

**MTN-003D Study-Specific Procedures Manual**  
**Overview of Section Contents and Identification of Current Section Versions**  
**Current Version Number: 2.0**  
**Current Version Date: 28 October 2013**

<b>Section Number</b>	<b>Section Title</b>	<b>Updates and Comments</b>
20.1	Introduction	<ul style="list-style-type: none"> <li>Clarified location of Investigator Signature form and DAIDS Investigator of Record Form</li> </ul>
20.2	Protocol	<ul style="list-style-type: none"> <li>No changes from Version 1.0</li> </ul>
20.3	Documentation Requirements	<ul style="list-style-type: none"> <li>Added guidance for Stage 2 file organization</li> <li>Added requirement for transcription certification</li> </ul>
20.4	Participant Accrual	<ul style="list-style-type: none"> <li>Added Stage 2 accrual instructions</li> </ul>
20.5	Informed Consent	<ul style="list-style-type: none"> <li>Added guidance for Stage 2 participants that have already completed Stage 1</li> </ul>
20.6	Visit Procedures	<ul style="list-style-type: none"> <li>Added guidance on scheduling Stage 2 IDIs and FGDs</li> <li>Added details on adherence discussion with participants, including use of the teapot PK discussion tool</li> <li>Added table 20-10: Stage 2 Discussion Tools</li> </ul>
20.7	Visit Checklists	<ul style="list-style-type: none"> <li>No changes from Version 1.0</li> </ul>
20.8	Participant Retention	<ul style="list-style-type: none"> <li>No changes from Version 1.0</li> </ul>
20.9	Reporting of Social Harms and Unexpected Safety Events	<ul style="list-style-type: none"> <li>No changes from Version 1.0</li> </ul>
20.10	Counseling Considerations	<ul style="list-style-type: none"> <li>No changes from Version 1.0</li> </ul>
20.11	Data Collection	<ul style="list-style-type: none"> <li>Added guidance on split and missed visits for FGDs</li> <li>Added note on confidentiality during FGDs</li> <li>Added details of the Interim Review for study monitoring purposes</li> </ul>