

SOP 201: MANAGEMENT AND COMPOSITION OF THE IRB

PURPOSE

The University of Utah Institutional Review Board (IRB) is composed of members in accordance with federal regulations. This SOP outlines the composition of the IRB and the procedure to appoint members. Additionally, this SOP outlines the evaluation of IRB members and IRB resources.

SCOPE

This SOP applies to the University of Utah IRB.

DEFINITIONS

- A. **Alternates** are board 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 Administrator.
- 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. Immediate family members are a person's spouse, domestic partner, and dependent children. 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

The University of Utah IRB evaluates the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The

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

University of Utah IRB strives to foster respect for its advice and counsel in safeguarding the rights and welfare of human subjects.

Each University of Utah IRB panel must consist of at least five regular, voting members. The institution will make every effort to have a diverse membership appointed to the University of Utah IRB, within the scope of available expertise needed to conduct its functions. Composition of the University of Utah IRB is to be adequate in light of the anticipated scope and complexity of the University of Utah's research activities, the types of subject populations likely to be involved, and the size and available resources of the institution.

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

Because the University of Utah IRB regularly reviews VA Salt Lake City Healthcare System (VASLCHCS) research, compensated VA employees serve 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 University of Utah IRB includes members who are knowledgeable about the concerns of participants who may be vulnerable (e.g., children, prisoners, and individuals with impaired decision-making capacity, 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 at 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 IRB panels and oversight of member appointments, IRB related activities, communications, and other administrative details are the responsibility of the IRB Director or designee.

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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.

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.

The University of Utah Vice President for Research along with the University of Utah Associate Vice President for Research Integrity & Compliance and IRB Director review the resources allocated to the IRB and other components of the University of Utah Human Research Protection Program (HRPP).

PROCEDURES

1. Appointing IRB Members

- 1.1. The IRB Director and assigned IRB staff member(s) 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 & Compliance and the VA Medical Center Director (for VA representation) in consultation with the IRB Chair and IRB Director appoint members to the IRB.
- 1.3. The VASLCHCS 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 & Compliance, and the VASLCHCS Medical Center Director (for VA representation).

2. Appointment of the IRB Chair(s)

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- 2.1. The IRB Director publishes notice of IRB Chair and Vice Chair vacancies on the IRB website and disseminates this notice to research leaders at the University of Utah and its affiliates, including current IRB members. . 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 & Compliance and the current IRB Chair(s) for qualified candidates.
- 2.2. 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.
- 2.3. 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. 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 & Compliance, 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. Evaluation of IRB Members

- 3.1. IRB members are evaluated at the conclusion of the first year of service and at the end of each term by the IRB Director or assigned IRB staff member using an evaluation tool. Interim evaluations of the IRB members may occur more frequently, as determined by the IRB Director or assigned IRB staff member.
- 3.2. A member may be removed at the discretion of the IRB Director before the conclusion of the term. A member may resign before the conclusion of the term. Vacancies are filled as quickly as possible.
- 3.3. The IRB Chair(s) is evaluated by the Vice President for Research (and may include the Associate Vice President for Research Integrity & Compliance and IRB Director) at the conclusion of the first year of service and at the end of each term as chair. 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 & Compliance, or the IRB Director.
- 3.4. A summary of the evaluation will be provided by the IRB Director to the IRB Chairs and IRB members via email or in-person. The evaluation tool may be retained as part of the member's profile in University of Utah Electronic Research Integrity and Compliance Administration system (ERICA).

4. Maintaining Roster and Board Member Information

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- 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 the beginning of each three-year term of service by IRB members in ERICA. A Confidentiality Agreement and Recusal Agreement are electronically submitted in ERICA by each board member at the beginning of their term(s) 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. Maintaining Sufficient IRB Resources

- 5.1. The University of Utah provides meeting space and sufficient staff to support the IRB's review and recordkeeping duties. The University of Utah will provide the IRB 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 & Compliance and IRB Director to meet the anticipated scope of research activities and the types of participant populations likely to be involved and the appropriateness 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, amendments, 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 & Compliance and the IRB Director discuss the findings of the report to evaluate whether the number of IRB panels 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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