

## MTN 004 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	3.2	3 June 2009	<ul style="list-style-type: none"> <li>• Updated Figure 1-1, MTN-004 Study Communication, to update Safety Physician contact information.</li> <li>• Updated Section 1.3, Study Activation Process, to include instructions for the MTN site</li> </ul>
2	Protocol	3.1	3 June 2009	<ul style="list-style-type: none"> <li>• Inserted Letter of Amendment #01</li> </ul>
3	Documentation Requirements	3.2	3 June 2009	<ul style="list-style-type: none"> <li>• Updated Section 3.2, Study Activation Requirements, to include instructions for the MTN site</li> <li>• Deleted Section Appendix 3-2 and renumbered all subsequent appendixes.</li> </ul>
4	Participant Accrual	3.1	3 June 2009	<ul style="list-style-type: none"> <li>• Updated study accrual plan to include all three sites</li> <li>• Increased study accrual duration to 14 months</li> <li>• Updated Replacing Participants Section 4.2.7.1 to alert PSRT if any participants require replacement.</li> </ul>
5	Informed Consent	3.1	3 June 2009	<ul style="list-style-type: none"> <li>• Updated Section 5.4, Informed Consent for Specimen Storage and Future Research Testing, to instruct sites not to collect storage specimens if the participant did not consent to storage.</li> </ul>
6	Participant Follow-Up	3.2	29 June 2009	<ul style="list-style-type: none"> <li>• Updated section 6.3.3, Incomplete Visits, to clarify requirements for completion of baseline web-based questionnaire.</li> </ul>
7	Visit Checklists	3.3	30 July 2009	<ul style="list-style-type: none"> <li>• Deleted site-specific visit checklists; included “sample” checklist for all sites</li> <li>• Rearranged pelvic exam procedures so that collection of cervical swabs for cytokine and innate factors testing occurs prior to colposcopic exam.</li> </ul>

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8	Participant Retention	3.0	6 Aug 2008	<ul style="list-style-type: none"> <li>• No changes</li> </ul>
9	Study Gel Considerations for Non-Pharmacy Staff	3.1	15 Oct 2008	<ul style="list-style-type: none"> <li>• No changes</li> </ul>
10	Clinical Considerations	3.4	3 June 2009	<ul style="list-style-type: none"> <li>• Updated collection of colposcopy images to include instructions for Pitt CRS</li> </ul>
11	Adverse Event Reporting and Safety Monitoring	3.4	11 Sept 2009	<ul style="list-style-type: none"> <li>• Incorporated Clarification 1 of the DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, dates August 2009</li> </ul>
12	Laboratory Considerations	3.3	29 June 2009	<ul style="list-style-type: none"> <li>• Edited shipping requirements for Pittsburgh site in sections 12.2, 12.4, 12.7.4, 12.7.5, 12.7.6 and Table 12-5.</li> <li>• Updated section 12.5.3: required dipstick urinalysis test</li> <li>• Updated email addresses in Appendix 12-2</li> </ul>
13	Behavioral Measures	3.1	3 June 2009	<ul style="list-style-type: none"> <li>• Updated contact information of SCHARP Project Manager</li> </ul>
14	Data Collection	3.1	15 Aug 2008	<ul style="list-style-type: none"> <li>• Updated SCHARP study staff</li> </ul>
15	Data Communiqués	3.0	6 Aug 2008	<ul style="list-style-type: none"> <li>• No changes</li> </ul>
16	Study Reporting Plan	3.0	6 Aug 2008	<ul style="list-style-type: none"> <li>• Updated SCHARP study staff</li> </ul>