Institutional Review Board (IRB)

OFFICE OF GRADUATE STUDIES AND RESEARCH

INNOVATION AND INSTRUCTION BUILDING, SUITE #3100

CSUDH IRB Team

Institutional Official- Dean Sheree Schrager

Research Compliance Officer- Judy Aguirre

Research Compliance Assistant- Alyanna Paulino

IRB Chair- Dr. Susan Einbinder

IRB Members (From various disciplines across campus)

What is the **purpose** of an IRB?

The sole purpose of an IRB is to protect the **rights** and **welfare** of human study participants.

Historical Context

- Historically, the rights of human subjects were violated.
  - The Nazi Experiments
  - Tuskegee Syphilis Study
- IRBs help **restore** the community's trust in science and research.

The Belmont Principles

Respect

- Individuals need to be treated as <u>autonomous agents</u>, and those with <u>diminished autonomy</u> are entitled to protection. (Voluntary consent geared toward the target study participant population.)

Beneficence

- <u>Minimize harm</u>, <u>maximize potential benefits</u> for participating in research. (Potential benefits are maximized and potential risks are minimized.)

Justice

- <u>Equitable distribution</u> of risks and benefits. (Risks and benefits are distributed equitably among study participants.)

Regulatory Information

- <u>Ethics</u> (Belmont Principles)
- <u>Federal Regulations</u>
  - Title 45 Public Welfare Department of Health and Human Services Part 46 Protection of Human Subjects (**Common Rule**)
  - **Additional Protections Separate from the Common Rule**
  - Subpart B – Pregnant Women, Human Fetuses and Neonates
  - Subpart C – Prisoners
  - Subpart D – Children
- Local regulations
- State regulations
- University policies

HOW TO SUBMIT A PROTOCOL

- ▶ Protocols are submitted on an online IRB system called Cayuse.
- ▶ You will complete the New Submission Template word document.
- ▶ The templates for consent documents can be **found on the IRB** homepage. https://www.csudh.edu/gsr/research/research-compliance/irb/
- ▶ Your instructor will then review and input your protocol and upload requisite attachments in Cayuse.

Section A: Study Personnel

- All study team members are required to complete the human subjects training on CITI before a submission will be reviewed.

- Be sure to list the <u>faculty member</u> as the PI.

- Students must create a document that lists their **names**, **email addresses**, and **department** for upload into this section.

Section A:
Study Personnel continued

- On-campus sites are **not** required to have a permission letter to conduct research activities.
- A permission letter or proof of permission to conduct research is <u>required</u> for:
  - Any **off-campus** site
  - Any <u>CLOSED</u> group on social media
- Permission must be obtained by an authorized person.

Section B: Research Objectives and Background

- ▶ Describe your research so people in different fields of study can understand your study objectives.

- ▶ Be sure to check for grammar, spelling, and typographical errors.

Section D: Participants, Recruitment, and Compensation

- Inclusion and exclusion criteria

- Your recruitment material (e.g. fliers) must have a 1.25" margin on the bottom for the IRB stamp.

  - CSUDH email address is required on recruitment material.

Section E: Study Methods and Procedures

- In this section, you will describe:
  - The study design and methodology
  - Sample size calculation
  - How you will analyze data
  - Any questionnaires or instruments used in this study will be attached to this section.

Section F: Informed Consent

▶ Types of consent for adult participants:

> ▶ Written/signed consent

> ▶ Information sheet

> ▶ Waiver of consent

▶ Templates are provided by the IRB for consent documents.

> ▶ Take your participants' **reading comprehension level** into consideration when drafting your documents.

Section G: Risk and Benefit Assessment

► Risks in socio-behavioral studies can be **less obvious** than in medical studies.

  ► Evaluate study risks mindfully.

  ► Risks can be subjective and relevant to the subject population.

► Do not overstate benefits.

