



HPTN Manual of Operations (MOP)
Summary of Changes
22 December 2023

Section	Revisions
Section 4: HPTN Science Committees, Working Groups and Protocol Teams	<ul style="list-style-type: none"> Section 4.5.1: Minor edit for clarity
Section 9: Protocol Development	<ul style="list-style-type: none"> Figure 9-1 and Section 9.2.2.2: Moved SDMC operational review from being simultaneous to DAIDS PSRC Review to being simultaneous to SRC Review and HPTN Leadership review Section 9.2.1: Clarified that the RSR will be posted to the HPTN website <i>as applicable</i> Section 9.2.1 and Section 9.2.2.3: Added that the RSR will be submitted along with the protocol at PSRC review Section 9.2.2.1: Minor edit for clarity
Section 12: Study Implementation	<ul style="list-style-type: none"> Section 12.1.5.3: Addition of language related to the decision and timing of unblinding trials that have been terminated before completion due to sponsor decision or DSMB recommendation Section 12.5.8: Revised language to include reference to the Cross-Network Protocol Deviation Reporting Guide and Protocol Deviation electronic Case Report Form
Section 17: Ancillary Studies/Investigations	<ul style="list-style-type: none"> Updated links to the Ancillary Study Application