

MTN-032 Study-Specific Procedures Manual Overview and Control Document – Version History and Notice of Changes


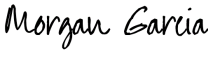
Section Number	Section Title	Version Number(s)*	Version Date(s)*	Notice of Changes*
1	Introduction	1.0 2.0 2.1 2.2	29 April 2016 21 December 2017 11 May 2018 06 August 2018	<ul style="list-style-type: none"> Format of page numbering updated and TOC updated with page numbers
2	Documentation Requirements	1.0 2.0 2.1 2.2 2.3	29 April 2016 21 December 2017 30 January 2018 11 May 2018 06 August 2018	<ul style="list-style-type: none"> Format of page numbering updated and TOC updated with page numbers Updated to clarify documentation of eligible and non-eligible participants and documentation of participant PTIDs
3	Participant Accrual, and Eligibility Determination	1.0 2.0 2.1 2.2	29 April 2016 21 December 2017 11 May 2018 06 August 2018	<ul style="list-style-type: none"> Format of page numbering updated and TOC updated with page numbers Updated to clarify definition of screening and enrollment, assignment and use of 025 and 032 PTIDs, and use of SCHARP Observation Number.
4	Informed Consent	1.0 2.0 2.1	29 April 2016 21 December 2017 06 August 2018	<ul style="list-style-type: none"> Format of page numbering updated and TOC updated with page numbers
5	Study Visit Procedures	1.0 1.1 2.0 2.1 2.2 2.3	29 April 2016 25 May 2016 21 December 2017 30 January 2018 11 May 2018 06 August 2018	<ul style="list-style-type: none"> Format of page numbering updated and TOC updated with page numbers
6	Safety and Counseling Considerations	1.0 2.0 2.1	29 April 2016 21 December 2017 06 August 2018	<ul style="list-style-type: none"> Format of page numbering updated and TOC updated with page numbers
7	Data Management	1.0 2.0 2.1 2.2	29 April 2016 30 January 2018 11 May 2018 06 August 2018	<ul style="list-style-type: none"> Format of page numbering updated and TOC updated with page numbers Updated to clarify guidance on study CRFs

8	Data Communiques	1.0 2.0 2.1	21 December 2017 11 May 2018 06 August 2018	DC #1: 29 April 2016 DC #2: 08 July 2016 DC #3: 23 August 2016 DC #4: 12 March 2018 DC #5: 06 August 2018 • Format of page numbering updated and TOC updated with page numbers
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***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.**

SSP Approval Sheet

Review Period: 20JULY2018—06AUG2018

Entity		Print Name	Signature	Date
Protocol Chair	All sections	Elizabeth Montgomery, Protocol Chair	DocuSigned by:  <small>ABA7F81CF3BC4B2...</small>	07AUG2018
FHI 360 CRM	All sections	Morgan Garcia, FHI 360	DocuSigned by:  <small>C70D9689A1BC4DA...</small>	06AUG2018

**Applicable section version numbers and dates as listed in Overview and Control Document table, Version 2.3, dated 06AUG2018*