

## MTN-038 Study-Specific Manual

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

Section Number	Section Title	Version Number(s)*	Version Date(s)*	Notice of Changes*
01	Introduction (Includes Protocol)	1.0 1.1	9 Nov 2018 19 Mar 2019	<ul style="list-style-type: none"> <li>Added LoA #1 to section 1.1</li> </ul>
02	Documentation Requirements	1.0 1.1	9 Nov 2018 20 Dec 2018	N/A
03	Accrual and Retention	1.0	9 Nov 2018	N/A – initial version
04	Informed Consent	1.0	9 Nov 2018	N/A – initial version
05	Study Procedures (SCR, ENR, FU)	1.0	9 Nov 2018	N/A – initial version
06	Behavioral Measures	1.0 1.1	9 Nov 2018 20 Dec 2018	N/A
07	Study Product Considerations for Non-Pharmacy Staff	1.0	9 Nov 2018	N/A – initial version
08	Clinical Considerations	1.0 1.1	9 Nov 2018 20 Dec 2018	N/A
09	AE Reporting and Safety Monitoring	1.0 1.1	9 Nov 2018 20 Dec 2018	N/A
10	Laboratory Considerations	1.0 1.1 1.2	9 Nov 2018 20 Dec 2018 19 Mar 2019	<ul style="list-style-type: none"> <li>Specimen Type updated for Vaginal swab for Microbiota Culture, and Tube or Container and tube size revised for Cervical Biopsy for PK in Table 10-2</li> <li>Creatinine clearance added to 10.6.2</li> <li>Shipping address street number correction in section 10.6.8</li> <li>Processing instruction for CVF swab for anti-HSV-2 activity revised in Table 10-3 and section 10.7.7</li> <li>Cotton swab added to wet prep materials list in section 10.7.2.2</li> <li>Section title and first sentence revised in section 10.7.10</li> <li>Steps 2 and 4 revised for cervical biopsy for PD collection in section 10.8.3</li> <li>Rectal swab preparation instruction revised in section 10.7.7 and 10.9</li> </ul>

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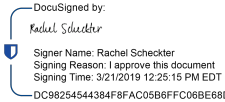

Section Number	Section Title	Version Number(s)*	Version Date(s)*	Notice of Changes*
11	Counseling Procedures	1.0	9 Nov 2018s	N/A – initial version
12	Data Collection	1.0 1.1	9 Nov 2018 20 Dec 2018	N/A
13	Data Communiques	1.0	9 Nov 2018	N/A – initial version
14	Study Reporting Plan	1.0	9 Nov 2018	N/A – initial version

**\*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.**

## MTN-038 Study-Specific Manual Overview and Control Document – Version History and Notice of Changes

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**Review Period: 7DEC2018-20DEC2018**

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<b>FHI 360 CRM</b>	All Sections	Rachel Scheckter, FHI 360	 <p>DocuSigned by: Rachel Scheckter Signer Name: Rachel Scheckter Signing Reason: I approve this document Signing Time: 3/21/2019 12:25:15 PM EDT DC98254544384F8FAC05B6FFC06BEB8D</p>	21-Mar-2019   12:25 EDT
<b>MTN LC Research Manager</b>	Section 10	May Beamer, MTN LC	 <p>DocuSigned by: May Beamer Signer Name: May Beamer Signing Reason: I approve this document Signing Time: 3/21/2019 11:12:57 AM EDT ABE60A1AA5794433B07FA7223D310D27</p>	21-Mar-2019   08:13 PDT

*\*Applicable section version numbers and dates as listed in MTN-038 Overview and Control Document, Version 1.2, dated 19 March 2019.*

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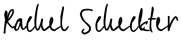
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