# MTN-034 Study-Specific Procedures Manual

## Overview and Control Document – Version History and Notice of Changes

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<th>Section Title</th>
<th>Version Number(s)</th>
<th>Version Date(s)*</th>
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| 01             | Introduction  | 1.4               | 02 July 2021     | • Added reference to CM#03 in section 1.1  
• Added reference to COVID-19 MTN-034 Contingency Plan to section 1.1  
• Updated DAIDS policy references  
• Added guidance around documentation of training and qualifications to section 1.3 |
| 02             | Documentation | 1.3               | 02 July 2021     | • Updated DAIDS policy references  
• Added guidance on how to report significant deviations following the obsoletion of the DAIDS critical events policy to section 2.9 |
| 03             | Accrual and Retention | 1.3 | 22 July 2020 | N/A – no updates |
| 04             | Informed Assent and Consent | 1.2 | 02 July 2021 | • Updated section to include references to the SCORE Manual for Informed Consent and Source Documentation guidelines. |
| 05             | Study Procedures | 1.4 | 02 July 2021 | • Updated DAIDS policy references  
• Changed COVID-19 Behavioral CRF administration timepoints in section 5.5.1  
• Added access to HIV prevention product to referrals upon study exit in section 5.12.5  
• Added guidance for documenting contacts made with participants for study results dissemination in section 5.12.6 |
| 06             | Study Product | 1.4 | 05 January 2021 | N/A – no updates |
| 07             | Clinical Considerations | 1.4 | 05 January 2021 | N/A – no updates |
| 08             | Adverse Event Reporting and Safety monitoring | 1.5 | 02 July 2021 | • Updated link to the paper EAE form and completion instructions in Section 8.2 |
| 09             | Laboratory Considerations | 1.4 | 22 July 2020 | N/A – no updates |
| 10             | Counseling Procedures | 1.5 | 02 July 2021 | • Removed requirement for counseling recording. |
| 11             | Behavioral Assessments | 1.4 | 05 January 2021 | N/A – no updates |
| 12             | Data Collection | 1.5 | 02 July 2021 | • Updated Table 2 to correct week number for Visit 24. |
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*Highest version number/date listed is current and supersedes all previous listed version(s). Notice of Changes summarizes any significant changes that have been made during the current review period.
### SSP Approval Sheet

**Review Period:** 05JAN2021-02JUL2021

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