



SOP 202: DUTIES OF IRB MEMBERS

PURPOSE

It is anticipated that each member of the University of Utah Institutional Review Board (IRB) will contribute meaningfully to the deliberations of the convened board meetings and be prepared to provide thoughtful reviews of human subject research. This SOP outlines the duties of IRB members.

SCOPE

This SOP applies to University of Utah IRB members.

DEFINITIONS

- A. **Ad hoc consultants** are individuals with competence in special areas who are invited to assist in the review of issues which require expertise beyond or in addition to that of available IRB panel members. Ad hoc consultants not voting members of the Institutional Review Board.
- B. **Nonscientific members** 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.
- C. **Scientific members** 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.
- D. **Unaffiliated members** have no affiliation with the University of Utah or its Human Research Protection Program, either self or immediate family member. Unaffiliated members, 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. Consideration should be given to recruiting individuals who speak for the communities from which the University of Utah will draw its research subjects. The unaffiliated members should not be vulnerable to intimidation by the professionals on the IRB, and their services should be fully utilized by the IRB.

POLICY

Each IRB member's primary duty is the protection of the rights and welfare of the individual human beings who are serving as the subjects of that research. The IRB member must understand that he or she is not serving on the IRB to expedite the approval of research, but to be a gatekeeper between the Investigator and the research subjects. 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 Utah germane to human subject protection.

Please contact the IRB Office at (801) 581-3655 or irb@hsc.utah.edu for additional guidance.



The IRB(s) is/are appointed as Institutional Committees. As such, the IRB members serve the University of Utah as a whole, rather than a particular department. Therefore, regular IRB members and ad hoc consultants (see SOP 306: Ad Hoc Consultant Reviewers for policy regarding 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 subjects. These members and ad hoc consultants must understand and comply with current University of Utah Conflict of Interest policies.

The task of making the IRB a respected part of the institutional community will fall primarily on the IRB members. IRB members must maintain the IRB's reputation for being fair and impartial, as well as invulnerable to pressure from the institution's administration, research faculty, study investigators, or any other professional and nonprofessional sources.

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. Nonscientific members should advise the IRB if additional expertise in a nonscientific area is required to assess if the research proposal adequately protects the rights and welfare of subjects.

Scientific members are expected to contribute to the evaluation of a study on its scientific and statistical merits and standards of practice. Additionally, these members may also advise the IRB in a nonscientific area to assess if the research proposal adequately protects the rights and welfare of subjects.

PROCEDURES

1. Duties of IRB Members

- 1.1. IRB members must complete currently required training on ethics and regulations as outlined in SOP 102: Training and Education.
- 1.2. IRB members should regularly attend convened meetings and complete reviews using board member checklists, as assigned. IRB members are invited to share input and participate in discussion at convened meetings.
- 1.3. IRB members who are designated expedited reviewers should complete assigned reviews using board member checklists, as assigned.
- 1.4. Board members should communicate with IRB staff if they are unable to complete reviews, have conflicts of interest, or cannot attend a meeting. Board members should communicate with IRB staff if they require additional information or guidance.

2. Duties of IRB Chair

- 2.1. In addition to the above responsibilities, the IRB Chair conducts meetings of the IRB. The IRB Chair performs expedited review, as assigned.

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- 2.2. IRB Co-Chair(s) or IRB Vice-Chair(s) may assist or act on behalf of the IRB Chair in particular IRB matters and at IRB meetings, either as a general procedure, or on a case-by-case basis.
- 2.3. The IRB Chair also may delegate any of his/her responsibilities as appropriate to other qualified individual(s). Any such delegation of responsibility is documented in writing and maintained by the IRB staff.
- 2.4. The IRB Chair designates the board members qualified to conduct expedited reviews. Qualified members will be selected based on 1) at least six months of IRB experience, research experience, any life experiences or background applicable to human subject research, and 2) any other qualification the IRB Chair deems appropriate. The designation of expedited reviewers is documented in writing and is maintained by the IRB staff.

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