The University of Oklahoma

Human Research Participant Protection
Institutional Review Board
Norman Campus

IRB Graduate Student: Training and Guidance

History –
IRB's were formed as a result of an unfortunate history of crimes against humanity in the name of science and research.

Outcomes:

- Tuskegee → the National Research Act of 1974 → National Commission for the Protection of Human Subjects
- This commission wrote the "**Belmont Report"** in 1979
- In 1981, the DHHS & FDA published regulations based on the Belmont Report
- In 1991, after 10 years of negotiation, 17 federal departments and agencies agreed to adopt the basic human subjects protections, referred to as the "**Common Rule**"
- Federal Oversight, governed by the Office for Human Research Participant Protections (OHRP), Title 45 Code of Federal Regulations Part 46 (45CFR 46).
- University of Oklahoma IRB policies and procedures.

Role of the IRB -

- The mission of the OU Office of Human Research Participant Protection (HRPP) and Institutional Review Board (IRB) is to **protect the rights, privacy, and welfare of all human participants** in research projects conducted by OU faculty, staff, and students, or otherwise conducted under its oversight. We operate as an **accredited institution** under the Association for Accreditation of Human Research Protection Programs, Inc. (AAHRPP).
- IRB Chairs & Vice Chairs review the materials presented to assess whether it meets the IRB's criteria for approval and determines the level of risk. Studies are pre-reviewed to determine if the risk is significant to be reviewed by a board or by an individual Chair/Vice Chair.

Human Subjects Research –

- What qualifies as Human Subjects Research?
  - A **systematic investigation** (research development, testing, and evaluation) designed to develop or contribute to **generalizable knowledge**.
    - Data collected by means of a systematic investigation of participants
    - Conclusions drawn from the analysis of aggregate data
    - Information from the investigation is to be disseminated
- Does my study qualify as human subjects research?
  - Classroom-based research projects – research activities that are considered a course requirement and are being conducted for the purpose of learning research skills as a course assignment, **are not required** to be submitted for IRB review.
  - Determination of Human Research Application– designed to use when you are not sure if your specific study requires IRB approval. Consists of a mini-application with four general questions. It is important to provide as much detail and information when addressing each question. Submit the application and it generates a determination by the IRB. The letter you receive can be given to the Graduate College to complete their requirements.

IRB Review –

- Guiding principles
- Determination of the level of risk
- Process of informed consent
- Inclusion of Vulnerable Populations

Principal Investigator Requirements –

- Completion of online education course on human subjects protections – Collaborative Institutional Training Initiative (CITI). This course is valid for 2 years. First time you will complete the Basic Course module, and then there are 2 refresher courses in the series.
- Graduate students must designate a Faculty Sponsor who must also complete the CITI
- Include the **Student as Principal Investigator** form to assure that you are qualified to conduct research.

Submission Requirements – use of electronic submission system called ***iRIS***

- IRB Application Form – provides information required by regulations.
- Protocol Description Form – provides more detailed information and summarizes how the project will be completed.
- Informed Consent – explains the important aspects of the study to potential participants in lay language. The templates provided on the website contain the essential elements required by regulations.
- Student As Principal Investigator Form – provides the IRB assurance that you are trained to conduct research. Your designated Faculty Sponsor signs the form to confirm.
- Supporting documents – provide copies of any instruments, funding information, letters of support, interview questions, surveys/questionnaires, and advertisements/recruitment materials for the IRB to review.

IRB Review Process –

- HRPP receives your electronic submission and checks your CITI status and if your submission materials are included.
- Studies are pre-reviewed to confirm if they can be sent on to the Chair/Vice Chair for further review.
- You will receive an email that explains your status and will instruct you how to proceed.
- Studies are reviewed by a Chair/Vice Chair and a notification of stipulations is sent to the Principal Investigator (PI) via email through ***iRIS***. You must log into iRIS to view and respond to these stipulations.
- Address all stipulations and contact the HRPP office if you require any additional assistance by phone or email.
- Once all stipulations have been satisfied, you will receive notification via email that your study has been approved. A formal approval letter and the stamped consent form (if applicable) will be available in ***iRIS***. The PI is required to make copies of the stamped version of the consent form for use when consenting participants.

