

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. ... An institution participating in a cooperative project may enter into a joint review arrangement, rely on the review of another IRB, or make similar arrangements for avoiding duplication of effort."

The following standards apply where an institution holding an OIA-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 OIA 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. Determination of PI
 - a) The determination of Reviewing IRB also determines who is listed as PI on applications to the IRBs at each institution.
 - b) If UCSD is the Reviewing IRB, the faculty mentor will be listed as PI on applications to the UCSD IRB and the student will be listed as PI on applications to the SDSU IRB.
 - c) If SDSU is the Reviewing IRB, the student will be listed as the PI on the application to the SDSU IRB and the UCSD IRB. The student's faculty advisor will be listed on the SDSU IRB application as the Co-PI/Faculty Advisor.
4. Initiating the Reliance Process
 - a) The process to initiate the reliance process is specific to the reviewing IRB. The PI should consult the following.
 1. If UCSD is the reviewing IRB, see the information at:
<https://irb.ucsd.edu/researchers/reliancesgeneral.html>
 2. If SDSU is the reviewing IRB see the information at:
https://research.sdsu.edu/research_affairs/human_subjects/smart_irb
 3. Questions regarding the process at UCSD can be sent to: irbrely@ucsd.edu.
 4. Questions regarding the process at SDSU can be sent to: adodge@sdsu.edu or irb@sdsu.edu.

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