California State University SAN MARCOS

Limited/Expedited or Full Review Application Form

Instructions:
Please fill out this application form using clear language and lay terms. Please answer each section as completely and as concisely as possible. Some questions may not apply to your study. In that case, please add "not applicable" in the text box. Please upload this application form along with additional documents that are supplemental (as applicable) to your submission in IRBNet. For more information, 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 the students to move forward, then the students will upload this application form along with additional documents to IRBNet. After the students upload all the documents, then they should share their IRBNet packages with their faculty advisors. Faculty advisors must have IRBNet accounts to approve the package as the "advisor" by logging into IRBNet. Faculty advisors will receive an e-mail notification when the packages have been shared with them stating that they need to sign the package in IRBNet. Students should not "submit" their packages in IRBNet until their faculty advisors have signed them. For more information, 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 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.

Checklist (continued…): Check the additional documents that are uploaded in IRBNet. Check ALL that apply.

☐ Recruitment flier(s), script(s), or advertisement for newspaper, listservs, radio, or TV.

☐ Consent and child assent form(s) or information sheets. You must provide a separate form for each population group. Please use consent and assent form templates on the IRB website. The information provided in this application form must match with the information provided in the consent form or information sheet.

☐ **Ed.D. students in the Joint Doctoral Program Only**: Sign, scan, and upload the UCSD-CSUSM JDP IRB Cover Sheet

☐ Verification of translation form (Only for consent and/or assent forms in languages other than English and Spanish)

1. Type of Review (Please select **one**.)

○ **Limited/Expedited Review:** Research studies that are minimal risk qualify for limited/expedited review. These studies include but are not limited to benign interventions that involve children (e.g. lab studies) and secondary research that involves collection of identifiable biospecimens where broad consent is required. If limited/expedited review is selected, your submission will be assigned and reviewed by an IRB committee member within three weeks.

○ **Full Review:** Research studies that are more than minimal risk are qualified for full review. If full review is selected, your submission will be reviewed by the IRB committee at a bi-monthly scheduled meeting during the academic year. The IRB committee does not meet during summer.

2. Funding: Is this research study funded?

○ Yes ○ No

If yes, please check one below:

○ Internally funded

○ Externally funded -> Please provide the funding source:

3. Purpose of Project

Describe the goal(s) of your project. List your research question(s) and discuss why the question is important and how your study will attempt to answer it. Include how your literature review supports this with at least three citations/references. [Please do not exceed two paragraphs and use lay language.]

4. Number of Participants

A) Provide the total number of participants (or number of participant records, specimens, etc.) for whom you are seeking IRB approval. If you have more than one population group, please list the expected number of participants for each population group in your research study.

B) Is this a multi-site study?

- ◯ Yes -> If yes, indicate the total number of participants to be enrolled across all sites
- ◯ No

5. Participant Population

A) Describe all characteristics of participants including their primary language, age, gender, race/ethnicity, and vulnerabilities. Explain why you are targeting this specific population.

B) Indicate whether anyone might be excluded from participating in your research study. If so, please explain why.

6. Participant Recruitment

A) How will you find, recruit, or identify potential subjects? How will you select the final group of participants from those who expressed interest in participating in your study? REMINDER: Please upload flyers, posters, or other oral or written invitations or recruitment scripts used to recruit potential participants to IRBNet.

B) Will participants receive compensation or other incentives?

- ◯ Yes ◯ No

If yes, please explain the type (e.g. course credit, gift cards, cash payment, parking, etc.), the amount and timing of compensation or incentive. Compensation plans should be incremental (not contingent upon study completion) to avoid coercion or undue influence.

7. Informed Consent Process

REMINDER: Please upload the consent (and child assent, if applicable) form, information sheet if requesting a waiver of consent or a waiver of documentation of consent, or broad consent form in IRB Net.

A) If participants are 18 years old or older, how and when will you explain the study including the required elements of informed consent to participants? How and when will participants receive the adult consent form?

B) If your study includes participants younger than 18 years old, how and when will you explain the study including the required elements of informed consent to parents and children? How and when will the parent receive the parent consent form? How and when will the child receive a verbal explanation of the study (if age 7 and younger) or the child assent form (for ages 8-17)? [Please note that signed parent consent forms must be received before obtaining child assent to participate in the study.]

C) Will you or a student/research assistant obtain consent from participants?

D) How much time will participants have to consider participating between the explanation of the study, the receipt of the consent form (and child assent form, if applicable), and the beginning of the study? [Please note that participants should be given sufficient time between when they receive the consent/assent form and when they are expected to sign and return the form to avoid coercion or undue influence.]

E) Are you requesting a Waiver of Consent or a Waiver of Documentation of Consent for collecting data other than secondary research for which consent is required? [Please note that electronic signatures and typed names are accepted as documentation of consent, so you do not need to request a Waiver of Documentation of Consent if you plan to obtain either of them. Additionally, you cannot request a waiver of consent if the research involves more than minimal risk.]

◯ Yes ◯ No

If yes, please explain:

(1) how the research cannot practically be done without the waiver of consent or a waiver of documentation of consent, AND
(2) how participants will be provided information about the study including the required elements of informed consent with an information sheet or verbally?

F) If your study will use incomplete disclosure of the purpose of the study or deception, explain the incomplete disclosure or deception, and provide a rationale explaining why it is necessary for the research.

G) If you will ask participants for broad consent for the use of identifiable private information or identifiable biospecimens, list the specific future uses of the information or biospecimens for which participants are giving consent.

