HPTN 084-01 Study-Specific Procedures Manual Overview and Version Control

Section Number	Section Title	Current Version Number	Current Version Date	Updates and Comments
1	Introduction	1.3	20Apr2022	Updates for Version 1.3 (20Apr2022) • Updated contact information in Table 1-1 • Section 1.4: Added references to the DAIDS Score Manual and removed references to archived DAIDs policy. • Section 1.5.4: Removed references to Advarra as it does not pertain to this study. • Section 1.5.6: Updated links for the template, instructions, and policy of the Delegation of Duties Log.
2	Protocol	1.3	6Dec2022	Updates for Version 1.3 (6Dec2022) • Added CM #2 to Protocol V1.0 • Added LoA #4 to Protocol V1.0 Updates for Version 1.2 (20Apr2022) • Added LoA #3 to Protocol V1.0

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3	Document Requirements	1.2	20Apr2022	Updates for Version 1.2 (20Apr2022) • Section 3.2: Updated links referencing Essential Documents that study sites must maintain for DAIDS sponsored studies. Added reference to generic non-FDA approved TDF/FTC, now allowable for site procurement in LoA #3 (V1.0) of the protocol. Updated links for reference materials. • Section 3.3: Added reference and links to the DAIDS Score Manual. • Section 3.3.1: Added two links to the Source Documentation standards and requirements. • Section 3.3.3.1: Added references to Source Documentation Requirements within the DAIDS Score Manual.
4	Recruitment Screening and Enrollment	1.1	04Feb2021	Updates for Version 1.1 (04Feb2021) • Only the footer was updated as per updated version of the SSP manual. No other edits were made.
5	Study Procedures	1.2	20Apr2022	Updates for Version 1.2 (20Apr2022) • Section 5.3: Updated the number of Appendices to include IV and V. Added a new paragraph providing details on how to manage participants transitioning to the HPTN 084 OLE (open label extension).

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6	Visit Checklists	1.3	6Dec2022	Updates for Version 1.3 (6Dec2022) • Step 2: Safety Visit – Added HCV testing to Week 33 of Step 2. Updates for Version 1.2 (20Apr2022) • Step 2: Safety Visit – Added a note about the provision of TDF/FTC only if the participant chooses to not remain on injections in Step 3. Added info about required HIV testing (inclusive of viral load), now to be done at all visits. • Step 2: Remaining Injection Visits - Added note that HIV testing is done for all visits. • Step 3: Open-label daily oral TDF/FTC – Week +8 is added back to targeted medical history and physical exam. Added HIV (inclusive of viral load RNA) testing to all visits. Removed Week +8 from CBC with differential. LFTs and chemistry panel are at Week +24 and +48 only. Added a clarifying note that GC/CT testing and Urinalysis are completed at all weeks except Week +8. Added adherence counseling to all visits except Week +8.
7	Participant Retention	1.1	04Feb2021	Updates for Version 1.1 (04Feb2021) • Only the footer was updated as per updated version of the SSP manual. No other edits were made.

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8	Study Product Considerations	1.2	29Apr2022	Updates for Version 1.2 (29Apr2022) • Section 8.1.5 – Updated section to reflect the option to enroll in open-label extension if the participant prefers to continue CAB-LA. • Added references to TDF/FTC throughout.
9	Clinical Considerations	1.2	20Apr2022	Updates for Version 1.2 (20Apr2022) • Section 9.1 – Added data communiqués as a resource for instructions on the EDC systems. • Section 9.4 – Corrected weeks for targeted physical examination, which now included week +8. • Section 9.4.4 – Weight will be recorded at every visit, including week +8. • Section 9.4.8.1 – Added instructions for sites to follow the appropriate DAIDS policy when procuring generic non-FDA approved TDF/FTC. • Section 9.4.8.2 – Clarified to state that the CMC consultation is required when prescribing precautionary or prohibited medications. • Section 9.7.3 – Added a note about reload injections in the case of a missed or late injection. • Section 9.8 – Added clarification to continue using Schwartz equation for participants over 18. • Section 9.11 – Added clarifying language to HIV testing considerations during study conduct.

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10	Adverse Event Reporting and Safety Monitoring	1.2	20Apr2022	Updates for Version 1.2 (20Apr2022) • Section 10.9 – Updated links.
11	Laboratory and Specimen Management Procedures	1.3	6Dec2022	Updates for Version 1.4 (6Dec2022) • Table 11-2 – Added HCV testing to Week 33 • Section 11.3.2 – Added HCV testing at Week 33 Updates for Version 1.3 (20Apr2022) • Section 11.1 – Updated links • Table 11-3 – Removed fasting lipid profile and footnote #3. Added clarifying language in footnote 1# to describe HIV RNA testing. • Table 11-4 – Added footnote #3 about HIV viral load. • Section 11.6 – Added clarifying language regarding plasma shipping.
12	Counseling Considerations	1.2	20Apr2022	Updates for Version 1.2 (20Apr2022) • Section 12.1 – Removed the exception of HIV pre-/post testing. • Section 12.2 – Removed the exception of HIV pre-/post testing. • Section 12.3 – added clarifying language regarding Steps 1 and 3, if TDF/FTC is chosen. • Section 12.4 – Added a note regarding instructions for product use of TDF/FTC.

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13	Data Management	1.2	29Apr2022	Updates for Version 1.2 (29Apr2022) • Added references to the HPTN 084 SSP throughout if the participant chooses the Open-Label Extension.
14	Computer Assisted Self-Interview (CASI)	1.1	04Feb2021	Updates for Version 1.1 (04Feb2021) • Minor formatting

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15	Reporting Plan	1.1	04Feb2021	Updates for Version 1.1 (04Feb2021) • Minor formatting
16	Data Communiques	1.1	04Feb2021	Updates for Version 1.1 (04Feb2021) • Minor formatting

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17	Qualitative	1.0	21Oct2021	Updates for Version 1.0 (21Oct2021) • New section
Appendix Ia	Record of Dispensation of Participant-Specific Study Product to Non-Pharmacy Staff	1.1	04Feb2021	Updates for Version 1.1 (04Feb2021) • No edits were made.

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Appendix Ib	Record of Return of Participant-Specific Study Product by Non-Pharmacy Staff	1.1	04Feb2021	Updates for Version 1.1 (04Feb2021) • No edits were made.
Appendix II	Participant Transfer and Receipt	1.1	04Feb2021	Updates for Version 1.1 (4Feb2021) • No edits were made.

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Appendix III	Guidance for Management of "discordant/discrepant" HIV testing results.	2.1	16Nov2021	This is an updated Guidance for HIV testing results, to reflect parent study milestones.
Appendix IV	Study Schema Graphic	1.0	12Aug2019	