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

WHAT IS THE PURPOSE OF AN IRB?

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

The IRB makes sure that research studies meet regulatory requirements prior to and during the course of the study

HISTORICAL CONTEXT

Historically, the rights of human subjects were violated.

- The Nazi Experiments
- Tuskegee Syphilis Stud
- Jesse Gelsinger Case

IRBs help restore the community's trust in science and research.

- By complying with federal regulations, state laws, and university policies.
- Belmont Principles are used as an ethical framework.

WHAT GUIDES THE ACTIONS OF AN IRB?

- Belmont Principles
- Federal Regulations
- Local regulations
- State regulations
- University policies

THE BELMONT PRINCIPLES

Respect	Beneficence	Justice
• Individuals need to be treated as autonomous agents, and those with diminished autonomy are entitled to protection.	• Minimize harm, maximize potential benefits for participating in research.	• Equitable distribution of risks and benefits. (Risks and benefits are distributed equitably among study participants.)

IRB WEBSITE

- https://www.csudh.edu/gsr/research/research-compliance/irb/
- Step 1: Verify whether your project requires IRB review.
- Step 2: Complete the online training course in Human Subject Protections.
- Step 3: Determine when to submit your proposal.
- Step 4: Cayuse Information
- Consent Forms

HOW TO SUBMIT A PROTOCOL

- Our campus uses an online submission system called, "Cayuse".
- Your faculty member is responsible for reviewing your protocol before submitting it on Cayuse.
- Your faculty member will enter and submit your submission.

OVERALL TIPS

- You will be able to use a template provided on the DH IRB website (step 4, entitled "New Submission Template" to articulate your submission.
- Your faculty mentor will use the information from the template to complete the Cayuse submission which includes uploading attachments.
- Please read and answer the questions on the template carefully.
- Be sure to check for grammar, spelling, and typographical errors. Excessive amounts of these types of errors may result in a submission not advancing from the pre-review queue to the review queue.

SECTION A: STUDY PERSONNEL

- Be sure to list the faculty members as the PI.
- Note that all study team members are required to complete human subjects CITI human subjects training before the submission will pass the pre-review process and advance to the review queue.

SECTION B: RESEARCH OBJECTIVES AND BACKGROUND

- Describe your research so that people in different fields of study can understand what your study objectives and background entail.

SECTION C: STUDY POPULATIONS

- Be sure to check off all boxes that are applicable to your study population.
- There may be more than one box that you will need to check for your given study population.

SECTION D: PARTICIPANTS, RECRUITMENT, AND COMPENSATION

- CSUDH email address is required on recruitment material.
- Be sure to indicate what the study entails and how long the study will take to complete.
- PDF recruitment material with a 1.25” margin.
- Be sure to upload all requisite site permissions documentation.

SECTION E: STUDY METHODS AND PROCEDURES

- Describe each step of your study methodology in a sequential manner. Sometimes bullet points may be useful.
- Indicate how you determined what your study sample size should be and how you will analyze the data.

SECTION F: INFORMED CONSENT DOCUMENTS

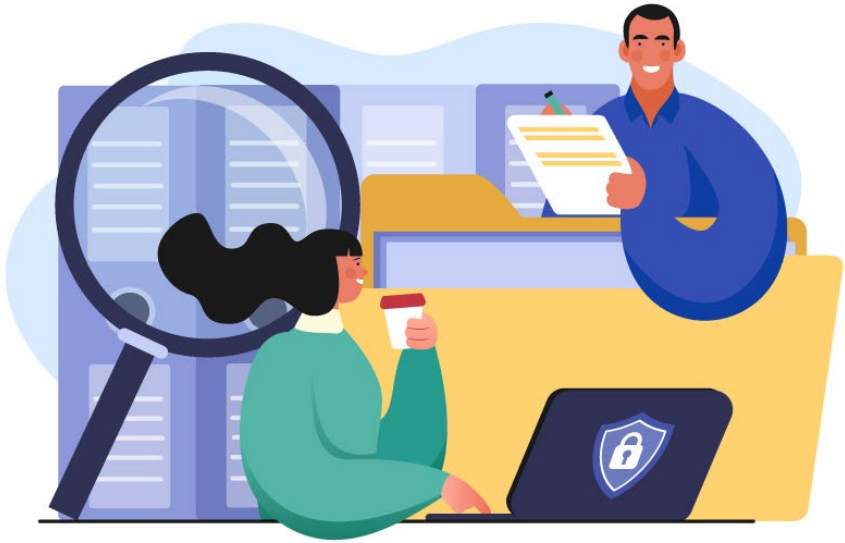
- Take your participant's reading comprehension level into account when drafting the consent documents.
- Templates are provided within the Cayuse form. Prompted by your responses.
  - Consent Form
  - Information Form
  - Parental Permission Form
  - Assent Form
- Make sure they have a 1.25" margin.

