History & Purpose

- Protection of human subjects and the researcher(s)
- The IRB process
  - Stanislaus State safeguards the rights and welfare of human subjects involved in all research projects conducted by an employee, faculty, or student. This responsibility is guided by the ethical principles set forth by the national Commission for the Protection of Human Subjects of Biomedical and Behavior Research in its report, *Ethical Principles and Guidelines for the Protection of Human Subjects of Biomedical and Behavioral Research* (commonly known as the Belmont Report). The Belmont Report sets forth three basic ethical principles for conduct of human subjects research...
Basic Ethical Principles

- **Respect for Persons**
  - Respect individual autonomy
  - Protect individuals with reduced autonomy
    - Informed consent
    - Protecting privacy and maintaining confidentiality
    - Additional safeguards of subjects vulnerable to coercion or undue influence

- **Beneficence**
  - Maximize benefits and minimize harms
    - IRB assessment of risk/benefit analysis including study design
    - Ensure that risks to subjects are minimized
    - Risk justified by benefits of the research

- **Justice**
  - Equitable distribution of research burdens and benefits
    - Ensure that selection of subjects is equitable
Human Subjects & Research

- **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.

- **Research**: A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.
Levels of Review

- Exempt
  - Fits pre-determined exempt categories
  - Reviewed by one member of IRB

- Expedited
  - Minimal risk to the participants
  - Reviewed by one member of IRB

- Full Board
  - Any activity qualifying as human subjects research that does not meet the criteria for Exempt or Expedited review
  - Involves more than minimal risk
  - Research on defined vulnerable populations
Required Elements in a Research Protocol

1. Title

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 Research Start Date: _____  Proposed Ending Date: _____

   Studies should be submitted well in advance of the proposed 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 nature of data to be collected:

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

3. Methods and Procedures

a. Describe in detail your methods and procedures for conducting your study. This will include your methods for selection and recruitment of participants, your data collection procedures, descriptions of the survey/instrument 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. Participant age range: Click here to enter text. Estimated Number of participants: Click here to enter text.

Sex: □ Males □ Females □ Both □

c. 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.
4. Risks to Subjects and Precautions taken

4. 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.

Future Risks

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

a. 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.

b. 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.

c. List dates and plans for storing and/or 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 years following completion of the research.
5. Informed Consent

Clearly outline 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).

6. Instruments to be Used

7. Letters of Support
Informed Consent

- Follow model provided by UIRB
- Describe the study
- State the risks/benefits
- Participation is voluntary
- Contact information
  - Protect yourself and do not include personal information
- Signature of participant
UIRB contact

- Website
  - www.csustan.edu/uirb

- Full Board meeting schedule
  - www.csustan.edu/office-research-sponsored-programs/UIRB/meeting-calendar

- Forms, additional information
  - www.csustan.edu/office-research-sponsored-programs/UIRB/forms-publications