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’
- 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:
  o Expedited & Full Board – complete the Continuing Review/Final Report form
  o 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:
  o For doctoral students – when your advisor/dissertation committee has approved your dissertation proposal
  o 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?
  o Exempt/Expeditied studies can take up to two weeks for review
  o Full Board studies can be longer because the board meets once a month
  o 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

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