MTN-042 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 1.1 1.2 1.3	19DEC2019 9APR2020 30JUN2020 17MAY2021	• Added reference to CM#01 and CM#02 to section 1.1 • Added reference to COVID-19 MTN-042 Contingency Plan to section 1.1 • Updated DAIDS policy references • Added guidance around documentation of training and qualifications to section 1.3 • Clarified that separate activation is not required for each cohort of the study in section 1.5
2	Documentation Requirements	1.0 1.1	19DEC2019 17MAY2021	• Updated DAIDS policy references • COVID preparedness checklist, Cohort 2 readiness checklist, and equipment calibration records added to list of study essential documents in section 2.1 • Clarified that participant declines of study product should be reported as protocol deviations in section 2.9 • Added guidance on how to report significant deviations following the obsoletion of the DAIDS critical events policy to section 2.9 • Reorganized record retention section 2.13 for clarity
3	Accrual and Retention	1.0 1.1 1.2 1.3	19DEC2019 9APR2020 30JUN2020 17MAY2021	• Added reference to cohort-specific readiness checklists and the IRP SOP to section 3.2.2 • Clarified that aside from the PPO visit, missed visits are not expected to be made up in section 3.3.1
4	Informed Consent	1.0 1.1	19DEC2019 17MAY2021	• Added reference to cohort-specific mother ICF in section 4.0 • Updates to DAIDS policy references • Added DAIDS guidance on timing of consent and re-consent of ICFs in 4.9
5	Study Procedures	1.0 1.1 1.2 1.3	19DEC2019 9APR2020 30JUN2020 17MAY2021	• Updated DAIDS policy references • Added guidance for providing IRP recommendations during IC process in section 5.3 • Removed cohort 1 reference to rescreening in section 5.3 • Added guidance for obtaining adequate ultrasound results for screening and updated GA parameters from cohort 1 to cohort 2 in section 5.3.1

				• Updated guidance for PTID Name Linkage and logs and Screening and Enrollment Log for cohort 2 in section 5.3.2 • Added SSP section references for GA dating in 5.4.11 • Revised IDI selection criteria and behavioral assessment guidance at Enrollment visits in section 5.4.1.2 • Updated follow-up visit types for cohort 2 in section 5.5 • Clarified guidance for conducting the PPO Phone contact and PPO visit in section 5.5 • Updated follow-up visit procedures for cohort 2 in section 5.5.3 • Clarified missed visit guidance in section 5.5.5 • Removed references to pre-LOA #1 procedures for infant seroconversion in section 5.6.3 • Clarified that participants who experience a pregnancy loss will be followed per their original visit scheduled in section 5.7 • Added access to HIV prevention product to referrals upon study exit in section 5.13.5 • Added guidance for documenting contacts made with participants for study results dissemination in section 5.13.6
6	Study Product Considerations for Non-Pharmacy Staff	1.0 1.1	19DEC2019 9APR2020	• No updates
7	Clinical Considerations	1.0 1.1 1.2	19DEC2019 9APR2020 17MAY2021	• Updated section 7.7 per protocol requirements for cohort 2 ultrasound results to be performed no later than the 28th week gestational age (GA) • Added clarification to section 7.7 regarding specific GA that ultrasounds must be from for all cohorts • Added reference to new gestational age redating tool to SSP section 7.8 and clarified the column headings in the table for redating based on ultrasounds

				• Added a reminder to section 7.10.2 that outcomes reported on the PO CRF should be reconciled with any maternal AEs reported prior to the mother's study exit • Specified that calibration records should be maintained as part of study essential documents in 7.11.1.1 • Updated section 7.12.5 to be reflective of vaginal swab changes issued as part of operational guidance #02 and clarification memo #02 • Added guidance for documentation of product holds for the reason of "suspected onset of labor or rupture of membranes" to section 7.17 • Added a footnote to table 7-3 to note the conditions that are scheduled reasons for discontinuation per protocol • Removed references to pre-LOA #1 procedures for infant creatinine testing in section 7.19.3 • Updated guidance regarding assessment, reporting, and photographing suspected congenital anomalies in sections 7.19.8 and 7.19.9 • Added the WHO guidelines for best practices in infant phlebotomy to section 7.19.11
8	Adverse Event Reporting and Safety Monitoring	1.0 1.1 1.2 1.3	19DEC2019 9APR2020 30JUN2020 17MAY2021	• Guidance on reporting intrapartum hemorrhage was added to section 8.4, and a grading table for this condition was added to 8.5 • Guidance on grading cephalon-pelvic disproportion as grade 2 was added to section 8.12.1 • Updates were made to AE reporting requirements for congenital anomalies in section 8.17 • Reference on archived DAIDS policy removed from section 8.19 • Updated assessment of social harms frequency in section 8.24 to include 1st 4-week Visit as per protocol schedule of procedures for Cohort 2
9	Counseling Considerations	1.0 1.1	19DEC2019 9APR2020	• No updates
10	Laboratory Considerations	1.0 1.1	19DEC2019 9APR2020	• No updates

