

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

MTN-043 Study-Specific Procedures Manual Overview and Control Document – Version History and Notice of Changes

				<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.**

MTN-043 Study-Specific Procedures Manual Overview and Control Document – Version History and Notice of Changes

SSP Approval Sheet

Review Period: 15JAN2021-29JAN2021

Entity	Sections Approved*	Print Name, Role	Signature/Date
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>

MTN-043 Study-Specific Procedures Manual Overview and Control Document – Version History and Notice of Changes

SCHARP CDM	Sections 5, 7-8, 11-13	Jillian Zemanek, SCHARP	<p>DocuSigned by: <i>Jillian Zemanek</i></p> <p>Signer Name: Jillian Zemanek Signing Reason: I approve this document Signing Time: 29-Jan-2021 09:05 PST 0A9B7C2E2AE24BFDB35EED6E8C63B31D</p>
MTN Pharmacy Director	Section 6	Cindy Jacobson, MTN LOC	<p>DocuSigned by: <i>Cindy Jacobson</i></p> <p>Signer Name: Cindy Jacobson Signing Reason: I approve this document Signing Time: 29-Jan-2021 08:47 PST B95A8DD6DFB747E7875F2D30389AF738</p>
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>
RTI Qualitative Research Coordinator	Section 14	Elizabeth Montgomery, RTI	<p>DocuSigned by: <i>Elizabeth Montgomery</i></p> <p>Signer Name: Elizabeth Montgomery Signing Reason: I have read and understand the contents of this document Signing Time: 01-Feb-2021 15:48 PST ABA7F81CF3BC4B24BA2C3B0521617943</p>
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

Certificate Of Completion

Envelope Id: AC40F84E1DA24515848618258D4338BD	Status: Completed
Subject: Please DocuSign: MTN-043 SSP Overview and Version Control_V1.1_29JAN2021.docx	
CF02:	
Project Code/Charge Code: 100123.801.001	
Source Envelope:	
Document Pages: 4	Signatures: 9
Certificate Pages: 7	Initials: 0
AutoNav: Enabled	Envelope Originator:
Envelopeld Stamping: Enabled	Rachel Scheckter
Time Zone: (UTC-05:00) Eastern Time (US & Canada)	359 Blackwell Street, Suite 200
	Durham, NC 27701-2477
	RScheckter@fhi360.org
	IP Address: 174.99.32.81

Record Tracking

Status: Original	Holder: Rachel Scheckter	Location: DocuSign
1/29/2021 11:08:52 AM	RScheckter@fhi360.org	

Signer Events

Cindy Jacobson
 rosecj@mwri.magee.edu
 Security Level: Email, Account Authentication (Required)

Signature

Cindy Jacobson

Signature Adoption: Pre-selected Style
 Signature ID:
 B95A8DD6-DFB7-47E7-875F-2D30389AF738
 Using IP Address: 128.147.28.61

With Signing Authentication via DocuSign password
 With Signing Reasons (on each tab):
 I approve this document

Timestamp

Sent: 1/29/2021 11:14:27 AM
 Viewed: 1/29/2021 11:46:46 AM
 Signed: 1/29/2021 11:47:34 AM

Electronic Record and Signature Disclosure:
 Accepted: 11/18/2019 10:29:41 AM
 ID: 84d2f0b8-77cd-44ed-870a-a7f2fe1744d8

Edward Livant
 elivant@mwri.magee.edu
 Security Level: Email, Account Authentication (Required)

DocuSigned by:

 9E61B06A181441D...

