

Series 401 Institutional Review Board

The Institutional Review Board from Series 401 of Standard Operating Procedures

I. The Institutional Review Board

The Institutional Review Board (IRB) at Utah State is a body established under the requirements of 45 C.F.R. 46 to, first and foremost, protect the rights and welfare of human participants in research. The IRB operates under Utah State University's Federalwide Assurance #00003308, on file with the U.S. Department of Health and Human Services. It ensures the protection of the rights and welfare of human participants in research by reviewing or appropriately delegating the review of each research protocol to ensure the protection of the participants involved. The IRB is an independent entity that must operate without influence from other units within Utah State University, especially those with business interests. The IRB has the sole authority to approve human subjects research conducted by Utah State University affiliates. IRBs are required to have (as a part of its regular membership) or gain (by the addition of members or use of consultants) scientific expertise in the areas of research it is responsible for reviewing.

The IRB reviews research involving human participants by utilizing exemption determinations, limited IRB approval, Expedited review procedures, review via the Convened IRB, review of proposed modifications, and local context reviews. The Institutional Review Board is also the sole entity with the ability to determine whether a project constitutes research with human participants, as defined in USU Policy 584.

II. Composition

The Institutional Review Board at Utah State University shall, at all times, meet the minimum membership requirements of 45 C.F.R. 46.107. IRB membership shall:

1. Have at least five members with varying backgrounds to promote the complete and adequate review of research activities commonly conducted by researchers at Utah State University;
2. Be sufficiently qualified through the experience, expertise, and professional competence of its members to review the types of research activities commonly conducted by researchers at Utah State University;
3. Have a diverse membership with regard to race, gender, cultural background, and educational attainment;
4. Include at least one member whose primary concerns are unrelated to scientific research, the research enterprise, or scientific concerns;
5. Include at least one member whose primary concerns are related to scientific research, the research enterprise, or scientific concerns;
6. Include at least one member who is not affiliated, other than their membership on the IRB, with Utah State University or have an immediate family member who is affiliated with USU;
7. Represent knowledge, expertise, experience, and characteristics which promote respect for its advice and counsel in safeguarding the rights and welfare of participants commonly involved in research conducted at Utah State University;
8. Have membership that permits the IRB to ascertain the acceptability of proposed research in the context of other institutional commitments, existing policies, institutional resources, applicable laws, applicable regulations, and relevant standards of professional conduct and practice;

9. Include members with either experience with or expertise in working with vulnerable populations commonly involved in research conducted by researchers at Utah State University, including as much as possible:
 - a. Children
 - b. Incarcerated individuals (commonly referred to in regulatory structures as “prisoners”)
 - c. Individuals with impaired or fluctuating decision making capacity;
 - d. Economically disadvantaged persons;
 - e. Educationally disadvantaged persons;
 - f. Undocumented populations;
 - g. LGBTQIA+ populations; and
 - h. Other populations that have been historically harmed or disregarded by the research enterprise.

The IRB is permitted to bring in, as needed, consultants whose expertise, experience, knowledge, or characteristics would be important to the review of any protocols or issues under consideration. Those individuals may not vote on the IRB.

No member of the IRB, or person involved in the day-to-day operations of the IRB, is permitted to have a role that involves them in the business interests of the university. This typically prohibits membership on the IRB from any of the following areas of the University: Department Heads (or higher administrative appointment), development officers or fundraisers, any person holding equity in corporate structures owned by the University, or any other individual participating in business development interests benefiting Utah State University. If any IRB member develops these interests or is appointed to positions that involve the business interests of the university during their term, these must be disclosed as soon as possible (but no later than 30 days following this new development) to the Institutional Official and IRB Chair.

III. Appointment & Termination

Members of the IRB are appointed by the Institutional Official. The Institutional Official shall consult with the IRB Chair and HRP Director prior to making such an appointment, in order to ensure that prospective members are able to contribute productively to the shared goals of protecting human research participants and the conduct of ethical research. In making such assessments with regard to scientific members, the Institutional Official shall consider the quality of previous submissions to the IRB, a history of meaningful engagement with human research protections, a role that permits them to provide meaningful feedback on colleagues' research, and career advancement that permits sufficient dedication of time to IRB matters (typically, this means that the member, if faculty, is beyond the third year review process). In making such assessments with regard to non-scientists and community members, the IO shall consider whether that person's perspective is representative of a population frequently targeted by research at USU, and whether their characteristics contribute to the diversity of the Institutional Review Board.

Professional staff in the Human Research Protections Office shall be appointed to the IRB after having successfully completed the required CITI Training and other required trainings at USU (such as sexual harassment prevention, FERPA, etc.) in order to facilitate the review of protocols, renewals, and amendments that are delegated by the IRB. At no time shall professional staff in the HRP Office outnumber members of the IRB who are not professional staff in the HRP Office, and their membership shall terminate along with their employment in the HRP Office.

