ECON 1960 - Human Subject Research and IRB

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What is Human Subject Research?

- **Research**: a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge
- Examples that are **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

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- **Human Subject**: 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

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Generalizable & Identifiable $\Rightarrow$ Need IRB Approval

Research Methods

- Interviews
- Questionnaires/Surveys
- Focus Groups
- Observations
- Records Reviews (medical, school, etc)
- Tests/Tasks
- Medical procedures (fMRI)
- Blood draws, genetic tests, saliva samples
- Secondary Data Analysis

Outline

Three Pillars

The Belmont Report identifies the ethical principles upon which the human subject protection regulations are based:

- Respect for Persons
  - Informed consent
  - Voluntariness
  - Additional protection for individuals with limited autonomy
- Beneficence
  - Minimize risk
  - Maximize benefit
- Justice
  - Treat individuals fairly
  - Design research such that its burdens and benefits are shared equitably

In the Field: Consent

In the Field: Equitable Treatment

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 you approaching potential subjects?
- Answer all questions to the satisfaction of potential subjects
- Enrolled subjects need to know
  - The study constitutes “research"
  - Participation is entirely voluntary
  - They are free to skip questions and stop at any point without any consequences

Privacy and Confidentiality

- 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
- 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

Unanticipated Problems and Adverse Event

- Despite best efforts, unanticipated problems (e.g., a confidentiality breach; using an outdated version of a study questionnaire; person faints during a blood draw) do happen
- Study team members must report any unanticipated problem or adverse event as soon as possible to PI
- The PI assumes overall responsibility for the study

Cultural Considerations

- Aware of researchers' own biases
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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

Outline

Do Undergraduate Projects Need IRB Review?

No, if **ALL** of the criteria are 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

When in doubt, consult your faculty advisor

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
- Undergraduate Work Involving Human Subjects: https://division-research.brown.edu/research-cycle/conduct-research/human-subjects-research/need-hrppirb-review/undergraduate
- Responsible Conduct of Research (RCR) Training: https://division-research.brown.edu/research-cycle/conduct-research/ethics-research/responsible-conduct-research-rcr-training