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.
  - Classroom Activities as Research
  - HIPAA and Research

- QA vs. Research
- Review types
  - Exempt Submissions
  - Expedited Submissions

myIRB

- Accessing myIRB
- Registration
- Training
- Researcher Manual
- Student Roles and PI Qualifications
- Application documents/Procedures
- Protocol
  - IRB01
  - IRB02
- Consent
  - IRB 01
  - IRB02
    - Which ICF Template Should I Use?
    - eConsent
- Consenting Subjects Who Cannot Speak or Read English
- Informed Consent for Minors in Research Studies.

- **Recruitment**
  - Advertising for Research Subjects (including social media)
  - Telephone Script for Recruiting Subjects
  - Mechanical Turk

- **Survey Tools**
  - Qualtrics for anonymous data
  - REDCap data containing PHI

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**Post Approval Responsibilities**

- **Revisions**
- **CRs**
  - Enrolled or not
  - Expired Study

- **Reportable Events**
  - Adverse Events
  - Deviations
  - Unanticipated Problems

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**Additional Resources and Links**

- Belmont Report
- Common Rule
- Investigator Guidelines

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**International Research**

- Addendum Q
- International Research Involving Humans Form