

Approved by IRB executive committee: January 9, 2008
Supersedes Document Dated: November 9, 2005; May 1, 2004
AAHRPP Elements II.1.D and II.2.B.

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 subjects protection, biomedical and behavioral research ethics, and the policies of University of Utah germane to human subjects protection.

PROCEDURES

1. Duty to the University of Utah

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 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 will understand and comply with current University of Utah Conflict of Interest policies.

2. Specific Duties

2.1. Duties of IRB Members

- 2.1.1. The task of making the IRB a respected part of the institutional community will fall primarily on the shoulders of the IRB members. The IRB must be perceived to be fair and impartial, immune from pressure either by the institution's administration, the Investigators whose protocols are brought before it, or other professional and nonprofessional sources.
- 2.1.2. 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.
- 2.1.3. Nonscientific members are expected to provide input on areas germane to their knowledge, expertise and experience, professional and otherwise. For example, members who are lawyers should present the legal views of specific areas that may be discussed, such as exculpatory language or state requirements regarding consent. 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.
- 2.1.4. Scientific members are expected to contribute to the evaluation of a study on its scientific and statistical 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 if the research proposal adequately protects the rights and welfare of subjects.

2.2. Duties of IRB Chair

- 2.2.1. In addition to the above responsibilities (germane to the member's capacity), the IRB Chair conducts meetings of the IRB. The IRB Chair performs expedited review when appropriate.
- 2.2.2. IRB Co-Chair or IRB Vice-Chair 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.
- 2.2.3. 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 Administrative Staff or IRB Staff.
- 2.2.4. 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. A list of the designated board members is kept by the IRB staff. The designation of expedited reviewers is updated on IRB Internal Rosters by the IRB Coordinator or designee.

3. Training Requirements

Regular IRB members and IRB Chairs are expected to complete currently required training on ethics and regulations as outlined in SOP 102.