

## Summary of Changes for VCU IRB Written Policy and Procedure revisions, effective 6-18-2021

WPPs available at: <https://research.vcu.edu/human-research/hrppirb/hrpp-policies-and-guidance/>

WPP #	Section	Change
WPP #: II-1 HRPP Overview	Revised section 2.1	Added the VCU Health Protocol Review Oversight Committees (PROCs) as a component of the HRPP. Updated names of offices and programs.
WPP #: VII-4 Reporting to Regulatory Agencies	Revised section 2.1	Clarified internal HRPP procedures for identifying events that need to be reported to federal agencies and departments. Updated names of offices and programs.
WPP #: IX-3 Personnel Qualifications	Revised Section 2.5	Deleted a reference to departmental approval being conducted only for VCU IRB studies because external IRB studies will also receive this verification.
WPP #: X-1 Conditions of Approval	Revised Sections 3.1	Changed IRB references to HRPP. Revised the terms for external exempt studies to be consistent with the VCU IRB exempt study conditions of approval in what kinds of changes require and amendment.
	Revised Sections 3.2	Changed IRB references to HRPP. Added clarifications that PIs are responsible for adhering to any applicable Virginia state laws and VCU institutional policies related to the research. Revised points 12-14 to more clearly outline VCU HRPP requirements. Added a new point 18 that PIs must notify the VCU HRPP when the study closes with the IRB of Record.
WPP #: XII-3 Health Insurance Portability and Accountability Act (HIPAA) Information and the Conduct of Research	Revised Section 4.1	Clarified that researchers must access VCU Health PHI according to the procedures of the VCU Health System. Added a reference to VCUHS policy <a href="#">Protected Health Information: Uses and Disclosures for Research (COMP-014)</a>