# CSUSM Logo

# **Limited, Expedited, or Full Review Application Form**

**Instructions: Please fill out this application form using clear language and lay terms. Answer each section completely. Some questions may not apply to your study. In that case, please add “not applicable or N/A.” Upload this application form along with additional required documents to your submission in IRBNet. For more information, please visit the** [**IRB website**](https://www.csusm.edu/gsr/irb/submission.html)**. For questions, please contact the IRB Office at (760) 750-4029 or** **irb@csusm.edu****. \* Note – applicants with incomplete applications and/or significant additions needed to supporting materials will be asked to revise their IRB package before review**

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| **Project Title** |  |
| **Proposed Start Date** |  |

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| **Faculty /Staff Investigators (Name Co-PIs and list their information as well)** |
| **Name:** |  |
| **Department:** |  | **College/School:** |  |
| **Work Phone:** |  | **Work E-mail:** |  |
| **Does the proposed study involve research team members from outside institutions?** |  [ ]  Yes [ ] No | **If yes, list the other institutions or organizations involved:**  |  |
| **Most non-exempt research that involves cooperative research conducted or supported by a federal department or agency** [**rely upon a single IRB for research in the U.S**](https://www.hhs.gov/ohrp/regulations-and-policy/single-irb-exception-determinations/index.html)**. If relevant to your study, please note if your proposed study has already been reviewed by another institution prior to submitting this application. Also include the date of the approval, and the institution’s IRB contact information below.**  |
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| **Student Investigator (if the student is the principal investigator)** |
| **Name:** |  |
| **Department:** |  | **College/School:** |  |
| **Phone:** |  | **CSUSM E-mail:** |  |
| **Date CITI Trainings Completed:** |  | **Currently an undergraduate or graduate student?** |  |
| **Faculty Advisor Name:**  |  | **Department/College:** |  |
| **CSUSM Phone:**  |  | **CSUSM E-mail:** |  |
| **Date Advisor’s CITI Training Completed:** |  |
| **REMINDER: After a student investigator has completed this application form, they must e-mail it to their faculty advisor for review and feedback. After the faculty advisor gives permission to the student to move forward, the student should upload this application form along with additional required documents to IRBNet. After the student uploads all documents, they should share the IRBNet package with their faculty advisor. The faculty advisor must have an IRBNet account to approve the package as the “advisor” by logging into IRBNet. The faculty advisor will receive a notification via e-mail that the package has been shared with them and they need to sign the package in IRBNet. IRBNet submissions will not be reviewed without the faculty member’s signature. For more information on how to share a package in IRBNet, please visit the IRB website and read** [**the IRB Picture Guide.**](https://www.csusm.edu/gsr/irb/documents/submission/irbnet-user-guide.pdf)  |

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| **International Research**Does the proposed study involve international research (i.e., research or participants that reside outside of the U.S. or research that will take place outside of the U.S.)?  |
|  [ ] Yes [ ] No |
|  If yes, list the countries involved, along with the following information listed for each of your international collaborators including co-investigators, research assistants, data handlers, or people helping you recruit study participants: name and professional title (if used), institutional affiliation, work e-mail, and work phone number.  |
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| **Note that if you are proposing international research, you may need to include additional consent procedures and other materials in your package that address relevant data protection laws. In addition, if your research includes international activities, be sure to refer to the Office of Graduate Studies & Research’s** [**Export Control webpage**](https://www.csusm.edu/gsr/export/index.html)**. An export control assessment will need to be done to determine if an export license(s) is/are needed. Contact OGSR at** **facultyresearch@csusm.edu** **before submitting your IRB package to discuss whether your research is subject to Export Controls and/or data protection laws.**  |

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

[ ] CITI Training Certificates for the principal investigator (students should include their two CITI certificates and their faculty advisor’s current certificate/s)

[ ] Letter of support (If you are collecting data off campus or gathering non-public data from or with an institution, you need to provide a letter of support from the research site and/or person giving you permission to access the data/ research recruitment 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 and/or knows how you will be using the data)

[ ] Recruitment flier(s), email recruitment script(s), social media posts, and other advertisements or recruitment tools that include the name of the primary researcher and role as student/faculty/staff at CSUSM. All QR codes on materials must be actively linked to study materials and accessible to reviewers.

