

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

Section Number	Section Title	Current Version Number	Current Version Date	Updates and Comments
1	Introduction	5.0	23Feb2024	<u>Updates for Version 5.0</u> <ul style="list-style-type: none"> <li>Added references to Protocol v5.</li> <li>Removed Molly Dyer from Table 1-1: HPTN Staff and Contact Information.</li> </ul>
2	Protocol	5.0	23Feb2024	<u>Updates for Version 5.0</u> <ul style="list-style-type: none"> <li>Added Protocol v5 and LOA#1</li> </ul>
3	Document Requirements	5.0	23Feb2024	<u>Updates for Version 5.0</u> <ul style="list-style-type: none"> <li>Added references to Protocol v5 to Table 3-1b.</li> </ul>
4	Continuation in Protocol Version 5.0	5.0	23Feb2024	<u>Updates for Version 5.0</u> <ul style="list-style-type: none"> <li>Added references to Protocol v5.</li> <li>Table 4-1: Added a question to the Assessment of Understanding.</li> </ul>
5	Study Procedures Overview	5.0	23Feb2024	<u>Updates for Version 5.0</u> <ul style="list-style-type: none"> <li>Added references to Protocol v5.</li> </ul>
6	Visit Checklists	5.0	23Feb2024	<u>Updates for Version 5.0</u> <ul style="list-style-type: none"> <li>Removed 4a &amp; 4b checklists which are no longer relevant.</li> <li>Aligned the Step 4c, 4d, 5 and 6 checklists with their respective protocol SOE</li> </ul>
7	Participant Retention	5.0	23Feb2024	<u>Updates for Version 5.0</u> <ul style="list-style-type: none"> <li>Added Protocol v5</li> </ul>
8	Study Product Considerations	5.0	23Feb2024	<u>Updates for Version 5.0</u> <ul style="list-style-type: none"> <li>Added to Appendix 8b: <ul style="list-style-type: none"> <li>Participants on Step 6 who complete 48 weeks (Week 56-96) of CAB-LA injection may receive up to two additional CAB-LA injection doses (Week 104 -112) per protocol.</li> <li>CAB-LA 600 mg administered as one 3 mL (600 mg) IM injection in the gluteal muscle every 8 weeks up to an additional 16 weeks (Week 104 - 112).</li> </ul> </li> </ul>
9	Clinical Considerations	5.0	23Feb2024	<u>Updates for Version 5.0</u> <ul style="list-style-type: none"> <li>Removed language for visits that are no longer applicable because all participants are past those visits.</li> <li>Section 9.5.4.1 (Precautionary and Prohibited Medications) <ul style="list-style-type: none"> <li>Removed list of medications and instead referenced the current IB.</li> </ul> </li> <li>Section 9.12 (Pregnancy) <ul style="list-style-type: none"> <li>Added language on management of participants who are pregnant but decline</li> </ul> </li> </ul>

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				<ul style="list-style-type: none"> <li>○ participation or are not eligible for 4d.</li> <li>○ If ultrasound not available contact SDMC.</li> <li>○ Added language around reporting congenital anomalies and a reference to the WHO birth defects surveillance- a manual for program managers.</li> </ul>
10	Adverse Event Reporting and Safety Monitoring	5.0	23Feb2024	<u>Updates for Version 5.0</u> <ul style="list-style-type: none"> <li>• Throughout clarified that regardless of the Step a pregnant participant is followed and pregnancy and infant outcome data (infant growth assessment at delivery and approximately 48 weeks post birth) will be collected.</li> <li>• Regardless of the Step, all infant SAEs that occur up to 48 weeks post-delivery will be collected and reported.</li> </ul>
11	Laboratory and Specimen Management Procedures	5.0	23Feb2024	<u>Updates for Version 5.0</u> <ul style="list-style-type: none"> <li>• Table 11-13: Added optional Weeks 104 and 112</li> <li>• Section 11.9: Added language to clarify the cord blood processing.</li> </ul>
12	Counseling Considerations	5.0	23Feb2024	<u>Updates for Version 5.0</u> <ul style="list-style-type: none"> <li>• No changes; only footer updated</li> </ul>
13	Data Management	5.0	23Feb2024	<u>Updates for Version 5.0</u> <ul style="list-style-type: none"> <li>• Table 13-2: Added weeks 104 &amp; 112 &amp; added footnote</li> <li>• Added several forms to Appendix 13A: HPTN084 Schedule of Form</li> </ul>
14	CASI	5.0	23Feb2024	<u>Updates for Version 5.0</u> <ul style="list-style-type: none"> <li>• Changes related to new SDMC system.</li> </ul>
15	Reporting Plan	5.0	23Feb2024	<u>Updates for Version 5.0</u> <ul style="list-style-type: none"> <li>• No changes; only footer updated</li> </ul>
16	Data Communiqués	5.0	23Feb2024	<u>Updates for Version 5.0</u> <ul style="list-style-type: none"> <li>• No changes; only footer updated</li> </ul>
17	COVID-19 Measures	5.0	23Feb2024	<u>Updates for Version 5.0</u> <ul style="list-style-type: none"> <li>• No changes; only footer updated</li> </ul>
Appx I	Guidance for the management of discordant/ discrepant HIV test results	V2.2	07Feb2023	<ul style="list-style-type: none"> <li>• No updates</li> </ul>