Institutional Review Board and YOU!

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Overview

- What is the IRB?
- Important historical events
- How the IRB review process applies to your work
- Things to consider
- How to submit an application
What is the IRB?

The IRB stands for the Institutional Review Board.

An IRB is a committee board which reviews human subjects studies to determine the benefits of the research outweigh the risk and has been formally designated to review research to ensure the rights and welfare of participants in the research are adequately protected.
The SDSU IRB

- Reviews all human subjects research conducted by SDSU and the membership is comprised of
- SDSU Faculty from a wide-range of academic disciplines
  - Education
  - Exercise and Nutritional Sciences
  - Public Health (includes a medical doctor)
  - Anthropology & Latin American Studies
  - Speech, Language and Hearing Sciences
  - School of Public Affairs
  - Psychology
- SDSU Student Representative
- Non-Affiliated Individual
- SDSU Staff
- We also invite outside experts to assist with the review of protocols as necessary
- Advocates for certain classes of participants are invited to aid in the review of certain types of research
Highlights of SDSU Education Research

- Research investigating California public high schools and how they have created safer schools for LGBT youth. (*Expedited Review Level)
- A study documenting the impact of the increasing Latino population in a neighborhood in San Diego that was once highly populated by African Americans and how this has impacted the climate at the high school. (*Expedited Review Level)
- Research examining the educational experience of a group of juvenile probationers participating in a reentry program (*Full Committee Review)
The Willowbrook Study: Mid 1950’s – Early 1970’s

✓ **Vulnerable population:** Involved infecting mentally disabled children with a Hepatitis virus to study the progression of the disease and to test new vaccinations. *(Juvenile probationers)*

✓ **Undue Influence:** The study was extremely coercive as parents often had a difficult time getting their children admitted to any mental health care facilities.

✓ Parents were manipulated by the researchers into allowing their children to participate and were told that their children could not enroll at Willowbrook unless they agreed to participate. *(Principals or Teachers doing research with students).*

✓ **Risks outweigh Benefits:** The nature of the experiments were extremely cruel and unjust. *(Risk to breach in confidentiality can cause repercussions to subjects- probationers disclosing illegal behaviors that can cause probation to be revoked).*
National Research Act (NRA) 
Belmont Report

- NRA - Required informed consent for all government sponsored studies and established IRBs
- Foundation of current federal regulations - outlines acceptable and ethical practices in research
- Three basic tenets of the Belmont Report include:
  - Respect: Informed Consent - Voluntary Participation (even if it includes tasks that participants are required to do outside the research context) - Privacy & Confidentiality
  - Beneficence: Maximize benefits - Minimize risk - Qualifications of researcher to carry out the study in a safe and appropriate manner? May require reworking your original plan of action for the research.
  - Justice:
    - Fair subject selection
    - Equitable distribution of risks & benefits
How the IRB Applies to Your Work

✓ The IRB reviews research involving human subjects Defined by 45 CFR 46.102(d) as:

A systematic investigation designed to develop or contribute to generalizable knowledge.

✓ Generalizable knowledge:
  – publication (article, thesis or dissertation)
  – professional presentation
What is a Human Subject?

✓ *Human subject* means a living individual about whom an investigator (whether professional or student) conducting research obtains

(1) Data through intervention or interaction with the individual, or

(2) Identifiable private information.
Things to Consider:
Education Research and Children

- **Minimal Risk:** The magnitude of harm or discomfort are not greater in an of themselves than those encountered in daily life or during routine...psychological examinations or test.

- Research activities in research which involve educational tests, research activities directly related to current curriculum or observations of public behavior where the investigator *does not participate* in the activities being observed may meet exemption criteria.

- If the investigator participates in the activities being observed then the study must be submitted via the vIRB using the expedited/Full Committee template.

- Per the CA Education Code Section 51513 written parental consent must be obtained prior to child participation in research involving tests, questionnaires, surveys, or examinations containing any questions about the student's or the student’s family’s personal beliefs or practices in sex, family life, morality, and religion. The SDSU IRB requires such research to be submitted through the Expedited template and will not be considered exempt.
Consider: Recruitment

✔ Recruitment should be done in a neutral fashion; avoid persuasive language or situations.
  − All recruitment materials must be submitted to IRB

✔ Access—How are teacher, students and parental information being accessed.

Do you have proper access to a person’s information for research purposes?

