

## MTN-025 Study-Specific Procedures Manual Overview and Control Document – Version History and Summary of Changes

Section Number	Section Title	Version Number(s)	Version Date(s)	Summary of Changes
1	Introduction	1.0 1.1 1.2	8 August 2016 18 May 2017 28June 2018	<ul style="list-style-type: none"> <li>Added reference to LoA #02</li> <li>Clarified that IoR documentation and procedures apply to temporary and permanent IoR changes.</li> <li>Format of page numbering updated and TOC updated with page numbers</li> </ul>
2	Decliner Group	1.0 1.1 1.2	8 August 2016 15 September 2016 28June 2018	<ul style="list-style-type: none"> <li>Format of page numbering updated and TOC updated with page numbers</li> </ul>
3	Documentation Requirements	1.0 1.1 1.2 1.3	8 August 2016 8 December 2016 18 May 2017 28 June 2018	<ul style="list-style-type: none"> <li>Added section on financial disclosure requirements.</li> <li>Format of page numbering updated and TOC updated with page numbers</li> </ul>
4	Participant Accrual, Screening and Enrollment	1.0 1.1 1.2 1.3 1.4	8 August 2016 15 September 2016 8 December 2016 18 May 2017 28June 2018	<ul style="list-style-type: none"> <li>Format of page numbering updated and TOC updated with page numbers</li> </ul>
5	Informed Consent	1.0 1.1 1.2	8 August 2016 8 December 2016 28June 2018	<ul style="list-style-type: none"> <li>Format of page numbering updated and TOC updated with page numbers</li> </ul>
6	Participant Follow-Up	1.0 1.1 1.2 1.3 1.4	8 August 2016 8 December 2016 18 May 2017 16 November 2017 28June 2018	<ul style="list-style-type: none"> <li>Clarified that product holds should not be completed at PUEV.</li> <li>Added reference to the HOPE Study Closeout Checklist and Operational Guidance #3.</li> <li>Format of page numbering updated and TOC updated with page numbers</li> </ul>
7	ACASI & Behavioral Assessments	1.0 1.1 1.2 1.3 1.4 1.5	8 August 2016 15 September 2016 8 December 2016 18 May 2017 04 January 2018 28June 2018	<ul style="list-style-type: none"> <li>Added reference to the Social Influences Supplement and the Administration Tool within the non-interviewer-administered forms table.</li> <li>Clarified that SD cards from different tablets have unique data which should not be mixed before they are merged.</li> <li>Format of page numbering updated and TOC updated with page numbers</li> </ul>
8	Participant Retention	1.0 1.1	8 August 2016 28June 2018	<ul style="list-style-type: none"> <li>Format of page numbering updated and TOC updated with page numbers</li> </ul>

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9	Study Product Considerations	1.0 1.1 1.2 1.3 1.4 1.5	8 August 2016 15 September 2016 8 December 2016 18 May 2017 16 November 2017 28 June 2018	<ul style="list-style-type: none"> <li>Format of page numbering updated and TOC updated with page numbers</li> </ul>
10	Clinical Considerations	1.0 1.1 1.2 1.3	8 August 2016 15 September 2016 8 December 2016 28 June 2018	<ul style="list-style-type: none"> <li>Moved guidance about Pap smear and cervical biopsy result grading and AE reporting to SSP section 11.4.</li> <li>Clarifications were made to section 10.1.2 regarding reconciliations between the family planning log and concomitant medication log, and use of trade and generic drug names.</li> <li>Updated section 10.2.3 regarding recommendations for frequency of calibrating scales.</li> <li>Added guidance to section 10.5.3 regarding follow-up for syphilis identified at PUEV.</li> <li>Added information about MTN-029 results to Section 10.8</li> <li>Updates made to 10.9 to reflect updated format of resistance reports provided.</li> <li>Format of page numbering updated and TOC updated with page numbers</li> </ul>
11	Adverse Event Reporting and Safety Monitoring	1.0 1.1 1.2 1.3 1.4 1.5	8 August 2016 15 September 2016 8 December 2016 18 May 2017 16 November 2017 28 June 2018	<ul style="list-style-type: none"> <li>Add clarifications regarding Pap smear and cervical biopsy results and AE reporting to section 11.4.</li> <li>Moved text from SSP section 10 regarding AE reporting for abnormal Pap smear results in follow-up to section 11.4.</li> <li>Clarified protocol required follow-up for AEs newly identified at study exit in section 11.7.</li> <li>Clarified CRF completion expectations in the event an AE is continuing at the SEV in Section 11.7.</li> <li>Format of page numbering updated and TOC updated with page numbers</li> </ul>
12	Counseling Considerations	1.0 1.1	8 August 2016 8 December 2016	<ul style="list-style-type: none"> <li>12.2.2.3 updated with additional information about residual drug feedback tools.</li> </ul>