Signature Adoption: Uploaded Signature Image
 Signature ID:
 9E61B06A-1814-41D3-A698-FBE00AECF2FC
 Using IP Address: 74.109.253.60

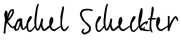
With Signing Authentication via DocuSign password
 With Signing Reasons (on each tab):
 I approve this document

Sent: 1/29/2021 11:14:28 AM
 Viewed: 2/1/2021 9:38:02 AM
 Signed: 2/1/2021 9:38:27 AM

Electronic Record and Signature Disclosure:
 Accepted: 2/1/2021 9:38:02 AM
 ID: bc54f24b-b9d8-46e2-89a7-ffd6126fe910

Signer Events	Signature	Timestamp
<p>Elizabeth Montgomery emontgomery@rti.org Security Level: Email, Account Authentication (Required)</p>	<p><i>Elizabeth Montgomery</i></p> <p>Signature Adoption: Pre-selected Style Signature ID: ABA7F81C-F3BC-4B24-BA2C-3B0521617943 Using IP Address: 161.69.123.10</p> <p>With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I have read and understand the contents of this document</p>	<p>Sent: 1/29/2021 11:14:27 AM Viewed: 2/1/2021 6:48:17 PM Signed: 2/1/2021 6:48:46 PM</p>
<p>Electronic Record and Signature Disclosure: Accepted: 11/12/2019 1:17:18 PM ID: e942b155-8ebe-43d0-a28e-832abbb702c3</p>	<p>DocuSigned by: Jennifer Balkus A34808D98D9B4F0...</p> <p>Signature Adoption: Pre-selected Style Signature ID: A34808D9-8D9B-4F0F-9AE8-C02F036FB20F Using IP Address: 97.113.136.106</p> <p>With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I approve this document</p>	<p>Sent: 1/29/2021 11:14:26 AM Viewed: 1/29/2021 5:52:58 PM Signed: 1/29/2021 5:53:22 PM</p>
<p>Jennifer Balkus jbalkus@uw.edu Security Level: Email, Account Authentication (Required)</p>	<p><i>Jillian Zemanek</i></p> <p>Signature Adoption: Pre-selected Style Signature ID: 0A9B7C2E-2AE2-4BFD-B35E-ED6E8C63B31D Using IP Address: 140.107.0.10</p> <p>With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I approve this document</p>	<p>Sent: 1/29/2021 11:14:26 AM Viewed: 1/29/2021 12:05:04 PM Signed: 1/29/2021 12:05:45 PM</p>
<p>Electronic Record and Signature Disclosure: Accepted: 1/29/2021 5:52:58 PM ID: b76de616-bd40-4a21-a966-5ee20b77f2f7</p>	<p>Jillian Zemanek</p> <p>Signature Adoption: Pre-selected Style Signature ID: 0A9B7C2E-2AE2-4BFD-B35E-ED6E8C63B31D Using IP Address: 140.107.0.10</p> <p>With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I approve this document</p>	<p>Sent: 1/29/2021 11:14:26 AM Viewed: 1/29/2021 12:05:04 PM Signed: 1/29/2021 12:05:45 PM</p>
<p>Electronic Record and Signature Disclosure: Accepted: 2/3/2020 3:28:47 PM ID: e9c3b0d5-937d-46bf-9d5f-0d4e45493bc9</p>		

