

# HUMAN SUBJECTS RESEARCH & WORKING WITH THE UIRB

University Institutional Review Board  
California State University, Stanislaus



# Background

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- What is the UIRB?
  - Committee responsible for reviewing human subjects research protocols
- Why do we need UIRB?
  - Protect the rights of human subjects in research and minimize any potential risks and/or harms
  - Protect researchers

# Basic Ethical Principles

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- Respect for Persons
  - Respect individual autonomy
  - Protect individuals with reduced autonomy
- Beneficence
  - Maximize benefits and minimize harms
- Justice
  - Equitable distribution of research burdens and benefits

# Definitions

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- Research: A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.
- Generalizable Knowledge: Meant to draw conclusions, facts, or principles derived from particulars (individuals, medical records, etc.) that are applicable to or affect a whole category (members of a class, kind, group, or field of knowledge) and enhance scientific or academic understanding.
- Human Subject: A living individual about whom an investigator conducting research obtains (1) data through **intervention or interaction** with the individual, or (2) identifiable private information or identifiable biospecimens.

# Applying to the IRB

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- Submit all materials via email
  - IRB application form
  - Informed consent(s)
  - Recruitment materials
    - Email invitations, flyers, letters
  - Instruments
    - Surveys, interview guides, questionnaires
  - Letter(s) of support

# IRB Application Form

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## 1. Title

UIRB Protocol Summary Template

Page 1

### Protocol Summary Template

#### 1. Title of Research Proposal:

Click here to enter or paste text – this field will expand as required. There is no word/page limit.

**Proposed Length of Research Study:**  (i.e., 12 months, 2 years, etc.)

Studies should be submitted well in advance of the anticipated start date to allow for processing, review, and approval.

**Research activities may not begin prior to final IRB approval.**

## 2. Hypotheses and/or Research Question, Purpose

### 2. Description of Research

a. Describe the purpose of your research and hypothesis and/or research question(s):

Click here to enter or paste text – this field will expand as required. There is no word/page limit.

b. Describe the type of data to be collected (i.e. interviews, surveys, recordings, and explain):

Click here to enter or paste text – this field will expand as required. There is no word/page limit.

# 3. Methods and Procedures

## 3. Methods and Procedures

- a. Describe in detail your methods and procedures for conducting your study.

What are your methods for selection and recruitment of participants?

Click here to enter or paste text – this field will expand as required. There is no word/page limit.

Describe your data collection procedures and include a descriptions of the survey/instruments to be used (including pre/post-tests, interview and focus group questionnaires, online surveys, etc.):

Click here to enter or paste text -- this field will expand as required. There is no word/page limit.

- b. Describe any incentives or compensation to be used:

Click here to enter or paste text – this field will expand as required. There is no word/page limit

- c. Participant age range: Click here to enter text. Estimated Number of participants: Click here to enter text.

# 4. Risks to Subjects and Confidentiality

## 4. Risks, Benefits, and Confidentiality

### Risks and Benefits

Describe in detail any psychological, social, legal, economic or physical risk that might occur to participants. *Note that all research may entail some level of risk, though perhaps minimal.*

- a. Description of anticipated risks and how the risks will be minimized:

Click here to enter or paste text – this field will expand as required. There is no word/page limit.

- b. Identify benefits to participants resulting from this research:

Click here to enter or paste text – this field will expand as required. There is no word/page limit.

### Confidentiality

How are participants protected from the potentially harmful use of the data collected in this research?

- c. Describe measures planned to ensure confidentiality or privacy.

Click here to enter or paste text – this field will expand as required. There is no word/page limit.

- d. Describe methods for storing data while study is underway.

Click here to enter or paste text – this field will expand as required. There is no word/page limit.

- e. List plans for storing and destroying data and media (video or audiotapes) once study is completed. Please note that all final records relating to conducted research, including signed consent documents, must be retained by the PI for at least **three (3) years** following completion of the research.

Click here to enter or paste text – this field will expand as required. There is no word/page limit.



# Informed Consent

## 5. Informed Consent

Describe the consent process to be followed in this study, include how and where consent will be obtained. Describe the process to allow for questions. If study involves minors describe parental consent and participant assent procedures. Be sure to attach the informed consent document(s) to this application (see sample on UIRB website, [www.csustan.edu/uirb](http://www.csustan.edu/uirb)).

Click here to enter or paste text – this field will expand as required. There is no word/page limit.

### Online Surveys

Will you use an online survey to obtain data from participants in this study?

No. *If no, skip to next section.*

Yes, I will use an online survey to obtain data in this study. If yes:

a. How will **online data** be collected and handled?

Data collected online will be handled in an anonymous manner (no identifiers will be collected).

Data collected online will be handled in a confidential manner (identifiers will be used).

b. Include an “I agree to participate” answer at the bottom of your consent page that must be clicked in order to proceed to the survey. Consider offering a “I do **not** agree to participate” answer. This is useful when using a survey system that automatically sends reminders to participants who have not yet completed the survey.

Ensure that the online consent document is the first page the participant sees after clicking on the link to your online survey.

### Minors as Participants

Will minors be included in this research?

Yes. Outline procedures to be used in obtaining the agreement (assent) of participants. Describe plans for obtaining consent of the parent, guardian, or authorized representative of these participants. For research conducted within the researcher’s own classroom, describe plans for having someone other than the researcher obtain assent so as to reduce the perception of coercion.

Click here to enter or paste text – this field will expand as required. There is no word/page limit.

