The Institutional Review Board

An Introduction

Social and Behavioral IRB Managers

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Topics

- What is an Institutional Review Board?
- When does research require IRB oversight?
- What to do when your research requires IRB oversight
What is an Institutional Review Board?
What is an Institutional Review Board?

- A panel of faculty, students, other professionals, and community members

- Ensures Human Subjects Research follows federal ethics regulations

- Federally mandated for any US institution that accepts Federal money to conduct Human Subjects Research
What is an Institutional Review Board?

- *The Belmont Report* outlines major ethical principles in Human Subjects Research (HSR)

- Next to the federal regulations (45 CFR 46), the most important document on HSR ethics

- *Belmont’s* principles are not laws, but a guide for thinking about ethical Human Subjects Research

- An excellent starting point for discussion about research ethics
What is an Institutional Review Board?

- Stanford has 8 IRBs
  - 7 Medical
  - 1 Non-Medical
- Similar panels that oversee:
  - Laboratory animal care and use
  - Radiation safety
  - Stem cell research
What does this mean to me?

- The IRB helps researchers navigate the federal Human Subjects Research ethics regulations
- Helps Human Subjects Research come to fruition
When does research require IRB oversight?
When does my work require IRB oversight?

- Academic work requires IRB oversight when:
  - It meets the federal government’s definition of research
  - It is about human subjects
When does my work require IRB oversight?

- **Research** is any *systematic investigation* designed to develop or contribute to *generalizable knowledge*

- **Human Subjects** are living individuals about whom a researcher obtains:
  - Data through *interaction or intervention* with the individual
  - *Identifiable* private information

Source: 45 CFR 46.102
How do I find out if my work requires IRB oversight?

› Ask Us!
  • We are happy to meet to discuss your project
  • Phone or face-to-face is usually best
What kinds of research require IRB review?

- **Examples include:**
  - Surveys, interviews, questionnaires
    - Even if no identifiable data is collected
  - Any analysis of Personally Identifiable Data
    - Including secondary data
  - Experiments involving Human Subjects
    - Including Field Experiments and Randomized Controlled Trials
What kinds of work DO NOT require IRB review?

- Examples include:
  - Research Practicum (class projects)
    - Unless they involve greater than minimal risk
  - Analysis of de-identified data
  - Program evaluation/Quality Improvement
  - Pilot studies with fewer than 10 subjects
  - Creative projects (art, fiction writing, etc.)
  - Journalism
  - Oral History
  - Any research not about Human Subjects

- These things usually do not require IRB review
  - It’s always best to ask to be sure!
My project is Human Subjects Research.

Now What?
My project is Human Subjects Research. Now what?

- 3 steps:
  - Complete CITI Human Subjects Training
  - Students must find an Academic Sponsor
    - Faculty need chair or dean review instead
  - Submit a protocol application
My project is Human Subjects Research. Now what?

- Complete CITI Human Subjects Training
  - www.citiprogram.org
    - “Log in Through My Institution” with your SUNet ID and password
    - Complete Group 2 training
  - Refresher course required every three years
  - All protocol personnel who will have access to identifiable data must complete CITI training
My project is Human Subjects Research. Now what?

- Academic Sponsor
  - Required for all students and postdocs
  - Sponsor must be a member of the Academic Council
  - Provide scientific review and oversight
  - Sponsor completes an online form
    - Must be received before protocol can be approved

- Faculty researchers need a similar review done by their chair or dean
My project is Human Subjects Research. Now what?

- Submit a Protocol application
  - eprotocol.stanford.edu
    - Non-Medical application

- Remember to:
  - Allow pop-up windows
  - Save frequently
  - Be patient!
My project is Human Subjects Research. Now what?

- Monthly Submission deadline
  - First day of the month
    - If the 1st falls on a weekend, deadline is the first weekday of the month.
  - Regular and Expedited protocols must be submitted by this date to be reviewed during a given month
My project is Human Subjects Research. Now what?

- Three review types
  - Regular
  - Expedited
  - Exempt
My project is Human Subjects Research. Now what?

- Three review types
  - **Regular** review
    - Studies with more than minimal risk
      - Asking about self-harm, suicidal ideation, etc.
      - Illegal behavior
      - Most studies involving prisoners
    - Reviewed by the full IRB at a convened meeting
      - Meetings are scheduled for the last Friday of each month
My project is Human Subjects Research. Now what?

- **Three review types**
  - ** Expedited review**
    - Studies with no more than minimal risk
      - Lab experiments (usually)
      - Mild deception
    - Reviewed and approved throughout the month
      - Do not need to wait for monthly meeting
My project is Human Subjects Research. Now what?

- Three review types
  - **Exempt** review
    - Studies with no more than minimal risk
      - Simple surveys
      - Simple interviews
    - Exempt from regulations and continued IRB oversight
      - But still need an initial review
    - Review and determinations made throughout the month
      - Do not need to wait for monthly meeting
My project is Human Subjects Research. Now what?

- Informed Consent
  - Consent templates at humansubjects.stanford.edu
    - “Forms and Templates” in left side menu
    - Templates contain all required elements
  - Important to tailor your consent form to your situation
    - Readability is very important
      - Translations, if used, must be attached to protocol
My project is Human Subjects Research. Now what?

- Informed Consent and deception
  - **Deception** is intentionally misleading subjects or providing false information about a study
  - Using deception in research is acceptable
    - Should be minimized
    - Must be able to justify deception
    - Debriefing is almost always required
My project is Human Subjects Research. Now what?

- When can I begin my work?
  - After you receive IRB approval
Other things to remember

- New Protocol Submission deadline!
- Answer all questions on the application
- Know your funding / payment procedures
- Know your recruitment strategy
- Informed consent process
- Attach surveys, interview questions, etc.
- OPACS review
- Modifications to approved protocols
  - Must be submitted for review
  - Not subject to the monthly deadline
Contact the IRB

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- [humansubjects.stanford.edu](https://humansubjects.stanford.edu)
  - Forms, FAQs, Guidance

- These slides available at: [https://goo.gl/2okeKx](https://goo.gl/2okeKx)
  - This link is case-sensitive!