Policies for On-going Actions Post-Approval

Modification Request Policy

Federal regulations require that the IRB review and approve any changes in the approved research prior to implementation, except when necessary to eliminate apparent immediate hazards to subjects. Modifications to protocols may be made at any time during the approval period. Most modifications are expeditable; but modifications related to full-board protocols that significantly alter the risk level or significantly change a project's goals or methodology may require review and approval by the full board (typically, at the next monthly meeting).

Download the current form: IRB Modification Form

Continuing Review Policy

If a PI will still be enrolling participants, collecting data, or interacting directly with the participants, a Continuing Review form must be filed at least one week prior to the approval expiry date indicated in the original IRB approval letter. Lapses in IRB approval constitutes non-compliance with Federal regulations, and all research must stop until approval is reissued.

Download the current form: IRB Application for Continuing Review form

Final /Closeout Report Policy

A Closeout Report should be submitted when no further contact with the participants will take place and all data and/or samples are permanently de-identified. A Closeout Report must also be submitted if 1) the study is never initiated, and no enrollment takes place; and 2) a Primary Investigator leaves UCA without requesting a change in PI. Following study closure, the researcher may not contact study subjects for further data collection.

Download the current form: IRB Final Report for Research form