

MTN-035 Study-Specific Procedures Manual Overview and Control Document – Version History and Notice of Changes

Section Number	Section Title	Version Number*	Version Date*	Notice of Changes*
1	Introduction	1.3	01JUNE2020	<ul style="list-style-type: none"> Updated Section 1.1. with information on COVID-19-related operational considerations
2	Documentation Requirements	1.2	01JUNE2020	<ul style="list-style-type: none"> Removed reference to study monitors in Section 2.1 Updated definition of “source documents” in Section 2.2 Amended the following phrase in Section 2.3.5: <i>“Care should also be taken to only refer to participants by PTID in email communication when people outside of the CRS site are included”</i>
3	Accrual and Retention	1.0	28DEC2018	None
4	Informed Consent	1.0	28DEC2018	None
5	Study Procedures	1.4	06FEB2020	None
6	Study Product Considerations	1.1	30SEPT2019	None
7	Clinical Considerations	1.2	01JUNE2020	<ul style="list-style-type: none"> Added “urine hesitancy” to list of UTI symptoms in Section 7.9 Amended the following phrase in Section 7.10: <i>“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:”</i> Clarified procedures for addressing seroconversion in Section 7.10
8	AE Reporting and Safety Monitoring	1.2	01JUNE2020	<ul style="list-style-type: none"> Updated Section 8.2 to include guidance on reporting COVID-19-related adverse events
9	Laboratory Considerations	1.0	28DEC2018	None
10	Counseling Considerations	1.1	30SEPT2019	None
11	Behavioral Measures	1.3	03FEB2020	None




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12	Data Collection	1.5	01JUNE2020	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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.**

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FHI 360	Sections 1, 2, 7, 8, 12, 14	Nicole Macagna, CRM	<p>DocuSigned by: <i>Nicole Macagna</i></p> <p> Signer Name: Nicole Macagna Signing Reason: I approve this document Signing Time: 01-Jun-2020 12:35 EDT CC15CFA60E3645A5A772E9F25F52D7C2</p>
SCHARP	Sections 12, 14	Jillian Zemanek, CDM	<p>DocuSigned by: <i>Jillian Zemanek</i></p> <p> Signer Name: Jillian Zemanek Signing Reason: I approve this document Signing Time: 01-Jun-2020 11:30 PDT 0A9B7C2E2AE24BFDB35EED6E8C63B31D</p>

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MTN LOC	Sections 7 and 8	Devika Singh, Protocol Safety Physician	<p>DocuSigned by: <i>Devika Singh</i></p> <p> Signer Name: Devika Singh Signing Reason: I approve this document Signing Time: 01-Jun-2020 10:39 PDT</p> <p>3B860306856D4E7CB2C8765040B741A2</p>
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**Applicable section version numbers and dates as listed in Overview and Control Document table, Version 1.8, dated 01JUNE2020*

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