SUNY Polytechnic Institute

SUBJECT – Institutional Review Board	**Effective Date –** September 2017
TITLE – Authority, Roles and Responsibilities of the Institutional Review Board	**Approved By –** SUNY Poly IRB; Michael Manning; Associate Provost

SCOPE – This policy applies to all Institutional members involved in the operation of the IRB, and to the Institutional Review Board (IRB) Committee.

PURPOSE – To establish the authority, roles and responsibilities of the Institutional Review Board.

POLICY – SUNY Polytechnic Institute shall establish and maintain an Institutional Review Board (IRB) for the protection of human subjects involved in research. The authority, roles and responsibilities of the IRB shall be clearly defined and in accordance with existing federal regulations, the institution's policies and established benchmarks.

Authority

The SUNY POLYTECHNIC INSTITUTE IRB shall review, and have the authority to approve, require modifications in (to secure approval), or disapprove all research activities involving human subjects, including proposed changes to previously approved research, conducted under the auspices of SUNY POLYTECHNIC INSTITUTE (including faculty, staff, students and the institution's facilities). The following definitions, established by the Office of Human Research Protections in *45 CFR 46*, shall apply:

(1) *Research* means 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 which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

(2) *Human subject* means a living individual about whom an investigator, whether professional or student, conducting research obtains (a) data through intervention or interaction with the individual, or (b) identifiable private information.

Research approved by the IRB may be subject to further appropriate review and approval or disapproval by institutional officials. However, those officials may not approve research that has not been approved by the IRB.

The IRB shall also have authority to:

(1) Request progress reports for a particular protocol at intervals defined by the IRB for the conduct of continuing review.
(2) Suspend or terminate approval of research that is not conducted in accordance with the requirements of the IRB or that has been associated with unexpected harm to subjects.
(3) Impose additional restrictions, as necessary, for the protection of human subjects.
(4) Observe, or have a third party observe, the consent process and the conduct of research, and monitor research to ensure compliance.
(5) Establish policies and procedures as necessary to ensure human subject protection.
(6) Review the credentials of investigators to ensure that they have the appropriate expertise to properly conduct the study.

(7) Determine when transfer of oversight responsibility to an external IRB is appropriate.

The IRB Chair shall have the authority to:

(1) Designate a voting member of the IRB to act in place of the Chair for matters where authorized by Regulation.
(2) Issue signatory authority of the IRB Chair to the IRB Coordinator. An appropriate record specifying this authority, along with the signature, shall be maintained in the Office of the IRB (Kunsela Hall, Room B219).

Roles and Responsibilities

Institutional Official **–** The Institutional Official (IO) shall be the Provost or designee. The IO has the legal authority to act and speak for the institution, and, as such, assures SUNY POLYTECHNIC INSTITUTE will comply with all requirements of 45 CFR Part 46 and all other appropriate federal regulations governing protection of human subjects. In addition, the IO sets the tone for an institutional culture of respect for human subjects through effective communications, guidance and oversight of all research and IRB functions. Responsibilities of the IO include the following:

(1) Establish an IRB, appropriately staffed with qualified members, including designation of the Chair.
(2) Provide sufficient resources for the effective operation of the IRB, including appropriate training for the IRB, researchers and staff.
(3) Ensure written procedures and guidelines to be followed by the IRB for the protection of human subjects, as specified in regulations.
(4) Implement appropriate mechanisms for institutional research oversight.
(5) Appoint individuals to fulfill certain administrative duties and to serve as official point of contact to regulating agencies, as appropriate.