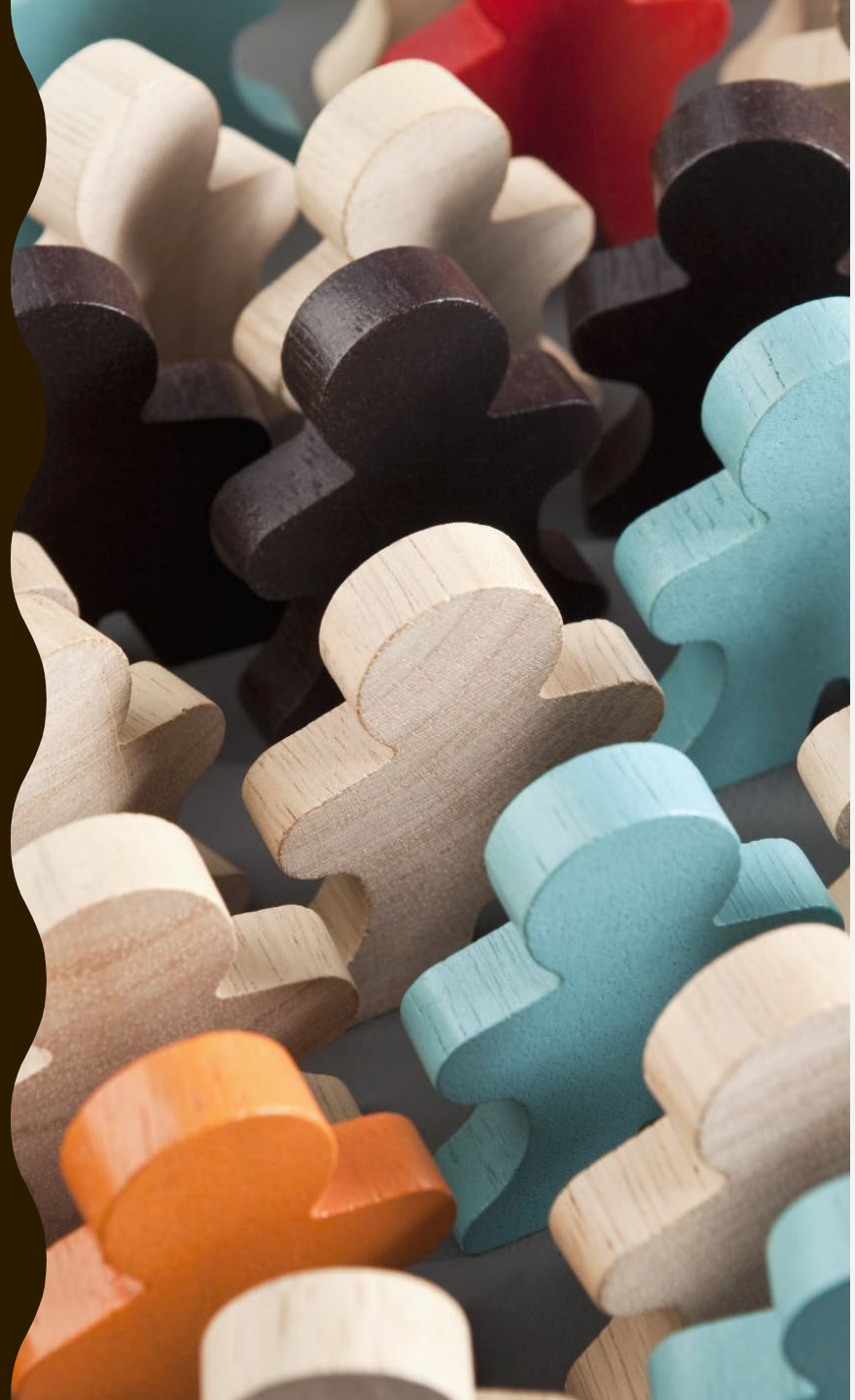
SECTION G: RISK AND BENEFIT ASSESSMENT

- Risks in socio-behavioral studies can be less obvious than a medical study. Think about emotional risk (major and minor), social risk, privacy risk, or economic legal risks.
- Evaluate study risks mindfully. Suggest stepping back from the logistics of the study and thinking how a study participant *may* feel as a consequence of participating in the study. (Empathy)
- Risks can be subjective and relevant to a particular subject/participant population. (Triggering)
- There is no formula to access risk as it can be subjective in nature.

SECTION H: PRIVACY AND CONFIDENTIALITY

- Be mindful of privacy issues and confidentiality issues in your study design.
- Coding data may be helpful.
- Using pseudonyms may be helpful.
- Use the first opportunity to remove identifiers from study data and store the identifiers separately from the study data. Itself.
- Remember to indicate when you plan on destroying the study data.





SECTION I: CONFLICT OF INTEREST

- Two types of conflict of interest
- The takeaway from this slide is to read the questions carefully to determine if you do have a general or financial conflict of interest. If so, describe how you mitigate the conflict of interest.
  - General (Pre-existing personal, professional, or social relationship(s) 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.

SECTION K: ADDITIONAL DOCUMENTATION

- Attach additional documentation as indicated.
- Please do not upload documents that are required to be uploaded in other Cayuse sections. This helps with the pre-review and review processes.

RESOURCES

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

Email: IRB@csudh.edu

QUESTIONS OR COMMENTS?