

**HPTN 091 Study-Specific Procedures Manual
(Version 1.1 & Version 1.2)
Overview and Version Control**

Section Number	Section Title	Current Version Number	Version Date	Updates and Comments
1	Introduction	1.2	20 October 2022	<u>Version 1.2:</u> <ul style="list-style-type: none"> • Section 1.2: To include updates to the protocol document table. • Section 1.3: To update team contact table
2	Documentation Requirements	1.2	20 October 2022	<u>Version 1.2:</u> <ul style="list-style-type: none"> • Section 2.5: To include updates to the eligibility criteria- the example provided for the risk-related behavior criteria
3	Accrual and Retention	1.1	20 October 2022	Section 3.2: To include updates per LOA #3 Section 3.8: Participant withdrawal; to include updates to the second paragraph
4	Study Procedures	1.3	18 April 2023	<u>Version 1.2:</u> <ul style="list-style-type: none"> • Section 4.3: <ul style="list-style-type: none"> ○ To include additional information regarding protocol required visits ○ To include updates to Table 4.1: Study Visit Windows • Section 4.4: To include updates to the Screening Visit Procedures section; updating from 30 days to 40 days • Sections 4.5 & 4.6: To add information about the GAHT initiation visit • Section 4.8: <ul style="list-style-type: none"> -To include a note about injectable cabotegravir (CAB LA) - To include updates to the PrEP table <u>Version 1.3:</u> <ul style="list-style-type: none"> • Section 4.7: To add the timeframe when the HIV Confirmation and Termination visits should be conducted. • Section 4.11: Update the DHI participant eligibility.
5	Study Product Considerations	1.1	20 October 2022	<ul style="list-style-type: none"> • Section 5.2: To include updates per LOA #3 • Section 5.3: To include updates per LOA #3
6	Clinical Considerations	1.2	20 October 2022	<u>Version 1.2:</u> <ul style="list-style-type: none"> • Section 6.1: To add information about the GAHT initiation visit • Section 6.2.2: To include updates per LOA #3

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7	AE Reporting and Safety Monitoring Considerations	1.0	28 January 2021	
8	Laboratory and Specimen Management Procedures	1.3	18 April 2023	<p><u>Version 1.2:</u></p> <ul style="list-style-type: none"> • Section 8.2.5: To add information regarding QCs in the SDQC Tool • Section 8.5: <ul style="list-style-type: none"> -To remove information about plasma shipping, per LOA #3 -To include updates to DBS shipping, per LOA #3 • Section 8.5.2: To remove minor information about pharmacology testing • Section 8.7.3: To include information about LDMS instructions <p><u>Version 1.3:</u></p> <ul style="list-style-type: none"> • Section 8.3.1: To add the timeframe to conduct the HIV Confirmation visit
9	Counseling and Behavioral Considerations	1.0	28 January 2021	
10	Data Management	1.2	20 October 2022	<p><u>Version 1.2:</u></p> <ul style="list-style-type: none"> • Section 10.4.1: To include additional information about the PTID creation and screening • Section 10.5: <ul style="list-style-type: none"> -To include updates to reminders for specific visits. - To include updates to table 10-1: Visit Codes, Target Dates, and Visit Windows
11	Data Communiqués	1.0	28 January 2021	
12	Study Reporting Plan	1.0	28 January 2021	
APPX I	Appendix I: Qualitative Sub-Study Procedures	1.2	20 October 2022	<p><u>Version 1.2:</u></p> <ul style="list-style-type: none"> • Section 1.1: To include additional information on participant enrolment in the qualitative sub-study guidance • Section 1.3: To include updates about scheduling IDIs with participants enrolled in the sub-study • Section 1.7: To update the process for transcribing audio files • Section 1.10: To provide clarifications

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APPX II	Appendix II: GAHT Management and Considerations	1.2	20 October 2022	<u>Version 1.2:</u> <ul style="list-style-type: none"> • Introduction: To include contact information • Section 2 – GAHT Initiation Visit: <ul style="list-style-type: none"> ○ To include update to risk factors for women ○ To include updates to estrogen and anti-androgen tables • Section 5: Minor edits to Appendix B- Feminizing Regimens table • To include updates to references
APPX III	Appendix III: Peer Health Navigation Guide	1.1	10 August 2021	<u>Version 1.1:</u> <ul style="list-style-type: none"> • New Section PHN Screening, Enrollment, and GAHT Initiation: To include diagrams illustrating procedures during the screening, enrollment, and GAHT initiation visits. • PHN Intervention Structure: To include information on properly documenting Peer Health Navigation visits