IRB Review and Submission Process: Amendments to Approved Research

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

### Additional Info

- **PI completes the amendment section and attaches any required documents (i.e. revised surveys, consent documents, command approvals, ethics training etc.).** When complete submits to the HRPP Specialist.

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

- **IRB reviews.** If the IRB requires revisions or additional information, the PI is notified.

- **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 and/or the IO.**

- **The HRPP Specialist notifies the PI.** Once approved the PI may implement amended research procedures and begin.

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**Change to approved research is needed.**

- PI completes Part 2 of the IRB Application Form
  - If a pre-NOV 2019 Protocol: PI completes IRB Amendment Form

- HRPP Specialist provides preliminary review & PI makes updates to package (if needed)

- **IRB conducts review**

  - PI submits required updates (if needed)

  - **Modification increases risk?**
    - Yes: IO reviews & approves or disapproves
    - No: IRB Chair reviews & approves or disapproves requested modifications

- PI is notified