

CSUSM/UCSD AGREEMENT FOR IRB REVIEW

A. Overview

Students enrolled in 1) a joint CSUSM/UCSD program or 2) CSUSM graduate program, and conducting research at a UCSD facility or with a CSUSM-affiliated site/project/population, who plan to involve human subjects in research are required to obtain approval from either the CSUSM or UCSD Institutional Review Boards in advance of initiating research. This document describes a cooperative review process that allows the UCSD and CSUSM Institutional Review Boards (IRB) to rely upon each other to avoid duplication of effort and reduce burden for investigators, IRB members and staff.

B. Regulatory Background

The Department of Health and Human Services (DHHS) regulations at [45 CFR 46.114](#) states: “Cooperative research projects are those projects covered by this policy which involve more than one institution. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy. With the approval of the department or agency head, an institution participating in a cooperative project may enter into a joint review arrangement, rely upon the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort.”

The following standards apply where an institution holding an Office of Human Research Protections-approved Assurance wishes to avoid duplication of effort, in accordance with DHHS regulations at 45 CFR 46.114, by relying upon the IRB review of another Assurance-holding institution:

1. The review arrangement must be approved in writing by the Office of Human Research Projects and by appropriate officials of the institutions involved.
2. The institution relying upon another institution's IRB has a responsibility to ensure that the particular characteristics of its local research context are considered, either (i) through knowledge of its local research context by the reviewing IRB; or (ii) through subsequent review by appropriate designated institutional officials, such as the Chairperson and/or other members of its local IRB.

C. Procedures

1. Eligibility Criteria

- a) The student must serve as the principal or co-principal investigator on the proposed project.
- b) Research that does not exceed minimal risk, as follows:
 1. Research that meets the criteria for exempt or expedited review can be reviewed under this agreement. Criteria for exempt review can be found [here](#). Criteria for expedited review can be found [here](#).
 2. Research requiring review by a convened IRB meeting may also be reviewed under this agreement if the reviewing IRB determines during a convened meeting that the research does not exceed minimal risk.
 3. Research that exceeds minimal risk **cannot** be reviewed under this agreement, and the study must undergo separate review by the two institutions.

2. Determination of Reviewing IRB

The Reviewing IRB is determined by the primary institutional affiliation of the faculty mentor responsible for oversight of the proposed research with consideration of the following:

- a) Projects that use the UCSD facilities including UCSD Medical Center, UCSD MRI facility, and Moores Cancer Center, or Rady Children's Hospital will be reviewed by UCSD.
- b) Research that involves the Center for Children and Families will be reviewed by CSUSM.

3. Submission

To initiate this review process, eligible students must provide a "CSUSM/UCSD IRB Application Cover Sheet." Applications will not be considered for review without this Cover Sheet. The Cover Sheet can be obtained at <http://www.csusm.edu/gsr/irb/forms.html> or https://irb.ucsd.edu/ucsd_csusm_joint_cover.pdf.

- a) When the CSUSM IRB is the Reviewing IRB: The student should submit their IRB application to their thesis advisor/dissertation committee Chair. Upon the chair's approval, the application must be electronically forwarded by the CSUSM thesis advisor/dissertation chair via the appropriate process to the CSUSM IRB committee. Complete submission instructions can be found at <http://www.csusm.edu/irb>.
- b) When the UCSD IRB is the Reviewing IRB: All IRB submissions will be prepared and submitted using the UCSD web-based electronic submission process (instructions for submissions can be found [here](#)). UCSD requires that the student sign both the CSUSM/UCSD IRB Application Cover Sheet and the Standard UCSD Application Facesheets. Signed cover sheets and Facesheets can be faxed to the UCSD HRPP office at 858-675-5100 or submitted by mail to the UCSD HRPP Office, mail code, 0052.
- c) Students must meet the human subjects training requirements as set forth by the *reviewing* IRB.

4. IRB Review Process

- a) Reviewing IRB: The Reviewing IRB will review the protocol. Upon completion of review and approval of the protocol application, the Reviewing IRB will provide the Relying IRB with an electronic copy of the Cover Sheet signed by a representative of the Reviewing IRB. The Reviewing IRB will retain copies of the complete protocol, supporting documents, approved informed consent document(s), and signed Cover Sheet. It shall not be necessary for the Reviewing IRB to forward all protocol-related documentation to the Relying IRB. However, upon request from the Relying IRB, the Reviewing IRB will forward electronic copies of protocol documentation to the Relying IRB. *Note that all investigator communication with the IRB should be directed to the Reviewing IRB only.*
 1. If it is determined that the project exceeds minimal risk, this agreement **cannot** be used and the study must be provided for separate review by the two institutions.
- b) Relying IRB: The Relying IRB will sign the CSUSM/UCSD IRB Application Cover Sheet acknowledging their acceptance of the Reviewing IRB's decision. The Relying IRB will then return an electronic copy the signed Cover Sheet to the Reviewing IRB.

The Relying IRB will retain electronic copies of documents received from the Reviewing IRB.

5. Approval of Project

Upon receipt of the Cover Sheet signed by both institutions, the Reviewing IRB will send an approval letter, stamped consent form(s) (when applicable), and a copy of the signed CSUSM/UCSD IRB Application Cover Sheet to the Principal Investigator (PI), and the research may then commence.

6. Modifications to an Approved Project

- a) To initiate review of a request for modification/amendment of an approved protocol, the PI will submit the request to the Reviewing IRB only.
 1. Reviewing IRB: The Reviewing IRB will review the modification/amendment request. If it is determined that the modification/amendment request causes the project to be more than minimal risk, this agreement cannot be used and the study must be provided for separate review by the two institutions.
 2. Relying IRB: The Relying IRB will have access to all documents associated with the review and approval of the modification/amendment request.
- b) Upon approval of the modification/amendment, the PI will receive an approval letter and revised and re-stamped, approved consent forms (when applicable) from the Reviewing IRB. Upon receipt of the approval letter and approved consent forms (when applicable) from the Reviewing IRB, the requested changes may be implemented.

7. Continuing Review/Renewal of Approved Project

- a) To initiate review of a request for renewal of an approved protocol, the investigator will submit the request to the Reviewing IRB **only**.
 - 1) Reviewing IRB: The Reviewing IRB will review the continuing review/renewal request. Upon completion of review and approval of the continuing review/renewal request, the Reviewing IRB will provide the Relying IRB with an electronic copy of the continuing review/renewal approval letter.
 - 2) Relying IRB: The Relying IRB will retain copies of all documents received from the Reviewing IRB.
- b) The investigator will receive a continuing review/renewal approval letter and re-approved consent forms (when applicable) from the Reviewing IRB and may continue research activities.