The Human Subjects Institutional Review Board


Presented by Alena Filip
IRB Coordinator
Office of Graduate Studies & Research
San Jose State University
IRB Who?
Meet the team

❖ IRB coordinator
  • Screens and assigns proposals

❖ 10-15 committee members
  • Mostly faculty volunteers
  • Number and composition must reflect capacity for ethics review in different disciplines

❖ AVP of GS&R
  • Institutional officer – final approval
IRB Why?
The pieces of the policy puzzle and balancing the ethics scale

Belmont Report
- Respect for persons (informed consent)
- Beneficence (risk/benefit analysis)
- Justice (equitable subject selection)

Federal Regulations (45CFR46)

SJSU Policy for the Protection of Human Subjects (S08-7)

The IRB protocol/proposal
IRB What & When?
A different process for different work

Before commencement of work!!

• Exclusion (2-5 business days)

• Exemption (7-10 business days)

• Expedited Review (one month)

• Full Review (no summer and winter schedule)

• Registration (2-5 business days)
**Exclusion**

The (only) two criteria for review

- **Is your work research?**
  - A **systematic investigation** designed to contribute to **generalizable knowledge**
  - Usually includes a publication/dissemination component

- **Does your work involve human subjects?**
  - Direct interaction / intervention with individuals
  - Analysis of or access to private records
Exemption
Oversight without a formal IRB review

• Research that’s no greater than minimal risk
• No protected groups – children, pregnant women, prisoners...
• Must fit into at least one of the prescribed categories
  (see exemption screening form)
• GS&R screens for eligibility and registers the research
• Complete protocol required
Formal (non-exempt) IRB Review Categories

“Expedited” is defined by how well prepared your protocol is

<table>
<thead>
<tr>
<th>Expedited Review</th>
<th>Full Review</th>
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<tr>
<td>• <strong>Default</strong> review process if research is not eligible for exemption</td>
<td>• IRB member optional recommendation</td>
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<td>• One reviewer evaluates and approves the protocol</td>
<td>• A majority of committee members must decide</td>
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<td>• Problematic protocols/ethical concerns</td>
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IRB Registration
One form for (almost) everything else

Express your intent to conduct human subjects research if you are:

• An SJSU investigator with a pending grant
• An SJSU investigator with IRB approval from an outside institution
• An outside investigator with IRB approval from home institution

No review takes place!
Creates a paper trail for documenting compliance
IRB How?
As in, “How long is this going to take? I needed approval yesterday!”

Possible reasons for delay:

• Not enough info from investigator/missing documents/conflicting info within protocol
• Protected groups
• Institutional concerns about liability
• Adversarial relationship between investigator and IRB
• Human error
IRB How?
As in, “How do I get the ball rolling?”

Utilize the many resources available:

• **IRB website:**
  [http://www.sjsu.edu/gradstudies/irb](http://www.sjsu.edu/gradstudies/irb)
• **IRB checklist**
• **IRB FAQs**
• **IRB workshop (student and discipline centered)**
• **CITI training**
• Contact the IRB coordinator...
IRB Questions?

Alena Filip
IRB / Thesis Coordinator
Phone: 408-924-2479
Email: Alena.Filip@sjsu.edu
Location: ADM 223
Address: Office of Graduate Studies & Research
San Jose State University
One Washington Square
San Jose, CA 95192-0025