CalPolyPomona

Office of Research Compliance

Institutional Review Board Application Process

November 14, 2023

Learning Objectives

- Purpose of the Institutional Review Board- Basics
- The research process and ancillary approval
- Protocol process and navigating the Cayuse IRB platform
- Adequate Resources to Conduct Research

Basics of the IRB

Institutional Review Boards

Basics of the IRB

Is it ‘R’esearch with human subjects?

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

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

1. (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
   (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

CPP Researcher Responsibility

- Encourage research participation
- Conduct yourself with integrity
- Follow University policy and sponsor conditions

IRB Members

The Cal Poly Pomona IRB

- The Committee
  - Bonny Burns- Whitmore, IRB Co-Chair
  - Greg Placentia, IRB Co-Chair
    - Members
      - Faculty with various backgrounds and expertise
      - One nonaffiliated member
      - One Nonscientist

Faculty Advisor and Student Investigator

Qualified by education, training, and/or experience

- Recent familiarity and experience with the topic of study
- IRB investigator
  - Principal Investigator or Co-PI
- Getting started with a new protocol (Faculty Information sheet)

Faculty Advisor and Student Investigator

Cal Poly Pomona IRB
IRB- Responsibilities of a Faculty Advisor

Academic Year 2022-2023

To guide student researchers through a successful study, the IRB recommends the faculty advisor to:

1. complete a Research Certification Form (as appropriate for Thesis/Project) – Contact your designated department
2. be sure that submitted information in the student PI's protocol is methodologically sound, accurate, and complete *prior to submitting the protocol through Cayuse*. The IRB highly recommends that all student PIs submit their protocol to their faculty advisor as a Word document for discussion and revision prior to Cayuse IRB for review process.
3. provide the student with your current, valid CITI training certificate so they may upload it into Cayuse.
4. certify the submitted protocol through the Cayuse system *after* you have reviewed the proposed research for accuracy and completeness. Administrative Review cannot begin until faculty mentor have certified the submission. (An email is sent to the faculty mentor from Cayuse when the submission has been submitted and is ready for faculty certification.)
5. ensure that the student PI promptly responds and supplies the IRB with requested information and revisions during the review process.
6. ensure that the student PI does not begin the study until AFTER IRB WRITTEN APPROVAL is granted.
7. meet regularly with the student PI to monitor the study. If you are not available to advise the student PI's research in person or by email/phone/video conference (during vacations, sabbaticals, etc.), you will arrange for another faculty mentor to carry out your responsibilities and will inform the IRB office of the change.

Understanding Ancillary Approvals

Some projects involve activities that require specialized review outside of the IRB

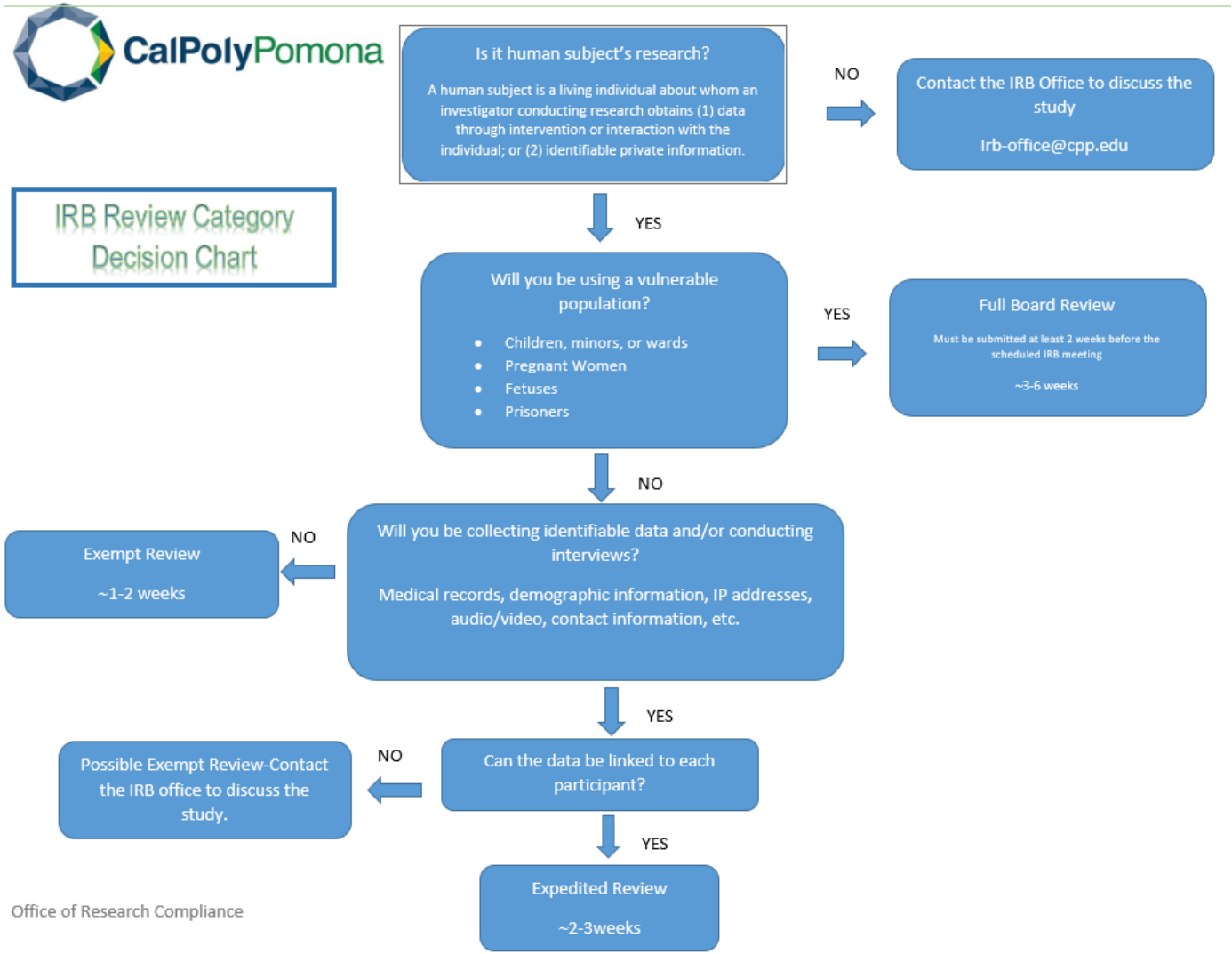
- Research Site Authorizations
- Departmental Access to Data
- Registrars' office-
  - FERPA
- Library deadlines

