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. Definitions

2.1. Research

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

2.2. 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.

2.3. Human subject

A living individual about whom an investigator (whether professional or student) conducting research: (1) obtains information or biospecimens through *intervention* or *interaction* with the individual, and uses, studies, or analyzes the information or biospecimens; or (2) obtains, uses, studies, analyzes, or generates *identifiable private information* or *identifiable biospecimens*.

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.

2.4. Intervention

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

2.5. Interaction

Communication or interpersonal contact between investigator and subject.

2.6. 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).

2.7. Identifiable private information

Private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

2.8. Identifiable biospecimen

Biospecimen for which the identity of the subject is or may readily be ascertained by the investigator associated with the biospecimen.

2.9. 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.

2.10. 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 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.

2.11. Public Health Authority

An agency or authority of the Unites States, a state, a territory, a political subdivision of a state or territory, an Indian tribe, or a foreign government, or a person or entity acting under a grant or authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is responsible for public health matters as part of its official mandate.

[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.

3. 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.

3.1. Project Based Guidance

When researchers are not certain whether their activities constitute human subject research, they should contact their CUNY college or school's HRPP Office for guidance.

4. Activities Deemed Not to be Research

4.1. Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

4.1.1. **NOTE**: Studies using participant observation and ethnographic methods, in which investigators gather information from individuals in order to understand their beliefs, customs, and practices, where the findings apply to the larger studied community or group (and not just the individuals from whom the information was obtained), however, **are** considered to be research.

4.2. Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority.

4.2.1. Such activities are **limited** to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products).

4.2.2. Such activities **include** those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

4.3. Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

4.4. Authorized operational activities (as determined by a federal agency) in support of intelligence, homeland security, defense, or other national security missions.

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,"* October 16, 2008