PTID	Mother:	Infant:	Staff Initial & Date	

Instructions: *Starting at the enrollment visit, use the table below to document the mother/infant pair's eligibility status by marking "yes" or "no." If ineligibility status is determined, any items not yet completed may be left blank. For an eligible mother/infant pair, the checklist must be completed for all items and have staff sign-off at the end of the form to confirm and verify eligibility. Complete the Inclusion Exclusion Criteria CRFs (mother and infant) for all screened participants once eligibility/enrollment status is determined. Note: 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.*

MOTHER INCLUSION CRITERIA		*Enrollment Visit Date*	
		Yes	*No*
I-1	Age 18 years or older at Screening, as verified per site Standard Operating Procedures (SOPs) • *Source: copy of identification card or other documents as specified in SOP*		
I-2	At Enrollment, between 6 to 12 weeks postpartum (defined as between 42 – 84 days after delivery, inclusive) • *Source: medical records or other documents as specified in SOP*		
I-3	By participant report at Screening and Enrollment, currently exclusively breastfeeding one infant and willing and able to continue exclusively breastfeeding that infant for the duration of their participation in the study • *Source: Screening Behavioral Eligibility Worksheet Item 1; Enrollment Behavioral Eligibility Worksheet Item 1, Feeding Assessment CRF*		
I-4	Consistently using an effective method of contraception per participant report at Enrollment, and intending to continue use of an effective method for the duration of study participation. Effective methods include contraceptive implants, intrauterine device, injectable progestin, oral contraceptive pills, and surgical sterilization. • *Source: Screening Behavioral Eligibility Worksheet Item 3; Enrollment Behavioral Eligibility Worksheet Item 3*		
I-5	Able and willing to comply with all study requirements and complete all study procedures. • *Source: Screening Behavioral Eligibility Worksheet Item 2; Enrollment Behavioral Eligibility Worksheet Item 2*		
I-6a	Able and willing to provide written informed consent to be screened for and to take part in the study • *Source: Signed Informed Consent Form*		
I-6b	Able and willing to provide written informed consent for the breastfed infant to be screened for and take part in the study. • *Source: Signed Informed Consent Form*		
I-7	Intention to stay within study catchment area for study duration and willingness to give adequate locator information, as defined in site SOPs. • *Source: Screening Behavioral Eligibility Worksheet Item 4; Enrollment Behavioral Eligibility Worksheet Item 4*		
I-8	HIV-uninfected • *Source: Local testing log, laboratory test results report or other sites-specific document at Screening and Enrollment*		
I-9	Willing to be randomized at time of enrollment to either of the study products, and to continue study product use for at least 12 weeks. • *Source: Screening Behavioral Eligibility Worksheet Item 5; Enrollment Behavioral Eligibility Worksheet Item 5*		
INFANT INCLUSION CRITERIA			
I-1	At Screening and Enrollment, infant is exclusively breastfed. • *Source: Screening Behavioral Eligibility Worksheet Item 1; Enrollment Behavioral Eligibility Worksheet Item 1, Feeding assessment CRF*		
1-2	At Screening and Enrollment, the infant is generally healthy, according to the judgment of the IoR/designee. • *Source: Physical Exam CRF; Baseline Medical History CRF; Infant Medical Records, Chart notes*		
I-3	At Enrollment, the infant is between the ages of 6 and 12 weeks postpartum (defined as between 42 - 84 days after delivery, inclusive). • *Source: medical records or other documents as specified in SOP*		

PTID	Mother:	Infant:	Staff Initial & Date	

	MOTHER EXCLUSION CRITERIA	*Enrollment Visit Date*	
		Yes	*No*
E-1	Breastfeeding infant ineligible for enrollment in the study. • *Source: Chart notes and this checklist*		
E-2a	Known adverse reaction to any of the study products (ever). • *Source: Screening Behavioral Eligibility Worksheet Item 6*		
E-2b	Known adverse reaction to latex and polyurethane (ever). • *Source: Screening Behavioral Eligibility Worksheet Item 7*		
E-2c	PEP for HIV exposure within 6 months prior to Enrollment • *Source: Screening Behavioral Eligibility Worksheet Item 8; Enrollment Behavioral Eligibility Worksheet Item 6*		
E-2d	Use of vaginal medications(s) or other vaginal products within five days prior to Enrollment. • *Source: Screening Behavioral Eligibility Worksheet Item 9; Enrollment Behavioral Eligibility Worksheet Item 7, Vaginal Practices CRF, Concomitant Medications Log*		
E-2e	Non-therapeutic injection drug use in the 12 months prior to Enrollment. • *Source: Screening Behavioral Eligibility Worksheet Item 10; Enrollment Behavioral Eligibility Worksheet Item 8*		
E-2F	History of exposure to any investigational drug(s) during pregnancy, including participation in MTN-042. • *Source: Screening Behavioral Eligibility Worksheet Item 11*		
E-3	Positive HIV test. • *Source: Local testing log, laboratory test results report or other site-specific document at Screening and Enrollment*		
E-4	Grade 2 or higher breast or genitourinary findings. • *Source: Physical Exam CRF; Pelvic Exam Diagram; Baseline Medical History CRF; or other site-specific documentation*		
E-5	Positive urinary pregnancy test • *Source: Local testing log, laboratory test results report or other site-specific document*		
E-6a	Positive for hepatitis B surface antigen (HBsAg). • *Source: Local testing log, laboratory test results report or other site-specific document*		
E-6B	Aspartate aminotransferase (AST)/alanine aminotransferase (ALT) ≥ Grade 2. • *Source: Local testing log, laboratory test results report or other site-specific document*		
E-6c	Creatinine ≥ Grade 1. • *Source: Local testing log, laboratory test results report or other site-specific document*		
E-6d	Estimated Creatinine Clearance ≥ Grade 2. • *Source: Local testing log, laboratory test results report or other site-specific document*		
E-7	Diagnosed with urinary tract infection (UTI), pelvic inflammatory disease (PID), STI or reproductive tract infection (RTI), requiring treatment per WHO Guidelines. • *Source: Local testing log, laboratory test results report or other site-specific document; Baseline Medical History CRF; Pelvic Exam Diagram; chart notes*		
E-8	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: Local testing log, laboratory test results report or other site-specific document; Physical Exam CRF; Baseline Medical History CRF; Chart notes*		
E-9	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 the study objectives. • *Source: Chart notes and this checklist*		

PTID	Mother:	Infant:	Staff Initial & Date	

E-10a	Participation in any research study involving drugs, vaccines, or medical devices 30 days or less prior to enrollment. • *Source: Screening Behavioral Eligibility Worksheet Item 12; Enrollment Behavioral Eligibility Worksheet Item 9*		
E-10b	Currently participating in other research studies involving drugs, vaccines, or medical devices. • *Source: Screening Behavioral Eligibility Worksheet Item 12; Enrollment Behavioral Eligibility Worksheet Item 9*		
E-10c	Expected to participate in other research studies involving drugs, vaccines, or medical devices during study participation. • *Source: Screening Behavioral Eligibility Worksheet Item 13; Enrollment Behavioral Eligibility Worksheet Item 10*		
	INFANTS EXCLUSION CRITERIA		
E-1	Has any condition that, in the opinion of the IoR/designee, would preclude eligibility, make study participation unsafe, complicate interpretation of study outcome data, or otherwise interfere with achieving the study objectives. *Note: Examples of exclusionary infant conditions include clinical evidence of stunting or illness.* • *Source: Chart notes and this checklist*		
E-2a	Infant birth weight less than 2000g • *Source: Infant Medical Records*		
E-2b	Participation in any research study involving drugs, vaccines, or medical devices since birth. • *Source: Screening Behavioral Eligibility Worksheet Item 14; Enrollment Behavioral Eligibility Worksheet Item 11*		
E-2c	Currently participating in other research studies involving drugs, vaccines, or medical devices. • *Source: Screening Behavioral Eligibility Worksheet Item 14; Enrollment Behavioral Eligibility Worksheet Item 11*		
E-2d	Expected to participate in other research studies involving drugs, vaccines, or medical devices for the duration of study participation. • *Source: Screening Behavioral Eligibility Worksheet Item 15; Enrollment Behavioral Eligibility Worksheet Item 12*		

For the participant to be eligible, all responses to Mother Inclusion Criteria (items I-1 to I-9) and Infant Inclusion Criteria (items I-1 to I-3) above must be "Yes" and responses to Mother Exclusion Criteria (items E-1 to E-10) and Infant Exclusion Criteria (items E-1 to E-2) above must be "No."

Final Sign-off of Participant Eligibility to Enroll:

Once a mother/infant pair is deemed eligible to enroll in MTN-043, have two different staff complete signatures below to confirm and verify final determination of eligibility of both participants. Only staff delegated per site DoD may sign for Eligibility Confirmation or Eligibility Verification.

ELIGIBILITY CONFIRMATION

Staff Signature: _____

Date: ___ ___ / ___ ___ ___/ ___ ___

Time: ___ ___: ___ ___

ELIGIBILITY VERIFICATION

Staff Signature: _____

Date: ___ ___ / ___ ___ ___/ ___ ___

Time: ___ ___: ___ ___