

**MTN-036 Study-Specific Manual**  
**Overview and Control Document – Version History and Notice of Changes**

<b>Section Number</b>	<b>Section Title</b>	<b>Version Number(s)*</b>	<b>Version Date(s)*</b>	<b>Notice of Changes*</b>
1	Introduction	1.0 1.1 1.2	4 Oct 2017 22 May 2018 7 Sep 2018	<ul style="list-style-type: none"> <li>Added LoA #2 to section 1.1</li> <li>Updated footer and TOC</li> </ul>
2	Documentation Requirements	1.0 1.1 1.2	4 Oct 2017 22 May 2018 7 Sep 2018	<ul style="list-style-type: none"> <li>Updated footer and TOC</li> </ul>
3	Accrual and Retention	1.0 1.1	4 Oct 2017 7 Sep 2018	<ul style="list-style-type: none"> <li>Updated footer and TOC</li> </ul>
4	Informed Consent	1.0 1.1	4 Oct 2017 7 Sep 2018	<ul style="list-style-type: none"> <li>Updated footer and TOC</li> </ul>
5	Study Visit Procedures	1.0 1.1 1.2	6 Oct 2017 22 May 2018 7 Sep 2018	<ul style="list-style-type: none"> <li>Changed offering condoms to if indicated and/or standard of care under study procedures in sections 5.3.2 and 5.4.1</li> <li>Addition of pregnancy test exemption for participants who have undergone supracervical hysterectomy or bilateral oophorectomy in sections 5.3.2 and 5.4.1</li> <li>Updated footer and TOC</li> </ul>
6	Behavioral Measures	1.0 1.1 1.2 1.3	4 Oct 2017 19 Feb 2018 22 May 2018 7 Sep 2018	<ul style="list-style-type: none"> <li>Updated footer and TOC</li> </ul>
7	Study Product Considerations (for non-pharmacy staff)	1.0 1.1	4 Oct 2017 7 Sep 2018	<ul style="list-style-type: none"> <li>Updated footer and TOC</li> </ul>
8	Clinical Considerations	1.0 1.1 1.2	4 Oct 2017 22 May 2018 7 Sep 2018	<ul style="list-style-type: none"> <li>Changed weight and height measure rounding to one decimal place in sections 8.4.1. and 8.4.2, respectively.</li> <li>Removed no longer existing weblink to CVL training video in section 8.5.4.</li> <li>Updated footer and TOC</li> </ul>
9	AE Reporting and Safety Monitoring	1.0 1.1	4 Oct 2017 7 Sep 2018	<ul style="list-style-type: none"> <li>Added sections 9.2.6 and 9.2.7 for HIV and AE Reporting and Sexual Assault Reporting, respectively</li> </ul>

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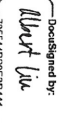
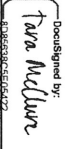
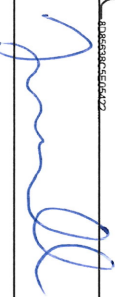
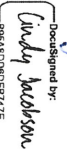
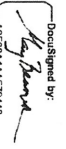
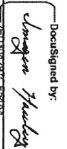
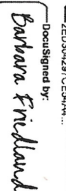
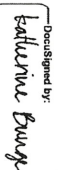
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				<ul style="list-style-type: none"> <li>Updated footer and TOC</li> </ul>
10	Laboratory Considerations	1.0 1.1 1.2 1.3 1.4	4 Oct 2017 1 Dec 2017 11 Dec 2017 19 Feb 2018 7 Sep 2018	<ul style="list-style-type: none"> <li>Revised HIV confirmation testing instructions in sections 10.6.3 to 10.6.3.3</li> <li>Revised CVL specimen storage instruction in section 10.7.7</li> <li>Updated footer and TOC</li> </ul>
11	Counseling Considerations	1.0 1.1 1.2	4 Oct 2017 22 May 2018 7 Sep 2018	<ul style="list-style-type: none"> <li>Clarification of post-HIV test counseling timing in section 11.1</li> <li>Addition of contraceptive counseling exemption for participants who have undergone supracervical hysterectomy or bilateral oophorectomy in section 11.2.1</li> <li>Updated footer and TOC</li> </ul>
12	Data Collection	1.0 1.1	4 Oct 2017 7 Sep 2018	<ul style="list-style-type: none"> <li>Updated SCHARP job roles in section 12</li> <li>Randomization guidance for CRFs amended in section 12.3.1</li> <li>Updated footer and TOC</li> </ul>
13	Data Communiques	1.0 1.1	4 Oct 2017 7 Sep 2018	<ul style="list-style-type: none"> <li>Updated footer and TOC</li> </ul>
14	Study Reporting Plan	1.0 1.1	4 Oct 2017 7 Sep 2018	<ul style="list-style-type: none"> <li>Updated SCHARP job roles in section 14</li> <li>Updated footer and TOC</li> </ul>

**\*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.**

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**SSP Approval Sheet**

**Review Period: 23JUL2018-07SEPP2018**

<b>Entity</b>	<b>Sections Approved*</b>	<b>Print Name, Role</b>	<b>Signature</b>	<b>Date</b>
<b>Protocol Chair</b>	All Sections	Al Liu, Protocol Chair	 <small>DocSigned by: Al Liu 26544800C38441</small>	09/10/2018
<b>FHI 360 CRM</b>	All Sections	Tara McClure, FHI 360	 <small>DocSigned by: Tara McClure 435638C5E5642D</small>	13SEP2018
<b>SCHARP CDM</b>	Sections 12, 13, 14	Tanya Harrell, SCHARP		14 Sep 2018
<b>MTN Pharmacy Director</b>	Section 7	Cindy Jacobson, MTN LOC	 <small>DocSigned by: Cindy Jacobson 885A3D00B7E74E</small>	09/13/2018
<b>MTN LC Research Manager</b>	Section 10	May Beamer MTN LC	 <small>DocSigned by: May Beamer A5E8D1AA575443</small>	9-13-18
<b>BRWG Project Coordinator</b>	Sections 6	Imogen Hawley, RTI	 <small>DocSigned by: Imogen Hawley 2ED3D977C597A...</small>	9/10/2018
<b>CASI Project Coordinator</b>	Section 6	Barbara Friedland, Population Council	 <small>DocSigned by: Barbara Friedland E7E3C8987A22E3</small>	9/14/18
<b>Protocol Safety Physician</b>	Sections 8, 9	Katherine Bunge, MTN LOC	 <small>DocSigned by: Katherine Bunge 7ED3C487746F...</small>	9/14/2018

\*Applicable section version numbers and dates as listed in MTN-036 Overview and Control Document, Version 1.1, dated 07SEPP2018.