

PROTECTION OF HUMAN SUBJECTS RESEARCH

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Contact: Director, Office of Sponsored Programs

Category: Research and Sponsored Programs

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Effective Date: Jan. 1, 1995

Implementation History: Revised on April 29, 2013

Keywords: Institutional Review Board, Human Subject Research

Background Information: Revised to reflect current legislation

Purpose

To ensure the ethical treatment of human subjects involved with Empire State University research projects, as well as to comply with federal and state regulations, the university has developed this policy as well as procedures with which to carry out the policy. Additionally, the university, in order to maintain its federal-wide assurance with the Office of Human Research Protections, which is necessary for federal grants, must have a policy for the protection of its human research subjects.

Definitions

Research: A systematic investigation including research development, testing and evaluation designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute “research” for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities.

Human Subject: A living individual about whom an investigator (faculty, staff or student) conducting research obtains:

1. Data through intervention or interaction with the individual, or
2. Identifiable private information.

Statements

All research involving human subjects conducted by university faculty, staff and students must be reviewed and approved by the Institutional Review Board prior to the start of the research. Those submitting protocols to the Institutional Review Board must have completed the CITI human subjects training within three years of the protocol submission or the protocol will not be approved.

Applicable Legislation and Regulations

U.S. Department of Health and Human Services, regulation 45 CFR 46 (<http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/>)

New York State Department of Health Institutional Review Board Guidelines for Researchers (https://www.health.ny.gov/professionals/irb/docs/irb_guidelines_for_research.pdf)

Related References, Policies, Procedures, Forms and Appendices

Empire State University human subjects in research guidance, procedures and protocol form (<http://www.sunyempire.edu/irb/>)