Signer Events	Signature	Timestamp
<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: 128.147.28.1</p> <p>With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I have read and understand the contents of this document</p>	<p>Sent: 1/29/2021 11:14:27 AM Viewed: 2/1/2021 2:49:29 PM Signed: 2/1/2021 2:50:25 PM</p>
<p>Electronic Record and Signature Disclosure: Accepted: 11/15/2019 2:50:55 PM ID: e92d1b54-e48b-4ca6-b4a1-c266a5b5dbe5</p>		
<p>Lisa Noguchi lnoguch1@jhu.edu Security Level: Email, Account Authentication (Required)</p>	<p><i>Lisa Noguchi</i></p> <p>Signature Adoption: Pre-selected Style Signature ID: 4E53F8B5-49F9-4E4E-881F-76E2DD7BB77E Using IP Address: 66.44.20.191</p> <p>With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I approve this document</p>	<p>Sent: 1/29/2021 11:14:26 AM Viewed: 1/29/2021 4:07:18 PM Signed: 1/29/2021 4:08:26 PM</p>
<p>Electronic Record and Signature Disclosure: Accepted: 6/4/2020 12:01:33 PM ID: d54d0ebd-2a07-46fd-8f88-fabe6d01c28f</p>		
<p>Maxensia Owor maxowor@mujhu.org Security Level: Email, Account Authentication (Required)</p>	<p><i>Maxensia Owor</i></p> <p>Signature Adoption: Pre-selected Style Signature ID: EB6268F1-0B83-4F16-A064-C6A46F8CFE64 Using IP Address: 197.221.140.226</p> <p>With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I approve this document</p>	<p>Sent: 1/29/2021 11:14:25 AM Viewed: 2/1/2021 10:20:31 AM Signed: 2/1/2021 10:21:28 AM</p>
<p>Electronic Record and Signature Disclosure: Accepted: 3/13/2020 11:24:59 AM ID: ec601af5-b2bf-4e87-88ce-70fa90e2d2c9</p>		

Signer Events	Signature	Timestamp
Rachel Scheckter rscheckter@fhi360.org Family Health International Inc - Part 11 Security Level: Email, Account Authentication (Required)	 Signature Adoption: Pre-selected Style Signature ID: DC982545-4438-4F8F-AC05-B6FFC06BE68D Using IP Address: 174.99.32.81 With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I approve this document	Sent: 1/29/2021 11:14:27 AM Viewed: 1/29/2021 11:14:51 AM Signed: 1/29/2021 11:15:17 AM
Electronic Record and Signature Disclosure: Accepted: 11/10/2019 1:24:12 AM ID: 46522219-4435-4b7d-b2f6-11bbd696ef45		
In Person Signer Events	Signature	Timestamp
Editor Delivery Events	Status	Timestamp
Agent Delivery Events	Status	Timestamp
Intermediary Delivery Events	Status	Timestamp
Certified Delivery Events	Status	Timestamp
Carbon Copy Events	Status	Timestamp
Witness Events	Signature	Timestamp
Notary Events	Signature	Timestamp
Envelope Summary Events	Status	Timestamps
Envelope Sent	Hashed/Encrypted	1/29/2021 11:14:28 AM
Certified Delivered	Security Checked	1/29/2021 11:14:51 AM
Signing Complete	Security Checked	1/29/2021 11:15:17 AM
Completed	Security Checked	2/1/2021 6:48:46 PM
Payment Events	Status	Timestamps
Electronic Record and Signature Disclosure		

ELECTRONIC RECORD AND SIGNATURE DISCLOSURE

From time to time, Family Health International Inc - Part 11 (we, us or Company) may be required by law to provide to you certain written notices or disclosures. Described below are the terms and conditions for providing to you such notices and disclosures electronically through the DocuSign system. Please read the information below carefully and thoroughly, and if you can access this information electronically to your satisfaction and agree to this Electronic Record and Signature Disclosure (ERSD), please confirm your agreement by selecting the check-box next to 'I agree to use electronic records and signatures' before clicking 'CONTINUE' within the DocuSign system.

Getting paper copies

At any time, you may request from us a paper copy of any record provided or made available electronically to you by us. You will have the ability to download and print documents we send to you through the DocuSign system during and immediately after the signing session and, if you elect to create a DocuSign account, you may access the documents for a limited period of time (usually 30 days) after such documents are first sent to you. After such time, if you wish for us to send you paper copies of any such documents from our office to you, you will be charged a \$0.00 per-page fee. You may request delivery of such paper copies from us by following the procedure described below.

Withdrawing your consent

If you decide to receive notices and disclosures from us electronically, you may at any time change your mind and tell us that thereafter you want to receive required notices and disclosures only in paper format. How you must inform us of your decision to receive future notices and disclosure in paper format and withdraw your consent to receive notices and disclosures electronically is described below.

