

## MTN-011 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 September 2012	
2	Protocol	1.0	24 September 2012	
3	Documentation Requirements	1.0	24 September 2012	
4	Participant Accrual and Enrollment	1.2	8 August 2013	<ul style="list-style-type: none"> <li>• Specified that screening visits for male and females participants can occur separately</li> <li>• Added requirement in section 4.3.6 to collect demographics for couples who re-enroll</li> </ul>
5	Participant Follow-Up	1.3	8 August 2013	Clarified window for the timing of sample collection after coitus in Figure 5.1
6	Participant Retention	1.0	24 September 2012	
7	Study Product Considerations For Non-Pharmacy Staff	1.0	24 September 2012	
8	Clinical Considerations and Safety Monitoring	1.4	8 August 2013	Described systemic immune modulators that are prohibited in the protocol in section 8.5
9	Laboratory Considerations	1.4	3 September 2013	<ul style="list-style-type: none"> <li>• Allowed for HIV Western Blot testing to be performed at the MTN NL, if needed</li> <li>• Included details on anti-HSV activity tested in the CVL sample</li> <li>• Included instructions to enter specimen weight into LDMS</li> </ul>
10	Data Collection	1.1	6 November 2012	Corrected Schedule of Forms
11	Data Communiqués	1.0	24 September 2012	
12	CASI Users Manual	1.1	21 February 2013	Added guidance on hard copy back-up questionnaires, in event of technical problems

13	Counseling Considerations	1.0	24 September 2012	
14	Study Reporting Plan	1.0	24 September 2012	