## IRBlogo-m

**For Official Use Only**

Protocol Log # \_\_\_\_\_\_\_\_\_ -- \_\_\_\_\_\_\_

#  California State University, Stanislaus

 **Institutional Review Board**

 Office of Research & Sponsored Programs, MSR 240

 Telephone (209) 667-3493

 Email: IRBAdmin@csustan.edu

|  |
| --- |
| Applicant Information |
| Principal Investigator (PI): |       | Co-Investigator(s): |       |
| PI’s preferred pronouns: | He/Him [ ]  She/Her [ ]  They/Them [ ]   | *If PI is a student*Student ID#: |       |
| Department: |       | Faculty Sponsor: |       |
| Phone: | (     )       | E-mail: |       |
| University Affiliation | STUDENT [ ]  STAFF [ ]  FACULTY [ ]   |
| **CITI HSR Training** | Completed [ ]   | Date of CITI expiration:  |       |  |
| Title of Project: |        |
| Type of Application:  | New [ ]  Renewal[ ]  Previous protocol number?       Changes? YES [ ]  NO [ ]  |
| Master’s Thesis/Project?  | YES [ ]  NO [ ]   | Doctoral Dissertation? | YES [ ]  NO [ ]   |
| Sponsored Project? | YES [ ]  NO [ ]  |  | Source of funds:  |       |
| Protocol Summary Instructions |
| **1. Complete the attached Protocol Summary Template** **2. Attach the following documents:**1. Informed Consent (see sample on UIRB website, [www.csustan.edu/uirb](http://www.csustan.edu/uirb))
2. Instruments to be used (survey, interview guide, recruitment materials, etc.)
3. Letters of support from outside agencies (school, hospital, etc. where study will take place)

**3. Submit all documents via email to** **IRBadmin@csustan.edu****.**  |  |
| Certification and Signature |
| [ ]  | I certify that I have completed the mandatory CITI training module for Human Subjects Research. I acknowledge that CITI training is required for the IRB to accept my application for review.  |
| [ ]  | By submitting this protocol I certify under the penalty of professional misconduct the attached statements are accurate and true. |
| [ ]  | My faculty sponsor has reviewed and approved this protocol, and I have obtained their permission to submit this protocol for IRB review. (student investigators) |
| [ ]  | I will copy (cc) my faculty sponsor on the email submission of this protocol to the IRB. (student investigators) |

PLEASE ALLOW 30 DAYS FOR REVIEW

**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. 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**

 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, 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.*

1. 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. |

**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:

1. 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).

1. 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.*

**6. Attachments**

1. **Informed Consent:** Attach copies of the informed consent document(s).
2. **Study Instruments:** Attach all study materials, including any surveys, interview guides, recruitment materials, online questionnaires, etc. Be sure to include translated versions of the materials if they are to be used in the study.
3. **Letters of Support:** Research that is conducted at an outside agency (school, hospital, business, etc.) is required to include a letter of support from the agency.

**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.

**Protocol Review**

Every research protocol, consent document, and survey instrument must be as complete as possible. If all items above have been addressed and all related documents are attached to the application, then your study is ready for review. Upon receipt the IRB administrator will review your application for completeness and will contact you if any items are missing. Once a complete application is received it will be sent to an IRB member for review. Feel free to contact the IRB Administrator at Irbadmin@csustan.edu or 667-3493 with any questions.