[ ] Survey(s), questionnaire(s), interview questions, and/or copies of any materials presented as part of a study. Please upload both hard copies of your documents **and** active links for any materials delivered online and/or websites used. (Note that demographic choices for interview and survey questions should be alphabetized to prevent undue harm to participants.)

[ ] 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)

[ ] Forms specific to international research (e.g., special consent forms to address data protection issues in another country, forms for data handlers, export control forms, Export Control CITI training certification, etc.; contact the IRB Office/IRB Chair prior to submission to discuss.)

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| **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 twice-monthly scheduled meeting during the academic year. The IRB Committee does not meet during summer.  |

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| **Funding: Is this research study funded?**  |
| 1. [ ]  Yes [ ] No
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| 1. If yes, please check one below:

[ ]  Internally funded [ ]  Externally funded🡪Please provide funding source:  |
| 1. Do you (the PI) or any of your research partners or family members have any [financial conflicts of interest](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/financial-conflict-of-interest/index.html) related to this study?

[ ]  Yes [ ] No1. If you have financial interests related to the design, implementation or reporting of human subject research findings list them here.
* Be sure to address how you will minimize possible harms to participants that result from this conflict in the risks and safeguards section of your consent forms and other relevant materials.
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| **Purpose of the 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.]**  |
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| **Number of Participants** |
| 1. Provide the total maximum number of participants (or number of participant records, specimens, etc.) you are planning to include in your study. If you have more than one population group, please list the expected number of participants for each population group in your research study. **Reminder: if you would like to go over this maximum number of participants after IRB approval, you will need to submit a minor modification package to request the change.**
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| 1. Is this a multi-site study?
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|  [ ]  No  |
|  [ ]  Yes 🡪 Please indicate the maximum number of participants to be enrolled across all sites:\_\_\_\_\_\_\_\_\_ |

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| **Participant Population** 1. Describe all characteristics of participants including their primary language, age, gender, race/ethnicity, and vulnerabilities. Explain why you are targeting this specific population.
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| 1. Indicate whether anyone might be excluded from participating in your research study. If so, please explain why.
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|  **6. Participant Recruitment** |
| 1. 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: Upload hard copies of fliers, posters, social media posts, videos and/or other oral or written invitations or recruitment scripts used to recruit potential participants to IRBNet. Contact the IRB Office to arrange special procedures for submitting large video files that will not upload to IRBNet.**
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| 1. Will participants receive compensation or other incentives?

[ ] Yes [ ]  No |
|  If yes, please explain the type (e.g. course credit, opportunity drawing with 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. (Tips: If you are using Sponsored Project funds see the [CSUSM Corporation Gift Card Guidance webpage](https://www.csusm.edu/corp/businesssrvcesandfinance/corpprocurement/giftcards/index.html) for required procedures. Also, for online surveys, add verification checks to ensure you will only be providing incentives to legitimate participants.) |
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| **Informed Consent Process****REMINDER: Please upload the consent (and child assent, if applicable) form, or an information sheet if requesting a waiver of consent or a waiver of documentation of consent, or broad consent form in IRBNet.**  |
|  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? |
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| 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)? [**Note that signed parent consent forms must be received before obtaining child assent to participate in the study.]** |
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|  C) Will you or a student/research assistant obtain consent from participants? |
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| 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.]** |
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|  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? If so, check the relevant waiver you are applying for. [**Please note that electronic signatures and typed names are accepted as documentation of consent, so you do not need to request a Waiver of Signed 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**.] |
|  **Waiver of Signed Documentation of Consent (check to see if initials are sufficient signed consent)** [ ] I’m requesting a waiver of signed documentation of consent (e.g., the use of a consent checkbox without a signature line on an online survey) Explain: 1. whether the signed consent form would be the only documentation of participants’ identity or
2. whether the research presents no more than minimal risk and involves no procedures for which written consent is normally required outside of the research context (e.g, online surveys)
3. how participants will be provided information about the study including the required elements of informed consent with an information sheet or verbally.

