



Title: Research Involving Human Subjects Policy	Policy Category: Research
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Policy Statement/Background:

None

Policy:

Stony Brook University 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 University. In the review and conduct of research, actions by the University 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 the University will also conform to all applicable federal, state, and local laws and regulations.

In order to fulfill this mission, the University has established 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 subject research.

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

- Be responsible for compliance with institutional policies and all applicable regulations for the protection of human subjects.
- Be the signatory authority for the Federal-wide Assurance to the Office of Human Research Protections.
- Provide support to the human research protections program within the means of the institution.

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.

To conduct its responsibility effectively, the University maintains an Institutional Review Board (IRB) to review research protocols involving human subjects. The Institutional Official can also designate an external IRB with review and approval authority, by way of a formal reliance agreement. The IRB is an autonomous administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of the University. 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 University, regardless of location of the research activities;
- 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 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 research.

Greater than minimal risk research (or those studies deemed to require a continuing review) is 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 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 all human subject research conducted under the auspices of the University, regardless of funding source or performance site. Research under the auspices of the institution includes research:

- Conducted at this institution;
- Conducted by or under the direction of any employee or agent of this institution (including students) in connection with his or her institutional responsibilities; and
- Conducted by or under the direction of any employee or agent (including students) of this institution using any property or facility of this institution, or involving the use of this institution's non-public information.

No research involving human subjects may begin until all required institutional approvals (including the IRB) are obtained.

The University 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 University 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.

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

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 research conducted under the auspices of the University, in conjunction with all other federal, state, and local laws and regulations, as well as institutional policies, as applicable.

Definitions:

None

Contact:

Additional information about this policy is available here:

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<https://www.stonybrook.edu/commcms/research-compliance/index.php>

Relevant Standards, Codes, Rules, Regulations, Statutes and Policies:

- [DHHS: Code of Federal Regulations, Title 45 Part 46](#): Protection of Human Subjects
- [FDA: Code of Federal Regulations, Title 21](#) Parts 50 (Protection of Human Subjects), 56 (Institutional Review Boards), 312 (Investigational New Drug Application), & 812 (Investigational Device Exemptions)
- [The Belmont Report: "Ethical Principles and Guidelines for the Protection of Human Subjects of Research"](#)
- [Stony Brook Human Subject Research Standard Operating Procedures](#)
- [Stony Brook Office of Research Compliance Human Subjects Research Website](#)
- [Stony Brook Office of Research Compliance External IRBs Website](#)