

MTN-017 STUDY VISITS AND PROCEDURES

	Visit 1 SCR	Visit 2 ENR Initiate Period 1	Visit 3 Mid Period 1	Visit 4 End Period 1 Visit	Visit 5 Initiate Period 2 Visit	Visit 6 Mid Period 2 Visit	Visit 7 Period 2 End Visit	Visit 8 Initiate Period 3 Visit	Visit 9 Mid Period 3 Visit	Visit 10 End Period 3 Visit/ Final Clinic/ Early Term
ADMINISTRATIVE AND REGULATORY										
Informed consent (SCR/ENR)	X									
Assign PTID	X									
Collect demographic data	X									
Locator information	X	X	X	X	X	X	X	X	X	X
Assess eligibility	X									
Confirm participant eligibility		X								
Provide reimbursement	X	X	X	X	X	X	X	X	X	X
Schedule next study visit/contact	X	X	X	X	X	X	X	X	X	*
Provide available test results	X	X	X	X	X	X	X	X	X	X
Randomization		X								
Provision of AE dial-in instructions										X
BEHAVIORAL/COUNSELING										
Baseline Behavioral Questionnaire (CASI)		X								
HIV pre-/post-test and HIV/STI risk reduction counseling	X	X	X	X	*	X	X	*	X	X
Protocol adherence counseling		X	X		X	X		X	X	
Product use instructions		X	X		X	X		X	X	
Product adherence counseling/interview		X	X	X	X	X	X	X	X	X
Follow-up Behavioral Questionnaire (CASI)				X			X			X
In-depth phone interview (subset)				X						
Rectal biopsy/fluid procedural counseling (Rectal biopsy/fluid subset only)	X	X		X			X			X
CLINICAL										
Medical history	X	X	X	X	X	X	X	X	X	X
Physical exam	X	X	*	*	*	*	*	*	*	X
Rectal exam	X	X	X	X	X	X	X	X	X	X
Record/update AEs		X	X	X	X	X	X	X	X	X
Concomitant medications	X	X	X	X	X	X	X	X	X	X
Treat for UTI/RTI/STI or refer	*	*	*	*	*	*	*	*	*	*
Hepatitis B vaccination or decline of vaccination		*	*	*	*	*	*	*	*	*
LABORATORY										
URINE										
Dipstick UA	X	*	*	*	*	*	*	*	*	*
NAAT for GC/CT	X	*	*	*	*	*	*	*	*	X
BLOOD										
CBC w/ diff and platelets	X	*	*	*	*	*	*	*	*	X
AST/ALT	X	*	*	*	*	*	*	*	*	X
Creatinine	X	*	*	X	*	*	X	*	*	X
Plasma for archive		X								
Plasma for storage				X			X			X
Blood for PK (PBMC and/or plasma)			X (Plasma only)	X		X (Plasma only)	X		X (Plasma only)	X
Syphilis RPR	X	*	*	*	*	*	*	*	*	*
HIV-1 serology	X	X	X	X	*	X	X	*	X	X

Protocol Version 1.0 dated 17 July 2012

Clarification Memo #01 3 August 2012

Letter of Amendment #01 25 February 2013

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HSV 1/2 antibody	X									
HBsAg and HBsAg	X									
Hepatitis C antibody	X									
Coagulation (PT/INR) (Rectal biopsy/fluid subset only)	X									
RECTAL										
HSV 1/2 detection	*	*	*	*	*	*	*	*	*	*
Rectal sponge for adherence PK			X	X	X	X	X	X	X	X
Rectal sponge for PD		X	X	X	X	X	X	X	X	X
Rectal sponge for mucosal immunology (Rectal biopsy/fluid subset only)		X		X			X			X
Rectal biopsies for PK (Rectal biopsy/fluid subset only)				X			X			X
Rectal biopsies for PD (Rectal biopsy/fluid subset only)		X		X			X			X
Rectal biopsies for mucosal immunology (Rectal biopsy/fluid subset only)		X		X			X			X
Anal HPV		X								
NAAT for GC/CT	X	X	*	X	*	*	X	*	*	X
STUDY PRODUCT/SUPPLIES										
Provision of study product		X	X		X	X		X	X	
Observe first dose and/or simulation of a first dose with SMS training		X			X			X		
Collect unused study product			X	X		X	X		X	X
Provision of male condoms	X	X	X	X	X	X	X	X	X	X
Provision of lubricant		*	*		*	*		*	*	

X= required,*= if indicated

NOTE: In addition to the procedures listed above, study staff will follow-up with participants via phone call 48-72 hours and again 14 days after Visit 2 (Enrollment), Visit 5 and Visit 8 to collect AEs. Sites will reference SOPs regarding participant reimbursement.

Disclaimer: The table serves as a reference only. It does not substitute or replace guidance presented in the protocol, LoA(s), CM(s) or its content. In the event this table is inconsistent with the information and guidance provided in the protocol LoA(s) or CM(s), the specifications in the protocol will take precedence. Should any inconsistencies between the protocol and this table be identified, please notify the MTN-017 Study Management Team at mtn017mgmt@mtnstopshiv.org. This document should only be referenced if the proper regulatory approvals for the protocol and modifications referenced below are in place.