

HPTN 035 Study Specific Procedures Manual

Overview of Section Contents and Identification of Current Section Versions

Section Number	Section Title	Current Version Number	Current Version Date	Comments
1	Introduction	2.0	31 JAN 07	Prior references to HPTN replaced where applicable with references to MTN; prior references to HPTN CL replaced where applicable with references to HPTN NL and/or MTN NL.
2	Protocol	2.0	31 JAN 07	Entire section updated to incorporate Protocol Version 3.0.
3	Documentation Requirements	2.0	31 JAN 07	<ul style="list-style-type: none"> • Prior references to HPTN replaced where applicable with references to MTN. • Section 3.4 updated to reflect protocol Version 3.0.
4	Participant Accrual	2.0	31 JAN 07	<ul style="list-style-type: none"> • Prior references to HPTN replaced where applicable with references to MTN. • Participant accrual targets updated to reflect protocol Version 3.0. • Past tense verbs used when describing the completed Phase II portion of the study.
5	Informed Consent	2.0	31 JAN 07	<ul style="list-style-type: none"> • Prior references to HPTN replaced where applicable with references to MTN. • Section 5.6 updated to reflect completion of piloting of ongoing informed consent comprehension assessment procedures. • Section 5.6.4 updated to reflect the requirement to record comment codes on the ICC-1 DataFax form. • Section Appendix 5-5 updated to include the current version of the Ongoing Informed Consent Comprehension Checklist (dated 14 DEC 06).
6	Participant Follow-up	2.4	18 APR 08	Updated Section 6.12 to reflect current study close-out plans.

HPTN 035 Study Specific Procedures Manual

Overview of Section Contents and Identification of Current Section Versions

Section Number	Section Title	Current Version Number	Current Version Date	Comments
7	Visit Checklists	2.3	1 APR 08	Updated study exit visit checklists to reflect administration of the Follow-up Partner Status form.
8	Participant Retention	2.0	31 JAN 07	<ul style="list-style-type: none"> • Prior references to HPTN replaced where applicable with references to the MTN. • Section 8.6 updated to include additional guidance for managing participant-initiated withdrawal from the study.
9	Study Product Considerations for Non-Pharmacy Staff	2.0	31 JAN 07	Prior references to HPTN replaced where applicable with references to MTN.
10	Clinical Considerations	2.1	7 NOV 07	<ul style="list-style-type: none"> • Section 10.4.2 updated to reflect collection of vaginal fluid swabs for archive at non-US sites. • PSRT Query Form updated to reflect current email addresses for Protocol Safety Physicians.
11	Adverse Event Reporting and Safety Monitoring	2.1	1 AUG 07	Section Appendix 11-2 updated to reflect current PSRT composition and current MTN CORE contacts.
12	Laboratory Considerations	2.1	7 NOV 07	<ul style="list-style-type: none"> • Section 12.3 updated to reflect the current version of LDMS (Version 5.5.4). • Section 12.5.7 updated to reflect current plans for HSV-2 testing. • Section 12.6.5 added to specify procedures for collection and storage of vaginal fluid swabs at non-US sites.
13	Data Collection	2.1	24 OCT 07	Updated to include the Protocol V3 LOA1 Consents form and the Vaginal Swab Collection form.
14	Data Communiqués	2.0	31 JAN 07	<ul style="list-style-type: none"> • Prior references to HPTN replaced where applicable with references to MTN. • Sixteen communiqués have been issued to date.

HPTN 035 Study Specific Procedures Manual
Overview of Section Contents and Identification of Current Section Versions

Section Number	Section Title	Current Version Number	Current Version Date	Comments
15	Study Reporting Plan	2.1	31 JAN 07	<ul style="list-style-type: none"> • Prior references to HPTN replaced where applicable with references to MTN. • Entire section updated to list current SDMC study staff and current study reporting procedures.
16	DAIDS SOPs for Essential Documents and Source Documentation	2.0	01 AUG 02	Current version available from DAIDS