

CUNY HRPP Policy: Multisite Non-Exempt Human Subjects Research

1. Applicability

This policy applies to non-exempt multi-site 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 multi-site protocol.

2. Multi-CUNY College Human Subjects Research

2.1. Principal Investigator (PI) Responsibilities

2.1.1. Submitting to the HRPP Office

When a research project is to be conducted in collaboration between two or more CUNY Colleges, or when research procedures are performed at two or more CUNY Colleges, the IRB Application should be submitted to the HRPP Office of the CUNY College 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.

2.1.2. Initial IRB Application Form

The PI must provide the following information in the IRB application for all CUNY sites:

- Identify all CUNY sites involved in the research
- Describe each CUNY site's role in the research

2.2. HRPP Staff Responsibility

Upon approval of a multi-CUNY College protocol, the HRPP Coordinator or IRB Administrator overseeing the review of the protocol shall send an informational email to HRPP Coordinators of all approved CUNY sites informing them of the following: a) name of PI; b) title of study; c) Ideate number for the study; and d) list of CUNY sites that are approved under this protocol.

3. Collaborative Research with Non-CUNY Sites

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.

3.1. NIH Funded Research Involving Collaboration with Other Domestic Sites

NIH requires a single IRB review covering all domestic sites of NIH-funded multi-site research. When preparing an NIH application or proposal, the CUNY PI must include a plan for the use of a single IRB that includes a statement that participating sites will adhere to the [NIH Policy on single IRBs](#) and describes how communications between sites and the single IRB of record will be handled. In order to develop the plan, the CUNY PI must submit the [CUNY HRPP Form for Selecting the IRB of Record](#) to hrpp@cuny.edu. CUNY's determination regarding the selected IRB of Record will then be provided to the PI via email within 3-5 business days, and an IRB Authorization Agreement with the collaborating site(s) will be entered into as appropriate. Considerations delineated in section 4 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.

3.2. Collaborative Research Not Funded by NIH

PIs proposing to conduct non-exempt human subject research that is not funded by the NIH may obtain IRB approval through one of the mechanisms delineated in this sub-section.

3.2.1. Option 1: IRB Approval from IRB of Each Participating Site

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

3.2.2. Option 2: IRB Approval from a single IRB

The CUNY PI may submit the [CUNY HRPP Form for Selecting the IRB of Record](#) to hrpp@cuny.edu to request review by a single IRB. 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 site(s) as appropriate. Considerations delineated in section 4 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. Selection of the IRB of Record

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

- Prime recipient of funding for the project
- Site where majority of the subject interaction and/or intervention takes place
- Site from which majority of the subjects are recruited
- Site from which majority of any personally identifiable information about the subjects will be obtained

5. PI Responsibilities

5.1. Federally funded collaborative research where CUNY is the prime awardee and/or coordinating center

For non-exempt federally funded human subjects research, where CUNY is the prime awardee and/or the coordinating center, the PI must maintain in the PI's records all of the following:

- Documentation of a current Federalwide Assurance (FWA) for each of the collaborating sites engaged in human subjects research;
- Documentation of any IRB Authorization Agreements entered into by CUNY, current IRB approval and IRB-approved consent documents from the designated IRB of each collaborating site engaged in human subjects research; and
- For NIH supported research, documentation of compliance with NIH Policy on the Use of Single IRBs for Multisite Research.

5.2. Federally funded collaborative research where CUNY is NOT the prime awardee and/or coordinating center

For non-exempt federally funded human subjects research, where CUNY is neither the prime awardee nor the coordinating center, the PI must maintain in the PI's records:

- documentation of any IRB Authorization Agreements entered into by CUNY, current IRB approval and IRB-approved consent documents from the designated IRB of the prime awardee and/or coordinating center; and
- For NIH supported research, documentation of compliance with NIH Policy on the Use of Single IRBs for Multisite Research.

5.3. Non-federally funded collaborative 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 site:

- For collaborating sites with a designated IRB, documentation of current IRB approval and IRB-approved consent documents from the designated IRB of each collaborating site engaged in human subjects research
- For collaborating sites that do not have a designated IRB, documentation of any IRB Authorization Agreements entered into by CUNY and/or applicable permission/authorization from the responsible institutional authority

5.4. Changes in Collaborating Sites When CUNY 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 sites prior to their engaging in human subjects research procedures; and
- Changes in a previously approved collaborating site'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 site during the previous approval period.

5.5. Oversight of research where CUNY is the prime awardee, the coordinating center, or CUNY PI is the lead PI

When CUNY is the prime awardee, the coordinating center, or the CUNY PI is the lead PI of a human subject protocol, 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 sites; and
- Procedures for ensuring timely communication amongst the collaborating sites 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 engagement determinations; and
- When a CUNY IRB is the IRB of Record for federally funded research, verify and document the current FWA number of each collaborating site.