MTN-013/IPM 026 Study Specific Procedures Manual
Overview of Section Contents and Identification of Current Section Versions

Section Number	Section Title	Current Version Number	Current Version Date	Updates and Comments
1	Introduction	1.0	02 September 2011	N/A
2	Protocol	1.1	19 December 2011	• Includes Clarification Memo #01 dated 12 July 2011 • Includes Letter of Amendment (LoA) #01 dated 14 December 2011
3	Documentation Requirements	1.0	02 September 2011	N/A
4	Participant Accrual	1.1	19 December 2011	• Updated Section Appendix 4-1 and 4-2 (Eligibility Checklists) to modify exclusion criteria to exclude participants with a Grade 2 or higher white blood count or are infected with Hepatitis B or Hepatitis C per LoA #01.
5	Informed Consent	1.1	19 December 2011	• Updated to include new Section 5.6 to provide guidance on the re-consenting process for participants who were not previously tested for Hepatitis B or Hepatitis C per LoA #01.
6	**Participant Follow-Up**	**1.3**	**21 May 2012**	• Updated to include new Section 6.13 to provide guidance on modified follow up visit procedures for participants who are found to be infected with Hepatitis B and C per LoA#01. • Subsequent protocol numbering following Section 6.13 has been updated. • Updated section 6.7.3 to reflect the Pittsburgh site will conduct both biofilm and residual drug analysis testing on vaginal rings. • **Updated to include new Section 6.7.5 to provide guidance to sites on how to address discoloration of the VR if identified. This section also included other minor section references corrections.**

7	Visit Checklists	1.3	13 April 2012	• Updated to clarify the timing of the tear test strips collection at Enrollment. Other updates include correction to the order of pelvic exam procedures on all other visit checklists. • Updated the Pelvic Exam Checklist to revise the required timing to conduct the naked eye and bimanual exams. • Updated the Screening Visit Checklist to include testing for HBsAG & Anti-HCV. • Updated the Pelvic Exam Checklist to revise the order of specimen collection.
8	Participant Retention	1.0	02 September 2011	N/A
9	Study Product Considerations for Non-Pharmacy Staff	1.0	02 September 2011	N/A

10	Clinical Considerations	1.5	13 April 2012	• Updated to clarify timing of collection of the Tear Test Strips at Enrollment. • Updated Section 10.3.3 to revise the required timing to conduct the naked eye and bimanual exams. • Updated Section 10.4.1 to clarify allowable windows for PK procedures and required collection times. • Updated Section 10.9 to clarify reference location for detailed clinical and product use guidance. • Updated Section 10.9.1 and 10.9.2 to include product use permanent discontinuation requirement in the event of Hepatitis B or C infection per LoA #01. • Updated Section 10.9.2 to include product use temporary hold requirements in the event of a participant presenting with signs/symptoms indicative of a Hepatitis B and/or C infection or symptomatic Candida vaginitis per LoA #01. • Updated Section 10.4.2.1 to modify tear test strip collection procedures to enhance greater absorption of vaginal fluid from the introitus. • Updated Section 10.4.2.1 to revise tear test strip collection procedures for vaginal fluid sampling from the introitus. • Updated Section 10.3.3 to revise the order of specimen collection during the pelvic examination
11	AE Reporting and Safety Monitoring	1.1	04 November 2011	• Updated to include new IPM representative to the PSRT Composition in Section Appendix 11-1.

12	Laboratory Considerations	1.8	13 April 2012	• Updated section 12.5.1 to clarify specimen collection procedures for urine testing for pregnancy and UTIs. • Updated section 12.9.1 to correct the appropriate cervical biopsy bite measurement to 3x5mm rather than 3x7mm. • Updated instructions for processing lab for Plasma for PK (Dapivirine and Maraviroc analysis) in Table 12-4, Section 12.6.7 and on applicable LDMS tracking sheets. • Updated Section 12.7.2 with revised shipping instructions for Gram Stains slides. • Updated MTN NL Pharmacology Core contact information for the shipment of PK specimens. • Updated to include reference of testing for HBsAG & Anti-HCV per LoA #01. • Updated section 12.9.3 to include instructions for collecting pre- and post- collection weights of cervical tissue (biopsy) PD specimens. • Updated instructions for processing lab for vaginal swab for PD and/or Biomarkers in section 12.7.9. • Updated Section 12.7.8 to modify tear test strip collection procedures to enhance greater absorption of vaginal fluid from the introitus. • Updated Section 12.7.8 to revise tear test strip collection procedures for vaginal fluid sampling from the introitus. • Updated Section 12.8.1 to reflect the Pittsburgh site will conduct both biofilm and residual drug analysis testing on vaginal rings.
13	Data Collection	1.1	14 September 2011	• Updated to include a new DataFax CRF to document assessment of cervical ectopy at Enrollment.
14	Data Communiqués	1.0	02 September 2011	• Includes Data Communiqué #1 dated 15 September 2011. • Includes Data Communiqué #2 dated 14 December 2011. • Includes Data Communiqué #3 dated 19 December 2011.

15	Study Reporting Plan	1.0	02 September 2011	N/A
16	**Behavioral Measures: CASI Questionnaires and the Semi-Structured Interview (SSI)**	**1.2**	**21 May 2012**	• Updated to include new Section 16.3.5.1 that provides guidance on using the electronic (MS Word) SSI template and uploading data to the FTP server directory. • **Updated Table 1, Section 16.3.2, and Section Appendix 16-1 to remove notation which specifies the Ring Adherence CASI questionnaire is completed at Early Termination.**
17	Counseling Considerations	1.1	19 December 2011	• Updated Section 17.5.1 and 17.5.2 to reflect exception to prohibited practices and medications for the treatment of symptomatic Candida vaginitis per LoA #01.