UNIVERSITY OF SOUTH ALABAMA

IRB SOP 201
Institutional Review Board: Membership and Duties

Purpose

The primary purpose of the Institutional Review Board (IRB) is to protect the rights of human participants in research and to facilitate ethical research. In order to accomplish this goal, IRB members must familiarize themselves with all IRB policies and procedures, as well as understand the federal regulations pertinent to the research under review.

Scope

These policies and procedures address the responsibilities of IRB members relating to duties, attendance at scheduled IRB meetings review of research proposals, and confidentiality requirements of IRB processes and procedures at monthly IRB meetings. Additionally, federal requirements for IRB membership are addressed.

Definitions

Alternate member: Alternate members may substitute for another member on a different IRB committee if his/her role (non-scientist or scientist) are comparable as determined by the IRB Office.

Nonscientific member: Nonscientific member(s) may include individuals whose main concerns are unambiguously in nonscientific areas. Nonscientific members are individuals whose education, training, work, experience or other interests are not solely in medical, biological, or other scientific areas.

Scientific member: Scientific member(s) may include physicians and Ph.D. level physical, biological or behavioral scientists, nurses, pharmacists, and other biomedical health professionals. Such members satisfy the requirement for at least one scientist.

Unaffiliated member: An unaffiliated member has no affiliation with the University or its Human Research Protection Program, either self or immediate family member. Unaffiliated member(s), who can be either scientific or nonscientific reviewers, should be knowledgeable about the local community and be willing to discuss issues and research from that perspective.

Policy

Each IRB (Biomedical Research IRB and Educational and Behavioral Research IRB) shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. Each IRB should also be able to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects research participants.

Each IRB member's primary duty is the protection of the rights and welfare of the individual human beings who are serving as participants in research. The IRB member must understand that they are not serving on the IRB to expedite the approval of research, but to be a gatekeeper between the Investigator and research participants. In order to fulfill their duties, IRB members are expected to be versed in regulations governing human subject protection, biomedical and behavioral research ethics, and the policies of University of South Alabama germane to human subject protection.

1.0 IRB Membership

The standards described below represent minimum membership requirements for each IRB committee:

- At least five members of sufficiently diverse backgrounds, including consideration of racial and cultural backgrounds of members and sensitivity to issues such as community attitudes;
- Persons who are able to ascertain the acceptability of research applications in terms of institutional commitments, applicable law, and professional standards;
- Members of both sexes;
- At least one member whose primary area of expertise is with children;
- At least one member whose primary concerns are in non-scientific areas;
- Members representing more than one profession;
- A member who is not affiliated/unaffiliated or related to a person who is affiliated with the institution;
- Persons who are primarily concerned with the welfare of vulnerable subjects (minors, prisoners, terminally ill, etc.);
- When needed, individuals with competence in special areas to assist in the review of complex issues;
- Participants in the initial or continuing review of projects who do not have a conflicting interest;

1.1 Community Members

The regulations at 45 CFR 46.107 require that the IRB have at least one (1) member not otherwise affiliated with the Institution and who is not part of the immediate family of a person who is affiliated with the institution. This role is designated as the Community Member. This individual should be sensitive to issues such as community feelings and thoughts. The Community Member serves as a public representative and as the ethical conscience of the IRB. The Community Member provides insight in evaluating the Informed Consent Document for clarity and understanding. The Community Member functions as an effective link to the IRB, Investigator and the community. The Community Member provides the perspective of the research participant.

1.2 Non-Voting Ex-Officio Members

Members designated as non-voting ex-officio members are selected and pointed because of their position or area of expertise. Their terms shall be indefinite unless otherwise decided.

1.3 Alternate Members

The appointment and function of alternate members is the same as that for primary IRB members, and the alternate's expertise and perspective are comparable to those of the primary member. The area of expertise of the alternates should match that of the regular member such that the federal policy requirements as described in 45 CFR 46.107 are met if a regular member cannot attend an IRB meeting. The role of the alternate member is to serve as a voting member of the IRB when the regular member is unavailable to attend a convened meeting. When an alternate member substitutes for a primary member, the alternate member will receive and review the same materials prior to the IRB meeting that the primary member received or would have received. The IRB roster identifies the primary member(s) for whom each alternate member may substitute. The alternate member will not be counted as a voting member unless the primary member is absent. The IRB minutes will document when an alternate member replaces a primary member. The length of term of the alternate will be the same as the term of the voting member.

