

**MTN-023/IPM 030 Study-Specific Procedures Manual**  
**Overview of Section Contents and Identification of Current Section Versions**

<b>Section Number</b>	<b>Section Title</b>	<b>Version Number</b>	<b>Version Date</b>	<b>Updates and Comments</b>
1	Introduction	2.1	23 February 2016	Updated per Protocol Version 2.0; Letter of Amendment #01
2	Documentation Requirements	2.0	25 February 2015	Updated per Protocol Version 2.0
3	Participant Accrual and Retention	2.0	25 February 2015	Updated per Protocol Version 2.0
4	Informed Consent	2.1	2 September 2015	Procedure for consenting an illiterate parent was added to section 4.1
5	Study Procedures	2.3	23 February 2016	Section 5.8.1 was updated per Protocol Version 2.0; Letter of Amendment #01
6	Study Product Considerations For Non-Pharmacy Staff	2.1	7 April 2015	Added section 6.10; study product complaints
7	Clinical Considerations	2.0	2 September 2015	Section 7.6.4 was updated to specify location of PK vaginal swab collection
8	Adverse Event Reporting and Safety Monitoring	2.0	25 February 2015	Updated per Protocol Version 2.0
9	Counseling Considerations	2.0	25 February 2015	Updated per Protocol Version 2.0
10	Laboratory Considerations	2.1	7 April 2015	Updated instructions for Sample 2 plasma storage and shipment, if seroconversion occurs during follow-up
11	Data Collection	2.2	1 February 2016	Updated SDMC staff listing; Updated requirements for datafax transmission
12	Data Communiqués	2.0	25 February 2015	Updated per Protocol Version 2.0
13	Study Reporting Plan	2.1	1 February 2016	Updated SDMC staff listing; Clarified components for missed visit report
14	Behavioral Considerations	2.2	23 February 2016	Updated per Protocol Version 2.0; Letter of Amendment #01