

## 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	1.2	15Feb2021	<p><u>Updates for Version 1.1 (04Feb2021)</u></p> <ul style="list-style-type: none"> <li>• Updated contact information in Table 1-1</li> </ul> <p><u>Updates for Version 1.2 (15Feb2021)</u></p> <ul style="list-style-type: none"> <li>• Included new language clarifying what should be reported in case of ‘critical events’ in the study, since DAIDS is retiring their Critical Events (CE) policy.</li> </ul>
2	Protocol	1.1	04Feb2021	<p><u>Updates for Version 1.1 (04Feb2021)</u></p> <ul style="list-style-type: none"> <li>• Added LoA #1 to Protocol V1.0 and CM #1 to LoA #1.</li> </ul>

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3	Document Requirements	1.1	04Feb2021	<p><u>Updates for Version 1.1 (04Feb2021)</u></p> <ul style="list-style-type: none"> <li><u>Table 3-2</u> – Updated Inclusion Criteria for “at enrollment, body weight” eligibility requirements; added inclusion criterion for participants currently on PrEP from a non-study source. Updated Eligibility Requirements to remove exclusion criterion for self-reported unprotected anal intercourse with someone living with HIV, greater than or equal to 5 partners, and illicit injection drug use (in last 6 months).</li> </ul>
4	Recruitment Screening and Enrollment	1.1	04Feb2021	<p><u>Updates for Version 1.1 (04Feb2021)</u></p> <ul style="list-style-type: none"> <li>Only the footer was updated as per updated version of the SSP manual. No other edits were made.</li> </ul>

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5	Study Procedures	1.1	04Feb2021	<p><u>Updates for Version 1.1 (04Feb2021)</u></p> <ul style="list-style-type: none"> <li>• <u>Section 5.2</u> – Added a note in Step 3 that participants also have the option to join an open-label CAB study.</li> </ul>
6	Visit Checklists	1.1	04Feb2021	<p><u>Updates for Version 1.1 (04Feb2021)</u></p> <ul style="list-style-type: none"> <li>• <u>Section 6.4</u> – Eligibility Checklist updated to add several clarifications to the inclusion and exclusion criteria.</li> <li>• <u>Screening Visit</u> – Added note about demographic information, which can now also be collected at screening (not just enrollment).</li> <li>• <u>Step 1: Enrollment, Week 0:</u> Added procedure to administer PHQ-9 (at Enrollment only); added a clarification about collecting demographic information; removed oral swabs.</li> <li>• <u>Step 2: Week 5 Visit</u> – Removed Fasting lipid profile.</li> <li>• <u>Step 2: Weeks 6, 10, 18, 26, 34</u> – Removed Fasting lipid profile and Urinalysis, which was under “Blood Collection”. Added Urine Collection section.</li> <li>• <u>Step 2: Remaining Injection Visits</u> – Removed fasting lipid profile.</li> <li>• <u>Step 3: (Open-label daily oral TDF/FTC)</u> – Updated formatting on collecting urine on every visit except week +8; removed fasting lipid profile.</li> </ul>

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7	Participant Retention	1.1	04Feb2021	<p><u>Updates for Version 1.1 (04Feb2021)</u></p> <ul style="list-style-type: none"> <li>Only the footer was updated as per updated version of the SSP manual. No other edits were made.</li> </ul>
8	Study Product Considerations	1.1	04Feb2021	<p><u>Updates for Version 1.1 (04Feb2021)</u></p> <ul style="list-style-type: none"> <li><u>Section 8.1.5</u> – Added clarification of visit at Last Injection +8 Week, (in Step 3). Truvada is not administered at this visit.</li> </ul>

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9	Clinical Considerations	1.1	04Feb2021	<p><u>Updates for Version 1.1 (04Feb2021)</u></p> <ul style="list-style-type: none"> <li>• <u>TOC</u> - Added Appendix 9a and Appendix 9b.</li> <li>• <u>Section 9.3.2</u> – Added note about site staff adding PHQ score to the AE log if the participant scores mild or above.</li> <li>• <u>Section 9.4.2</u> – Added a clarification about the BMI calculation and height measurements and how BMI does not need to be calculated at Safety Visits in Step 3 (RE: appropriate needle size for injections).</li> <li>• <u>Section 9.15</u> – Added Appendix 9b: Toxicity Management Diagrams without the version and date (unnecessary and would need to be maintained)</li> </ul>
10	Adverse Event Reporting and Safety Monitoring	1.1	04Feb2021	<p><u>Updates for Version 1.1 (04Feb2021)</u></p> <ul style="list-style-type: none"> <li>• Only the footer was updated as per updated version of the SSP manual. No other edits were made.</li> </ul>

