



RE: Good Clinical Practice Training

To Whom it May Concern:

In alignment with applicable NIH and institutional policies, the IRB will assume a larger role in the enforcement of Good Clinical Practice (GCP) training requirements for clinical trials. This is under advisement from Penn's Office of Audit, Compliance, and Policy.

This requirement applies to study personnel engaged in research when the protocol meets the NIH definition of a clinical trial:

*"A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes."*

The IRB staff will continue to assess if the research meets the definition of a clinical trial and have been trained on recent NIH policy changes. **At initial review, IRB staff will now start to withhold approval for GCP training completion.**

Good Clinical Practice Training expires every 3 years. **The IRB staff will begin to flag expired training during the review of amendments and continuing reviews.** Failure to complete the training or the refresher within a timely manner may lead to the following:

- Withheld approval of amendments, or
- Conditional reapproval of continuing review (if continuing review is required)

To prevent the above from occurring, please note the following:

1. *If training is improperly documented*, please email the certificate to [IRBCITISupport@lists.upenn.edu](mailto:IRBCITISupport@lists.upenn.edu) and ask for the eIRB profile to be updated with the completed training. This will update it for all protocols.
2. *If training is incomplete or expired*, and cannot be completed within a timely manner, consider removing the individual until training is completed.
  - Remove the individual from associated IRB protocols in eIRB before submitting to the IRB. This can be done quickly for non-PI personnel in the [eIRB Personnel tracker](#) (NOTE this cannot be done while a submission is under review with the IRB).
  - When training is complete, you may add them back to applicable protocols using the eIRB [Multi-protocol personnel amendment tool](#);

- NOTE: Please be advised that the Research Team panel table updates in real time with Penn's data warehouse feed to eIRB. However, this feed can take 2-3 business days to reach eIRB.

Applicable Policies:

- Per [NIH policy](#), Good Clinical Practice training is required to be completed by awardees conducting clinical trials every 3 years.
- Per [Penn Medicine policy](#), Good Clinical Practice training is required to be completed by Penn Medicine personnel conducting clinical trials every 3 years, regardless of funding source.
- Per Penn [IRB SOP RI 802](#): The IRB shall establish standards of training required for all individuals engaged in human research.

Please contact the IRB with any questions or concerns.

Sincerely,



Jessica L. Yoos, MA, M.Phil., CIP  
Director, Human Research Protections

cc:

Office of Clinical Research  
Office of Audit and Compliance