

## Overview

Students enrolled in a SDSU/CGU Joint Ph.D. Program in Education (JPPE) who conduct human subjects research engage both San Diego State University (SDSU) and Claremont Graduate University (CGU) in human subjects research. Usually this requires Institutional Review Board (IRB) review from both institutions. However, in cases such as this, federal regulations ([45 CFR 46.114](#)) allow institutions to enter into a cooperative research agreement to allow one IRB to rely on the review of another to avoid duplication of effort by investigators and IRB members. This document describes eligibility criteria and a cooperative review process that allows the SDSU and CGU IRB to rely upon each other.

## Procedures

### 1. Eligibility Criteria

1. The student must be serving as the principal or co-principal investigator on the proposed project.
2. Research must present no more than minimal risk, as follows:
  1. Research that meets exemption criteria at 45 CFR 46.101.
  2. Research that meets expedited criteria at 45 CFR 46.110.
  3. Research reviewed at a convened IRB meeting where the reviewing IRB determines the research is minimal risk.

**Important:** Research that the IRB determines is greater than minimal risk cannot be reviewed under this agreement. The study must undergo separate review by both the SDSU and CGU IRB.

### 2. Determination of Reviewing IRB

1. In consultation as needed with the JPPE Program Director at CGU, the Program Director at SDSU will review all dissertation plans of JPPE students and assign those involving human subjects for review, on an alternating basis to either the SDSU or CGU IRB. The SDSU program director will direct students to identify their JPPE program affiliation and list both faculty advisors and contact information on the IRB application. **Note:** Principal Investigators should direct any inquires to the *Reviewing IRB only*.

### 3. Submission

1. To initiate this review process, eligible students must include a [SDSU/CGU JPPE Cover Sheet](#) with their IRB submission. Proposals submitted for IRB review without this coversheet will be considered incomplete and will not be reviewed until the coversheet is submitted to the IRB.
  1. When the SDSU IRB is the Reviewing IRB: All IRB applications will be prepared and submitted [SDSU/CGU JPPE Cover Sheet](#) using the SDSU IRB e-submission system.
  2. When the CGU IRB is the Reviewing IRB: All IRB submissions will be prepared and submitted according to the instructions posted at <http://www.cgu.edu/pages/1075.asp>

**Important:** Students must meet the human subjects training requirements, and include all submission documents as required by the reviewing IRB.

#### 4. **IRB Review Process**

1. **Reviewing IRB:** The Reviewing IRB will review the protocol. Upon completion of review and approval or denial of the protocol application, the Reviewing IRB will provide the Relying IRB with copies of the approved informed consent/assent document(s) (as applicable), the approval or denial letter, and the SDSU/CGU JPPE Cover Sheet signed by a representative of the Reviewing IRB.
2. **Relying IRB:** The Relying IRB will review the documents and sign the SDSU/CGU JPPE Coversheet acknowledging their acceptance of the Reviewing IRB decision, and return the signed coversheet to the Reviewing IRB.

#### 5. **Approval of Project**

1. A copy of the JPPE Program Cover Sheet for Application signed by **both** IRBs will be provided to the PI. Upon receipt of the signed SDSU/CGU JPPE Cover Sheet, research may commence.

#### 6. **Modifications to an Approved Project**

1. Proposed amendments/modifications to studies previously approved by the IRB should be submitted to the *Reviewing IRB only* according to their required submission processes. *Proposed changes to previously IRB approved documents may not be implemented prior to IRB review and approval.* The Reviewing IRB will provide the Relying IRB with the documents associated with the amendment/modification. **Important:** If the IRB determines that the amendment/modification increases the risk level of the study to be greater than minimal risk, this agreement cannot be used and the study must be reviewed by both the SDSU and CGU IRB.

#### 7. **Continuing Review/Renewal of an Approved Project**

1. The PI is required to submit their study for continuing review at least once every 365 days (or as determined by the IRB). Continuing Review/Request for Renewal for a Research project should be submitted to the *Reviewing IRB only* according to their required submission processes. The Reviewing IRB will provide the Relying IRB with the documents associated with the continuing review.

#### 8. **Reports of Problems in Research**

1. The PI is required to report any unanticipated problems involving risk, unanticipated serious adverse events, and deviations from the approved protocol, or any instances of non-compliance to the *Reviewing IRB only* for review. The Reviewing IRB will provide the Relying IRB with the documents associated with the review of the report. For more information see the SDSU HRPP Standards and Practices here: [https://newscenter.sdsu.edu/researchaffairs/files/05042-Human\\_Research\\_Protection\\_Program\\_09-04-15\\_Approved\\_09-22-15.pdf](https://newscenter.sdsu.edu/researchaffairs/files/05042-Human_Research_Protection_Program_09-04-15_Approved_09-22-15.pdf). For information on reporting requirements for CGU <http://www.cgu.edu/pages/1075.asp>