



# 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 who plan to involve human subjects in research are required to obtain approval from both the SDSU and UCSD Institutional Review Boards 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 burden for investigators, IRB members and staff. The JDP or Master's degree student investigator may submit an IRB application to **either** SDSU or UCSD to initiate the review process.

#### 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) The student must be serving 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.
- c) Projects that involve the UCSD MRI facility, Moore’s Cancer Center and/or Rady Children’s Hospital will receive review by UCSD.
  - d) 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 with one exception: the UCSD IRB will be the Reviewing IRB for all eligible studies that involve the UCSD MRI facility, Moore’s Cancer Center, and/or Rady Children’s Hospital.
3. Submission
- a) To initiate this review process, eligible students must provide a [“UCSD/SDSU Joint Doctoral/Master’s Degree Programs Cover Sheet for Application.”](#) Applications will not be considered for review without this Cover Sheet.
    1. When the SDSU IRB is the Reviewing IRB: All IRB applications will be prepared and submitted (along with the Joint Doctoral/Master’s Degree Programs Cover Sheet for Application) 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 (instructions for submission can be found [here](#)). UCSD requires that the PI sign both the Joint Doctoral/Master’s Degree Programs Cover Sheet for Application and the Standard UCSD Application Face Sheet. Signed Cover and Face sheets can be faxed to the UCSD HRPP office at 858-657-5055, submitted by mail to the HRPP Office, mail code, 0052, or brought to the HRPP Office in person.
    3. 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 access to the complete protocol and supporting documents. An electronic copy of the approved informed consent document(s), and the Cover Sheet signed by a representative of the Reviewing IRB will be sent to the Relying IRB. *Note that all investigator communication 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 review the documents and sign the Joint Doctoral Programs Cover Sheet for Application acknowledging their acceptance of the Reviewing IRB decision.

5. Approval of Project

- a) A copy of the Joint Doctoral/Master's Degree Programs Cover Sheet for Application signed by both IRBs will be provided to the PI. Upon receipt of the signed Cover Sheet, research may commence.

6. Modifications to an Approved Project

- 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 only.
  - 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 will provide the Relying IRB with notification of the review and access to a copy of the request and any revised supporting document including the revised informed consent document(s) and a copy of the modification/amendment request approval letter. 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 Principal 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.

7. Continuing Review/Renewal of an Approved Project

- 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 IRB with access to the documents associated with the review (an electronic copy of the request, the re-stamped, approved consent document(s) and a copy of the continuing review/renewal approval letter).
  - 2. Relying IRB: The Relying IRB will have access to all documents associated with the review and approval of the continuing review/renewal request.
- b) The Principal Investigator will receive an approval letter and approved consent form(s) (when applicable) from the Reviewing IRB and may continue research activities.

*\* It is, however, recommended that students associated with these joint programs use the joint agreement to avoid delays and/or later complications should the student wish to use the data collected under a single institution review to fulfill the requirements of the joint program (i.e., thesis/dissertation). It should be noted that the IRB is unable to grant retroactive approval for research.*