Post Approval Modifications –

- You may modify your study at any time after your study has been approved.
- Submit the Modification form located in iRIS and explain what you are specifically changing.
- If the revision requires changes to other forms or documents, include a copy of the revised form.
- YOU MUST HAVE YOUR MODIFICATION APPROVED PRIOR TO IMPLEMENTING THE NEW CHANGE.

Continuing Review Application –

- If your study is approved as Expedited or Full Board, the study is approved for one year. You must submit a *Continuing Review/Final Report Form* to renew for an additional year.
- If your study is approved as Exempt, your study remains active and does not require follow up unless you modify.
- You will receive a notification 60 days in advance to your expiration date to remind you that your study is due to expire.
- Check your CITI to see if this is current, if not, you must update. This also applies to any Key Study Personnel or Faculty Sponsor.
- The Continuing Review Application will ask the status of your study. You must address all questions in order to renew.

Closing Your Study –

- Notify the IRB that you study is completed and you have successfully defended and have been approved by the Graduate College to deposit your thesis/dissertation.
- The inactivation process is as follows:
    - Expedited & Full Board – complete the *Continuing Review/Final Report form*
    - Exempt – complete the *Exempt Study Progress/Closure Report form*
- **NOTE: The process does take some time to complete so avoid waiting until the day of final deposit.**
- If you are listed as Key Study Personnel rather than a PI, you will need to get the PI to close the study or file a Modification to remove you from the study.
- If you are continuing the research after graduation, contact the IRB directly to get the necessary approval.

Guidance & Resources –

- Determine when to begin and how much time you will need to complete the entire process (submission; conduct research study; analyze data; prepare thesis/dissertation; defend; close study; deposit).
- When to submit to the IRB:
    - For doctoral students – when your advisor/dissertation committee has approved your dissertation proposal
    - For master's students – when you file the Master's Thesis Topic and Committee Membership form
- The IRB works together with the Graduate College to help graduate students meet graduation requirements.
- If you have IRB approval, the Graduate College will ask for a copy of your approval letter.
- When your thesis/dissertation is complete, check the box indicating your work was subject to IRB review on the Graduate College's request for defense form.
- Your IRB-approved thesis/dissertation research study must be officially inactivated before a manuscript can be filed at Bizzell Library.
- How long does the IRB approval process take?
    - Exempt/Expedited studies can take up to two weeks for review
    - Full Board studies can be longer because the board meets once a month
    - These estimates assume approval without significant problems or stipulations

TIPS

- Answer all the questions, even if N/A. Be consistent in your response with all documentation.
- Check all documents for consistency before submitting
- Review all documents with your Faculty Sponsor prior to submission
- Add your Faculty Sponsor as a study contact
- Write a clear summary of your research design. The more specific and detailed is best, however **do not** cut and paste your entire thesis/dissertation into this section.
- Complete all documents and have them ready to upload prior to completing the application
- Include all documents – refer to the checklist at the end of the application
- Write the protocol for understanding (avoid technical language) and review the information/examples provided
- Write the consent form using lay language
- Don't assume you can use information from students, employees, etc., for research purposes just because you have access to that information as a function of your job or position. Consent is required for use of non-research materials for research purposes
- Templates are available on the IRB website for your use
- All stipulations must be addressed before you resubmit. If you are not able, please note and explain the reason why
- Make an appointment or call the IRB office for assistance if you need clarification regarding the stipulations
- Respond promptly to IRB requests (missing documents, revisions, etc.)
- If you disagree with stipulations-provide a response or justification why you disagree
- ***iRIS*** will keep a copy of all submitted documents
- Retain all research records as noted in the IRB application
- Do not wait until the last minute to submit
- Do not change any research activity without prior approval from the IRB
- Maintain good record keeping. You may have an evaluation of your study

Office of Human Research Participant Protection (HRPP) - Administration

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Call to schedule an appointment

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