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

[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

Activity	HRPP/IRB Review Required
Open-ended interviews, that ONLY document a specific historical event or the experiences of individuals without intent to draw conclusions or generalize findings	NO
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).	YES
Creation of archives for the purpose of providing a resource for others to do research. The *intent* of the archive is to create a repository of information for other investigators to conduct research.	YES

5. Example: Scholarship of Teaching & Learning (SoTL) and Educational Activities

Activity	HRPP/IRB Review Required
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.	NO
Systematic SoTL inquiry designed to produce knowledge that is available to those outside CUNY to use and build on.	YES
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).	NO

6. Example: Quality Assurance / Quality Improvement Activities

Activity	HRPP/IRB Review Required

Evaluation of a specific program, procedure, etc. when the primary *intent* is solely for internal assessment or improvement, with no plans to publish or present the results outside of CUNY.	NO
Systematic evaluation to determine whether an existing, new or modified procedure or program is effective and can be applied to environments outside CUNY.	YES

References

1. Code of Federal Regulations, Title 45 – Public Welfare DHHS, Part 46 – Protection of Human Subjects

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

3. DHHS Office of Human Research Protections, "Guidance of Engagement of Institutions in Human Subjects Research"