

Economics 1960 – Research ethics and IRB

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What is Human Subjects Research?

- **Research**: a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge
- Examples of *not* research
 - Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship)
 - Public health surveillance activities
 - Certain activities authorized by law or court order solely for criminal justice or criminal investigative purposes
 - Certain activities in support of intelligence, homeland security, defense, or other national security missions

What is Human Subjects Research?

- **Human Subjects:** a living individual about whom an investigator (whether professional or student) conducting research obtains:
 - Information or biospecimens through *intervention or interaction* with the individual, and uses, studies, or analyzes, or generates *identifiable private information*; or
 - Obtains, uses, studies, analyzes or generates identifiable private information or identifiable biospecimens

What is Human Subjects Research?

- If it's generalizable research; and
- If it involves human subjects that are potentially identifiable

⇒ **Need IRB approval**

Research methods

- Interviews
- Questionnaires/Surveys
- Focus groups
- Observations
- Records reviews (medical, school, etc.)
- Tests/tasks
- Secondary data analysis
- Medical procedures (fMRI)
- Blood draws, genetic tests, saliva samples

The Belmont Report

- Unethical human experimentation was common in the early, mid-1900s
- Stanford Prison Experiment (1971), Tuskegee Syphilis Study (1932–1972)
- Massive ethical problems identified in Tuskegee Syphilis Study prompts the creation of a National Commission regarding protection of human subjects
- Led to the Belmont Report

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- Justice
 - Treat individuals fairly
 - Design research such that its burdens and benefits are shared equitably

Informed consent

- Not just obtaining a signature to a document or selecting “yes” to a question
- Begins with recruitment
 - What is your sampling strategy?
 - How are subjects being approached?
- Answer all questions to the satisfaction of potential subjects
- Enrolled subjects need to know
 - What they’re participating is “research”
 - Participation is voluntary
 - They can skip questions and stop at any point without any repercussions
- Consent is not a one-time event, it’s ongoing throughout the research process!

Privacy and confidentiality

- Concepts are often confused
- **Privacy**: Control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others
- **Confidentiality**: Information will not be divulged to others not approved by the protocol
 - Data security
 - Research team management

Deception and incomplete disclosures

- **Deception** Intentionally providing misleading or false information to participants
- **Incomplete disclosure**: Withholding information about the true purpose or nature of the study
- Acceptable if
 - minimal risk
 - no undisclosed risks
 - truly necessary
 - plan for debrief and dissemination
- *Aside for economics research*: Experimental economics norm is to not use deception!

Unanticipated problems and adverse events

- Despite best efforts, there can be unanticipated problems (e.g., data breach, using an outdated version of a study questionnaire, personal faints during study)
- Study team members should report any unanticipated problems or adverse event as soon as possible to PI
- The PI assumes overall responsibility for the study

Cultural considerations

- Be aware of your own biases
- Be sensitive to and curious about cultural differences
 - Ask, don't assume
- Sometimes when working in countries outside the U.S., your home IRB may ask for additional review from a review board local to the study

Misconduct

- **Research misconduct**: Defined as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results
 - **Fabrication**: Making up results and recording or reporting them
 - **Falsification**: Manipulating research materials, equipment or processes or changing or omitting data or results such that the research is not accurately represented in the research record
 - **Plagiarism**: The appropriation of another person's ideas, processes, results, or words without giving appropriate credit

IRB review for undergraduate projects

- Not necessary if *all* of the following conditions met:
 - No plans to present the results at conferences or similar events, and no set timeline for preparing a formal manuscript for journals
 - Data is collected with *minimal risk* to participants (probability and magnitude of harm or discomfort anticipated in the research $\leq$ ordinarily encountered in daily life of the general population)
 - Not involving vulnerable populations (e.g., children, prisoners, or individuals with cognitive impairments)
 - Participants are not identifiable in data collection
- Consult your faculty advisor if in doubt
- Qualtrics link to Brown self-determination tool for undergraduates
https://brown.co1.qualtrics.com/jfe/form/SV_6M5KqYNtfSb0ZE0

Useful links

- **Human Subjects Research at Brown:** <https://division-research.brown.edu/research-cycle/conduct-research/human-subjects-research>
- **Brown IRB:** <https://division-research.brown.edu/about/review-regulatory-boards/institutional-review-board-irb>
- **Belmont Report:** <https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/read-the-belmont-report/index.html>
- **Self-Determination Tools for Brown IRB:** <https://division-research.brown.edu/research-cycle/conduct-research/human-subjects-research/need-hrppirb-review>
- **NIH Decision Tool:** <https://grants.nih.gov/policy/humansubjects/hs-decision.htm>
- **Responsible Conduct of Research (RCR) Training:**
<https://division-research.brown.edu/research-cycle/conduct-research/ethics-research/responsible-conduct-research-rcr-training>