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 that is 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
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
How do I find out if my work requires IRB oversight?

- Application for Determination of Human Subjects Research
  - Available at humansubjects.stanford.edu
  - Click on “Forms and Templates” in the menu on the left
  - Email to afbailey@stanford.edu
  - You will get a Notice of Determination in return
    - Two outcomes:
      - Not HSR – no need to submit a protocol
      - HSR – you must submit a protocol
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
  - 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 via SSO” 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.
  - Protocols must be submitted by this date to be reviewed during a given month.
My project is Human Subjects Research. Now what?

- Protocol application form

**Instructions:**
- Click the image of the binoculars (next to the Name) to search for the person you wish to add. Once found and selected, edit the information as needed. Email addresses must be valid, or the processing of your protocol application may be delayed.
- At minimum, a Protocol Director (PD) and Administrative Contact must be entered; the same person may be entered for both roles if needed.
- If the PD is a student (e.g. Undergraduate, Graduate, Post-Doc, Medical, Medical Fellow), you must also enter a Faculty Sponsor.
- Only those entered in the following roles will have access to edit the protocol application: PD, Admin Contact, Co-PD, Other Contact.
- Click the link in the Other Personnel section towards the bottom of the page to enter additional personnel (including persons without SUNetIDs).

**Protocol Director**

<table>
<thead>
<tr>
<th>Name</th>
<th>Degree (program/year if student)</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ratan Banik</td>
<td></td>
<td>eProtocol Affiliate</td>
</tr>
</tbody>
</table>

**E-mail**

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**Dept**

| Vice Provost and Dean of Research - Research Compliance

**CITI Training completed in the last two years?**

- Yes
- No
My project is Human Subjects Research. Now what?

- **eProtocol New User Training sessions**
  - Held monthly
  - 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 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**
  - 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?

- 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
- Explain and justify deception, if applicable
- Know your funding / payment procedures
- 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

- Adam Bailey, Non-Medical IRB Manager
  - afbailey@stanford.edu
  - 650-723-2480

- Sam Felice, Non-Medical IRB Associate
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- humansubjects.stanford.edu
  - Forms, FAQs, Guidance

- These slides available at: https://goo.gl/2okeKx