GETTING STARTED WITH THE CUNY UI-IRB:
Submission Guidance Documents

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CUNY HRPP Guidance: When is CUNY HRPP or IRB Review Required?

1. Purpose
   The purpose of this guidance document is to assist the CUNY research community in determining when CUNY HRPP or IRB review is required.

2. When is CUNY HRPP or IRB review required?
   CUNY HRPP or IRB review is required when ALL of the following criteria are met:
   1. The investigator is conducting research or clinical investigation;
   2. The proposed research or clinical investigation involves human subjects; AND
   3. CUNY is engaged in the research or clinical investigation involving human subjects.

2.1. CUNY HRPP human subject determinations
   When researchers are not certain whether their activities constitute human subject research, they should submit a Human Subject Research Determination form in IRBNet to their College’s HRPP Office. The HRPP Coordinator will issue a determination of whether the proposed activities constitute human subject research.

   2.1.1. If the HRPP Coordinator determines that the research does NOT constitute human subject research, the researcher should retain this documentation in their research files.

   2.1.2. If the HRPP Coordinator determines that the research DOES constitute human subject research, and CUNY is engaged in the research, the researcher must submit a CUNY Initial Application in IRBNet to their College’s HRPP Office.

3. Definitions

3.1. Research
   A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

3.2. Clinical investigation
   Any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the Food and Drug Administration (FDA) under the Federal Food, Drug and Cosmetic Act (the Act), or is not subject to requirements for prior submission to the FDA under the Act, but the results of which are intended to be submitted later to, or held for inspection by, the FDA as part of an application for a research or marketing permit.
3.3. Human subject
A living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.

When FDA regulations apply, human subject is an individual who is or becomes a participant in research, either as a recipient of the test article or as a control.

3.4. Intervention
Both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

3.5. Interaction
Communication or interpersonal contact between investigator and subject

3.6. Identifiable
The identity of the subject is or may readily be ascertained by the investigator or associated with the information.

3.7. Private information
Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record).

3.8. Test article
Any drug (including a biological product for human use), medical device for human use, human food additive, color additive, electronic product, or any other article subject to FDA regulations.

3.9. Engaged
CUNY is considered engaged in a particular human subjects research project when CUNY employees or agents\(^1\) obtain, for the purposes of the research project, (1) data about the subjects of the research through intervention or interaction with them; (2) identifiable private

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\(^1\) For the purposes of this document, employees or agents refers to individuals who: (1) act on behalf of CUNY; (2) exercise institutional authority or responsibility; or (3) perform institutionally designated activities. Employees or agents can include staff, students, contractors, and volunteers, among others, regardless of whether the individual is receiving compensation.
information about the subjects of the research; or (3) the informed consent of human subjects for the research.

**Note:** CUNY applies OHRP Guidance on Engagement of Institutions to determine CUNY's engagement in all research, regardless of funding.

### 4. Example: Oral History Projects

<table>
<thead>
<tr>
<th>Activity</th>
<th>HRPP/IRB Review Required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Open-ended interviews, that ONLY document a specific historical event or the experiences of individuals without intent to draw conclusions or generalize findings</td>
<td>NO</td>
</tr>
<tr>
<td>Systematic investigations involving open-ended interviews that are designed to develop or contribute to generalizable knowledge (e.g., designed to draw conclusions, inform policy, or generalize findings)</td>
<td>YES</td>
</tr>
<tr>
<td>Creation of archives for the purpose of providing a resource for others to do research. The <em>intent</em> of the archive is to create a repository of information for other investigators to conduct research.</td>
<td>YES</td>
</tr>
</tbody>
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### 5. Example: Scholarship of Teaching & Learning (SoTL) and Educational Activities

<table>
<thead>
<tr>
<th>Activity</th>
<th>HRPP/IRB Review Required</th>
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<tbody>
<tr>
<td>SoTL activities designed for localized improvement efforts that will result in changing the design of a course at CUNY, changing the kinds of assessments used in courses at CUNY, changing student expectation at CUNY, etc., where the results will be limited to dissemination or implementation within CUNY.</td>
<td>NO</td>
</tr>
<tr>
<td>Systematic SoTL inquiry designed to produce knowledge that is available to those outside CUNY to use and build on.</td>
<td>YES</td>
</tr>
<tr>
<td>Activities designed for educational purposes ONLY. Results will NOT contribute to generalizable knowledge (e.g., published outside classroom, presented in an article, result in a dissertation or poster session).</td>
<td>NO</td>
</tr>
</tbody>
</table>

