



MTN-045 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	1.1	16JUL2020	<ul style="list-style-type: none"> Updated Section 1.1 to reference Clarification Memo #01 and include information on COVID-19-related operations
2	Documentation Requirements	1.0	12NOV2019	None
3	Accrual, Eligibility Determination and Study Procedures	1.0	12NOV2019	None
4	Informed Consent	1.0	12NOV2019	None
5	Safety and Counseling Considerations	1.0	12NOV2019	None
6	Data Collection and Management	1.0	12NOV2019	None
7	Data Communiqués	1.0	12NOV2019	None

***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.**

MTN-045 Study-Specific Procedures Manual Overview and Control Document – Version History and Notice of Changes

SSP Manual Approval Sheet

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RTI International	Section 1	Alexandra Minnis, Protocol Chair	<p>DocuSigned by: <i>Alexandra Minnis</i></p> <p> Signer Name: Alexandra Minnis Signing Reason: I approve this document Signing Time: 20-Jul-2020 08:41 PDT 27C3DB1DC76E4B2ABA2539342371BAA3</p>
FHI 360	Section 1	Nicole Macagna, Clinical Research Manager	<p>DocuSigned by: <i>Nicole Macagna</i></p> <p> Signer Name: Nicole Macagna Signing Reason: I approve this document Signing Time: 17-Jul-2020 08:55 EDT CC15CFA60E3645A5A772E9F25F52D7C2</p>

*Applicable section version numbers and dates as listed in Overview and Control Document table, Version 1.1, dated 16JUL2020

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