

MTN-041 Study-Specific Procedures Manual Overview and Control Document – Version History and Notice of Changes

Section Number	Section Title	Version Number(s)*	Version Date(s)*	Notice of Changes*
1	Introduction	1.0 1.1	06MAR2018 31AUG2018	<ul style="list-style-type: none"> Updated Section 1.1 to document Letter of Amendment (LoA) #01, dated 31 July 2018 Format of page numbering updated and TOC updated with page numbers
2	Documentation Requirements	1.0 1.1 1.2	30MAR2018 06APR2018 31AUG2018	<ul style="list-style-type: none"> Format of page numbering updated and TOC updated with page numbers
3	Accrual, Eligibility Determination, & Study Procedures	1.0 1.1 1.2	13MAR2018 06APR2018 31AUG2018	<ul style="list-style-type: none"> Format of page numbering updated and TOC updated with page numbers
4	Informed Consent	1.0 1.1	06MAR2018 31AUG2018	<ul style="list-style-type: none"> Format of page numbering updated and TOC updated with page numbers
5	Safety and Counseling Considerations	1.0 1.1	06MAR2018 31AUG2018	<ul style="list-style-type: none"> Format of page numbering updated and TOC updated with page numbers
6	Data Management	1.0 1.1	30MAR2018 31AUG2018	<ul style="list-style-type: none"> Format of page numbering updated and TOC updated with page numbers
7	Data Communiqués	1.0 1.1	06MAR2018 31AUG2018	<ul style="list-style-type: none"> Data Communiqué #01, dated 26 June 2018 Data Communiqué #02, dated 03 July 2018 Data Communiqué #03, dated 30 July 2018 Format of page numbering updated and TOC updated with page numbers

***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: 14AUG2018--31AUG2018

Entity	Sections Approved*	Print Name, Role	Signature	Date
RTI	All	Ariane van der Straten, Protocol Chair	DocuSigned by: Ariane van der Straten F30F588437D8478...	2 sept2018
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RTI	All	Julia Ryan, Research Public Health Analyst	DocuSigned by: Julia Ryan 49307B9885AB4A7...	09 Sept 2018

**Applicable section version numbers and dates as listed in Overview and Control Document table, Version 1.2, dated 31AUG2018.*