No. *All studies excluding minors as participants should include language within the consent document stating that only participants aged 18 and over may participate in the study.*

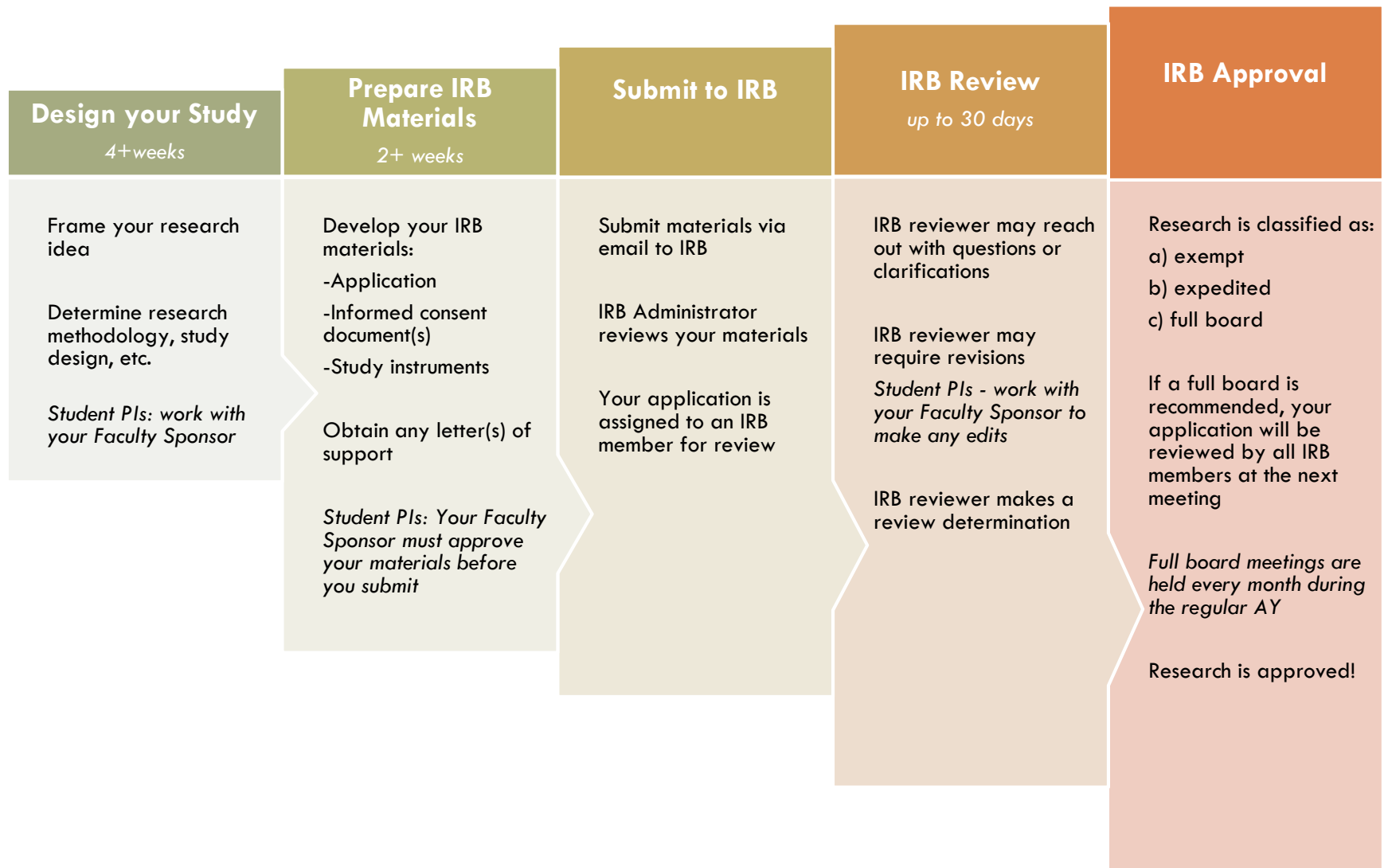
# Informed Consent - Guidelines

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- Investigators must use the template(s) provided on the UIRB website.
- Provide the information that a *reasonable person* would want to have in order to *make an informed decision about whether to participate*
  - Risks/benefits
  - Time commitment
  - Confidentiality
  - Compensation?
- Present the information in a clear, focused manner at an eighth-grade reading level

# IRB Review and Approval

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# When is IRB approval not enough?

## 7. Additional University Approvals

Some human subjects research studies may require additional review and approval by the University, particularly with the Office of Safety & Risk Management. Examples of activities that may require additional approval include : medical procedures with sharps, medical procedures where public vital signs are documented, physical activities, and food preparation for public consumption.

If your research will involve any of these activities, or others that would rise to the level of requiring Safety & Risk, please contact Safety & Risk Management ([www.csustan.edu/safety-risk-management](http://www.csustan.edu/safety-risk-management)) to obtain any additional approvals required at the university for these activities. It is the responsibility of the Principal Investigator (PI) to obtain any required additional approvals.

# Contacts & Resources

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- Website
  - [www.csustan.edu/uirb](http://www.csustan.edu/uirb)
- Contact
  - [IRBadmin@csustan.edu](mailto:IRBadmin@csustan.edu)
  - 209-667-3493
- Full Board meeting schedule
  - Thursday, November 14<sup>th</sup>
  - Thursday, December 12<sup>th</sup>