



SOP 201: MANAGEMENT AND COMPOSITION OF THE IRB

DEFINITIONS

- a) **Alternate Member** Alternates are members appointed on any of the other University of Utah IRB panels. These members may substitute for another member on a different panel if his/her role (non-scientist or scientist) are comparable as determined by the IRB Coordinator or Administrator.
- b) **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.
- c) **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.
- d) **Unaffiliated Member** An unaffiliated member has no affiliation with the University of Utah 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. 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 member(s) 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 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.

Therefore, each IRB must consist of at least five regular, voting members. Qualified persons from multiple professions and of both sexes are considered for membership. The institution will make every effort to have a diverse membership appointed to the IRB, within the scope of available expertise

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needed to conduct its functions. Composition of the membership of the IRB is to be adequate in light of the anticipated scope and complexity of Utah's research activities, the types of subject populations likely to be involved, and the size and available resources of the Institution.

Each IRB panel includes at least one scientific member and at least one nonscientific member whose primary concerns are in nonscientific areas. Each IRB panel must include at least one unaffiliated member. One member can be unaffiliated with the institution and have a primary concern in a non-scientific area. This individual would satisfy two of the membership requirements of the regulations.

Each IRB will have two or more compensated VA employees, as voting members. Officials in Research and Development administration including, but not limited to the Associated Chief of Staff for Research and Development and the Administrative Officer for Research and Development, do not serve as voting members of the IRB.

The IRB includes members who are knowledgeable about the concerns of participants who may be vulnerable (e.g. children, prisoners, pregnant women, and handicapped or mentally disabled persons, etc.). Examples of such members might be nurses, social workers, chaplains, teachers or previous prisoners. In general, a member representing a vulnerable group of participants should provide at least one of the following:

- A direct affiliation to the special group(s)
- Work or life experience with the special group(s)
- Research experience with special group(s)
- Hold certification or licensures that permits the treatment, counseling, or other direct relationship of the special group(s)

Individuals responsible for business development the University of Utah or affiliated institutions will not serve as voting members of the IRB. This may include, but is not limited to, the following individuals:

- Employees of the institutions' granting or research contracting offices
- Employees of the institutions' Vice President for Research offices

The management of the membership of the IRBs and oversight of member appointments, IRB related activities, communications, and other administrative details are the responsibility of the IRB Director or designee.

The Vice President for Research along with the Associate Vice President for Research Integrity and IRB Director will review the resources allocated to the human research protection program to the IRBs and other components within the human research protection program.

PROCEDURES

1. Procedures for Appointing IRB Members

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The Academic Senate, Vice President for Research and/or the Associate Vice President for Research Integrity and the VA Medical Center Director (for VA representation) in consultation with the IRB Chair and IRB Director have the authority to appoint members to the IRB. Members will be solicited from the University of Utah and greater Salt Lake communities.

Participation by University of Utah faculty, staff, or students is considered a component of their job responsibilities as established by their supervisors. Regular members who are not affiliated with the University of Utah shall receive reimbursement for parking and other miscellaneous expenses upon request.

Members have liability insurance coverage as part of their IRB membership in their capacity as agents of the University of Utah.

- 1.1. The IRB Director and IRB administrators conduct an annual review of IRB membership to ensure the composition of the IRB meets regulatory and organizational requirements.
- 1.2. Based upon the annual evaluation or any interim need to adjust the composition of the IRB, the IRB Director requests appointment of new IRB members. The Academic Senate, Vice President for Research and/or the Associate Vice President for Research Integrity and the VA Medical Center Director (for VA representation) in consultation with the IRB Chair and IRB Director will appoint members to the IRB.
- 1.3. The VA Medical Center Director officially appoints VA IRB members and alternates in writing. The VA IRB member must be appointed for 3 years and may be re-appointed indefinitely.
- 1.4. Appointed members, including the IRB Chair and alternates, will serve on the IRB for a term of three years. Reappointment for additional terms may occur, by mutual agreement of the IRB Chair, Vice President for Research, and Associate Vice President for Research Integrity, and the VA Medical Center Director (for VA representation).

