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

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1.1 Community Members

45 CFR 46.107 requires representation on the IRB that is sensitive to issues such as community feelings and thoughts. The Community Member serves as a consumer 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 subject. The regulations at 38 CFR 16.107 require that the IRB have at least one (1) member not otherwise affiliated with the Institution.

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

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department to supersede their duty to protect the rights and welfare of research subjects. 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 human subjects
- 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 members include reviewing human subject application materials in advance of meetings and being prepared to discuss issues related to human subject's protections, serving as primary reviewer when requested by the chair, and having an understanding of the specific requirements of human subject's regulations. See SOP 506: Criteria for IRB Approval of Research for additional details. Duties include:

- Determining risks are minimized
- Determining that risks to subjects are reasonable in relation to anticipated benefits to subjects
- Ensuring that investigators:
    - use of procedures are consistent with sound research design and that do not expose subjects to risks
    - when appropriate, use procedures already being performed on the subjects for diagnostic or treatment purposes, and
    - ensuring that the investigator follows a procedure for properly documenting

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