		1.2 1.3	30JUN2020 01FEB2021	
11	Data Collection	1.0 1.1 1.2 1.3	19DEC2019 9APR2020 30JUN2020 17MAY2021	• Updated SCHARP study team member list • Updated guidance for documenting a second screening attempt • Updated pre-PO visits throughout to include up to visit 13 • Changed references to week 2 and week 4 bi-weekly visits to 2-week and 4-week visits • Updated tables 1 and 3 to include cohort 2 visits • Updated table 5 to list forms for cohort 2 visits
12	Data Communiques	1.0	19DEC2019	• (no updates)
13	Reporting Plan	1.0 1.1	19DEC2019 17MAY2021	• Updated SCHARP study team member list • Removed Mother-Infant Listing
14	DELIVER Qualitative Component	1.0 1.1	19DEC2019 9APR2020	• Updates related to cohort 2 will be released separately

***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: 01APR2021—14MAY2021

Entity	Sections Approved*	Print Name, Role	Signature/Date
Protocol Chair	All Sections	Katherine Bunge, Protocol Chair	DocuSigned by: Katherine Bunge Signer Name: Katherine Bunge Signing Reason: I have read and understand the contents of this document Signing Time: 17-May-2021 | 13:23 PDT 7ED1C5A6877240FDBBF82FFE3C69B1FA
Protocol Chair	All Sections	Bonus Makanani, Protocol Chair	DocuSigned by: Bonus Makanani Signer Name: Bonus Makanani Signing Reason: I approve this document Signing Time: 18-May-2021 | 02:03 PDT B645CFD21C1F43BC9147C2D6D6471DC3
Protocol Co-Chair	All Sections	Lee Fairlie, Protocol Chair	DocuSigned by: Lee Fairlie Signer Name: Lee Fairlie Signing Reason: I approve this document Signing Time: 17-May-2021 | 23:18 PDT 5532C86B99CA4262B4DEBCAE10D33C14
FHI 360 CRM	All Sections	Ashley Mayo, FHI 360	DocuSigned by: Ashley Mayo Signer Name: Ashley Mayo Signing Reason: I approve this document Signing Time: 17-May-2021 | 16:18 EDT E35C3483DC334F639685A017DB5F043C

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SCHARP CDM	Sections 5, 7-8, 11-13	Tanya Harrell, SCHARP	DocuSigned by: Tanya Harrell Signer Name: Tanya Harrell Signing Reason: I approve this document Signing Time: 17-May-2021 | 16:33 EDT 7CFE3850AA7E4DCB84A1AE4FF6736AD0
Protocol Safety Physician	Sections 7, 8	Catherine Chappell, MTN LOC	DocuSigned by: Catherine Chappell Signer Name: Catherine Chappell Signing Reason: I approve this document Signing Time: 18-May-2021 | 12:21 CDT 15F372D806EC4E9C9175092C8F464FB1

**Applicable section version numbers and dates as listed in Overview and Control Document table, Version 1.4, dated 17MAY2021*

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Katherine Bunge kbunge@mail.magee.edu Security Level: Email, Account Authentication (Required)	 Signature Adoption: Pre-selected Style Signature ID: 7ED1C5A6-8772-40FD-BBF8-2FFE3C69B1FA Using IP Address: 128.147.28.1 With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I have read and understand the contents of this document	Sent: 5/17/2021 4:18:03 PM Viewed: 5/17/2021 4:22:55 PM Signed: 5/17/2021 4:23:44 PM
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Lee Fairlie LFairlie@wrhi.ac.za Security Level: Email, Account Authentication (Required)	 Signature Adoption: Pre-selected Style Signature ID: 5532C86B-99CA-4262-B4DE-BCAE10D33C14 Using IP Address: 41.193.90.114 With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I approve this document	Sent: 5/17/2021 4:18:03 PM Viewed: 5/18/2021 2:18:00 AM Signed: 5/18/2021 2:19:07 AM
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Tanya Harrell tharrell@scharp.org Security Level: Email, Account Authentication (Required)	 Signature Adoption: Pre-selected Style Signature ID: 7CFE3850-AA7E-4DCB-84A1-AE4FF6736AD0 Using IP Address: 140.107.0.10 With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I approve this document	Sent: 5/17/2021 4:18:03 PM Viewed: 5/17/2021 4:32:19 PM Signed: 5/17/2021 4:33:40 PM
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