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11	Laboratory and Specimen Management Procedures	1.2	04Feb2021	<p><u>Updates for Version 1.1 (14Aug2020)</u></p> <ul style="list-style-type: none"> <li>• <u>Table of Contents</u> : Updated to reflect changes in section</li> <li>• <u>Section 11.4</u>: Changed “084.1” to “084-01” (LDMS will not accept 084.1).</li> <li>• <u>Section 11.5.9</u>: Changed “084.1” to “084-01” (LDMS will not accept 084.1).</li> <li>• <u>Figure 11.5</u>: Updated language to “Screenshot will be updated to show 084-01”</li> </ul> <p><u>Updates for Version 1.2 (04Feb2021)</u></p> <ul style="list-style-type: none"> <li>• <u>Table 11.1</u> – Updated Footnotes 1-8.</li> <li>• <u>Table 11.2</u> – Updated Footnotes 1-6.</li> <li>• <u>Table 11.3</u> – Updated Footnotes 1-6.</li> <li>• <u>Table 11.4</u> – Updated Footnotes 1-5.</li> <li>• <u>Section 11.3.5</u> – Revised instructions that fasting lipid profile will be collected at enrollment and week 34.</li> </ul>
12	Counseling Considerations	1.1	04Feb2021	<p><u>Updates for Version 1.1 (04Feb2021)</u></p> <ul style="list-style-type: none"> <li>• Only the footer was updated as per updated version of the SSP manual. No other edits were made.</li> </ul>

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13	Data Management	1.1	04Feb2021	<p><u>Updates for Version 1.1 (04Feb2021)</u></p> <ul style="list-style-type: none"> <li>• Minor formatting edits throughout.</li> <li>• <u>Section 13.6</u> – Note of clarification that all injection visits must be conducted within +/- 3 day target window.</li> <li>• <u>Section 13.13 Schedule of Forms</u> – Added note in follow-up visit section indicating that Fasting Lipid Test Results are collected at Week 34 only.</li> </ul>
14	Computer Assisted Self-Interview (CASI)	1.1	04Feb2021	<p><u>Updates for Version 1.1 (04Feb2021)</u></p> <ul style="list-style-type: none"> <li>• Minor formatting</li> </ul>

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15	Reporting Plan	1.1	04Feb2021	<u>Updates for Version 1.1 (04Feb2021)</u> <ul style="list-style-type: none"> <li>• Minor formatting</li> </ul>
16	Data Communiques	1.1	04Feb2021	<u>Updates for Version 1.1 (04Feb2021)</u> <ul style="list-style-type: none"> <li>• Minor formatting</li> </ul>



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17	Qualitative	1.0	21Oct2021	<u>Updates for Version 1.0 (21Oct2021)</u> <ul style="list-style-type: none"> <li>• New section</li> </ul>
Appendix Ia	Record of Dispensation of Participant-Specific Study Product to Non-Pharmacy Staff	1.1	04Feb2021	<u>Updates for Version 1.1 (04Feb2021)</u> <ul style="list-style-type: none"> <li>• No edits were made.</li> </ul>

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Appendix Ib	Record of Return of Participant-Specific Study Product by Non-Pharmacy Staff	1.1	04Feb2021	<u>Updates for Version 1.1 (04Feb2021)</u> <ul style="list-style-type: none"> <li>• No edits were made.</li> </ul>
Appendix II	Participant Transfer and Receipt	1.1	04Feb2021	<u>Updates for Version 1.1 (4Feb2021)</u> <ul style="list-style-type: none"> <li>• No edits were made.</li> </ul>

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Section Number	Section Title	Current Version Number	Current Version Date	Updates and Comments
Appendix III	Guidance for Management of “discordant/discrepant” HIV testing results.	1.2	06Mar2019	
Appendix IV	Study Schema Graphic	1.0	12Aug2019	