Student Researchers

Do I need IRB Review?

- Does the project constitute research, based on the federal definition? Does it involve human subjects?
 - Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge (§46.102)
 - Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains
 - (1) Data through intervention or interaction with the individual, or
 - (2) Identifiable private information.
 - o Classroom Activities as Research
 - o HIPAA and Research
- QA vs. Research
- Review types
 - Exempt Submissions
 - o Expedited Submissions

myIRB

- Accessing myIRB
- Registration
- Training
- Researcher Manual
- Student Roles and PI Qualifications

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- Application documents/Procedures
- Protocol
 - o IRB01
 - o IRB02
- Consent
 - o IRB 01
 - o IRB02
 - Which ICF Template Should I Use?
 - eConsent

- Consenting Subjects Who Cannot Speak or Read English
- Informed Consent for Minors in Research Studies.
- Recruitment
 - o Advertising for Research Subjects (including social media)
 - o Telephone Script for Recruiting Subjects
 - o Mechanical Turk
- Survey Tools
 - Qualtrics for anonymous data
 - REDCap data containing PHI

Post Approval Responsibilities

- Revisions
- CRs
 - o Enrolled or not
 - Expired Study
- Reportable Events
 - o Adverse Events
 - o **Deviations**
 - o <u>Unanticipated Problems</u>

Additional Resources and Links

- Belmont Report
- Common Rule
- Investigator Guidelines

International Research

- Addendum Q
- International Research Involving Humans Form