavioral Eligibility Worksheet, Enrollment Behavioral Eligibility Worksheet*	Review and proceed accordingly	☐ ☐ _____
g) Pre-exposure prophylaxis (PrEP) for HIV prevention within the 6 months prior to Enrollment *Source: Screening Behavioral Eligibility Worksheet, Enrollment Behavioral Eligibility Worksheet*	Review and proceed accordingly	☐ ☐ _____
h) Last pregnancy outcome 6 months or less prior to Enrollment *Source: Screening Behavioral Eligibility Worksheet, Enrollment Behavioral Eligibility Worksheet*	Review and proceed accordingly	☐ ☐ _____
i) Gynecologic or genital procedure (e.g., tubal ligation, dilation and curettage, piercing) 90 days or less prior to Enrollment *Source: Baseline Medical History Questions Sheet*	Review and proceed accordingly	☐ ☐ _____
j) Currently breastfeeding *Source: Screening Behavioral Eligibility Worksheet, Enrollment Behavioral Eligibility Worksheet*	Review and proceed accordingly	☐ ☐ _____

Note: *In order for the participant to be eligible, all of the responses to items 6a-6j above must be 'no'.*

Exclusion Criteria	**Screening Visit**	**Enrollment Visit**
	Yes No	**Yes No**
k) At Screening, severe pelvic relaxation such that either the vaginal walls or the uterine cervix descend beyond the vaginal introitus with valsalva maneuver *Source: Pelvic Exam Diagram*	☐ ☐	*not required*
l) Participation in any other research study involving drugs, medical devices, vaginal products, or vaccines, in the 45 days prior to Enrollment *Source: Screening Behavioral Eligibility Worksheet, Enrollment Behavioral Eligibility Worksheet*	Review and proceed accordingly	☐ ☐
7. 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 *Source: Baseline Medical History Questions Sheet, Physical Exam CRF, and Pre-existing Conditions CRFs*	Review and proceed accordingly	☐ ☐
8) Has any of the following laboratory abnormalities at Screening Visit: *Source for 8a-8e: laboratory test results reports* a) Aspartate aminotransferase (AST) or alanine transaminase (ALT) Grade 1 or higher*	☐ ☐	*not required*
b) Creatinine Grade 2 or higher*	☐ ☐	*not required*
c) Hemoglobin Grade 2 or higher*	☐ ☐	*not required*
d) Platelet count Grade 1 or higher*	☐ ☐	*not required*
e) Pap result Grade 2 or higher**	Review and proceed accordingly	☐ ☐

Note: *Otherwise eligible participants with an exclusionary test may be re-tested during the screening process.*

Note: *Women with a documented normal result within the 12 months prior to Enrollment need not have a Pap smear during the screening period. Women with a Grade 1 abnormal Pap smear can be enrolled upon completion of the initial phase of evaluation if no current treatment is indicated (based on local standard of care for management of abnormal cervical cytology). Need for a repeat Pap within 6 months does not preclude Enrollment prior to that result becoming available. If the participant has had a hysterectomy for reasons not related to cervical dysplasia, a Pap smear need not be performed.*

Note: In order for the participant to be <u>eligible</u> , all of the responses to items 6k-8e above <u>must be 'no'.</u>

Exclusion Criteria	Screening Visit	Enrollment Visit
	Yes No	Yes No
9. Has any other condition that, in the opinion of the IoR/designee, would preclude informed consent, make study participation unsafe, complicate the interpretation of study outcome data, or otherwise interfere with achieving the study objectives *Source: chart notes*	Review and proceed accordingly	☐ ☐ _____

Note: In order for the participant to be <u>eligible</u> , all of the responses to item 9 above <u>must be 'no'.</u>

*Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events Version 1.0, December, 2004 (Clarification dated August 2009)

**Female Genital Grading Table for Use in Microbicide Studies Addendum 1 to the Division of AIDS (DAIDS) Table for Grading Adult and Pediatric Adverse Events, Version 1.0, December 2004 (Clarification dated August 2009)

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

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