

The **CUNY Human Research Protection Program (HRPP)** is responsible for the protection of the rights and welfare of human subjects in research projects conducted at CUNY or by CUNY faculty, staff and students and RF CUNY staff. The program provides oversight, administrative support and educational training to ensure that CUNY research complies with federal and State regulations, University policy and the highest ethical standards. The CUNY HRPP comprises of 5 University Integrated Institutional Review Boards (IRBs) and 19 on-site HRPP offices.

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.

Research protocols that meet ALL of the above criteria must be submitted using the electronic submission system (<http://ideate.cuny.edu>) to the HRPP office at the CUNY campus with which the faculty member or faculty advisor for student research protocols is primarily housed.

HRPP policies, procedures and guidelines are available here:

<http://www2.cuny.edu/research/research-compliance/human-research-protection-program-hrpp/hrpp-policies-procedures/>

OHRP regulations are available here: <http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html>

For faculty and students of faculty who are primarily affiliated with the Graduate Center, please visit the GC HRPP website at: www.gc.cuny.edu/hrpp

Helpful Definitions:

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

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.

5. **Interaction:** Communication or interpersonal contact between investigator and subject.

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

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).

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.

9. **Engaged:** CUNY is considered engaged in a particular human subjects research project when CUNY employees or agents 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.