MTN-008 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	24 March 2011	
2	Protocol	1.0	23 February 2011	• At first site activation, includes reference to LoA #1, 23 Nov2010, and LoA#2, 23 Feb 2011.
3	Documentation Requirements	1.0	24 March 2011	
4	Participant Accrual	1.0 1.1 1.2 1.3 1.4	24 March 2011 18 April 2011 26 August 2011 15 November 2011 05 March 2012	• Updated SSP references included. • Section 4.5.5: elaborated on acceptable PK sample collection windows • Section 4.3.3:added instructions on condom brand sites to provide for participants with latex allergy • Section 4.6: revised instructions on enrolling replacement participants for both Pregnancy and Lactation Cohorts
5	Informed Consent	1.0 1.1	24 March 2011 15 July 2011	• • Includes guidance on obtaining IC based on LoA#2 IC language updates.
6	Participant Follow-Up	1.0 1.1 1.2 1.3	24 March 2011 18 April 2011 18 May 2011 22 December 2012	• Addition of section 6.6.1 • Includes additional guidance on definition of evaluable participants and what constitutes a “completed” Day 6 Visit • Further guidance on evaluable Day 6 Visit Procedures. • Section 6.10 includes modification to collection of infant blood via heel stick procedure
7	Visit Checklists	1.0 1.1 1.2	04 May 2011	• Updated order of lab samples to be drawn. • Includes addition of Breast Milk LDMS Tracking Sheet for Lactation Cohort Visit Checklists.
8	Participant Retention	1.0	24 March 2011	
9	Study Product Considerations For Non-Pharmacy Staff	1.0 1.1	24 March 2011 05 May 2011	• Updated delayed study product return process in the last paragraph of Section 9.5.

10	Clinical Considerations	1.0 1.1	24 March 2011 05 May 2011	• Section 10.6.1: Removed "lavage of visual obstructions" language and clarified that lavage should only be used for removal of gel in case of reaction. • Section 10.6.2: Updated gram stain sample collection site to lateral wall, and corrected language to indicate that vaginal pH is collected at all visits other than screening, in which vaginal pH should be collected only if clinically indicated. • Section 10.8: Updated information on collection site of GC/CT NAAT testing pre-gel (cervical swab) and post-gel (urine test) application. • Added Section 10.14: Delivery Visit Procedures.
11	Adverse Event Reporting and Safety Monitoring	1.0 1.1 1.2 1.3	24 March 2011 16 June 2011 19 August 2011 15 November 2011	• Added Figure 11-2: Reporting hospitalizations as AEs • Sections 11.2/ Figure 11.3: modified AE follow-up procedures • Section 11.9.2: updated composition of PSRT • Section 11.1.1: clarification of expected conditions related to pregnancy/lactation to report as AEs vs expected conditions related to conduct of study procedures
12	Laboratory Considerations	1.0 1.1 1.2	24 March 2011 04 May 2011 19 August 2011	• Update of LDMS tracking sheets included. • Section 12.3: added instructions for what to do for uncollected samples • Appendix 12-3: updated rows 1 and 3 for tenofovir serum and cord blood collections. • Section 12.8: elaboration on tenofovir blood sample collection process
13	Behavioral Assessments	1.0	24 March 2011	
14	Data Collection	1.0	24 March 2011	
15	Data Communiqués	1.0	05 April 11 05 May 2011 26 May 2011 04 October 2011 20 October 2011	Data Communique#1 Data Communique#2 Data Communique#3 Data Communique#4 Data Communique#5
16	Study Reporting Plan	1.0	24 March 2011	