



UNIVERSITY OF CALIFORNIA, SAN DIEGO
HUMAN RESEARCH PROTECTIONS PROGRAM

FACT SHEET

SDSU/UCSD Agreement for JDP/Master's Degree IRB Review

A. Overview

Students enrolled in a SDSU/UCSD Joint Doctoral Program (JDP) or Master's degree program engaging both SDSU and UCSD in non-exempt human subjects research are required to obtain IRB approval in advance of initiating research. This document describes eligibility criteria and a cooperative review process ([45 CFR 46.114](#)) that allows the UCSD and SDSU Institutional Review Boards (IRB) to rely upon each other to avoid duplication of effort and reduce the burden for investigators, IRB members, and staff.

B. Regulatory Background

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 HRPP-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 HRPP 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) Research that meets the definition of minimal risk as defined at 45 CFR 46.102(j)
 1. Research that meets the criteria for expedited review can be reviewed under this agreement. Criteria for expedited review can be found [here](#). Research requiring review at a convened IRB meeting may also meet the requirements of this agreement provided that the reviewing IRB determines the risk level for the research is minimal risk.
 2. Research that exceeds minimal risk **cannot** be reviewed under this agreement, and the study must undergo separate review by the two

institutions unless otherwise required by regulation.

- b) Human subjects research involving only a single campus and NOT proposed as thesis research to fulfill the requirements of a joint Master's or PhD degree is exempt from requiring IRB approval from both institutions. IRB reliance by the non-engaged campus is not required.
2. Determination of Reviewing IRB
 - a) The Reviewing IRB is determined by the primary institutional affiliation of the faculty mentor responsible for oversight of the proposed research.
 3. Submission
 - a) To initiate this review process, the eligible faculty mentor must submit the request for reliance using the SMART IRB Online Reliance System (ORS).
 1. All submissions whether submitted to the SDSU or the UCSD IRB will be submitted via the web-based IRB submission platform used by the reviewing institution.
 4. IRB Review Process
 - a) Reviewing IRB: The Reviewing IRB will review the proposal. Upon completion of review and approval of the research proposal, the Reviewing IRB will provide the researcher the approval letter, complete protocol and supporting documents.
 1. If UCSD is the reviewing IRB, the UCSD researcher must submit an Administrative application. In the application, indicate that UCSD will be serving as the IRB of record by selecting "Yes, UCSD IRB will be IRB of record for other sites" in the General Information section of the application in our submission platform. Then complete the Participating Site Section to add the SDSU site. In the Attachment section of the Participating Sites page, upload the SMART IRB ORS determination letter.
 - b) 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.
 - c) Relying IRB: The Relying IRB will review the documents and agree to rely on the reviewing IRB for review on the SMART IRB platform. Once the relying IRB agrees to rely on the reviewing IRB, and the reviewing IRB approves the research project, the research can commence.
 1. If UCSD is the relying site, the UCSD researcher creates and submits a "Request to Rely on non-UCSD IRB" Administrative Registration and submits a research protocol, study consent form, UCSD specific consent form (if participants will be consented at UCSD), Investigator's Brochure or Package insert (if applicable), any other study related documents, and the SDSU SMART IRB ORS Determination Letter. For more detail on the UCSD required submission process, please visit [IRB Reliance \(Single IRB Review\) \(ucsd.edu\)](https://ucsd.edu/irb-reliance).
 5. Modifications to an Approved Project--Amendments
 - a) To initiate review of a request for modification/amendment of an approved protocol, the Principal Investigator will submit the request to the Reviewing IRB.
 1. Reviewing IRB: The Reviewing IRB will review the modification/amendment request. Upon completion of the review and approval of the request, the Reviewing IRB provides the relying researcher the amendment approval and approved documents. 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. Once the amendment is approved by the reviewing IRB, the approved changes can be implemented.

1. If UCSD is the relying site, the UCSD researcher creates and submits an amendment to the approved project if it meets the criteria for reliance amendments. For more information on the criteria for what amendments need to be submitted and the submission process, please visit [IRB Reliance \(Single IRB Review\) \(ucsd.edu\)](#) section Reliance Requests; UCSD Relying; Post-Reliance submissions.

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6. Continuing Review/Renewal of an Approved Project (This only applies to studies where continuing review is required.)

- a) To initiate review of request for continuing review/renewal of an approved protocol, the Principal 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 the review and approval of the request, the Reviewing IRB will provide the Relying researcher with the approval letter and the approved consent document(s).
 2. If UCSD is the relying site, the UCSD researcher creates and submits a renewal application for the approved project before the continuing review date and include the SDSU IRB's continuing review approval letter.

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