Protocol Reviews

Types of Review

- **Exempt**
  - Anonymous or identifiable surveys or interviews – less than minimal risk
- **Expedited**
  - Collection of data from voice, video- less or greater than minimal risk
- **Full board**
  - Present more than minimal risks to subjects
  - Studies involving prisoners, persons with undocumented status, research on illegal activities, incarcerated youth, among others

Decision Tree 2023



The IRB Protocol Application-Sections

What must be included in the IRB protocol application

1. Research and focus	6. *Data Security*
2. *Methods*	7. Potential Risks
3. Subjects and Recruitment	8. Affiliations
4. *Data Collection*	9. *Informed Consent & Assent Forms*
5. Vulnerable subjects	10. Study Declaration

"Confidential" research participation means that the data from the research subject(s) **can** potentially be identified or linked to a particular individual. Thus, **any** data collected face-to-face (consumer survey, focus groups, standing in front of a classroom, collecting IP addresses, etc.) is automatically considered in the category of being "confidential"

A **"strictly anonymous"** study design is one in which it is impossible to trace data or information back to the research subject from whom it was obtained. In other words, the data **cannot** be identified to any research participant, not even by the researcher.

The IRB Protocol Application-Section 2

Methods

Summarize the overall design of your proposed study

Example: Procedures involving human subjects, including participant observation, as well as up to 100 semi-structured interviews and life histories, will examine the perceived risks or benefits for local community members of proposed mining development projects, as well as past experiences with social and environmental systems under stress from anthropogenic changes to land, territory and resources. The new Lithium Valley project at the Salton Sea, offers an opportunity to lead students in ethnographic field training that combines community-based action research with citizen science.

The IRB Protocol Application-Section 3

Subject and Recruitment

A human subject is a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual or identifiable private information. (Dept. of Health and Human Services, 45CFR46)

Describe the characteristics of the subject group(s) that will be used in the study.

- Example: Participants in the study will include Indigenous people, activists, residents, squatters, as well as migrant farmworkers and geothermal plant operators who are 18 years old or older. The subject pool will include members of the California Energy Commission's Lithium Valley Commission, as well as other stakeholders, decision-makers and experts on the role of mining in the energy transition more broadly.

The IRB Protocol Application-Section 6

Data Security

The researcher must provide a plan sufficient to protect personal information from improper use and disclosures, including sufficient administrative, physical, and technical safeguards to protect personal information from reasonable anticipated threats to the security or confidentiality of the information.

- **Will personally identifiable information (PII) be collected/used?**
- **Who will have access to the data?**
- **How will the raw data be kept protected and secure?**

The IRB Protocol Application-Section 9

Elements of informed consent include …

- Explanation of the purpose(s)
- Description of the procedure(s)
- Summary of the data to be collected
- Description of any foreseeable risks/ discomforts
- Description of the benefits to the subject/ including compensation.
- Explanation of how the investigator (PI) will maintain confidentiality of records.
- Contact information of all PI's and the IRB office, protocol number
- A statement that participation is voluntary, that refusal to participate involves no penalty and that the subject may discontinue at any time.
- Anything else that will help the subject to understand.

Library Resources

- Subject Librarians
  - https://www.cpp.edu/library/reference-instruction/contact-subject-librarian.shtml
  - https://libguides.library.cpp.edu/datamgmt
- Workshops (citation, Topic/Research areas and methods)
  - Library Calendar:
    - https://cpp.libcal.com/
- Writing Center
  - Website:
  - https://www.cpp.edu/lrc/our-team/writing-center.shtml
- Bronco Scholar
  - FAQ's:
    - https://www.cpp.edu/library/digital-collections/bronco-scholarworks/faq.shtml
- Qualtrics
  - https://www.cpp.edu/cba/customer-insights-lab/resources/qualtrics.shtml

IRB checklist

- Follow a timeline to ensure you are on track
- Conduct yourself with integrity
- Follow University policy and sponsor conditions
- Remember to submit modifications

QUESTIONS/Additional Info

- More info:
  - Human subject research https://www.cpp.edu/research/research-compliance/index.shtml
  - IRB protocol application process https://www.cpp.edu/research/research-compliance/irb/protocol.shtml
  - Irb-office@cpp.edu or 909-869-4215
  - www.hhs.gov/ohrp/
  - Ask for Maya/IRB Office staff/or
  - Members of the IRB- Your college/discipline representative
- Questions?