

**Date:** February 22, 2024

**RE:** Continuing Review and Expiration of IRB Approval for Protocols Reviewed by the Convened Committee

To Whom It May Concern,

This memo serves as notification that the Penn Institutional Review Board (IRB) has amended Section RR 405 Criteria For Renewal Consent Process Guidance Document for Human Subject Research (IRB Standard Operating Policies (SOP) Version 13 February 2023) as of January 1, 2024. This updated SOP will align expiration dates of new protocols as well as continuing reviews of protocols reviewed annually by Convened Committees with scheduled IRB meetings, in an effort to prevent expiration of studies.

Federal regulations at 45 CFR 46.109(e) and 21 CFR 56.109(f) require an IRB to conduct continuing review of research at intervals appropriate to the degree of risk posed to the participants, but not less than once a year. Under 21 CFR 56.108(a)(2) and 56.109(f), the IRB must determine the frequency of continuing review for each clinical investigation to ensure the continued protection of the rights and welfare of research subjects.

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. IRB Meeting dates are posted on the IRB website: <https://irb.upenn.edu/events-calendar>. This updated policy applies to submissions requiring continuing review by a convened Committee.

The IRB SOP will be updated on the website at a future date. This memo will be posted on the IRB website for reference, here: <https://irb.upenn.edu/homepage/about-the-irb/irb-policies>.

If you have any questions about the information in this letter, please contact the IRB Senior staff. Contact information is available at our website: <https://irb.upenn.edu/homepage/staff-directory>.

Sincerely,

Diane Pinder  
Associate Director of Compliance, Human Research Protections