H) If using secondary research where broad consent has already been obtained for collecting, storing, and maintaining identifiable private information or identifiable biospecimens, explain the informed consent process that was followed to obtain consent from participants.

I) If any participants are not fluent or comfortable with English, please explain how you will ensure that participants understand the research activities and required elements of informed consent before giving their consent to participate in your study.

REMINDER: If participants need consent and/or assent forms in a language other than English or Spanish, the researcher must upload the Verification of Translation form in IRBNet after the English version of the consent form has been reviewed and approved.

8. Data Collection and Procedures

A) Describe the type of data you plan to collect as part of your research study. Please check ALL that apply.

- ☐ Biospecimens (including blood, urine, saliva, hair, sweat, etc.)
- ☐ Surveys, questionnaires, or interviews
- ☐ Observation of participants
- ☐ Audio, video, image, digital or non-digital records
- ☐ Other:

B) Please provide a step-by-step explanation of how you will collect the type of data you checked above in the order you will collect it. Additionally, indicate the duration of each data collection method as applicable. For example, if using surveys, questionnaires, or interviews, explain how often participants will be asked to complete them and how long it will take for participants to complete them. If using biospecimens, explain how much and how many times biospecimens will be obtained from the participants.

REMINDER: Please upload a copy of the survey(s), questionnaire(s), interview(s) and/or observation protocol (if applicable) in IRBNet.

C) Provide the projected dates/timeframe in which you plan to conduct your research study starting with the informed consent process. Include when each data collection will take place.

9. Risks and Inconveniences

A) Explain potential risks and/or inconveniences for each population group and data collection method mentioned above in section 8A. Risks may be physical or psychological (e.g., strong emotional reactions to researcher's questions). Inconveniences may include time required to participate in the research study. [Please be sure the risks listed here match the risks listed in your consent form or information sheet. For face-to-face studies, the risks/inconveniences listed should address participants' fear/ anxiety related to contracting COVID-19 and the possibility they could contract the virus]

B) If applicable, please select which of the following vulnerable population will be involved in your research study:

- ☐ Prisoners
- ☐ Children
- ☐ Other vulnerable populations such as persons with impaired decision-making capacities, economically or educationally disadvantaged persons, etc.

C) Describe any special risks to vulnerable populations.

10. Safeguards

Please identify a safeguard for each risk you mentioned in section 9A. Explain how you will minimize each risk. If there is a risk for participants to have a strong emotional response or a physical inquiry, please list referrals and/or resources that may be offered (e.g. clinics or shelters, medical or psychological referrals). [Please be sure the safeguards listed here match the risks listed in your consent form or information sheet. For all face-to-face studies, be sure to list the precautions you will take to minimize participants' fears/anxiety of contacting COVID-19 and those you will take to minimize the actual risk of exposure to the virus.]

11. Data Management and Confidentiality

A) Please explain how the consent and assent forms will be secured. Add the duration of time these forms will be kept and how they will be disposed. [These forms should be stored separately from the rest of the data collected as part of the study. They must be kept in a secure place for three years by the researcher.]

B) Will personal identifying data (e.g. participants' names, phone number, home and/or e-mail address, student ID, birth date, etc.) be recorded?

◯ Yes ◯ No

If yes, explain what information will be recorded, how this information will be stored, and how you will protect the identity of the participants.

C) Please explain who will have access to the data collected, where and how data will be stored (e.g., password-protected computers, locked filing cabinets, cloud storage, etc.), how long the data will be stored and how they will be disposed of.

D) If biospecimens will be banked for future use, describe where the specimens will be stored, how long they will be stored, how the specimens will be accessed, and who will have access to the specimens.

E) If biospecimens will be banked for future use, describe the procedures for releasing specimens including the process to request a release, approvals required for release, who can obtain specimens, and the data to be provided with specimens.

12. Location of Study

Where will the research be conducted? Describe any risks to the participants or confidentiality issues related to using this location. [If your research study involves multiple sites, describe risks and confidentiality issues for each research site. Address concerns related to using online platforms, such as Zoom, if relevant.] REMINDER: If you are collecting data off campus, please upload the Letter of Support from the organization in IRBNet.

13. Safety Monitoring (Only for studies that are more than minimal risk and need full review)

Please explain how you will periodically evaluate the data collected regarding harms and benefits to determine whether participants remain safe.

14. Data Sharing (Only for studies that include multiple research sites)

Please explain how you will store and share data across multiple research sites and who will have access to it.

15. Alternative to Study Participation (If Applicable)

Describe alternative activities non-participants can do during data collection. For example, if using a classroom survey, explain how those who decide not to participate in your study will spend their time while participants take your survey.

16. Participant Debriefing or Feedback (If Applicable)

Describe any feedback or information you will offer participants at the end of the study. [If deception is involved in your research, participants must be debriefed about the nature of the study as soon as possible. Participants must be made aware of the incomplete disclosure of the purpose of the study or deception, including their right to withdraw any record of their participation. You may consider giving participants the opportunity to request a copy of the results of the study.]

17. Study Benefits

A) Discuss any potential individual and/or societal benefits. [Please note that often there is no direct benefit for the participants, however, the study contributes to the literature or future research.]

B) Please explain how the benefits from this study exceed the risks to participants.

18. Qualifications of the Researcher(s)

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

B) If the principal investigator is a student, briefly outline the faculty advisor's qualifications.

C) 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' CITI training certificate on their record.

19. 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.