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Summary of Changes: HRP-103, Investigator Manual

Approving Body	University of Miami
Date Approved	2/10/2023
Date Implemented	2/10/2023
Summary of Changes from Previous Version	**References where the IRB will approve has been modified to where the IRB renders determinations unless the word approved is in the regulation.* <u>Chapter 1:</u> • Emphasis on Principal Investigator being the responsible party for the conduct of research including understanding the Investigator Manual. • Expansion and clarification of definitions. • Examples and situations where IRB approval would be required. • PI eligibility and processes for exceptions <u>Chapter 2:</u> • Clarification on whether staff is engaged and need to be listed on the protocol. • Emphasis that the PI is responsible for maintaining and assuring proper and current training and disclosures of all research staff. • Process to access to IBISResearch • Removal throughout document referencing eProst. • Update of COI training and resource information. <u>Chapter 3:</u> • Updated processes and links in IBISResearch. • Emphasis on PIs responsibilities when submitting modifications. • Addition of sub-section on re-consenting • Emphasis that new RNIs must not be submitted via a continuing report function. • Addition of section of PI departure from the University of Miami. • Minor editorial changes for clarifications of procedures to access the system and related materials.

	• PI expectations and recommendations when writing an investigator-initiated study. <u>Chapter 4:</u> • External IRB to review plan. • Responsibilities after Starting the Study details • Study Updates and Site Modifications, continuing reports and RNI details • UM acknowledgment requirements. • Clarification on the order to approval process. • Clarification on deviation of UM consent language process. <u>Chapter 5:</u> • Updated levels of review • Clarification on implications of Not HSR. • Clarification of exemption determinations. • Condensing criteria for approval. • Addition of all determinations the IRB is allowed to make based on revised AAHRPP SOPs. • Addition of determination decisions and PI responsibilities. <u>Chapter 6:</u> • Refining recruitment details and strategies. • Refining recruitment details when HIPAA is involved. • Addition of different recruitment strategies. • Condensing recruitment materials to reference HRP-315 • Participant payment methods outlined and requirements for specific methods of payment or reimbursement. <u>Chapter 7:</u> • Minimizing coercion for students and employees. • Categories of Consent/Assent Processes and Documents updates for website and editorial. • Reduction of information found in HRP-314B and HRP-403. • Adding guidance on remote consent. • Removal of duplicative information. • Condensing Section 7.6 to refer to SOP-090 rather than duplicating information. • Addition of Section 7.12- re-consent <u>Chapter 8:</u> • Revise to clarify all reportable events require reporting via RNI.

	• Distinguishing different types of reportable events and non-compliance. • Addition of reference table for different types of activities. <u>Chapter 9:</u> • Explicit clarifications about PI responsibilities. • Conducting Research Outside of the United States <u>Chapter 10:</u> • Outlining different forms of confidentiality. • Addition of UM Policy "Data Classification" • Outlining more detailed definitions of HIPAA including ePHI. • Outlining possible HIPAA authorizations and waivers and regulatory requirements for each. • Addition of Secondary Subjects in Research. <u>Chapter 11:</u> • N/A <u>Chapter 12:</u> • N/A <u>Chapter 13:</u> • N/A <u>Chapter 14:</u> • N/A
Supersedes	Investigator Manual Revised 04/07/2022