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, staff or students 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 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>
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<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>
</table>

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

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<tr>
<th>Activity</th>
<th>HRPP/IRB Review Required</th>
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<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