Weill Cornell Medicine

Institutional Review Board

IRB Guidance on Lapses in IRB Approval: Continuing Reviews and PAM-AR (Post-Approval Monitoring – Annual Reports)

Continuing Reviews submitted 90 days *after* the expiration will be administratively withdrawn by the IRB and the protocol will be administratively closed. If you would like to continue the study, a new initial IRB application must be submitted in order to proceed with research activities (including subject recruitment, enrollment, intervention, and data analysis). If submitted within the 90-day window, the application must include documentation of what, if any, research activities occurred during the lapse in IRB approval. If none occurred, this should be stated.

Post-Approval Monitoring – Annual Reports (PAM-ARs) submitted 90 days *after* the due date will be administratively withdrawn by the IRB and the protocol will be administratively closed. If you would like to continue the study, a new initial IRB application must be submitted in order to proceed with research activities (including subject recruitment, enrollment, intervention, and data analysis).

Submitting a New Initial Application after Lapse in IRB Approval

WRG-HS allows Principal Investigators to create a new initial application while copying information from the expired protocol; however, the application must be updated to account for current requirements and include the following:

- In the General Study Design section, a lay synopsis (lay summary) that includes:
    - A statement that this is a continuation of the previously lapsed protocol [specify protocol #] that was administratively closed due to approval lapse;
    - How many subjects have been enrolled (or charts reviewed) to date;
    - What, if any, research activities have taken place during the lapse (including if none have occurred during the lapse); [Note: If any activities have occurred during the lapse, make a separate protocol deviation submission to the IRB.]
    - Information on the research activities that will be conducted going forward. While the new initial application should contain the minimum amount of background information necessary to provide context to the IRB, the application should primarily focus on research activities that will be conducted under the newly issued IRB approval rather than activities that occurred under the prior approval.
- Uploaded attachments that include:
    - A protocol document using the most current Investigator-Initiated Protocol Template available at https://jcto.weill.cornell.edu/investigators/study-activation-and-conduct/researchers-toolbox. Protocol summaries from eIRB will not be accepted.
    - Updated study materials that reflect the new protocol number and utilize the most current Informed Consent and HIPAA Authorization for Research template (and Assent template, as applicable) available at https://research.weill.cornell.edu/institutional-review-board-irb.

Contact irb@med.cornell.edu with questions.

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