Consequences of changing your mind

If you elect to receive required notices and disclosures only in paper format, it will slow the speed at which we can complete certain steps in transactions with you and delivering services to you because we will need first to send the required notices or disclosures to you in paper format, and then wait until we receive back from you your acknowledgment of your receipt of such paper notices or disclosures. Further, you will no longer be able to use the DocuSign system to receive required notices and consents electronically from us or to sign electronically documents from us.

All notices and disclosures will be sent to you electronically

Unless you tell us otherwise in accordance with the procedures described herein, we will provide electronically to you through the DocuSign system all required notices, disclosures, authorizations, acknowledgements, and other documents that are required to be provided or made available to you during the course of our relationship with you. To reduce the chance of you inadvertently not receiving any notice or disclosure, we prefer to provide all of the required notices and disclosures to you by the same method and to the same address that you have given us. Thus, you can receive all the disclosures and notices electronically or in paper format through the paper mail delivery system. If you do not agree with this process, please let us know as described below. Please also see the paragraph immediately above that describes the consequences of your electing not to receive delivery of the notices and disclosures electronically from us.

How to contact Family Health International Inc - Part 11:

You may contact us to let us know of your changes as to how we may contact you electronically, to request paper copies of certain information from us, and to withdraw your prior consent to receive notices and disclosures electronically as follows:

To contact us by email send messages to: nzimmerman@fhi360.org

To advise Family Health International Inc - Part 11 of your new email address

To let us know of a change in your email address where we should send notices and disclosures electronically to you, you must send an email message to us at nzimmerman@fhi360.org and in the body of such request you must state: your previous email address, your new email address. We do not require any other information from you to change your email address.

If you created a DocuSign account, you may update it with your new email address through your account preferences.

To request paper copies from Family Health International Inc - Part 11

To request delivery from us of paper copies of the notices and disclosures previously provided by us to you electronically, you must send us an email to nzimmerman@fhi360.org and in the body of such request you must state your email address, full name, mailing address, and telephone number. We will bill you for any fees at that time, if any.

To withdraw your consent with Family Health International Inc - Part 11

To inform us that you no longer wish to receive future notices and disclosures in electronic format you may:

- i. decline to sign a document from within your signing session, and on the subsequent page, select the check-box indicating you wish to withdraw your consent, or you may;
- ii. send us an email to nzimmerman@fhi360.org and in the body of such request you must state your email, full name, mailing address, and telephone number. We do not need any other information from you to withdraw consent.. The consequences of your withdrawing consent for online documents will be that transactions may take a longer time to process..

Required hardware and software

The minimum system requirements for using the DocuSign system may change over time. The current system requirements are found here: <https://support.docusign.com/guides/signer-guide-signing-system-requirements>.

Acknowledging your access and consent to receive and sign documents electronically

To confirm to us that you can access this information electronically, which will be similar to other electronic notices and disclosures that we will provide to you, please confirm that you have read this ERSD, and (i) that you are able to print on paper or electronically save this ERSD for your future reference and access; or (ii) that you are able to email this ERSD to an email address where you will be able to print on paper or save it for your future reference and access. Further, if you consent to receiving notices and disclosures exclusively in electronic format as described herein, then select the check-box next to ‘I agree to use electronic records and signatures’ before clicking ‘CONTINUE’ within the DocuSign system.

By selecting the check-box next to ‘I agree to use electronic records and signatures’, you confirm that:

- You can access and read this Electronic Record and Signature Disclosure; and
- You can print on paper this Electronic Record and Signature Disclosure, or save or send this Electronic Record and Disclosure to a location where you can print it, for future reference and access; and
- Until or unless you notify Family Health International Inc - Part 11 as described above, you consent to receive exclusively through electronic means all notices, disclosures, authorizations, acknowledgements, and other documents that are required to be provided or made available to you by Family Health International Inc - Part 11 during the course of your relationship with Family Health International Inc - Part 11.