### MTN-035 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*</th>
<th>Version Date*</th>
<th>Notice of Changes*</th>
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<tbody>
<tr>
<td>1</td>
<td>Introduction</td>
<td>1.3</td>
<td>01JUNE2020</td>
<td>• Updated Section 1.1. with information on COVID-19-related operational considerations</td>
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<td>2</td>
<td>Documentation Requirements</td>
<td>1.2</td>
<td>01JUNE2020</td>
<td>• Removed reference to study monitors in Section 2.1</td>
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<td></td>
<td>• Updated definition of “source documents” in Section 2.2</td>
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<td>• Amended the following phrase in Section 2.3.5:</td>
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<td></td>
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<td>“Care should also be taken to only refer to participants by PTID in email communication when people outside of the CRS site are included”</td>
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<td>3</td>
<td>Accrual and Retention</td>
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<td>28DEC2018</td>
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<td>4</td>
<td>Informed Consent</td>
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<td>Study Procedures</td>
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<td>6</td>
<td>Study Product Considerations</td>
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<td>7</td>
<td>Clinical Considerations</td>
<td>1.2</td>
<td>01JUNE2020</td>
<td>• Added “urine hesitancy” to list of UTI symptoms in Section 7.9</td>
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<td>• Amended the following phrase in Section 7.10:</td>
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<td></td>
<td>“Symptoms of acute HIV infection may be indistinguishable from a typical viral syndrome, as well as from COVID-19, and may include a combination of the following:”</td>
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<td></td>
<td></td>
<td>• Clarified procedures for addressing seroconversion in Section 7.10</td>
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<td>8</td>
<td>AE Reporting and Safety Monitoring</td>
<td>1.2</td>
<td>01JUNE2020</td>
<td>• Updated Section 8.2 to include guidance on reporting COVID-19-related adverse events</td>
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<td>Laboratory Considerations</td>
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<td>Counseling Considerations</td>
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<td>Behavioral Measures</td>
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**MTN-035 Study-Specific Procedures Manual**  
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</table>
| 12      | Data Collection | 1.5 | 01JUNE2020 | • Updated LDO Data Coordinator contact in Section 12  
• Removed reference to PPD monitors in Section 12.1.1 |
| 13      | Data Communiqués | 1.0 | 28DEC2018 | None |
| 14      | Study Reporting Plan | 1.2 | 01JUNE2020 | • Added ‘Special COVID-19-specific reports’ to Table 14-2  
• Added description of ‘Special COVID-19-specific reports’ to Section 14.2 |

*Highest version number/date listed is current and supercedes all previous listed version(s). Notice of Changes summarizes any significant changes that have been made during the current review period.*
## SSP Manual Approval Sheet

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<th>Signature/Date</th>
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### Sections 7 and 8

Devika Singh, Protocol Safety Physician

*Applicable section version numbers and dates as listed in Overview and Control Document table, Version 1.8, dated 01JUNE2020*
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nmacagna@fhi360.org
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