

## **Policy 1.191 Human Research Protections Program**

CUNY strives to foster a research environment that promotes respect for the rights and welfare of individuals recruited for, or participating in, research conducted by or under the auspices of CUNY. In the review and conduct of human subjects research, actions by CUNY will be guided by the principles (i.e., respect for persons, beneficence, and justice) set forth in the Ethical Principles and Guidelines for the Protection of Human Subjects of Research (often referred to as the Belmont Report). The actions of CUNY will also conform to all applicable federal, state, and local laws and regulations and this Policy.

All institutional and non-institutional human subjects research performance sites for CUNY, domestic or foreign, are obligated by this Policy to conform to ethical principles which are at least equivalent to those of CUNY or as may be determined by the Department of Health and Human Services (DHHS) Secretary.

### **1 Human Research Protections Program**

In order to fulfill its human subjects research mission, CUNY has established a human research protections program (HRPP). The purpose of the HRPP is to:

- Safeguard and promote the welfare of human research subjects by ensuring that their rights, safety and well-being are protected;
- Provide timely and high quality review and monitoring of human subjects research projects; and
- Facilitate excellence in human subjects research.

### **2 Institutional Official**

CUNY has designated an Institutional Official who has overall responsibility for CUNY's HRPP. The duties of the Institutional Official are as follows:

- Be responsible for compliance with all applicable laws and CUNY policies for the protection of human subjects.
- Be the signatory authority, along with the President of The Research Foundation of The City University of New York, for CUNY's Federal-wide Assurance to the Office of Human Research Protections.
- Provide support to the HRPP within CUNY's means.

The Institutional Official has the authority to delegate the performance of such activities as may be necessary in order to fulfill these duties.

### **3 Institutional Review Boards**

To conduct its HRPP responsibilities effectively, CUNY maintains at least one Institutional Review Board (IRB) to review research protocols involving human subjects. Each IRB is an autonomous administrative body established to protect the rights and welfare of human research

subjects recruited to participate in research activities conducted by or under the auspices of CUNY. Each IRB has the following authority:

- To approve, require modifications to secure approval, defer, or disapprove all human subjects research activities overseen and conducted by or under the auspices of CUNY, regardless of location of the research activities;
- To suspend or terminate approval of human subjects research not being conducted in accordance with the IRB's requirements or applicable law or policy, or that has been associated with unexpected serious harm to participants;
- To observe, or have a third party observe, the consent process; and
- To observe, or have a third party observe, the conduct of the human subjects research.

All IRB-approved research studies are subject to ongoing review, which must be conducted at least once annually by an IRB. If approval by the IRB lapses, all research activity must stop. The investigator can petition the IRB to continue an individual participant's research intervention/interaction during a period of lapsed IRB approval if the investigator believes there is a safety concern or ethical issue such that it is in the best interests of the individual participant to do so.

The IRB has jurisdiction over, and maintains policies regarding, all human subject research conducted by or under the auspices of CUNY, regardless of funding source or performance site. Research by or under the auspices of CUNY includes research:

- conducted at any CUNY facility;
- conducted by or under the direction of any student, faculty member, staff member or agent of CUNY in connection with his or her institutional responsibilities;
- conducted by or under the direction of any student, faculty member, staff member or agent of CUNY using any CUNY property or facility; or
- involving the use of CUNY's non-public information.

No research involving human subjects may commence until all required CUNY approvals (including IRB) are obtained.

CUNY may review any research protocol and has the right to disapprove the implementation of a research protocol that has been approved by the IRB. However, no one at CUNY shall approve the implementation of any research protocol nor may it override the decision of the IRB concerning a research protocol that has not been approved by the IRB.

#### **4 Operating Procedures**

The Institutional Official and the IRB shall adopt operating procedures to implement this Policy. These procedures shall serve as the governing procedures for the conduct and review of all human subjects research conducted by or under the auspices of CUNY.