FERPA Compliant—The Family Educational Rights and Privacy Act (FERPA). Generally, schools must have written permission from the parent or eligible student in order to release any information from a student's education record.
Questions re: Existing Data

✔ Usually best to contact IRB prior to submitting or submit a questionnaire to irb@mail.sdsu.edu. The questionnaire can be found at: https://newscenter.sdsu.edu/researchaffairs/hrpp.aspx
IRB Review Levels

✓ Full Committee: greater than minimal risk
  • deception
  • vulnerable subjects depending on what the research tasks are
  • Tasks/questions being asked

✓ Expedited - research involving no more than minimal risk which falls under certain categories*
  *Minimal risk = probability of harm/discomfort in research is not greater than that encountered in daily life

✓ Exempt
  • Often analysis of existing anonymous data falls into this category
  • Observation of public behavior-
  • Non-anonymous data as long as no risk is posed if confidentiality is breached
  • the study would not solicit information from a participant that, if disclosed, would reasonably place the subject at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
Things for you to consider: Your Research Design

- Will Interviews, observations, questionnaires, using assignments that will be conducted as part of normal curriculum for research purposed? A combination of several of these things?

- One subject population? OR Several?
  These are important points to keep in mind and are integral in organizing your submission.
- For Example: The LGBT Study we spoke of earlier

Subject Involvement- Section Instructions
Describe the tasks the subject will be asked to complete and indicate the amount of time that the subject will be involved in each aspect of the study.
Expedited and Exempt Examples

Does the study solicit information from a participant that, if disclosed, would place the subject at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

Expedited-Consider:

✓ Students disclosing detailed information about their treatment by other students in school because they are LGBT - could be damaging to the subjects and secondary subjects standing in school and/or reputation. What is the management plan for this?

✓ Open ended questions to Counselors, Teaching Staff and Advisors about specific experiences with students and the support of lack of support they receive from administration - could be damaging to the subjects and secondary subjects' financial standing, employability or reputation. What is the management plan for this?

Exempt

✓ Anonymous online surveys of Counselors, Teaching Staff and Advisors - yes/no questions about current policies and if they think they’re working
Consent: Respect for Persons

- Not just a written form, but an on-going open discussion of participant rights and study details. *Think about this especially with studies that include multiple data collection points (i.e. Pre and Post), time between different tasks, description of risks and your management plan.*

- **Inadequate consent forms**-Language should be understandable to the audience for which it is written.

- **Inconsistent with protocol**

- Adequate Details so they are clear about whether or not to participate.-*Consistent with the protocol.*
Consent/Assent

- **Templates may be found at:**
  [https://newscenter.sdsu.edu/researchaffairs/templates.aspx](https://newscenter.sdsu.edu/researchaffairs/templates.aspx)
  - Child Assent—A child’s affirmative agreement to participate in research—not objecting should not be construed as assent. This is a requirement for children seven years old or greater.
  - Parental Permission form – The IRB may find permission from only one parent/guardian is sufficient.

Save yourself time and stress… use SDSU templates!
Additional IRB Review…

If you have other affiliations…

- Joint Student
- Hospital
- University
- If you will be conducting a study through another institution, you must receive their IRB approval before submitting to the SDSU IRB.
The following criteria apply for this cooperative review:

a) The student must be serving as the principal investigator on the proposed project.
b) Research must not exceed minimal risk, as follows:
   1. Research that meets the criteria for exempt or expedited review per 45 CFR 46 and associated OHRP guidance can be reviewed under this agreement.
   2. All other research requiring review during a convened IRB meeting may also be reviewed under this agreement if the Reviewing IRB determines during a convened meeting that the research does not exceed minimal risk.
   3. In the event a Reviewing IRB determines that the proposed research exceeds minimal risk, the SDSU program director will inform the student that this agreement cannot be used and the study must be submitted for separate review by the two institutions.

Ensure the Investigator Experience Section of the protocol also includes- your CGU co-chair's name and email address.
Information:
Go to our website
https://newscenter.sdsu.edu/researchaffairs/hrpppguidance.aspx
✔ How to use vIRB
✔ Faculty Assurance forms- Link to the Human Subjects tutorial
✔ Link to Guidebook
✔ Templates
Your Protocol Submission: Contact Information

✓ List yourself as the Principal Investigator (PI)
  – Email address
  – Phone number

✓ List your Thesis Chair (Masters) or Faculty Sponsor (Doctoral) as the Co-I
  – Email address
  – Office phone number
Upload Supporting Documents

Upload all applicable documents:

- Letters of Authorization
- Recruitment Materials
- Informed Consent Forms
- Study Instruments
- Grant Narrative (if funded)

The current vIRB system is most compatible with documents that are .doc (97-2003 document) and not .docx. Also consents must be submitted as Word documents.
Good luck!

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