



UNIVERSITY OF CALIFORNIA, SAN DIEGO HUMAN RESEARCH PROTECTIONS PROGRAM

SDSU/UCSD Agreement and Process for Joint IRB Review of Faculty Protocols

Overview

When faculty from both SDSU and UCSD jointly conduct a research study involving human subjects, the study must receive approval from each institution's Institutional Review Board in advance of initiating research. This document describes a cooperative review agreement and process that allows the SDSU and the UCSD Institutional Review Boards (IRBs) to rely upon each other for review and approval of such studies to avoid duplication of effort and reduce burden for investigators, IRB members and staff. The Principal Investigator will submit an IRB application to **either** SDSU or UCSD to initiate the review process depending the factors outlined below. This agreement and process will be continually evaluated to determine whether the needs of both the institutions and the investigators are appropriately served without compromising human research protections.

Regulatory Background

Basic Health and Human Services Policy for Protection of Human Research Subjects, 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."

When an institution holding an OHRP-approved Assurance wishes to avoid duplication of effort, in accordance with 45 CFR 46.114, by relying upon the IRB review of another Assurance-holding institution, the following standards apply:

1. Each institution must retain for their records an Institutional Review Board Authorization Agreement signed by their respective Institutional Officials listing.
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.

Procedures

1. Determination of Reviewing IRB
 - a) The Reviewing IRB is determined by the institutional affiliation of the faculty member responsible for oversight of the proposed research. For funded research, this would be the person noted as the Principal Investigator. When there are co-principal investigators, the Reviewing IRB will be the institution with primary responsibility for oversight and reporting of the project. Note: the application must clearly indicate the Principal Investigator at both institutions.
2. Exceptions for Determination
 - a) For projects that involve the SDSU Exercise Physiology Laboratory, the SDSU IRB will be the Reviewing IRB.
 - b) For projects that use the UCSD MRI facility, UCSD Moores Cancer Center or Rady Children's Hospital – San Diego facilities, the UCSD IRB will be the Reviewing IRB.
3. Study Submission
 - a) To initiate this cooperative review process, eligible faculty must provide a "SDSU/UCSD Joint Review of Faculty Protocols Cover Sheet for IRB Application." The Cover Sheet can be obtained [here](#).
 1. When the SDSU IRB is the Reviewing IRB: All IRB applications will be prepared and submitted (along with the Joint Cover Sheet for Application and the standard UCSD Application Face Sheet) using the SDSU vIRB web-based system.
 2. When the UCSD IRB is the Reviewing IRB: All IRB submissions will be prepared and submitted using the UCSD web-based electronic submission process. UCSD requires that the PI sign both the Joint Cover Sheet for Application and the Standard UCSD Application Face Sheet. Signed cover sheets can be faxed to the UCSD HRPP office at 858-455-9540 or submitted by mail to the UCSD HRPP Office, mail code, 0052.
4. IRB Review Process
 - a) Reviewing IRB: The Reviewing IRB will review the application. Upon completion of review and approval of the protocol, the Reviewing IRB will, upon request, provide the Relying IRB with an electronic copy of the complete application, and supporting documents. The approved informed consent document(s) and the Cover Sheet signed by a representative of the Reviewing IRB will be submitted to the Relying IRB for all approved protocols. *Note that all investigator communication with the IRB should be directed to the Reviewing IRB only.*
 - b) Relying IRB: The Relying IRB will sign the Joint Cover Sheet for Application acknowledging their acceptance of the Reviewing IRB decision and will have access to all documents reviewed by the

Reviewing IRB. The Relying IRB will then return the signed Cover Sheet for Application to the Reviewing IRB.

5. Approval of Project
 - a) 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 Cover Sheet to the Principal Investigator and the research may then commence.
6. Informed Consent Document Review and Approval
 - a) When Informed Consent documents are submitted to the Reviewing IRB, they must comply with the format of the Reviewing IRB's institution. Format considerations include the following:
 1. Reviewing IRB contact information
 2. Participant cost section
 3. Standard harm clause language
 4. Principal Investigator's institutional contact information
 - b) Once approved by the IRB, the Informed Consent document will be stamped by the Reviewing IRB. Only a single approval stamp will be required.
7. Modifications to an Approved Project
 - a) To initiate review of a request for modification/amendment of an approved protocol, investigators will submit the request to the Reviewing IRB **only**.
 1. Reviewing IRB: The Reviewing IRB will review the modification/amendment request. Upon completion of review and approval of the modification/amendment request, the Reviewing IRB will, upon request, provide the Relying IRB with an electronic copy of the request, any revised supporting documents including revised informed consent document(s), and a copy of the modification/amendment request approval letter.
 2. Relying IRB: The Relying IRB will have access to all documents received from the Reviewing IRB.
 - b) Upon approval of the modification, the investigator 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. A modification is given approval only to the expiration date that was received at the most recent initial or continuing review.
8. Continuing Review/Renewal of Approved Project
 - a) To initiate review of a request for continuing review approval of an approved protocol, the Principal Investigator will submit the request according to the institutional policies of the reviewing campus to the Reviewing IRB **only**.

1. Reviewing IRB: The Reviewing IRB will review the renewal request. Upon completion of review and approval of the renewal request, the Reviewing IRB will provide the Relying IRB with an electronic copy of the request, the stamped consent document(s), and a copy of the renewal approval letter.
 2. Relying IRB: The Relying IRB will have access to all documents received by the Reviewing IRB.
- b) The Principal Investigator will receive an approval letter and approved consent forms (when applicable) from the Reviewing IRB and may continue research activities.
9. Reporting Adverse Events, Protocol Deviations or Noncompliance to the IRB
- a) The responsibility for reporting adverse events, non-compliance, protocol deviations and all other relevant information to the IRB rests with the Principal Investigator of the approved protocol.
 - b) The Principal Investigator shall file all reports to the Reviewing IRB according to the institutional policies of the reviewing campus.
 - c) Any incident report that results in modification to the research plan, informed consent document, alters the risks of participation as determined by the reviewing IRB must be reported to the Relying IRB.
 1. The reporting of an incident report and IRB determination to the Relying IRB is the responsibility of the Principal Investigator.