

MTN-034 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*
01	Introduction	1.4	02 July 2021	<ul style="list-style-type: none"> • Added reference to CM#03 in section 1.1 • Added reference to COVID-19 MTN-034 Contingency Plan to section 1.1 • Updated DAIDS policy references • Added guidance around documentation of training and qualifications to section 1.3
02	Documentation	1.3	02 July 2021	<ul style="list-style-type: none"> • Updated DAIDS policy references • Added guidance on how to report significant deviations following the obsolescence of the DAIDS critical events policy to section 2.9
03	Accrual and Retention	1.3	22 July 2020	<ul style="list-style-type: none"> ○ N/A – no updates
04	Informed Assent and Consent	1.2	02 July 2021	<ul style="list-style-type: none"> • Updated section to include references to the SCORE Manual for Informed Consent and Source Documentation guidelines.
05	Study Procedures	1.4	02 July 2021	<ul style="list-style-type: none"> • Updated DAIDS policy references • Changed COVID-19 Behavioral CRF administration timepoints in section 5.5.1 • Added access to HIV prevention product to referrals upon study exit in section 5.12.5 • Added guidance for documenting contacts made with participants for study results dissemination in section 5.12.6
06	Study Product	1.4	05 January 2021	<ul style="list-style-type: none"> ○ N/A – no updates
07	Clinical Considerations	1.4	05 January 2021	<ul style="list-style-type: none"> ○ N/A – no updates
08	Adverse Event Reporting and Safety monitoring	1.5	02 July 2021	<ul style="list-style-type: none"> • Updated link to the paper EAE form and completion instructions in Section 8.2
09	Laboratory Considerations	1.4	22 July 2020	<ul style="list-style-type: none"> ○ N/A – no updates
10	Counseling Procedures	1.5	02 July 2021	<ul style="list-style-type: none"> • Removed requirement for counseling recording.
11	Behavioral Assessments	1.4	05 January 2021	<ul style="list-style-type: none"> ○ N/A – no updates
12	Data Collection	1.5	02 July 2021	<ul style="list-style-type: none"> • Updated Table 2 to correct week number for Visit 24.

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13	Data Communiques	1.0	04 January 2019	<ul style="list-style-type: none">○ N/A – initial version Note: Data Communiqués 1-7 available on REACH website
14	Study Reporting Plan	1.3	22 July 2020	<ul style="list-style-type: none">○ N/A – no updates

***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: 05JAN2021-02JUL2021

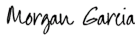

Entity	Sections Approved*	Print Name, Role	Signature/Date
Protocol Chair	All Sections	Gonasagrie Nair, Protocol Chair	<p>DocuSigned by: <i>Gonasagrie (Lulu) Nair</i></p> <p> Signer Name: Gonasagrie (Lulu) Nair Signing Reason: I approve this document Signing Time: 06-Jul-2021 05:04 EDT 2F5EA93D6916407BBB26F9510EFB0769</p>

**Applicable section version numbers and dates as listed in MTN-034 Overview and Control Document, Version 1.5, Protocol Version 2.0, dated 02 July 2021.*

MTN-034 Study-Specific Procedures Manual
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Review Period: 05JAN2021-02JUL2021



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FHI 360 CRM	All Sections	Morgan Garcia, FHI 360	<p>DocuSigned by:   Signer Name: Morgan Garcia Signing Reason: I approve this document Signing Time: 02-Jul-2021 10:08 EDT 3991C5E7871D4407BA5974DA54EF0078</p>

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MTN Pharmacy Director	Section 6	Cindy Jacobson, MTN LOC	<p>DocuSigned by:   Signer Name: Cindy Jacobson Signing Reason: I approve this document Signing Time: 07-Jul-2021 05:59 PDT B95A8DD6DFB747E7875F2D30389AF738</p>

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Protocol Safety Physician	Sections 7,8	Katherine Bunge, UPMC	<p>DocuSigned by:  Signer Name: Katherine Bunge Signing Reason: I approve this document Signing Time: 04-Jul-2021 12:37 PDT 7ED1C5A6877240FDBBF82FFE3C69B1FA</p>

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MTN LC Research Manager	Section 9	Edward Livant, MTN LC	<p>DocuSigned by:</p>  <p> Signer Name: Edward Livant Signing Reason: I approve this document Signing Time: 05-Jul-2021 10:13 EDT 9E61B06A181441D3A698FBE00AECF2FC</p>

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BRWG Project Coordinator	Section 11	Sarah Roberts, RTI	<p>DocuSigned by:   Signer Name: Sarah Roberts Signing Reason: I approve this document Signing Time: 02-Jul-2021 11:48 EDT 02C2DE1172B049629E6F687EFC33799B</p>

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SCHARP CDM	Sections 12, 13, 14	Jennifer Schille, SCHARP	<p>DocuSigned by:   Signer Name: Jennifer Schille Signing Reason: I approve this document Signing Time: 06-Jul-2021 13:25 EDT DC7D5F52A94B47D4B47AC9B0B9692704</p>

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<p>Jennifer Schille jens@scharp.org Jennifer Schille, CDM Security Level: Email, Account Authentication (Required)</p>	<p><i>Jennifer Schille</i></p> <p>Signature Adoption: Pre-selected Style Signature ID: DC7D5F52-A94B-47D4-B47A-C9B0B9692704 Using IP Address: 67.182.128.56</p> <p>With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I approve this document</p>	<p>Sent: 7/2/2021 10:07:01 AM Resent: 7/6/2021 11:24:12 AM Viewed: 7/6/2021 1:24:29 PM Signed: 7/6/2021 1:25:38 PM</p>
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<p>Katherine Bunge kbunge@mail.magee.edu Security Level: Email, Account Authentication (Required)</p>	<p><i>Katherine Bunge</i></p> <p>Signature Adoption: Pre-selected Style Signature ID: 7ED1C5A6-8772-40FD-BBF8-2FFE3C69B1FA Using IP Address: 96.236.226.165</p> <p>With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I approve this document</p>	<p>Sent: 7/2/2021 10:07:01 AM Viewed: 7/4/2021 3:36:42 PM Signed: 7/4/2021 3:37:22 PM</p>
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<p>Morgan Garcia mgarcia@fhi360.org Senior Clinical Research Manager Family Health International Inc - Part 11 Security Level: Email, Account Authentication (Required)</p>	<p><i>Morgan Garcia</i></p> <p>Signature Adoption: Pre-selected Style Signature ID: 3991C5E7-871D-4407-BA59-74DA54EF0078 Using IP Address: 108.247.36.36</p> <p>With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I approve this document</p>	<p>Sent: 7/2/2021 10:07:01 AM Viewed: 7/2/2021 10:08:08 AM Signed: 7/2/2021 10:08:35 AM</p>

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