### 6. Example: Quality Assurance / Quality Improvement Activities

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<thead>
<tr>
<th>Activity</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Evaluation of a specific program, procedure, etc. when the primary <em>intent</em> is solely for internal assessment or improvement, with no plans to publish or present the results outside of CUNY.</td>
<td>NO</td>
</tr>
<tr>
<td>Systematic evaluation to determine whether an existing, new or modified procedure or program is effective and can be applied to environments outside CUNY.</td>
<td>YES</td>
</tr>
</tbody>
</table>

**References**


2. Code of Federal Regulations, Title 21 – Food and Drugs, Part 50 – Protection of Human Subjects

GETTING STARTED with IDEATE: Creating IRB Applications
(Initial Applications, Continuing Reviews, Amendment Requests, & Closure/Final Reports)

1. IDEATE Log-in Instructions: Log into IDEATE (https://ideate.cuny.edu) using your CUNY Portal credentials.
   a. If you do not remember your CUNY Portal Log-in information, please reset your password: https://cunyportal.cuny.edu/cpr/authenticate/portal_login.jsp
   b. If you continue to have difficulty logging-in, please contact the Hunter College HRPP Office at hrpp@hunter.cuny.edu (Subject: IDEATE Log-In Issue).

2. Create New IRB Application within IDEATE:
   a. Click on “Create New” from the menu bar at the top of the LiveList Screen
   b. Then click on “IRB Application”
   c. Enter the Protocol Title of your project in the field provided
   d. Then click on the blue “Lookup” link to select the Principal Investigator
   e. Once you’ve selected the PI for this study, please select the Department by using the drop down box.
   f. Click on “Begin Application” once all of the above information has been entered.

3. Creating an Amendment Request/Continuing Review/Closure Reports:
   a. On the LiveList Screen, click on the protocol number of the project to open your protocol.
   b. In the Actions drop-down box (right-hand side of screen), please choose “Create Amendment”, “Create Continuing Review”, or “Create Final Report”. Then click “Go”.
   c. For Amendment Requests:
      i. Complete the Amendment Summary (first page of application) by describing each requested change. Be as descriptive as possible.
      ii. Revise the application to reflect any modified study procedures and attach all revised documents in the Attachments page of the application.
   d. For Continuing Reviews:
      i. Complete the Continuing Review application in its entirety.
      ii. If enrollment numbers do not add up in the Enrollment tab, please include the study enrollment numbers in the Research Summary (first page of application).
      iii. Please attach all documents that will be used within the upcoming year.
   e. For Final Reports:
      i. Complete the Final Report application in its entirety.
      ii. If enrollment numbers do not add up in the Enrollment tab, please include the enrollment numbers in the Final Report Summary (first page of application).
      iii. Please include a clear description of the research conducted and attach any presentation/publication articles in the Summary page.

4. Adding New Research Personnel (CUNY-affiliated) in Amendments:
   a. In the Amendment Summary (first page of Amendment): Please state their Name, CUNY status, study responsibilities, training and/or qualifications. Provide a rationale for adding them to the protocol.
   b. Add new research personnel in the Personnel page: If the individual is not in the Ideate system, please instruct them to log into the Ideate system using their CUNY Portal credentials (see “Guide for New Users & Pls with Existing Projects” document). Once they have logged into the system, they must accept the pending invitation to be part of the study, which will appear on their To Do List (left-hand side) of the LiveList.
   c. Please attach their Human Subjects Research (HSR) CITI certificate (Social and Behavioral training) in the Attachments page.
CUNY HRPP Policy: Researcher Responsibilities

1. Overview
   Researchers are responsible for i) the ethical conduct of their research, including the protection of human subjects; ii) complying with all applicable regulations and CUNY policies; and iii) adhering to CUNY UI-IRB’s stipulations. Though the research team shares these responsibilities, the Principal Investigator (PI) is ultimately held responsible for the ethical conduct of research and for compliance with applicable regulations, policies and IRB stipulations.

2. Researcher Defined
   For the purposes of CUNY HRPP/IRB, a researcher is any individual who i) serves as the PI or co-investigator; ii) interacts directly with the research subjects for research purposes; or iii) has access to identifiable private information about the human subjects for research purposes.

