The Institutional Review Board

AN INTRODUCTION

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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 individuals about whom a researcher obtains:
  - Data through interaction or intervention with the individual
  - Identifiable private information

Source: 45 CFR 46.102
When does my work require IRB oversight?

- Upcoming changes to the regulations
  - Scheduled to take effect on January 21, 2019
  - More social and behavioral research can be exempt
  - Renewals are eliminated for most Expedited protocols
  - Should simplify IRB review and approval process
How do I find out if my work requires IRB oversight?

Two ways:

› **Ask!**
  • Usually best to talk via phone or face-to-face

› **OR:** Complete an Application for Determination of Human Subjects Research via eProtocol
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
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 1\textsuperscript{st} 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?

- eProtocol New User Training sessions
  - Held monthly
  - Sign-up and schedule available at researchcompliance.stanford.edu
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?

- Stanford Exempt Category 7
  - Covers research involving “Benign Behavioral Interventions”
    - Brief in duration
    - Not harmful or embarrassing to subjects
    - Subjects must be informed
      - Deception must be agreed upon
    - Not federally funded
My project is Human Subjects Research. Now what?

- Informed Consent
  - Eight required elements (45 CFR 46.116)
    - The study is *research*
    - Purposes and procedures of the research
    - Duration of participation
    - Risks/benefits to participants
    - Alternatives to participation
    - How confidentiality will be maintained
    - Researcher and IRB contact information
    - Participation is voluntary
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
    - 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
- 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
  - Forms, FAQs, Guidance

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