2. Procedures for Appointment of the IRB Chair(s)

The IRB Chair will be a highly respected individual, from the University of Utah or its affiliated institutions, fully capable of managing the IRB and the matters brought before it with fairness and impartiality.

- 2.1. The IRB Director sends written notification to Department heads and current IRB members regarding a vacancy for the appointment of IRB Chair(s). The written notification requests any nominations or persons who wish to volunteer be submitted to the IRB Director. The IRB Director will review the nominations and volunteers with the Associate Vice President for Research Integrity and the current IRB Chair(s) for qualified candidates. Qualified candidates will be selected based on (but not limited to) their current standing with the University and community, IRB experience (if any), research experience with human subjects (if any), education and professional background, professional and personal interests.
- 2.2. Once qualified candidates have been determined, the Associate Vice President for Research Integrity, the IRB Director and current IRB Chair(s) will conduct interviews with each individual.

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In a collaborative effort, the three most qualified candidates will be selected from the interview process and will be re-interviewed with the Vice President of Research, the Associate Vice President for Research Integrity, the IRB Director and current IRB Chair. The Vice President for Research will make the final appointment of the qualified candidate for IRB Chair.

3. Procedures for Evaluation of IRB Members

- 3.1. Performance of the IRB members is evaluated no less than annually by the IRB Chair and/or IRB Director (and may include input from the IRB administrator and/or IRB coordinator). A member may be removed at the discretion of the IRB Chair and/or IRB Director before the conclusion of his/her term. A member may resign before the conclusion of his/her term. Vacancies are filled as quickly as possible.
- 3.2. The IRB Chair(s)' performance and role is evaluated no less than annually by the Vice President for Research (and may include the Associate Vice President for Research Integrity and IRB Director). Interim evaluations of the IRB Chair(s) may occur more frequently, as determined by the Vice President for Research, Associate Vice President for Research Integrity or the IRB Director.
- 3.3. Feedback from the evaluations will be provided by the IRB Director to the IRB Chairs and IRB members in writing.

4. Procedures for Maintaining Roster and Board Member Information

- 4.1. To ensure that board members meet the needs of the IRB in its review of research, board member information forms and current CV's/résumés are completed or updated at least annually by IRB members in the ERICA system. A Confidentiality Agreement and Recusal Agreement are electronically submitted in the ERICA system by each board member at the beginning of their term of service.
- 4.2. In order to maintain rosters of IRB membership, the following information is collected and maintained in ERICA: member names; earned degrees; scientific status; representative capacity; indications of experience sufficient to describe each member's chief anticipated contribution to the IRB's deliberations; employment or other relationship between each member and the IRB and/or the University of Utah (e.g., full-time employee, etc.); affiliation status; and office/membership status (e.g. vice-chair, etc.).

5. Procedures for Maintaining Sufficient Resources

- 5.1. The University of Utah will provide meeting space and sufficient staff to support the IRB's review and recordkeeping duties. The University of Utah will provide the IRB administrative staff with resources sufficient to conduct IRB duties.
- 5.2. The adequacy of the existing IRB(s) is evaluated at least annually by the Associate Vice President for Research Integrity and IRB Director to meet the anticipated scope of research activities and the types of participant populations likely to be involved and the appropriateness

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of the proposed and initial and continuing review procedures in light of probable risks, and the size and complexity of the University of Utah.

- 5.3. The IRB Director requests a report from the ERICA Systems Analyst consisting of but not limited to the following:
- Number of new studies submitted;
 - Number of studies according to risk assessment;
 - Review process (i.e. expedited, convened board) for initial studies, modifications, continuing review, and unanticipated problems, if applicable;
 - Time required for approval of each type of application;
 - Number of studies from Social/Behavioral Research versus Biomedical Research;
 - Number of studies involving vulnerable populations.
- 5.4. The Associate Vice President for Research Integrity and the IRB Director discuss the findings of the report to evaluate whether the number of IRBs is appropriate for the volume and types of human subject research being reviewed, and whether the review process is being accomplished in a thorough and timely manner.

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