MTN-024/IPM 031 Study-Specific Procedures Manual
Overview of Section Contents and Identification of Current Section Versions

Section Number	Section Title	Version Number	Version Date	Updates and Comments
1	Introduction	1.2	11February 2015	• Updated section 1.1 to reflect current specifications of the protocol under which sites are expected to operate under.
2	Documentation Requirements	1.1	11 February 2015	• Updated section 2.2.2.1 to clarify that in the rare event study product is not returned, any attempts to retrieve study product should be documented in chart notes.
3	Participant Accrual, Screening and Enrollment	1.2	11 February 2015	• Updated section 3.4.5 to clarify how to screening laboratory results are documented, per Operational Guidance #01
4	Informed Consent	1.0	27 September 2013	
5	Participant Follow-up and Retention	1.1	16 June 2014	• Updated section to clarify requirements for follow up phone contact occurring one week after the 12-Week Final Clinic Visit.
6	Study Product Considerations For Non-Pharmacy Staff	1.0	27 September 2013	
7	Clinical Considerations	1.2	11 February 2015	• Updated section 7.1.2 to provide further guidance on how to document post-menopausal medical history at baseline and to clarify 'age of menopause' as noted on the Screening Menstrual History Form, per Operational Guidance #02
8	Adverse Event Reporting and Safety Monitoring	1.1	13 May 2014	• Updated section 8.6 to clarify the subset of AEs requiring reassessment following study termination.
9	Counseling Considerations	1.2	11 February 2015	• Updated section 9.5 to provide clarification on protocol guidance stipulating that participants abstain from inserting anything into their vagina for 72 hours prior to each clinic visit, including abstaining from the use of study approved lubricant and vaginal intercourse, per Operational Guidance #01
10	Laboratory Considerations	1.1	13 May 2014	• General updates to replace all MTN Network (NL) Laboratory references with Laboratory Center (LC). • Updated Table 10-4 to correct aliquot volume for cervical cytobrush specimens.

				• Section 10.6.2 updated to clarify confirmatory testing procedures for sites in accordance with Letter of Amendment #02. • Updated Appendix 10-1 to include revised HIV Algorithm for HIV Antibody Testing for Screening and Enrolled Participants.
11	Data Collection	1.1	14 May 2014	• Updated Table 11-1: Visit Timing Requirements to correct visit open and close windows for the 13-Week Follow-up Phone Call (visit 7.0).
12	Data Communiqués	1.0	27 September 2013	• Data Communique #01 dated 20 March 2014 • Data Communique #02 dated 20 June 2014
13	Study Reporting Plan	1.0	27 September 2013	
14	Behavioral Measures	1.1	21 July 2014	• Updated Section 14.4.2.4 to include guidance on reporting the outcome of potential AEs/SHs evaluations by clinic staff following notification by the qualitative interviewer.