Institutional Review Board – The Institutional Review Board functions independently of, but in coordination with other committees, agencies and personnel to ensure protection of the rights, welfare and safety of human subjects recruited to participate in research. It shall be the responsibility of the SUNY POLYTECHNIC INSTITUTE IRB to:

(1) Conduct ethical review of all proposed research activities involving human subjects. For approved research, ensure that:
    (a) Informed consent is sought from each participant, that basic information as specified in 46.116 is provided to subjects as part of the informed consent process, and that it is documented, unless waived by the board. The board shall require additional information be provided to subjects, as appropriate.
    (b) Risks to subjects are minimized and are reasonable in relation to the anticipated benefits to the subject and/or to society.
    (c) Equitable selection of subjects according to the setting and purpose of the research, and ensure that additional safeguards are included whenever vulnerable populations participate.
    (d) Adequate provisions are provided to ensure protection of subject privacy and confidentiality and monitoring of data.
(2) Conduct continuing review of research at intervals appropriate to the degree of risk but not less than once per year.

(3) Evaluate adverse events, interim findings and recent literature that may be relevant to the research and determine if actions are required.
(4) Notify investigators and the institution in writing of its decision to approve or disapprove proposed research, or of modifications required to secure IRB approval.
(5) Assess suspected or alleged protocol violations, complaints expressed by research participants, or violations of institutional policies.
(6) Accomplish initial and on-going training requirements, be knowledgeable of regulations and policies governing research, and be informed of current literature and events appropriate to the institution's research activities.

IRB Chair – The IRB Chair ensures the protection of human subjects through fair and impartial management of board activities and the matters brought before it. In addition, the Chair ensures board compliance with all applicable federal, state, and local regulations and policy. Responsibilities of the IRB Chair include the following:

(1) Preside over and ensure all meetings are conducted appropriately and efficiently and that a quorum is maintained and documented.
(2) Conduct expedited review and approval of research submissions that involve no more than minimal risk, for minor changes in approved research and as otherwise authorized in accordance with existing regulations.
(3) Determine when submissions are exempt from review in accordance with regulations.
(4) Maintain open channels of communication with investigators, IRB staff and institutional officials to facilitate the collaborative conduct of safe ethical research.
(5) Ensure that all required elements of review are addressed and that substantive and meaningful discussion occurs, as appropriate and according to regulations.
(6) Ensure promulgation of policies and procedures in compliance with federal regulations for the efficient conduct of the IRB.
(7) Provide oversight and leadership to the IRB in the review of complaints and noncompliance allegations.
(8) Designate an alternate chair and notify the IRB Coordinator when unable to attend a scheduled meeting.
(9) Assist in educating the IRB and researchers.

IRB Coordinator – The IRB Coordinator provides oversight of all IRB activities and supports the IRB process by facilitating timely, thorough and complete review of research protocols. In addition, the Coordinator provides administrative and clerical support. The responsibilities of the IRB Coordinator include the following:

(1) Advise researchers and staff, the IRB membership and Chair, and the Institutional Official, as necessary, on such issues as regulations, policy and procedures, and ethical principles governing research to ensure compliance through interpretation and application.
(2) Manage protocol review, and communication with IRB and researchers.
(3) Ensure training and education of IRB members, investigators and research staff as required by federal regulations and institutional policy.
(3) Prepare and maintain adequate documentation of IRB activities, including minutes, records of continuing review activities, and copies of all correspondence between the IRB and other agencies, in accordance with regulatory and institutional standards and expectations.

(5) Ensure timely submission of required reports to regulating agencies, the institution, sponsors and investigators according to regulations.
(6) Develop, implement and interpret policy and procedures to ensure the consistent, transparent and legally effective administration of IRB processes and determinations.
(7) Assist the IRB Chair and the Institutional Official, as appropriate, to investigate and respond to allegations, complaints and non-compliance.

References

45 CFR 46.109; 46.113; 46.116
21 CFR Part 56
IRB Guidebook
Institutional Review Board Management and Function, 2nd ed. (Bankert & Amdur, 2006)
Northshore IRB
Public Responsibility of Medicine and Research (PRIM&R)
OHRP Assurance Training Modules
SUNY Upstate Medical Center IRB
University of Kentucky IRB