California State University SAN MARCOS

Exempt IRB Review Application Form

Instructions:

Please fill out this application form using clear language and lay terms. Answer each section as completely as possible. Some questions may not apply to your study. In that case, add "not applicable" in the text box. Please upload this application form along with additional supplemental documents to your submission in IRBNet. For more information about whether your study should be submitted for an exempt review , please visit the IRB website. For questions, please contact the IRB office at (760)750-4029 or irb@csusm.edu.

Project Title

Proposed Start Date

Faculty/Staff Investigator:

Name | Department/College

Phone Number | E-mail:

Date CITI Training Completed

Student Investigator: *(if the student is the principal investigator)*

Name | Department/College

Phone Number | E-mail:

Date CITI Training Completed

Faculty Advisor Name | Department/College

Phone Number | E-mail:

Date CITI Training Completed

REMINDER: Once student investigators have completed this application form, they must e-mail it to their faculty advisor for review and feedback. Once the faculty advisor gives permission to a student to move forward, then the student will upload this application form along with additional documents to IRBNet. After uploading all the documents, the student will share the IRBNet package with the faculty advisor. The faculty advisor must have an IRBNet account to approve the package as the "advisor" by logging into IRBNet. Faculty advisors will receive a notification via e-mail that the package has been shared with them and that they need to sign the package in IRBNet. For more information on how to share a package in IRBNet, please visit the IRB website.

Checklist: Check the additional documents that are uploaded in IRBNet. Check **ALL** that apply:

- ☐ CITI Training Certificate for the principal investigator/s and the faculty advisor, if applicable.
- ☐ Letter of support (if you are collecting data off campus, you need to provide a letter of support from the research site. The letter of support must include the letterhead of the organization and list the research activities to provide evidence that the organization is knowledgeable about the study).
- ☐ Survey(s), questionnaire(s), and/or interview questions. If you are using an online survey, please upload a PDF copy of the survey.
- ☐ **Ed.D Students in the Joint Doctoral Program Only:** Sign, scan, and upload the UCSD-CSUSM JDP IRB Cover Sheet in IRBNet.

A. **Exempt Review Categories**: The following categories of research are currently approved for exemption. Please check the relevant exemption category/categories for your study.

☐ **Category 1.** Research conducted in **established or commonly accepted educational settings**, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, research on the effectiveness of the comparison among instructional techniques, curricular, or classroom management methods.

☐ **Category 2.** Research that only includes interactions involving **educational tests** (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) **IF** (i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects **OR** (ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation. If child participants are involved, the data cannot readily be traced back to them by direct or indirect identifiers and only ed tests and/or observations without interaction are included).

☐ **Category 3.** Research involving **benign behavioral interventions** in conjunction with the collection of information **from an adult** subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection **IF** (i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects **OR** (ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation.

☐ **Category 4. Secondary research** (study of existing data including documents, records, or biospecimens) for which consent is not required; **AND IF** (i) The identifiable private information or identifiable biospecimens are publicly available; **OR** (ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects; **OR** (iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated for the purposes of "health care operations" or "research" or for "public health activities and purposes;" **OR** (iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities.

☐ **Category 5.** Research and demonstration projects which are conducted by or subject to the approval of appropriate Federal Department of Agency heads, and which are designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; **OR** (ii) procedures for obtaining benefits or services under those programs; **OR** (iii) possible changes in or alternatives to those programs or procedures; **OR** (iv) possible changes in methods or levels of payment for benefits or services under those programs.

☐ **Category 6. Taste and food quality** evaluation and consumer acceptance studies if the food has been found to be safe by the FDA or other food safety agency.

B. Please answer the following questions about your research study.

○ Yes ○ No	My research participants belong to a **vulnerable population** (e.g. children under 18 years of age if studied outside a normal classroom setting, prisoners, or any other vulnerable population.)
○ Yes ○ No	I will record data from participants in such a way that their identity can be readily ascertained, directly or indirectly through identifiers linked to the participants **AND** any disclosure of participants' data outside of the research could be damaging to them or place them at risk of criminal or civil liability, be socially stigmatizing, or influence employability, financial standing, insurability, access to services, educational advancement, or reputation.
○ Yes ○ No	My research participants will experience more **physical, emotional, or mental stress, discomfo**rt than they do in the course of daily life or a routine medical or psychological exam.
○ Yes ○ No	My research involves secondary research where broad consent from research participants will be or has been obtained for collecting, storing, and maintaining identifiable private information or identifiable biospecimens (e.g. saliva, urine, blood, etc.)
○ Yes ○ No	My research involves the deception of participants (meaning participants are not provided with or misled about the purpose of the research study in the beginning of the study) AND participants will not be prospectively agreeing to participate in a study that contains deception.

If you answered 'yes' to any of the above questions, you need to fill out a limited/expedited/ full review application.

If you answered 'no' to ALL questions in Section B AND your research study fits within at least one of the exempt categories in Section A, then proceed to answer the following questions about your research study. Please answer each question thoughtfully.

1. Describe the **nature and purpose** of your research study, including the significance of your research project and your research questions, and how your study will attempt to answer them. Please include three citations in your description. Do not include methodology in this section.

2. Provide a step-by-step explanation of your research activities that involve human subjects including data collection methods and how you will store the data you plan to collect. Be thorough. You must provide enough detail so that the IRB can determine that your research qualifies for exemption.

3. For research conducted in **established educational settings**, please state HOW the **research activity** (not the instructional material) is a "normal educational practice."

4. For secondary research using biospecimens for which consent is not required, please explain how the identifiable biospecimens are publicly available or data recorded by the researcher such that they are anonymous. Additionally, explain where and how the data will be stored and will be disposed.

5. Describe the participants that will be involved in your research. How will you be selecting/recruiting your population? Will anyone be *excluded* from participating? If you have multiple participant groups such as students and teachers or children and parents, please **describe each population**.

6. **How many participants** will be involved in your research? Provide a quantity for each population group.

7. Are you employed at the research site where you plan to collect data? ○Yes ○No

8. Briefly outline the principal investigator's qualifications and experiences related to the research study.

9. If the principal investigator is a student, outline your faculty advisor's qualifications.

10. If using student or research assistants, please explain how you will ensure that these assistants are trained and qualified to assist the project including obtaining consent forms and collecting data. All assistants must complete the CITI training before starting to work on the project. It is the faculty member's responsibility to keep a copy of student assistants' up-to-date CITI training certificates on their record or to upload them to their CITI packages.

11. **For Student Principal Investigators Only:** Please check the box below to verify that you will share your package and obtain your faculty advisor's signature in IRBNet:

☐ I verify that I will share my package with my faculty advisor in IRBNet after I upload this application and other materials, but *before* submitting the package for review.

12. Is this project funded externally? ◉ Yes ○ No
If Yes, please provide the name of the funder: