Penn IRB SOP Version 14
Summary of Substantive Changes

Un-bolded text is existing language. **Bolded text is new language.**

Applicable Sections	Summary of Changes	Rationale for Changes
Throughout	Language has been updated throughout to update the word "subject" to participant." Language has been updated throughout to update the word "prisoner" to "incarcerated person."	Changes are related to DEI initiatives.
GA 108	Added a new SOP entitled: Response Plan For Emergencies Impacting The HRPP This policy describes the process for initiating a response to an emergency/disaster situation impacting the HRPP or HRPP operations. Challenges to HRPP operations or the conduct of Human Research may arise, for example, from: 1.1.1 Extreme weather events. 1.1.2 Natural disasters. 1.1.3 Man-made disasters. 1.1.4 Infectious disease outbreaks.	Required for AAHRPP Accreditation
RR 405 CRITERIA FOR RENEWAL	Updated to reflect the IRB's new policy on IRB Meeting Dates & Study Expirations. **The following text has been added:** For research determined to pose greater than minimal risk, **requiring continuing review by the convened Committee (IRB Board), the expiration date will be set to align with the following year's Convened Committee date. The expiration date will ensure continuing review of the research at least once per year. The IRB will inform investigators of the expiration date in a letter following the meeting. The annual progress report must be reviewed on or before the expiration date, even if the research activity may not begin until sometime after the IRB has given approval.**	Minimize expiration of greater than minimal risk research.

RI 801 IRB-REQUIRED INVESTIGATOR ACTIONS, 3.5 Periodic and Final Reports	Updated to reflect the IRB's new policy on IRB Meeting Dates & Study Expirations. The following text has been added: **For protocols requiring continuing review by the convened Committee (IRB Board), the expiration date will be set to align with the following year's Convened Committee date. The expiration date will ensure continuing review of the research at least once per year. The IRB will inform investigators of the expiration date in a letter following the meeting.**	Minimize expiration of greater than minimal risk research.
IC 703 CONSENT DOCUMENTATION, 3.2 Obtaining Informed Consent from Non-English Speakers	The following text has been added: • **For federally funded research, the NIH policy 3014-301 – Informed Consent must be followed.** • **For FDA regulated research, consult the FDA guidance Informed Consent Guidance for IRBs, Clinical Investigators, and Sponsors AUGUST 2023 for best practices.**	Updated to reflect the new policy on informed consent from the NIH as well as the updated FDA guidance on informed consent.