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		1.2 1.3 1.4	18 May 2017 16 November 2017 28 June 2018	<ul style="list-style-type: none"> <li>Format of page numbering updated and TOC updated with page numbers</li> </ul>
13	Laboratory Considerations	1.0 1.1 1.2 1.3 1.4	8 August 2016 8 December 2016 18 May 2017 16 November 2017 28 June 2018	<ul style="list-style-type: none"> <li>13.9 edited to allow for more flexibility in terms of where hair samples are collected from.</li> <li>13.9.1 added to explain hair PK validation subset, to be collected at the three Zimbabwe sites.</li> <li>13.10 edited with information on Parexel's use of LDMS.</li> <li>Format of page numbering updated and TOC updated with page numbers</li> </ul>
14	Data Collection	1.0 1.1 1.2 1.3 1.4 1.5	8 August 2016 15 September 2016 8 December 2016 18 May 2017 16 November 2017 28 June 2018	<ul style="list-style-type: none"> <li>Updated SDMC Staff</li> <li>Clarified all queries must be resolved prior to inactivation of forms and/or log lines</li> <li>Additional information provided on visit codes for participants who enrolled after the formal accrual period</li> <li>Format of page numbering updated and TOC updated with page numbers</li> </ul>
15	Data Communiqués	1.0 1.1	8 August 2016 28 June 2018	<ul style="list-style-type: none"> <li>Format of page numbering updated and TOC updated with page numbers</li> </ul>
16	Reporting Plan	1.0 1.1 1.2 1.3 1.4 1.5	8 August 2016 15 September 2016 8 December 2016 18 May 2017 16 November 2017 28 June 2018	<ul style="list-style-type: none"> <li>Updated SDMC Staff</li> <li>Updated frequency on Residual Drug Reports</li> <li>Noted the Retention Report includes through Month 12 only</li> <li>Format of page numbering updated and TOC updated with page numbers</li> </ul>
17	Qualitative Component	1.0 1.1 1.2 1.3 1.4 1.5	12 October 2016 8 December 2016 22 December 2016 18 May 2017 16 November 2017 28 June 2018	<ul style="list-style-type: none"> <li>Storage requirements for audio files clarified.</li> <li>17.6.1 and 17.8 updated with instruction about accompanying documents to submit with debriefing reports to RTI.</li> <li>Minor administrative updates/corrections made.</li> <li>Format of page numbering updated and TOC updated with page numbers</li> </ul>
18	CHARISMA	1.0 2.0 2.1	5 December 2016 13 January 2017 28 June 2018	<ul style="list-style-type: none"> <li>Format of page numbering updated and TOC updated with page numbers</li> </ul>

### SSP Approval Sheet

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Entity	Sections Approved*	Print Name	Signature	Date
Protocol Chair	All Sections	Jared Baeten, Protocol Chair	DocuSigned by: Jared Baeten CE49F460A0744DE...	6/26/2018
FHI 360 CRM	All Sections	Ashley Mayo, FHI 360	DocuSigned by: Ashley J. Mayo E33C3463DC334F6...	6/26/2018
SCHARP CDM	Sections 14, 15, 16	Melissa Peda, SCHARP	DocuSigned by: Melissa Peda 84517E23E3E449B...	6/26/2018
MTN Pharmacy Director	Section 9	Cindy Jacobson, MTN LOC	DocuSigned by: Cindy Jacobson B85A8DD6DFE747E...	6/27/2018
MTN LC Research Manager	Section 13	Edward Livant, MTN LC	DocuSigned by: Edward Livant 9E619B6A181441E...	6/26/2018
BRWG Project Coordinator	Sections 7, 17	Ariana Katz, RTI	DocuSigned by: A. Katz 9226024AE2D441F...	6/26/2018
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Protocol Safety Physician	Sections 10, 11	Katherine Bunge, MTN LOC	DocuSigned by: Katherine Bunge 7ED1C5A6B77240E...	6/26/2018
CHARISMA Research Manager	Section 18	Miriam Hartmann, RTI	DocuSigned by: Miriam H. Hartmann B9DA5C5EAB94D2...	6/27/2018

\*Applicable section version numbers and dates as listed in Overview and Control Document table, Version 1.5, dated 28JUN2018