

MTN-043 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	30APR2020	<ul style="list-style-type: none"> None (v1.0 initial release)
2	Documentation Requirements	1.0	30APR2020	<ul style="list-style-type: none"> None (v1.0 initial release)
3	Accrual and Retention	1.0	30APR2020	<ul style="list-style-type: none"> None (v1.0 initial release)
4	Informed Consent	1.0	30APR2020	<ul style="list-style-type: none"> None (v1.0 initial release)
5	Study Procedures	1.0 1.1	30APR2020 29JAN2021	<ul style="list-style-type: none"> Removed Ages and Stages at Screening throughout Added COVID Behavioral Assessment to 5.4.1.2 Added guidance in 5.7 about participants who become pregnant and test positive for HIV Added guidance 5.13 about missed PUEVs and in 5.13.2 about PrEP Counseling at SEV
6	Study Product Considerations for Non-Pharmacy Staff	1.0	30APR2020	<ul style="list-style-type: none"> None (v1.0 initial release)
7	Clinical Considerations	1.0 1.1	30APR2020 29JAN2021	<ul style="list-style-type: none"> Updated vaginal swab types in Table 7.2 Added guidance in 7.15 about management of AEs reported in retrospect Clarified that Ages and Stages is only required at Enrollment and PUEV
8	Adverse Event Reporting and Safety Monitoring	1.0	30APR2020	<ul style="list-style-type: none"> None (v1.0 initial release)
9	Counseling Considerations	1.0	30APR2020	<ul style="list-style-type: none"> None (v1.0 initial release)
10	Laboratory Considerations	1.0 1.1	30APR2020 29JAN2021	<ul style="list-style-type: none"> Added flexibility throughout for LC to approve alternate test kits, if needed Added information to 10.7.2 about Abbot purchase of Alere Corrected table 10-1 Updated temperature requirements for DBS in 10.7.8 Updated guidance on collection of vaginal swabs for microbiota and biomarkers in 10.8.3 and 10.8.4

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				<ul style="list-style-type: none"> Updated vaginal ring storage documentation instructions in 10.8.5 and shipping instructions in 10.10 Plasma for HIV algorithm added to Appendix 10-2 Appendix 10-5 updated
11	Data Collection	1.0 1.1	30APR2020 29JAN2021	<ul style="list-style-type: none"> Schedule of Forms tables in 11.5.4 updated
12	Data Communiques	1.0	30APR2020	<ul style="list-style-type: none"> None (v1.0 initial release)
13	Reporting Plan	1.0	30APR2020	<ul style="list-style-type: none"> None (v1.0 initial release)
14	B-PROTECTED Qualitative Component	1.0 1.1	30APR2020 29JAN2021	<ul style="list-style-type: none"> Flexibility added throughout to allow for implementation of sampling contingency plan, should initial strategy not yield the desired numbers at each site

***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: 15JAN2021-29JAN2021

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Protocol Chair	All Sections	Maxensia Owor, Protocol Chair	<p>DocuSigned by:</p> <p><i>Maxensia Owor</i></p> <p>Signer Name: Maxensia Owor Signing Reason: I approve this document Signing Time: 01-Feb-2021 07:21 PST EB6268F10B834F16A064C6A46F8CFE64</p>
Protocol Co-Chair	All Sections	Jennifer Balkus, Protocol Co-Chair	<p>DocuSigned by:</p> <p>Jennifer Balkus</p> <p>Signer Name: Jennifer Balkus Signing Reason: I approve this document Signing Time: 29-Jan-2021 14:53 PST A34808D98D9B4F0F9AE8C02F036FB20F</p>
Protocol Co-Chair	All Sections	Lisa Noguchi, Protocol Co-Chair	<p>DocuSigned by:</p> <p><i>Lisa Noguchi</i></p> <p>Signer Name: Lisa Noguchi Signing Reason: I approve this document Signing Time: 29-Jan-2021 13:08 PST 4E53F8B549F94E4E881F76E2DD7BB77E</p>
FHI 360 CRM	All Sections	Rachel Scheckter, FHI 360	<p>DocuSigned by:</p> <p><i>Rachel Scheckter</i></p> <p>Signer Name: Rachel Scheckter Signing Reason: I approve this document Signing Time: 29-Jan-2021 11:15 EST DC98254544384F8FAC05B6FFC06BE68D</p>

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MTN LC Research Manager	Section 10	Edward Livant, MTN LC	<p>DocuSigned by: <i>Edward Livant</i></p> <p> Signer Name: Edward Livant Signing Reason: I approve this document Signing Time: 01-Feb-2021 09:38 EST 9E61B06A181441D3A698FBE00AECF2FC</p>
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Protocol Safety Physician	Sections 7, 8	Katherine Bunge, MTN LOC	<p>DocuSigned by: <i>Katherine Bunge</i></p> <p> Signer Name: Katherine Bunge Signing Reason: I have read and understand the contents of this document Signing Time: 01-Feb-2021 11:50 PST 7ED1C5A6877240FDBBF82FFE3C69B1FA</p>

*Applicable section version numbers and dates as listed in Overview and Control Document table, Version 1.1, dated 29JAN2021

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