

SUNY Polytechnic Institute

SUBJECT – Institutional Review Board	EFFECTIVE DATE – 12/11/2012
TITLE – IRB Membership	APPROVED BY – SUNY POLYTECHNIC INSTITUTE IRB; Michael Manning

SCOPE – This policy applies to the Institutional leadership responsible for establishing the IRB and to the Institutional Review Board (IRB) Committee.

PURPOSE - To establish guidelines for the selection of the Institutional Review Board (IRB) membership.

POLICY – State University of New York Institute of Technology (SUNY POLYTECHNIC INSTITUTE) shall maintain an Institutional Review Board for the protection of human subjects who participate in all behavioral, social science and medical research. IRB membership shall be consistent with federal requirements outlined in 45 CFR 46.107; 21 CFR 56.107 and 38 CFR 16.107 in order to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.

General Description

The SUNY POLYTECHNIC INSTITUTE IRB membership shall consist of a minimum of five (5) voting members sufficiently qualified through experience and expertise to promote complete and adequate review of research activities commonly conducted by the institution. Additionally, the membership shall be professionally competent to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct. The membership should also be appropriately diverse with respect to race, gender, and cultural backgrounds.

The IRB will include at least one member whose primary concerns are in scientific areas, and at least one member whose primary concerns are in non-scientific areas. The IRB will also include at least one member who is not affiliated with the institution. One member may fill the non-scientific and the not affiliated roles.

If the IRB regularly reviews research that involves a vulnerable category of subjects, the membership will include one or more individuals knowledgeable about and experienced in working with those subjects.

The IRB invites (non-voting) individuals with competence in special areas to assist in the review of issues requiring expertise beyond, or in addition to that available on the board.

Procedures

- (1) The Institutional Official (IO) appoints the IRB Chair and confirms members to the IRB.
- (2) The IRB membership nominates candidates. Whenever an IRB vacancy occurs, the IRB Chairman solicits recommendations from the membership. Full board consideration is given to each nomination, subject to the approval of the IO.
 - (a) A member volunteers to discuss IRB membership with the nominee. If the nominee agrees, the IRB Coordinator provides written invitation to attend a convened meeting.
 - (b) Membership confirmation requires confirmation of the IO and a majority vote of approval by the membership.

- (3) Terms are for three years; the member may be reappointed at the end of the three years. Each new member must complete the web-based training (*Collaborative Institutional Training Initiative (CITI)*) for IRB members prior to participation in voting activities. The IRB Coordinator will assist as necessary and will issue an IRB Handbook to the new member.
- (4) The IRB Coordinator shall notify the Institutional Official of all changes in membership.
- (5) When required, the IRB Chair shall solicit recommendations from the membership for ad hoc and cultural consultants with competence in special areas to assist in the review of issues that require expertise beyond, or in addition to, that available on the IRB. Ad hoc and cultural consultants will not vote or count toward a quorum. They may attend a convened meeting or provide their comments in writing to the Office of the IRB prior to the meeting.
- (6) A curriculum vitae should be on file in the Office of the IRB for each member while serving in that capacity.

IRB Chair

- (1) Members under consideration for appointment as an IRB Chair must meet the following requirements:
 - (a) Completion of human research protections training;
 - (b) Recent experience as a voting IRB member for at least one year prior to nomination as an IRB Chair;
 - (c) Display adequate knowledge of ethical principles, professional standards, federal regulations and other applicable law through IRB meeting attendance and participation;
 - (d) Demonstrate professional competence necessary to review specific research activities.
- (2) The IRB Chair serves a term of three years with the possibility of appointment renewal at the end of the three year term.

OHRP IRB Registration / IRB Membership Roster

- (1) The IRB Coordinator completes the Office for Human Research Protections (OHRP) IRB registration forms and updates the registration whenever IRB membership changes. The OHRP registration form serves as the official IRB roster. Additionally, the IRB Coordinator shall:
 - (a) Provide a copy of the OHRP registration report to the Institutional Official as soon as it is submitted to OHRP;
 - (b) Maintain membership records. The OHRP membership list denotes the scientific / non-scientific status of each member, identifies the non-affiliated member, and is used to determine the quorum.
 - (1) **Nonscientific** - members who have had little or no scientific or medical training or who do not currently hold positions which involve scientific research or clinical practice.
 - (2) **Scientific** – members who are physicians or who hold Ph.D., Pharm. D., or other advanced degrees and who are actively engaged in research in the physical, educational, social, behavioral or biological sciences and disciplines and/or hold regular faculty appointments.

- (3) **Non-** affiliated – An IRB membership status designating the member’s association with the institution. The IRB must include at least one person who is not affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

References:

45 CFR 46

21 CFR 56

Federal-Wide Assurance

Institutional Review Board Management and Function, 2nd ed. (Bankert & Amdur, 2006).

IRB Guidebook

Northshore IRB

OHRP Guidelines

SUNY Binghamton IRB

SUNY Upstate IRB

University of Kentucky IRB