**IRB PROTOCOL REVIEW**

**PROCESS**

**Pre-Submission**
- Determine if your project meets the definition of "Research," and that your project involves "Human Subjects."
- For assistance, refer to the ORI website or contact the IBC coordinator.

**Submission**
- Complete the application form and any necessary documents (e.g., research proposal, consenting document, recruitment materials, CITI training certifications). Graduate students must include Thesis/Dissertation Approval Sheet.
- Propose what review process is required for your research — Exempt, Expedited, or Full-Board.
- Submit forms and other necessary documents through IRBNet. Directions on how to submit through IRBNet are available on the ORI website.

**Administrative Review**
- ORI staff will review for completeness. If information is missing, ORI staff will contact you to correct your documents, prior to forwarding to the chair for review.

**Exempt or Expedited Review**
- ORI staff, in concert with the IRB chair, will review to determine if the research:
  - meets one of the six categories of exempt research specified by DHHS or,
  - meets one of the seven categories of research that qualify for expedited review.
- If research can be reviewed and determined to be exempt or can be reviewed through expedited process, skip to PI Modifications step.

**Full Board Review**
- If the project requires full board review, the protocol will be placed on the agenda for the next available meeting. See IRB meeting calendar for submission deadlines.
- ORI staff will ask the PI (and student if applicable) to attend the IRB meeting and provide an overview.
- The IRB will review the protocol to ensure the research can be completed ethically and in compliance with applicable regulations. The IRB will either approve, require modifications to secure approval, withhold approval, or table.

**PI Modifications**
- In many cases, modifications are required to secure approval. In this case, ORI staff will prepare a detailed memo describing the changes required by the IRB.
- Submitted modifications are reviewed by the Chair. If acceptable, the protocol will be approved. If not acceptable, the PI will be contacted. Modifications must be received within 8 weeks.
- If your project is tabled, you will be asked to modify your protocol and to attend the next IRB meeting.

**Approval**
- When a protocol, renewal or amendment is approved (or determined to be exempt), ORI will generate an official approval letter in IRBNet and send to the PI. **Work can not commence until approval or determination has been granted.**
- By Federal Regulation and Policy, non-exempt protocols must be reviewed annually. ORI will notify PI’s when expiration dates are approaching so that PI’s can submit a completed continuing review form.

For more information on the IRB review process, refer to the ORI website or contact Mary Riedford, IRB Coordinator.