

IRB Review and Submission Process: Amendments to Approved Research

Any proposed changes in IRB approved research must be reviewed and approved by the IRB and Institutional Official (IO) prior to implementation except where necessary to eliminate apparent and immediate hazards to research participants and subjects.

Additional Info

PI completes the IRB Action Request, Summary of Changes and attaches any required documents (i.e. revised surveys, consent documents, command approvals, ethics training etc.). When complete submits to the IRB Administrator.

IRB Administrator reviews for completeness and compliance. PI is contacted if updates are needed. When complete, package is sent to the IRB for review.

IRB reviews. Minor changes that do not increase risk to subjects are reviewed by the IRB Chair/Vice Chair. More than minor changes and changes that increase risk are reviewed by the convened IRB.

If the IRB requires updates the PI is notified. IRB makes a recommendation to the Institutional Official.

Institutional Official reviews research. Approves, requires updates or disapproves.

Forwarding endorsement is prepared and the PI is notified of the approval. Once Institutional Official approves the PI may implement amended research procedures and begin.