Section H:
Privacy and Confidentiality

- Privacy:
  - a participant's ability to control how other people see, touch or obtain information about them.
- Types of Confidentiality:
  - Identifiable
  - Coded
  - Anonymous
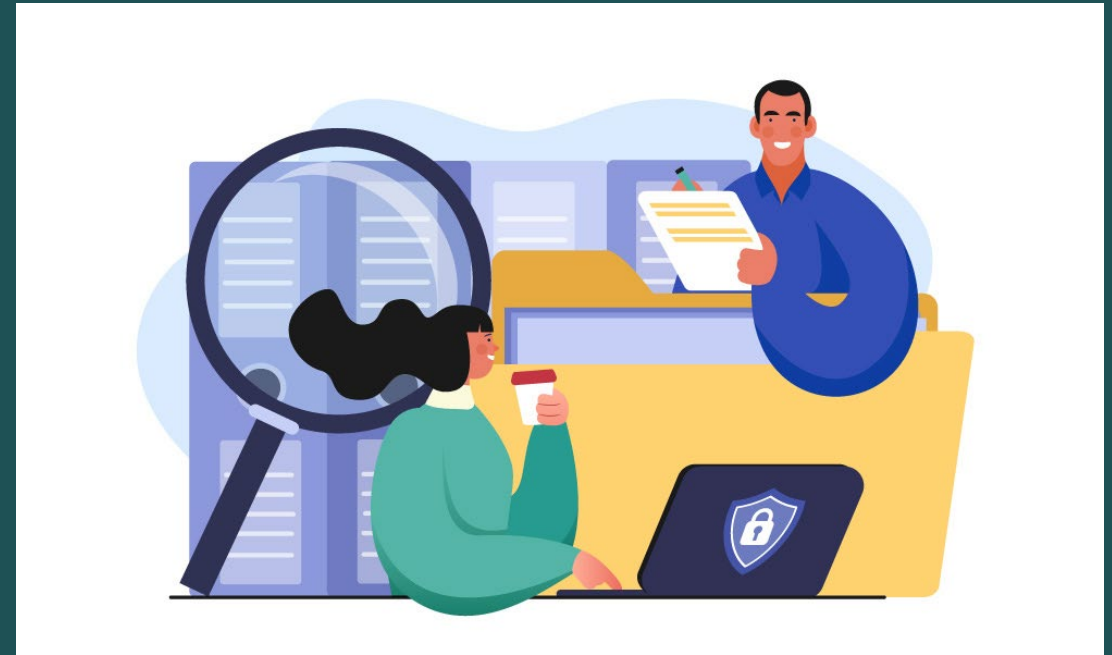
Section I: Conflicts of interest (COI)

- Two types of conflict of interest:
  - General
    - Pre-existing personal, professional, or social relationship may create an appearance of a conflict of interest.
  - Financial

Section J: Researcher Qualifications

- Be sure to include prior research and training for all study team members, including the study PI.

Section K: Additional Documentation

- Attach additional documentation not requested elsewhere in Cayuse (e.g. site permissions).

- Please **do not** attach documents that are required in other Cayuse sections (Survey instruments, recruitment materials etc.)

- Make sure that the training you upload is the **"Socio-Behavioral Learners"** module certificate from CITI.

Outcome of a study proposal review

- Approved

OR

- Returned to the study team for changes, clarification, or a request for additional documents.

Modifications

- You required to submit a modification when you are making **changes** to your study that are **different** from what you indicated on your initial submission.

  - For example:

    - Adding a recruitment site

    - Changing how you will analyze the data

    - Increasing your sample size

General Tips

- Ensure that there is **consistency** throughout your proposal.
- Double-check for an typos, grammar, or spelling errors.
- Ensure that you receive permission from sites as appropriate and that these documents are attached as part of section K.

Additional Questions?

Website: https://www.csudh.edu/gsr/research/research-compliance/irb/

Email: **IRB@csudh.edu**

Resources