

MTN-033 Study-Specific Procedures Manual Overview and Control Document – Version History and Notice of Changes

Section Number	Section Title	Version Numbers*	Version Dates*	Notice of Changes*
1	Introduction	2.0 2.1 2.2	26MAR2018 13AUG2018 05NOV2018	<ul style="list-style-type: none"> Updated TOC and footer
2	Documentation Requirements	2.0 2.1	26MAR2018 05NOV2018	<ul style="list-style-type: none"> Updated TOC and footer
3	Accrual and Retention	2.0 2.1	26MAR2018 05NOV2018	<ul style="list-style-type: none"> Updated TOC and footer
4	Informed Consent	2.0 2.1	26MAR2018 05NOV2018	<ul style="list-style-type: none"> Updated TOC and footer
5	Study Procedures	2.0 2.1	26MAR2018 05NOV2018	<ul style="list-style-type: none"> Updated TOC and footer
6	Study Product Considerations for Non-Pharmacy Staff	2.0 2.1 2.2	26MAR2018 13AUG2018 05NOV2018	<ul style="list-style-type: none"> Updated TOC and footer
7	Clinical Considerations	2.0 2.1 2.2	26MAR2018 13AUG2018 05NOV2018	<ul style="list-style-type: none"> Updated TOC and footer
8	Safety Monitoring	2.0 2.1	26MAR2018 05NOV2018	<ul style="list-style-type: none"> Updated TOC and footer
9	Lab Considerations	2.0 2.1	26MAR2018 05NOV2018	<ul style="list-style-type: none"> Updated TOC and footer
10	Counseling Considerations	2.0 2.1 2.2	26MAR2018 13AUG2018 05NOV2018	<ul style="list-style-type: none"> Updated TOC and footer
11	Behavioral Measures	2.0 2.1 2.2	26MAR2018 13AUG2018 05NOV2018	<ul style="list-style-type: none"> Updated TOC and footer Updated Appendix 11-3 to remove backup BRWG IDI contact
12	Data Collection	2.0 2.1	26MAR2018 05NOV2018	<ul style="list-style-type: none"> Updated footer
13	Data Communiqués	2.0 2.1	26MAR2018 05NOV2018	<ul style="list-style-type: none"> Updated footer
14	Study Reporting Plan	2.0 2.1	26MAR2018 05NOV2018	<ul style="list-style-type: none"> Updated footer




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***Highest version number/date listed is current and supersedes all previous listed versions. 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: 06NOV2018—08NOV2018

Entity*	Sections Approved**	Print Name, Role	Signature	Date
FHI 360	All Sections	Nicole Macagna, CRM	 <small>DocuSigned by: Nicole Macagna CC45CEA60E3645A</small>	07Nov2018
University of Pittsburgh CRS	All Sections	Ken Ho, Protocol Chair/Site IoR	 <small>DocuSigned by: Ken Ho 0698A75D37D84D3</small>	08Nov2018
BRWG (UPenn)	Section 11	Ryan Tingler, Project Manager	 <small>DocuSigned by: Ryan Tingler 79853B6B8F347E...</small>	07Nov2018

* Other section authors were not required to sign off as no content changes were made, only formatting changes.

**Applicable section version numbers and dates as listed in Overview and Control Document table, Version 1.2, dated 05NOV2018