3. Protection of Human Subjects
   Researchers are responsible for protecting human subjects throughout the research process: recruitment, screening, consenting, study procedures and end of study considerations. Specifically, researchers should:
   - Develop research studies using sound research design, which minimizes risks to subjects, does not unnecessarily expose subjects to research-related risks, and maximizes benefits
   - Planning and implementing fair and equitable recruitment practices, which avoid the potential for coercion and undue influence
   - Obtaining legally effective informed consent for subject participation
   - Ensuring availability of adequate resources (including personnel, time commitment, facilities, funding, etc.), such that the research may be conducted in a manner that protects the rights and welfare of human subjects and that ensure integrity of the research
   - Responding promptly to subject complaints, concerns or request for information and reporting any significant complaints or concerns to the IRB

4. Complying with Regulations, Policies and IRB Stipulations
   To ensure compliance, researchers must:
   - Seek HRPP guidance if uncertain about HRPP/IRB review requirements
   - Ensure that all human subjects research receive either HRPP exemption or IRB approval prior to its initiation (including any subject recruitment)
   - Ensure that all IRB approved protocols receive continuing review by the IRB at least annually
   - Ensure that changes to exempt or IRB approved protocols receive HRPP/IRB review, and exemption or approval, prior to their implementation

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1 To determine whether an activity constitutes human subjects research, please refer to the guidance document, "When is CUNY HRPP or IRB Review Required?"
• Promptly report any unanticipated problems involving risks to subject or others to the IRB
• Promptly report any serious or continuing non-compliance with applicable regulations or CUNY policies
• Accurately and thoroughly complete all relevant IRB application materials
• Comply with all applicable regulations
• Comply with all applicable CUNY policies
• Comply with all sponsor requirements, when applicable
• Comply with IRB’s determinations and stipulations
• Cooperate with the HRPP staff and IRB members during any inquiries or audits concerning human subject research review and oversight.

5. Training and education
Researchers must be qualified by education, training and experience to conduct the research they are proposing. Additionally, researchers are required to complete the CUNY-required modules of the Collaborative Institutional Training Initiative’s (CITI) online training in the protection of human subjects. Detailed CUNY policy concerning this requirement is available at http://www.cuny.edu/research/compliance/training-education.html

6. Recordkeeping
Researchers are required to retain research records in accordance with applicable regulations, CUNY policies and sponsor requirements. Specifically, researchers must:

• Retain records of all IRB approved submissions, including:
  o All correspondence between the IRB and the researcher
  o All IRB approved documents, including but not limited to IRB application, sponsor protocol (if any), recruitment materials, screening documents, consent documents and data collection tools
  o Documentation of subject eligibility, when applicable
  o Documentation of consent process for each subject, when applicable
  o All signed consent documents, when applicable
• Retain all records for a minimum of three years after the end of the study; OR a minimum of six years for studies involving Protected Health Information (HIPAA applicable); AND in accordance with sponsor requirements.
• Maintain confidentiality of research records in accordance with IRB approved protocol and sponsor requirements.

References

1. DHHS Office for Human Research Protections (OHRP) Investigator Responsibilities – FAQs.

CUNY HRPP Policy: Training in the Protection of Human Subjects

1. Purpose
The purpose of this policy is to set forth CUNY's requirements for training in the protection of human subjects.

2. Training Requirements
All key research personnel involved in human subjects research must complete the CUNY-required modules of the Collaborative Institutional Training Initiative's (CITI) on-line training in the protection of human subjects (basic course) prior to IRB approval of a new or continuing review application, or an amendment application that requests addition of key personnel. Instructions for completing this training are available at http://www.cuny.edu/research/compliance/training-education/citi-training.html.

2.1. Refresher Course
On-line training certificates will be valid for three years. Key personnel are required to take the CITI training in the protection of human subjects (refresher course) every 3 years following completion of the basic course.

3. Definition
Key personnel are defined as the Principal Investigator, co-investigators and research personnel who interact directly with human subjects or who have access to private information related to human subjects during the course of a research project. Key personnel also include faculty sponsors/advisors who provide direct oversight of research with human subjects or research using private information about human subjects.

4. Non-CUNY Collaborators
CUNY HRPP will accept training in the protection of human subjects provided by and in accordance with the collaborating institution's policies. IRB approval from the collaborating institution's IRB will serve as documentation of completion of such training. Collaborators from institutions relying on CUNY UI-IRBs will be required to complete CITI training described in Section 2 above.