**Waiver of Consent**[ ] I’m requesting a waiver of consent. Explain :1. How the research *involves no more than minimal risk* to the subjects, and
2. how the research cannot practically be done without the waiver of consent and
3. how participants will be provided information about the study including the required elements of informed consent with an information sheet or verbally.
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| 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. |
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| 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. |
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| 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. |
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| 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.** |
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| **Data Collection and Analysis 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 (online) or non-digital records [ ] Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| B). 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 as well as links to websites that may be used and electronic versions of materials that will be presented to participants on electronic platforms (such as Qualtrics).** |
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| C) Provide the projected dates/timeframe when you plan to conduct your research study, starting with the informed consent process. Address when each phase of your data collection will take place. |
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| **Risks and Inconveniences** 1. 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, Risk 1: \_\_\_\_\_\_\_) For face-to-face studies, the risks/inconveniences listed may address participants' fear/ anxiety related to contracting COVID-19 and the possibility they could contract the virus.]**
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| 1. If applicable, please select which of the following vulnerable populations will be involved in your research study:
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| [ ] Children[ ] Prisoners[ ] Other vulnerable populations such as persons with impaired decision-making capacities, economically or educationally disadvantaged persons, people who are undocumented, etc.)  |
| C) Describe any special risks to vulnerable populations. |
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| **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 will be offered to participants in the study (e.g., a list of clinics or shelters, medical or psychological referrals, and hotlines, in addition to any CSUSM resources listed). [**Please match the safeguards listed here in the same order as those listed on your consent form or information sheet, e.g., Safeguard 1 should address Risk /Inconvenience 1. For face-to-face studies, you may 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.]** |
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| **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. **[Reminder: 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.]** |
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| B) Will personal identifying data (e.g., participants’ names, phone numbers, home and/or e-mail addresses, student IDs, birth dates, etc.) be recorded? |
|  [ ] Yes [ ]  No |
| 1. If yes, explain what information will be recorded, how this information will be stored, and how you will protect the identity of the participants.
2. Also, state whether your study is likely one to trigger responses that necessitate a mandatory reporting statement on your consent form.

**(Reminder: *All CSUSM researchers (faculty, students, and staff) are mandatory reporters of suspected abuse or neglect of children, elders, and dependent adults. If your proposed study addresses sexual misconduct/intimate partner violence/and/or stalking, please contact the*** [***CSUSM Title IX Office***](https://www.csusm.edu/title9/contactus/index.html) ***to discuss current reporting policies.***  |
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| 1. i. Explain who will have access to the data collected, where and how data will be stored (e.g., password-protected computers in password-protected or encrypted files, shared drives, locked file cabinets, on Qualtrics, Zoom, Amazon Mechanical Turk, etc.), how long data will be stored and whether and how they will be disposed of.

ii. Explain if you are planning to share de-identified data from your study in an online repository upon publication.  |
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|  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. |
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| **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 or recruiting off-campus (e.g., school, business, non-profit, etc.) upload a letter of support from a site administrator in IRBNet.**  |
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| **13.Safety Monitoring**Please explain how you will periodically evaluate the data collected regarding harms and benefits to determine whether participants remain safe.   |
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| **14. Data Sharing (Only for studies that include multiple research sites)**Explain how you will store and share data across multiple research sites. Also address who will have access to the data.  |
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| **15. Alternatives 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. |
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| **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.)** |
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| **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.]** |
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| B) Please explain how the benefits from this study exceed the risks to participants. |
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| **Qualifications of Researcher/s** 1. Briefly outline the principal investigator’s (or Co-PIs’) qualifications and experiences related to the research study.
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| 1. If the principal investigator is a student, briefly outline the faculty advisor’s qualifications.
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| 1. 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 student assistants must complete their [required CITI training/s](https://www.csusm.edu/gsr/irb/training.html) 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. Graduate PIs must upload their certificates to IRBNet.)
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| **19.For Student Principal Investigators Only**Please check the blank below to verify that you will share your package and obtain your faculty advisor’s signature in IRBNet **prior to submitting your IRB package**: |
|  [ ] 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. |