

Southeastern University Institutional Review Board Standard Operating Procedures		
Composition of the IRB	SOP #	OR 101
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1. POLICY

The Institutional Review Board (IRB) at Southeastern University (SEU) will consist of a minimum of five primary voting members sufficiently qualified through experience to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. The University will make every effort to have a diverse IRB through consideration of profession/discipline, race, ethnicity, cultural background, and gender.

Specific Procedures

1.1 Membership Selection Criteria

1.1.1 The members of the IRB will be sufficiently qualified through experience and expertise to review research proposals in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. Therefore, the IRB will include individuals who are knowledgeable in these areas.

1.1.2 IRB membership will be diverse. Thus, membership recruitment will consider race, ethnicity, gender, cultural background, research experience, and academic discipline/profession, as well as sensitivity to community attitudes and issues. IRB membership will not consist entirely of men or entirely of women, so long as no selection is made to the IRB on the basis of gender. No IRB may consist entirely of members of one profession. Every attempt will be made to recruit non-affiliated members, such as clergy, attorneys, and licensed physicians from the local community.

1.1.3 There will be at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.

1.1.4 There will be at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with SEU.

1.2 Composition of the Board

1.2.1 Primary Members

The backgrounds of the primary members of the IRB will be varied in order to promote complete and adequate review of the types of research activities commonly conducted by agents of the University. Primary members must include:

- A. Scientific Members: The IRB will include at least one member whose primary concerns are in scientific areas. A physical or biological scientist or physician who is, or has been, actively engaged in research or practice in the physical, educational, social, behavioral, or biological sciences and disciplines satisfies this membership requirement.
- B. Nonscientific Member(s): The IRB will include at least one member whose primary concerns are in nonscientific areas. Nonscientific members are individuals whose background, training, and occupation predisposes them to view research from a vantage point that is external to any biomedical or behavioral scientific discipline. These members have little or no scientific or medical training and do not currently hold positions that involve scientific research or clinical practice (e.g., administrative positions).
- C. Nonaffiliated Member(s): The IRB will include at least one member who is not otherwise affiliated with SEU and who is not part of the immediate family of a person affiliated with SEU. As a result, an individual could not be considered for IRB membership as a nonaffiliated member if he/she is a retiree of the university or has a spouse, parent, child, or sibling currently affiliated with SEU. However, a graduate of SEU from at least one year prior or someone whose family member attended SEU in the past could be considered. The nonaffiliated member(s), who can also serve as either a scientific or nonscientific member, must be knowledgeable about the local community and be willing to discuss issues and research from that perspective. Consideration will be given to recruiting individuals who speak for the communities from which SEU Investigators draw research subjects. The nonaffiliated member(s) will not be vulnerable to intimidation by other IRB members, and their services will be fully utilized by the IRB.
- D. Vulnerable Populations: When the IRB reviews research involving a vulnerable population, including categories of subjects vulnerable to coercion or undue influence, the review process will include one or more individuals who are knowledgeable about and experienced in working with these subjects. If the IRB regularly reviews such research (e.g., research involving prisoners), consideration will be given to including one or more individuals knowledgeable about and experienced in working with these subjects on the IRB.
- E. Special Consultants: The IRB chair, or designee, may invite individuals 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. These individuals will not vote with the primary and alternate members of the IRB and their presence or absence will not be used in establishing a quorum for a convened IRB meeting. Consultants will be used at the chair's or designee's discretion, or when requested by a board member.
- F. Chair/Co-Chair: The individuals appointed as the IRB Chair and Co-Chair will be highly respected individuals, who are members of the SEU faculty and have previously served on the IRB. These individuals will be capable of chairing convened meetings of the IRB and facilitating matters brought before it with fairness and impartiality.
- G. Program Representatives: Each research-based program should have representation on the IRB.

1.2.2 Alternate Members

1.2.2.1 Alternate members are non-voting members of the IRB who attend an IRB meeting in order to draw on their expertise in an area that may be relevant to that meeting's deliberations, but may not be used to establish a quorum. Alternate members are encouraged to attend meetings and to participate in discussion as long as they reviewed all applicable meeting materials in advance. Alternate members may be asked to review applications qualifying for expedited review.

1.2.2.2 Alternate members will be generally selected from among undergraduate and graduate students at SEU.

1.3 Appointments

1.3.1 The Provost has the authority to appoint Primary IRB members. Primary members will be recruited from SEU and the local community. The Provost may seek input on IRB appointments from College deans, the IRB Chair, or Co-Chair. Furthermore, the Provost or her or his designee, will seek the concurrence of the prospective member and the prospective member's department head. Each appointment may be re-evaluated after one year by the IRB Chair, IRB Manager and the member to determine if the level of commitment remains a good match for both the member and the IRB.

1.3.2 Newly appointed members will receive an official appointment letter stating the term of their appointment and outlining the basic duties of a primary or alternate IRB member, as appropriate. An IRB Non-Disclosure Agreement form will be included for signature by the newly appointed member.

1.4 Terms of Office

1.4.1 Members, including the Chair, will serve on the IRB for a term of three (3) years. Reappointment for additional terms may occur by mutual agreement of the IRB member, her or his department head when appropriate, and the Provost.

1.4.2 Three members may be appointed as Permanent Members (PMs) based upon their research expertise and availability in order to provide continuity to the Board. However, PMs may resign or be removed with the approval of the Provost.

1.4.3 One primary IRB member who is a member of the SEU faculty will be designated as the IRB Chair by the Provost. Another primary IRB member who is a member of the SEU faculty will be designated as the IRB Co-Chair by the Provost. The Chair and Co-Chair will have served as primary members of an IRB and must understand all functions, policies, and procedures of the SEU IRB. The Chair will serve as the official representative of the IRB, and will chair IRB meetings. The Co-Chair will assist the Chair as needed and in the absence of the Chair, the Co-Chair will perform the duties of the Chair, including chairing IRB meetings.

1.5 Resignation and Removal

Members may resign before the conclusion of their terms. Vacancies will be filled according to the needs of the IRB (e.g., area of expertise). A member, including the Chair or Co-Chair, who is not fulfilling her or his IRB responsibilities will be dismissed from the IRB by the Provost.

2. SCOPE

This policy and procedures apply to members of the IRB.

3. RESPONSIBILITY

The Provost is responsible for ensuring that the IRB has adequate resources to identify and recruit qualified prospective members. The IRB Chair and Co-Chair are responsible for managing the day-to-day activities of the human research protection program, which includes ensuring that the IRB is duly constituted in accordance with federal regulations and SEU policy.

4. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.107

5. REFERENCES TO OTHER APPLICABLE SOPS

This SOP affects all other SOPs

6. ATTACHMENTS

None