

CUNY HRPP Policy: Non-Exempt Cooperative Human Subjects Research

1. Applicability

This policy applies to non-exempt cooperative research involving human subjects in which CUNY is engaged. Please refer to [CUNY HRPP Guidance: When is CUNY HRPP or IRB Review Required](#) for assistance in determining whether CUNY is engaged in a cooperative project.

2. Definition

Cooperative research projects are those projects that involve more than one institution (45 CFR 46.114(a)).

3. Cooperative Research Within CUNY

3.1. Principal Investigator (PI) Responsibilities

3.1.1. Submitting to the HRPP Office

When a research project is to be conducted in cooperation between two or more CUNY colleges or schools, or when research procedures are performed at two or more CUNY colleges or schools, the IRB Application should be submitted to the HRPP Office of the CUNY college or school with which the PI¹ of the project has primary affiliation. The Application should only be submitted to one CUNY HRPP Office, regardless of the number of CUNY campuses collaborating on the project.

3.1.2. Initial IRB Application Form

The PI must provide the following information in the IRB application for all CUNY colleges or schools engaged in the research:

- Identify all CUNY colleges or schools engaged in the research;
- Describe each CUNY college or school's role in the research.

3.2. HRPP Staff Responsibility

Upon approval of a cooperative project within CUNY, the HRPP Office or IRB Administrator overseeing the review of the project shall send an informational email to HRPP Coordinators of all approved CUNY colleges or schools informing them of the following: a) name of PI; b) title of study; c) IRB number for the study; and d) list of CUNY colleges and/or schools that are approved under this protocol.

4. Cooperative Research with Non-CUNY Institutions

An IRB review and approval is required for all non-exempt human subjects research activities for which CUNY-affiliated individuals obtain: 1) data about the subjects through intervention or interaction; 2) identifiable private information about the subjects; or 3) informed consent of human subjects for the research. This section outlines the mechanisms by which IRB approval may be obtained.

¹ In case of student researchers, the Application will be processed by the HRPP Office of the College with which the Faculty Advisor has the primary affiliation.

4.1. Federally Funded Cooperative Research

When CUNY is engaged in federally funded cooperative research, all institutions located in the United States that are engaged in the project must rely upon approval by a single IRB for the portion of the research that is conducted within the United States. The reviewing IRB is identified by the Federal department or agency supporting or conducting the research or proposed by the lead institution subject to the acceptance of the Federal department or agency supporting the research.

4.1.1. CUNY UI-IRB as the IRB of Record

When CUNY UI-IRB is identified as the IRB of Record, the CUNY PI must request an IRB Authorization Agreement by contacting the [Agreements Designee for their College or School](#).

4.1.2. Exceptions

The following research is not subject to the single IRB requirement:

- a. Cooperative research for which more than single IRB review is required by law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe); or
- b. Research for which any Federal department or agency supporting or conducting the research determines and documents that the use of a single IRB is not appropriate for the particular context.

4.2. Non-Federally Funded Cooperative Research

PIs proposing to conduct non-exempt cooperative human subject research that is not federally funded may obtain IRB approval through one of the two mechanisms delineated below:

a. Option 1: IRB Approval from IRB of Each Participating Institution

PIs obtain IRB approval from the IRB of Record of each participating institution.

b. Option 2: IRB Approval from a single IRB

PIs may propose to use a single IRB. The CUNY PI must submit the [CUNY HRPP Form for Selecting the IRB of Record](#) to hrpp@cuny.edu to request review by a single IRB for cooperative research. CUNY's determination of the selected IRB of Record will then be provided to the PI via email within 3-5 business days, and an IRB Authorization Agreement will be entered into with the collaborating institution(s), as appropriate. Considerations delineated in section 4.2.1 of this policy will be used to select the IRB of Record. PIs are required to comply with the responsibilities delineated in section 5 of this policy.

4.2.1. Selection of the IRB of Record

The following elements will be taken into consideration when selecting the IRB of Record:

- Prime recipient of non-federal funding for the project, where applicable;

- Institution where majority of the subject interaction and/or intervention takes place;
- Institution from which majority of the subjects are recruited;
- Institution from which majority of any personally identifiable information about the subjects will be obtained.

5. PI Responsibilities

5.1. **Federally funded cooperative research where CUNY UI-IRB is the IRB of Record**

CUNY PI must maintain in the PI's records all of the following:

- Documentation of a current Federal-wide Assurance (FWA) for each of the collaborating sites engaged in human subjects research;
- Documentation of any IRB Authorization Agreements entered into by CUNY; and
- Current IRB approval and IRB-approved consent documents covering each institution engaged in human subject research.

5.2. **Federally funded cooperative research where CUNY UI-IRB is NOT the IRB of Record**

The PI must maintain in the PI's records:

- Documentation of any IRB Authorization Agreements entered into by CUNY; and
- Current IRB approval and IRB-approved consent documents from the IRB of Record.

5.3. **Non-federally funded cooperative research where CUNY PI is the lead PI**

For non-exempt non-federally funded human subjects research, where the CUNY PI is the lead PI, the PI must maintain in the PI's records one of the following for each collaborating institution:

- For collaborating institutions with a designated IRB, documentation of current IRB approval and IRB-approved consent documents from the designated IRB of each collaborating institution engaged in human subjects research
- For collaborating institutions that do not have a designated IRB, documentation of an IRB Authorization Agreements entered into with CUNY.

5.4. **Changes in Collaborating Institutions When CUNY UI-IRB is the IRB of Record**

5.4.1. **Amendment Requirements**

The CUNY PI must submit an amendment and appropriate supporting documents to obtain CUNY UI-IRB review and approval of the following:

- Addition of new institutions prior to their engaging in human subjects research procedures; and
- Changes in a previously approved collaborating institution's role prior to engaging in the implementation of these changes.

5.4.2. Notification Requirement

As part of the continuing review submission, the PI shall notify the IRB of any discontinuation of a previously-approved collaborating institution during the previous approval period.

5.5. Oversight of research where CUNY UI-IRB is the IRB of Record

When CUNY UI-IRB is the IRB of Record, the PI must include the following information in the IRB application form, and comply with the IRB-approved protocol for the following:

- Procedures for CUNY PI's oversight of the conduct of research at the collaborating institutions; and
- Procedures for ensuring timely communication amongst the collaborating institutions with regards to:
 - Modifications to the protocol and related documents; and
 - Unanticipated problems involving risks to subjects or others.

6. CUNY HRPP Staff Responsibilities

The HRPP Coordinator or the IRB Administrator responsible for overseeing the review of the protocol shall confirm and document the following for each institution relying on CUNY UI-IRB:

- Each institution is engaged in human subject research activities; and
- For federally funded research, the current FWA number of each institution.