SUMMARY OF REVISIONS - HRPP MANUAL September 2026

Page	Section	Topic
Cover/Footers		
28	1.9.3.3	The term "IRB reliance agreement" was added for ease of searchability for research teams and future audits per the recommendation of the FDA investigator. The language regarding local IRB review was revised to make our process more clear. Removed old IRB "acknowledgement" verbiage.
38	2.4.5.1	IRB Chair/Vice-Chair appointment term language revised to reflect new continuous appointment policy.
39	2.4.6.1	IRB Member appointment term language revised to reflect new continuous appointment policy.
55	2.9.1.2	Typos corrected from "or" to "of" in the notes of category 2(i), (ii), and (iii).
61	2.9.3.4	Quorum is further detailed and an OHRP guidance is linked per the recommendation of the FDA investigator.
88	2.13	PHI Disclosure language added per requirements from internal TTU System Auditors.
92	2.16.2	Internal guidance document added to IND application section to further expand upon expanded access, compassionate use and/or emergency use cases.
92	2.16.3.1 HUD (new)	Humanitarian Use Device (HUD) section added to the manual following guidance from 2026 FDA inspection. Guidance document previously provided to research teams upon request externally linked as discussed.
95	2.16.4	Emergency Use/Compassionate use guidance document linked per suggestion in FDA audit.
		Overall document formatting and pages revisions were required following the completion of all revisions. This included correcting section numbers that incorrectly auto-numbered throughout the document, formatting alignment and repagination.