

MTN 016 Study Specific Procedures Manual

Overview of Section Contents and Identification of Current Section Versions

Section Number	Section Title	Current Version	Current Version Date	Updates and Comments
1	Introduction	1.0	16 November 2009	First Final Version
2	Protocol	1.0	16 November 2009	First Final Version
3	Documentation Requirements	1.0	16 November 2009	First Final Version
		1.1	01 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	04 February 2013	Clarifications regarding certified copies, chart noting.
4	Participant Accrual	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.
5	Informed Consent	1.0	16 November 2009	First Final Version
6	Participant Follow-Up	1.0	16 November 2009	First Final Version
		1.1	04 February 2013	Addition of participant transfer guidance, Section 6.5
7	Visit Checklists	1.0	16 November 2009	First Final Version

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8	Co-Enrollment Considerations	1.0	16 November 2009	First Final Version
9	Participant Retention	1.0 1.1	16 November 2009 04 February 2013	First Final Version Sections 9.4 and 9.5
10	Clinical Considerations	1.0 1.1 1.2 1.3	16 November 2009 25 May 2011 01 December 2011 04 February 2013	First Final Version 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. 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. Added Sections 10.6.3.1, 10.6.3.2, and 10.9.1
11	Safety Monitoring and Reporting	1.0 1.1 1.2	16 November 2009 9 June 2010 01 December 2011	First Final Version Updated to include modified EAE language reflected in Manual for Expedited Reporting of AEs to DAIDS, v. 2.0, January 2010. Section 11.1.1: description of additional Infant Safety Event log for infants born to mothers from VOICE.

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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	09 December 2011	Update to LDMS Tracking Sheet, version 3.0, 08Dec2011
		1.3	04 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)
13	Data Collection	1.0	29 July 2009	First Final Version
14	Data Communiqués	1.0	16 June 2009	First Final Version
15	Study Reporting Plan	1.0	16 June 2009	First Final Version