**Best Practices:** **Research Involving Human Subjects**
**Effective Date:** **August 2013**

The State University of New York (SUNY) fosters 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, the Colleges and Universities in the SUNY System ("SUNY campuses").

In the review and conduct of research, action by SUNY campuses 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 termed the Belmont Report). The actions of SUNY campuses will also conform to all applicable, federal, state and local laws and regulations. As part of this commitment, SUNY and the Research Foundation for SUNY (RF) share the obligation for the ethical conduct of activities involving human subjects.

Implementation of these best practices constitutes an important first step in achieving the ultimate goal of obtaining accreditation from an entity that accredits human research protection programs.

## Human Research Protections Program

In order to fulfill this mission, SUNY campuses involved in human subjects research must establish a human research protections program (HRPP). The mission 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 research projects; and
- facilitate excellence in human subjects research.

## Institutional Official

Each SUNY campus will designate an Institutional Official who has overall responsibility for the campus HRPP. The duties of the Institutional Official are as follows:

- ensure compliance with institutional policies and all applicable regulations for the protection of human subjects;
- serve as the signatory authority for the Federal-wide Assurance to the Office of Human Research Protections (when the campus receives federal funds for such research); and
- provide support to the HRPP within the means of the campus.

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

## Institutional Review Board

To conduct its responsibility effectively, the SUNY campus must maintain an Institutional Review Board (IRB) to review research protocols involving human subjects. Note that, alternatively, the campus may enter into a written agreement with another SUNY campus, another institution, or an independent IRB for such services. The IRBs are

autonomous administrative bodies established to protect the rights and welfare of human research subjects recruited to participate in research activities conduced under the auspices of the SUNY campus. The IRB has the following authority:

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

All IRB-approved research studies are subject to ongoing review, which must be conducted at least once annually by the IRB. If approval by the IRB lapses, all research activity must stop. The investigator can petition the IRB to continue an individual subject'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 subject to do so.

The IRB has jurisdiction over all human subjects research conducted under the auspices of the SUNY campus, regardless of funding source or performance site. Research under the auspices of the campus includes research:

- conducted at the campus;
- conducted by or under the direction of any SUNY or RF employee or agent of the campus (including students) in connection with his or her institutional responsibilities;
- conducted by or under the direction of any SUNY or RF employee or agent (including students) of the campus using any property or facility of the campus; or
- involving the use of the campus's non-public information.

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

The SUNY campus Institutional Official 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 the campus shall approve the implementation of any research protocol nor may it override the decision of the IRB concerning a research protocol that has been disapproved by the IRB.

The Department of Health and Human Services (DHHS) Code of Federal Regulations, Title 45 Part 46: Protection of Human Subjects, requires that all performance sites for the SUNY campus, on or off-campus, domestic or foreign, are obligated to conform to ethical principles which are at least equivalent to those of the campus or as may be determined by the DHHS Secretary.

The Institutional Official and the IRB shall adopt and implement operating procedures for research involving human subjects. These procedures shall serve as the governing process for the conduct and review of all human research conducted under the auspices of the SUNY campus, in conjunction with all other federal, state, and local laws and regulations; and institutional policies, as applicable.

## Resources

- Department of Health and Human Services (DHHS)Code of Federal Regulations, Title 45 Part 46: Protection of Human Subjects
- Food and Drug Administration (FDA) Code of Federal Regulations, Title 21 Parts 50 (Informed Consent), 56 (IRB's), 312 (Investigational New Drugs), 812 (Investigational Device Exemptions)
- The Belmont Report: "Ethical Principles and Guidelines for the Protection of Human Subjects of Research"
- Appropriate Articles of the New York State (NYS) Public Health Law