Summary of Key Changes to WU IRB Policies and Procedures
Policy Date: May 10, 2024

Section	Topic	Change	Rationale
II.F.7	Reporting Requirements and Exempt Research	Updated the description of the myIRB approval memo provided for exempt research.	The myIRB approval memo was updated to remind investigators to adhere to applicable PI reporting requirements.
IV.D.2	IRB Membership and Conflicts of Interest	Revised to update HRPO Confidentiality and Conflict of Interest Agreement requirements for IRB members.	A signed HRPO Confidentiality and Conflicts of Interest Agreement is no longer an annual requirement of IRB members.
IV.G.3	IRB Membership and Ongoing Education	Updated educational opportunities available to IRB members. Revised the ongoing education requirements for IRB members and how adherence is monitored.	Educational opportunities for IRB members are no longer published on the HRPO website. Ongoing education expectations for IRB members were updated. Additionally, adherence to ongoing education expectations is monitored by the IRB Executive Chair on a quarterly basis.
VII.B.1 and VII.B.2	Waiver of Alteration of the Requirement to Obtain Informed Consent	Revised to include FDA regulatory citations.	In December of 2023, the FDA issued their final rule permitting IRB waiver or alteration of informed consent for certain minimal risk clinical investigations.

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X.B.4	PI Reporting Requirements	Updated the PI reporting requirements for for-cause audits, inspections, inquiries, and FDA audits.	When reporting is required, the PI is responsible for notifying both the IRB Executive Director as well as the Associate Director (Education and Compliance). Upon conclusion of the audit, inspection or inquiry a final notification is required even when there are no reporting findings. Additional detail was provided about required follow-up information during and after conclusion of an FDA audit.
X.I.1.i	Exempt Research and Reporting Requirements	Revised IRB requirements for reporting of IRB determinations of serious and/or continuing noncompliance, unanticipated problems involving participants or others, or suspensions/terminations of IRB approval.	The reporting of IRB determinations of serious and/or continuing noncompliance, unanticipated problems involving participants or others, and suspensions/terminations of IRB approval will only occur for non-exempt research.
Appendix 2: Covered Organizations	NA	Revised the list of covered organizations.	Community Health Improvement was added as an organization that has designated the WU IRB and PARC IRB as their IRBs of Record.