Procedures

1. Duty to the University of South Alabama

The IRB(s) is/are appointed as Institutional Committees. As such, the IRB members serve the University of South Alabama as a whole, rather than a particular department. Therefore, IRB members and ad hoc consultants must not allow their own interest or that of their department

to supersede their duty to protect the rights and welfare of research participants. These members and ad hoc consultants will understand and comply with current University of South Alabama Conflict of Interest policies.

2. Specific Duties

2.1 Duties of the IRB

- Protecting rights and welfare of participants in human subjects research
- Unaffiliated members are expected to provide input regarding their knowledge about the local community and be willing to discuss issues and research from that perspective
- Nonscientific members are expected to provide input on areas germane to their knowledge, expertise and experience, professional, and otherwise
- Scientific members are expected to contribute to the evaluation of a study on its scientific merits and standards of practice. These members should also be able to advise the IRB if additional expertise in a nonscientific area is required to assess the research proposal

2.2 Criteria for IRB Approval

Duties of IRB members include reviewing human subjects research application materials in advance of meetings and being prepared to discuss issues related to human subjects protections, serving as primary or secondary reviewer, and having an understanding of the specific requirements of human subjects regulations.

Members vote for approval, disapproval, or suggest modifications to research based on institutional and regulatory requirements. Specific criteria required for IRB approval of research can be found in *SOP 506: Criteria for IRB Approval of Research*.

2.3 Chairperson Responsibilities

In addition to the above duties, IRB Chairs:

- Convene meetings
- Call special meetings when necessary
- Make decisions in emergency situations to protect participants and remain in compliance with regulations
- Confirm primary/secondary reviewer assignments made by IRB staff, as requested
- Conduct review of all protocols discussed at convened meetings
- Conduct expedited review of protocols, as needed
- Review policies and procedures, as needed
- Serve as an advisor/educator in the institution's research community

2.4 Vice-Chair(s) Responsibilities

- Performs duties of the chair in their absence
- Assists chairperson and IRB staff, as needed

3. Committee Member Appointment

Committee members are identified by the Office of Research Compliance and Integrity and recommendations made by the College of Medicine Dean's Office. Committee members are appointed by the Vice President for Research and Economic Development. Prospective members may also be identified by the IRB chair and staff who review the nature and demands of the IRB. IRB members are appointed for three year terms which are renewable. If a member resigns prior to the end of their term, a person may be appointed to complete the original term. Members have liability insurance coverage as part of their IRB membership in their capacity as agents of the University of South Alabama.

3.1 Attendance Requirements & Meeting Schedule

The Biomedical Research IRB meeting dates are scheduled a year in advance and provided to members during IRB orientation, as well as posted on the IRB's website. The Educational and Behavioral IRB meeting dates are scheduled each academic semester. Additional meetings may be scheduled on an ad hoc basis.

Members are expected to regularly attend meetings. Members are expected to inform the IRB Office of anticipated absences from meetings so the office can ensure quorum is maintained and assignments will not be designated for review.

3.2 Non-voting Members

Non-voting members from among the academic or administrative staff of the University are appointed to aid the IRB in conducting its duties. These members may take part in all meetings of the IRB, participate in discussions and make recommendations, but they may not vote on the decisions. Non-voting members are not included in determining or establishing a quorum at the meetings. IRB meeting minutes reflect the presence of non-voting members.

3.3 Termination of Appointment

Appointment to the IRB may be terminated before the expiration of the three-year term. The Institutional Official may remove an IRB member if they, in consultation with the IRB chair or other parties, determine that the member fails to perform his or her duties as a member.

The Institutional Official or designee may remove IRB members, IRB chairs, and if used, other officers (i.e., vice-chairs) with consultations from the Assistant Vice President, Research Compliance and Integrity and IRB chair(s).

3.4 Confidentiality Agreement

Upon appointment to the IRB or attendance at an IRB meeting, members (voting or otherwise), consultants, guests, etc., will sign a confidentiality agreement.

University Related Documents

IRB SOP 506: Criteria for IRB Approval of Research

History:

Revisions: November 2018, March 2026

Responsible Office:

Office of Research Compliance and Integrity