CUNY HRPP Procedures: Multisite Non-Exempt Human Subjects Research

1. Applicability
These procedures apply 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 PI\(^1\) 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) IRBNet ID number for the study; and d) list of CUNY sites that are approved under this protocol.

3. Collaborative Research with Non-CUNY Sites
CUNY UI-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.

\(^1\)In case of student researchers, the Application should be submitted to the HRPP Office of the College with which the Faculty Advisor has the primary affiliation.
3.1. PI Responsibilities

3.1.1. Initial IRB application form for all collaborative research
For all collaborative studies, the PI must provide the following information in the IRB application:
- Identify all collaborating sites and their respective PI’s
- Describe CUNY’s role in the research
- Describe each non-CUNY site’s role in the research

3.1.2. Initial IRB application form for 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 include in the IRB application a written assurance that the PI will maintain in their records all of the following:
- Documentation of current Federalwide Assurance (FWA) for each of the collaborating sites engaged in human subjects research
- Documentation of current IRB approval and IRB approved consent documents from the designated IRB of all collaborating sites engaged in human subjects research

3.1.3. IRB application forms for 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 include the following with their IRB submission:
- **Initial Review**: Provide a written assurance in the IRB application that the PI will maintain in their records documentation of current IRB approval and IRB approved consent documents from the designated IRB of the prime awardee and/or coordinating center
- **Initial AND Continuing Review**: Attach the current IRB approval from the designated IRB of the prime awardee and/or coordinating center to the submission package

3.1.4. Initial IRB application form for non-federally funded collaborative research where CUNY PI is the lead PI
For non-exempt non-federally funded human subjects research, where CUNY PI is the lead PI, the PI must include in the IRB application a written assurance that the PI will maintain in their records one of the following:
- For collaborating sites with a designated IRB, documentation of current IRB approval and IRB approved consent documents from the designated IRB of all collaborating sites engaged in human subjects research
- For collaborating sites that do not have a designated IRB, documentation of appropriate permission/authorization from the responsible institutional authority
3.1.5. **Addition of Collaborating Sites**
The CUNY PI must submit an amendment and appropriate supporting documents to obtain CUNY UI-IRB review and approval of additional sites prior to engaging in human subjects research procedures at the new site.

3.1.6. **Change in the role of a previously approved collaborating site**
The CUNY PI must submit an amendment and appropriate supporting documents to obtain CUNY UI-IRB review and approval of changes in a previously approved collaborating site’s role prior to engaging in the implementation of these changes.

3.1.7. **Discontinuation of a previously approved collaborating site**
As part of the continuing review submission following the discontinuation of a previously approved collaborating site, the PI shall notify the IRB of any discontinuations during the previous approval period.

3.1.8. **Record Keeping**
All records identified below must be available for audit by the CUNY HRPP/IRB at any time.

3.1.8.1. **All Collaborative Research**
For all collaborative research, the PI is responsible for maintaining the following records in the research files:
- Documentation of all communications with the CUNY UI-IRB
- Documentation of all communications with the collaborators and funding agency (when applicable)

3.1.8.2. **Federally funded research where CUNY is the prime awardee and/or coordinating center**
For non-exempt federally funded human subjects research, where CUNY is either the prime awardee or the coordinating center, the PI is responsible for maintaining the following additional records in the research files:
- Documentation of current FWA for each of the collaborating sites engaged in human subjects research
- Documentation of current IRB approval and IRB approved consent documents from the designated IRB of all collaborating sites engaged in human subjects research
  - The PI must ensure that such documentation is received by the PI prior to initiation of research at the non-CUNY collaborating sites

3.1.8.3. **Federally funded research where CUNY is NOT the prime awardee or coordinating center**
For non-exempt federally funded human subjects research, where CUNY is neither the prime awardee nor the coordinating center, the
PI is responsible for maintaining the following additional records in the research files:

- Documentation of current IRB approval and IRB approved consent documents from the designated IRB of the prime awardee and/or coordinating center
- Documentation of all communications with the primary awardee and/or coordinating center

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

For non-exempt non-federally funded human subjects research, where CUNY PI is the lead PI, the PI is responsible for maintaining the following additional records in the research files:

- For collaborating sites with a designated IRB, documentation of current IRB approval and IRB approved consent documents from the designated IRB of all collaborating sites engaged in human subjects research
- For collaborating sites that do not have a designated IRB, documentation of appropriate permission/authorization from the responsible institutional authority

3.1.9. **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 CUNY PI is the lead PI of a human subject protocol, the PI must include the following information in the initial IRB application form:

- Procedures for CUNY PI’s oversight of the conduct of research at the collaborating sites
- 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

3.2. **CUNY HRPP Staff Responsibilities**

The HRPP Coordinator or the IRB Administrator responsible for overseeing the review of the protocol shall:

- Confirm engagement determinations
- Verify that the PI has submitted required documents and assurances as noted in herein
- For federally funded research where CUNY is NOT the prime awardee, verify and document the current FWA number of the prime awardee institution

3.3. **CUNY as the IRB of Record**

CUNY UI-IRB’s approval of collaborative research serves as an IRB approval for CUNY’s involvement in the research. It does NOT constitute an approval for the collaborating sites, EXCEPT when CUNY has agreed to serve as the IRB of Record for the collaborating institution as described in this section.
3.3.1. When will CUNY UI-IRB serve as the IRB of Record for the Collaborating Institution?
CUNY UI-IRB will agree to serve as the IRB of Record for collaborating institutions engaged in federally funded research on a case-by-case basis depending on the nature of the collaboration and the collaborators’ role in the research.

3.3.2. Request for CUNY UI-IRB to serve as the IRB of Record
The request for CUNY UI-IRB to serve as the IRB of Record for a collaborating institution must be made in writing as a part of CUNY PI’s submission of the IRB application. The request should include the following information:
- Role of the collaborating institution in the research
- Whether the collaborating institution has a designated IRB
  - If yes, why the collaborating site’s designated IRB will not serve as the IRB of Record for the project in question

3.3.3. Procedures
The request shall be processed as follows:
1. The HRPP Coordinator or the IRB Administrator responsible for overseeing the review of the protocol will confirm the collaborating site’s engagement in the federally funded research.
2. Once confirmed, the HRPP Coordinator or the IRB Administrator responsible for overseeing the review of the protocol will forward the request to the University Director for Research Compliance.
3. The University Director for Research Compliance will determine whether the CUNY UI-IRB will serve as the IRB of Record.
4. If the CUNY UI-IRB will serve as the IRB of Record, the University Director of Research Compliance will draft an Agreement for signature by the Vice Chancellor for Research (VCR).
   NOTE: VCR is the ONLY individual authorized to sign such Agreements on behalf of the University.
5. Once signed by the VCR, the Agreement will be forwarded to the collaborating institution for their authorized individual’s signature.
6. The Agreement will go into effect after both parties have signed the Agreement, and the PI has submitted a copy of the signed Agreement to the CUNY UI-IRB.

3.3.4. Collaborating Institution’s Responsibility
The collaborating institution must obtain a FWA and list CUNY UI-IRB as a designated IRB, when appropriate.