

Section Number	Section Title	Current Version Number	Current Version Date	Updates and Comments
1	Introduction	1.0	16 November 2009	First Final Version
		2.0	1 April 2014	Updated contact information for MTN CORE and SDMC added.
		2.1	7 July 2017	Updated contact information and website links; added detail about the protocol signature page, DAIDS IoR Agreement, and other regulatory requirements.
2	Protocol	1.0	16 November 2009	First Final Version
		2.0	1 April 2014	Added updated table of protocol versions and clarification memos.
3	Documentation Requirements	1.0	16 November 2009	First Final Version
		1.1	1 December 2011	Section 3.2 updated to include guidance on handling discrepant participant histories; Section 3.2.1 includes further details on documentation of case histories; Appendix 3-4: addition of Infant Safety Event form for VOICE sites.
		1.2	4 February 2013	Clarifications regarding certified copies, chart noting.
		2.0	1 April 2014	Guidance on protocol deviation reporting added to be in line with revised MTN Protocol Deviation Policy.
		2.1	6 June 2017	References to Woman End of Study Inventory and Infant End of Study Inventory removed.
4	Participant Accrual	2.2	7 July 2017	Added detail about making certified copies of electronic data.
		1.0	16 November 2009	First Final Version
		1.1	9 June 2010	Updated to include definition of missed menses for eligibility criteria and updated version of screening and enrollment log samples.
		1.2	13 January 2012	Clarification on eligibility criteria in reference to TOP and minimum number of days between first two positive pregnancy tests.

		2.0	1 April 2014	Pregnancy confirmation requirements updated in Figure 4-1; Woman screening and enrollment and newborn initial visit procedures added.
		2.1	4 May 2015	Updates to 4.2 regarding pregnancy confirmation around time of parent study exit.
		2.2	16 September 2015	Updates to definition of infant enrollment in 4.2.3.
		2.3	7 July 2017	Updated with additional details about recruitment efforts in section 4.1.
5	Informed Consent	1.0	16 November 2009	First Final Version
		2.0	1 April 2014	Off-site visit ICF added; reconsenting requirements and procedures outlined in section 5.5; IC coversheet and comprehension checklists updated.
6	Participant Follow-Up	1.0	16 November 2009	First Final Version
		1.1	4 February 2013	Addition of participant transfer guidance, Section 6.5
		2.0	1 April 2014	Visit window parameters deleted (covered in Section 13); section on off-site visit procedures added; guidance on termination procedures as well as early termination and participant withdrawal from MTN-016 added.
7	Visit Checklists	1.0	16 November 2009	First Final Version
		2.0	1 April 2014	Minor administrative/formatting changes; updates to all visit checklists except Quarterly Woman and Woman Interim.
8	Co-Enrollment Considerations	1.0	16 November 2009	First Final Version
		2.0	1 April 2011	Additional ideas for ways to streamline MTN-016 and parent protocol visits provided.
		2.1	7 July 2017	Added allowance for sites to maintain a centralized locator form for MTN-016 and parent protocol during co-enrollment.
9	Participant Retention	1.0	16 November 2009	First Final Version

		1.1	4 February 2013	Sections 9.4 and 9.5
		2.0	1 April 2014	Off-site visits added to list of retention strategies.

10	Clinical Considerations	1.0	16 November 2009	First Final Version
		1.1	25 May 2011	Updated to include guidance on Ballard Gestational Age Assessment and Worksheet in Appendix I and added major malformation journal reference to Section 10.7.4.
		1.2	1 December 2011	Section 10.5.3: clarified infant visit procedures, including weight and length percentile calculations, calibration of portable infant scales; 10.6.4-clarified training for Denver Developmental Assessment Exams; Added Cape Town to site listing in Section 10.7.4.
		1.3	4 February 2013	Added Sections 10.6.3.1, 10.6.3.2, and 10.9.1
		2.0	1 April 2014	Ballard Assessment and Denver Developmental Assessment deleted; additional guidance on using infant growth charts provided in 10.6.3.1; clarification added to 10.8.1 on conditions <i>not</i> considered major malformations
11	Safety Monitoring and Reporting	1.0	16 November 2009	First Final Version
		1.1	9 June 2010	Updated to include modified EAE language reflected in Manual for Expedited Reporting of AEs to DAIDS, v. 2.0, January 2010.
		1.2	1 December 2011	Section 11.1.1: description of additional Infant Safety Event log for infants born to mothers from VOICE.
		2.0	1 April 2014	Infant Safety Event Log form deleted

12	Laboratory Considerations	1.0	16 November 2009	First Final Version
		1.1	23 November 2011	Section 12.5.3: update from 6 to 2 hours for HIV resistance sample processing time window; update to LDMS Tracking Sheet
		1.2	9 December 2011	Update to LDMS Tracking Sheet, version 3.0, 08Dec2011
		1.3	4 February 2013	Update to LDMS Tracking Sheet, version 3.1, 08Aug2012, Table 12.1, Sections 12.4, 12.5.2, and Appendix 12-2.
		1.4	20 March 2013	Update to Flow Chart for Testing HIV Exposed Infant within MTN-016 (Appendix12-3)
		2.0	1 April 2014	Network Lab changed to Laboratory Center; updated contact information for MTN Core Virology Lab added.
		2.1	7 July 2017	Updated HIV test kits/methods, procedures for submitting LDMS questions, guidance on HIV resistance testing, and contact information.
13	Data Collection	1.0	29 July 2009	First Final Version
		2.0	1 May 2014	Updated 13.1 DataFax Overview section with more info about transmission and Quality Control; Added new section 13.2. Case Report Forms (this new section discusses CRF distribution, making changes to CRFs after they have been issued, printing CRFs, and standard elements of a CRF; I moved info about PTIDs, visit codes, page numbers and pregnancy numbers here); Added two new sub-sections to the CRF Completion Guidelines section (Correcting a PTID Error and Rounding Lab Values); Added information about the CRF Tracking System to the Faxing CRFs section; Added more information about infant missed visits in the Missed Visit subsection (in Study Visit Timing); Updated the Schedule of Forms (removed reference to Infant Developmental Screening CRF and added footnote about infant enrollment); Added all CRF information that was included in previous data communiques to this section.

		2.1	16 September 2015	Updates to definition of infant enrollment in 13.6.2
		2.2	2 June 2017	Updated staff roster; removed references to Woman End of Study Inventory and Infant End of Study Inventory; added details about the Parent Protocol Participation, Woman Follow-up Visit, and Woman Interim Visit CRFs to 13.10.16.
14	Data Communiqués	1.0	16 June 2009	First Final Version
		2.0	1 May 2014	Administrative updates
15	Study Reporting Plan	1.0	16 June 2009	First Final Version
		2.0	1 May 2014	Removed SCHARP staff from Section 15 (already included in Section 13); Changed organization of reports (no longer separated by 'reports posted on Atlas' and 'reports distributed by email'); Removed reference to SMC Report Changed Site Specimen Repository Report to Specimen Monitoring Report and clarified the scope of the Specimen Monitoring Report; Updated description of Enrollment and Retention Reports (to include specific Enrollment and Retention Reports for participants whose parent protocol is ASPIRE); Revised description of Visit Adherence Report; Removed reference to Adjunct Major Malformation Data Report; Added Interim Review Report