MATRIX-007 SSP Overview and Control Log

#	Title	Version, date	Summary of Changes
1	Introduction, Study Activation & Documentation Requirements	V1.0 14NOV2024	• Section 1.1 added CM #1 • Table 1-4 minor updates • Section 1.11 updated review guidance for Protocol Deviations • Other minor editorial updates
2	Study Structure and Oversight	V1.0 14NOV2024	• Section 2.1.5 added Country Data Manager role
3	Informed Consent	V1.0 14NOV2024	• Section 3.6 updated reconsenting guidance • Section 3.8 added guidance for study resumption
4	Accrual and Retention	V1.0 14NOV2024	No changes
5	Study Procedures	V1.0 14NOV2024	• Section 5.4.3 added guidance for PD reporting • Section 5.5.2 added guidance for off-site visit locations • Section 5.6 added guidance for split visit reasons • Section 5.7 updated guidance on phone contact reasons • Section 5.8 removed guidance to report PDs for missed visits • Section 5.9 added interim visit criteria, visit code guidance, and examples • Section 5.10 updated guidance on exiting participants after a pregnancy loss • Section 5.11 updated guidance on exiting participants after an infant loss • 5.13 added guidance for omitting HIV testing for participant who seroconvert and additional references • Section 5.15 updated participant transfer procedures • Section 5.16 added more guidance on study exit • Section • Section 5.17 updated guidance or rejoining study • Other minor editorial updates
6	Clinical and Safety Considerations	V1.0 14NOV2024	• Section 6.1 clarified guidance for obtaining medical records • Section 6.2.3 clarified abstraction guidance • Section 6.3.3 added guidance about reportable medications

			• Section 6.3.3.1 clarified to PrEP use documentation • Section 6.4.4 clarified ultrasound procedures • Section 6.5.1 modifications to pregnancy dating • Section 6.7 changed location of Infant Outcome CRF in REDCap and added guidance on documenting maternal death • Section 6.9 updated guidance for verifying POC proficiency certification for study staff • Section 6.9.2 added guidance for omitting HIV testing for participants who seroconvert • 6.9.3 updated syphilis testing guidance • Section 6.10 updates to infant medical and medications guidance • Section 6.12.1 revision of infant growth measurement procedures • 6.12.2 minor updates to infant surface exam procedure • Section 6.13 updated guidance on congenital anomalies, including how to use the GBD App. • Section 6.13.4 updated to CA review process
7	Data Collection and Management	V1.0 14NOV2024	• Section 7.2 added to describe CARE PrEP Data SharePoint • Section on general REDCap completion guidelines moved to the CCRF Completion Guidelines document • Other minor editorial updates
8	Data Communique and Operational Guidance	V1.0 14NOV2024	• Minor editorial updates
9	Data Reporting Plan	PENDING	
10	Study Closeout	PENDING	