Doing Research with Human Subjects at CSUB

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THE NIT-PICKING IRB

HOW THE IRB MEMBERS SEE THEMSELVES:

www.researchcartoons.com
Above any existing law or regulation, it is our duty to conduct research in a manner consistent with proper and responsible conduct of individuals expected in the University community.
IRB Organizational Flow-Chart

Academic Provost: IO

GRASP
AVP & Compliance Officer

Research Ethics Review Coordinator (RERC)
Isabel Sumaya

Training Program
CITI

HSIRB
Chairperson
Roseanna McCleary

Gwen Parnell,
Research Compliance Analyst

IACUC
Chairperson
Steven Gamboa
CSUB HSIRB Membership

- **Scientific Concerns**
  - Roseanna McCleary, Social Work, Chair
  - Marianne Wilson, Psychology
  - Chandra Commuri, Public Administration

- **Non-Scientific Concerns**
  - Steven Gamboa, Philosophy/Religious Studies
  - Nate Olson, Philosophy/Religious Studies
  - Chris Livingston, Library

- **Community Concerns**
  - Grant Herndon, Schools Legal Service
  - Tommy Tunson, DBA, Ex-Chief of Police, Arvin, Ca
Meeting Dates 2017-2018

Fall Meeting I: Sept. 8, 2017 Submission Deadline: Aug 25, 2017

Fall Meeting II: Nov. 17, 2017 Submission Deadline: Nov. 3, 2017

Spring Meeting I: Feb. 16, 2018 Submission Deadline: Feb. 2, 2018

Spring Meeting II: May 16, 2018 Submission Deadline: May 2, 2018
Is a project human subjects research?

1. The **subjects** are the living individuals about whom an investigator conducting research obtains

   (1) data through *intervention* or *interaction* with the individual

   OR

   (2) identifiable private information
How an IRB Makes Decisions

Is a project human subjects research?

2. Research is as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

A "systematic investigation": prospective plan that incorporates data collection, either quantitative or qualitative, and data analysis to answer a question.

Examples of systematic investigations include:

- surveys and questionnaires
- interviews and focus groups
- analyses of existing data or biological specimens
- epidemiological studies
- evaluations of social or educational programs
- cognitive and perceptual experiments
- medical chart review studies
nature of that activity and the use of the data

Not sure???
Overview of the IRB Process

Step #1
Protocol Submission

Step #2
Protocol Review

Step #3
Protocol Authorization

Do Research!
Pre Step: Human Subjects Training
Step #1: Protocol Submission - Qualtrics

- **What to submit?**
  - “Human Subjects Protocol”
  - “Third Party Access to Existing Data” Protocol

- Fill out form and describe how human subjects will be involved in detail:
  - Purpose
  - Methods
  - Procedures
  - Security
  - Risks /Adverse Reactions
  - Attach Consent Form, Survey etc.
How an IRB Makes Decisions

The IRB must know what it is being asked to authorize.

- Levels of review:
  - Standard (Full Board)
  - Expedited (Two Board Members)
  - Exemption from Full Review (RERC)

**Exempt** → lowest amount of risk: participants cannot be considered vulnerable (children, prisoners, pregnant women, fetuses, neonates, institutionalized, economically & educationally disadvantaged, mentally disabled, physically handicapped) cannot involve deception, and if participants can be identified, then disclosure cannot put participants at risk.

**Expedited** → no more than minimal risk as expected in normal life.

**Standard Review** → greater than minimal risk.
Step #2: Protocol Review

- How does this work?
- Logged in at GRASP
- Checked for Completeness at GRASP
- Sent to RERC
- RERC determines level of review
  - Exemption (RERC): Revisions!
  - Expedited (Sent to two IRB Members for review): Revisions!
  - Standard (Full Board): Wait for next Full Board Meeting Revisions!

How long does it take? It depends…
Step #3: Protocol Authorization

- Happens when all requests for revision and clarification have been satisfied
- The IRB authorization Letter
  - Authorization is for one year
  - You must request Renewal
Step #4: Conduct of the Research

- Must correspond to what has been proposed and authorized
- Reporting of adverse events, protocol violations
- Research monitoring
Investigator Responsibilities for Ethical Research

<table>
<thead>
<tr>
<th>Design &amp; Plan Ethical Study</th>
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</thead>
<tbody>
<tr>
<td>Submit to IRB</td>
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- If changes, obtain IRB approval for changes
- If need be renew study on a yearly basis

Retain signed consent forms for 3 years
Common Problem #1

- What I plan to do doesn’t need IRB review
  - I already have access to these data
  - This is just what I do everyday in my job
  - I’m just getting information from people

- Bottom Line: submit and let the IRB decide
Common Problem #2

- I submitted something, I must be good to go
  - Submission is step #1 in the submission, review, authorization sequence

- Bottom Line: the IRB authorization letter is the only valid signal that you are good to go
  - No research contact with potential participants until then
Common Problem #3

- The “Purpose” section: isn’t my getting a degree an adequate purpose?
  - For authorization, IRB must judge benefits to outweigh the costs/risks
  - Benefits to you personally don’t count

- Bottom Line: Use the “Purpose” section of the protocol to make your case for “benefits”
  - “... an explicit statement of what is and is not known about the topic. Indicate what the proposed research could add ...”
Timing is Everything

► Start a project NOW. It’s never too early to start planning.
► Allow more time than you think you need
► IRB review may take longer than anticipated depending on the complexity of your study, protocols in the que, etc…
► Respond promptly to correspondence from the IRB.
► Please **do not** submit your project on Thursday at 4:30 pm and say that you need it by Saturday.
Thank You!

Questions?