Changes to IRB Approved Research Protocols

Modified: January 2017

Background:

Federal regulations require that changes to IRB approved research may not occur without prior IRB review and approval, “no matter how minor” unless a change is required to eliminate an apparent immediate hazard to subjects. If the change was made to eliminate an apparent immediate hazard to subjects, it must be submitted to the UF IRB promptly for review. “Prompt” reporting at the University of Florida means as soon as possible, but not later than five (5) working days.

Approval notices sent to the PI by the UF IRB state the requirement for UF IRB review and approval of any changes to approved research prior to the activation of those changes.

Q: What is required for a UF IRB approved protocol revision review?

To initiate the review of a change in research request, the PI must submit via myIRB a revision request summarizing the revisions and the reason the revisions are being requested. If the request involves a change to the protocol or Consent Form, a tracked-change version of the revised documents must be uploaded as part of the myIRB revision request. All new documents which are part of the request must also be uploaded to the appropriate section of the myIRB application.

Q: How will the change(s) in research request be reviewed if the research qualified for expedited review in the past?

If the research met the criteria for expedited review during the initial or last continuing review, and the proposed change does not affect that status, the UF IRB review will be conducted using an expedited review procedure. If the proposed change does not qualify for an expedited review procedure, the proposed change will be reviewed at a convened meeting of the UF IRB and the status of the study will be changed from expedited review to Full Board review.

Q: How will the change(s) in research request be reviewed if the research required Full Board review in the past?

a) If the research required convened review at the initial or last continuing review, but the proposed change is minor, the UF IRB review may be conducted using an expedited review procedure.

b) If the research required convened review at the initial or last continuing review and the change is not minor, the review of the request must be conducted during a convened meeting of the UF IRB.

Please Note: The IRB makes the final determination as to whether or not expedited or full board review is required.
Q: What action may the IRB take on a revision request?

The UF IRB may act on a change in research request in one of four ways:
   (a) The request may be approved;
   (b) The request may be approved with contingencies that must be addressed by the PI;
   (c) The request may be tabled pending submission of additional revisions or clarifications;
   (d) The request may be disapproved

(Note: a request may not be disapproved in an expedited review procedure. If the reviewer determines that the request should be disapproved, the request will be scheduled for review at a convened meeting.)

Written notification of actions taken after review of the request is provided to the PI through myIRB. If the action is approved, the final approved version of respective consent form(s) will be uploaded in myIRB. The research and consent forms are approved only for the period specified by the IRB. Generally, approval of a change(s) in research will not change the date that the research will expire. If a consent form is revised in association with the change(s) in research, it is valid only until the original approval date for the research expires. In cases where the request is disapproved, the IRB will provide its rationale for the action taken.