The Human Subjects
Institutional Review Board


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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**

“Expeditied” 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
- IRB checklist
- IRB FAQs
- IRB workshop (student and discipline centered)
- CITI training
- Contact the IRB coordinator...
IRB Questions?

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