Termination of membership shall occur at the end of the Term of Membership as outlined in Section IV of this SOP. Or, it may be terminated for cause for reasons which include, but are not limited to:

1. Review assignments which are consistently late or incomplete;
2. Repeated tardiness or absence from meetings of the Convened IRB;
3. Demonstrated unwillingness to prioritize the rights and welfare of research participants during the review process;
4. Unresponsiveness to training and feedback provided by HRPP leadership; or
5. A change in a member's role such that competing interests would jeopardize the independence or perceived independence of the IRB from institutional pressures or business interests.

IV. Term of Membership

Professional staff in the Human Research Protections Office shall have ongoing terms. New members of the IRB shall serve an initial term of one year, to ensure that membership is feasible for their workload and that their membership contributes productively to the IRB. At the end of that first year, mutual agreement between the member, the Institutional Official, and the IRB Chair shall extend the term to a full three year term (i.e. two years will be added to the one year already served). Following the first completed term, membership may be renewed for three year terms at the mutual agreement of the member, the IO, and the IRB Chair. In considering renewal decisions, the IO and IRB Chair shall consider whether composition of the IRB is appropriate for the volume and type of research the Board reviews. Non-renewal is not an indication that the individual's contributions to the Board are not valued; rather, the IO and IRB Chair must ensure that the membership of the IRB is representative of its workload and is not so unwieldy that obtaining a quorum becomes difficult.

V. Types of Membership

The IRB Chair

The IRB Chair is a scientific member of the IRB who oversees the review process and chairs board meetings. The IRB Chair should have experience as an IRB member prior to their appointment in this leadership role that demonstrates their qualifications and expertise to lead the IRB. The IRB Chair may delegate one or more experienced reviewers from among voting members of the IRB to have the authority to perform expedited review when appropriate. The Chair is empowered to suspend the conduct of a research project if participants are placed at an unacceptable level of risk, pending IRB review. The Chair is also empowered, pending IRB review, to suspend the conduct of a study if they determine that an investigator is not following regulations, policies, or IRB requirements. The IRB Chair makes initial determinations regarding the handling of unanticipated events, deviations, noncompliance, and adverse events, and works closely with the HRP Director to oversee the substance of reviews that are conducted outside of the Convened IRB review process. The IRB Chair may delegate any of their responsibilities, as appropriate, to other qualified individuals. For example, the IRB Chair may delegate to the IRB Vice Chair or to an experienced IRB Member actions on behalf of the IRB Chair on particular IRB matters. This may include the chairing of meetings, determinations regarding noncompliance inquiries, and other duties specifically assigned to the IRB Chair person.

The IRB Vice Chair

The IRB Vice Chair may step into any of the roles and perform any of the duties of the IRB Chair in their absence or inability to serve. The IRB Vice Chair is a scientific member of the IRB who oversees the review process and chairs board meetings. The IRB Vice Chair should have experience as an IRB member prior to their appointment in this leadership role that demonstrates their qualifications and expertise to lead the IRB.

Scientific Members

Scientific members are expected to contribute to the evaluation of a study on its scientific merits and relevant disciplinary standards of practice. These members should also be able to advise the IRB if additional expertise in a scientific area is required to assess whether a protocol adequately protects the rights and welfare of research participants. Scientific members understand that the scientific structure and integrity of the research design necessarily impacts the ethical review of the study, and work to integrate their scientific expertise and professional standards with the ethical review of the study. Scientific members often serve as the designated reviewer for protocols related to their designated areas of expertise or experience.

Nonscientific Members

Nonscientific members are expected to provide input on areas germane to their knowledge, expertise, and experience. 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 non-scientific area is required to assess whether a protocol adequately protects the rights and welfare of research participants.

Unaffiliated Members

Unaffiliated members are members who have no affiliation with Utah State University except for their membership on the IRB. They are expected to provide input regarding their knowledge about the local community or the community under study, and/or their perceptions of the research from the perspective of a person outside of the university. They must be willing to discuss issues and research from that perspective. The input from the IRB's unaffiliated member(s) is crucial, as it is necessarily a perspective that cannot be replaced from within the institution. Thus, full, active, and informed participation is necessary for these members.

Alternate Members

Alternate members are asked to serve with the same expectations for participation and expertise as regular members, and may be either scientists or nonscientists, affiliated with USU or nonaffiliated. The primary difference is that alternate members are called upon in the absence of regular members to attend meetings, participate in deliberations, and vote with the IRB. Alternate members are identified as being qualified to participate in IRB meetings in the absence of regular members with overlapping areas of expertise. An alternate may be qualified to represent multiple members of the IRB, but may only participate in place of one member during a meeting. If the alternate and the regular member are both in attendance, only one of them may vote, though the alternate should participate in the discussion at the same level of involvement.

VI. Training, Education, & Evaluation

Prior to joining the IRB, members must undergo a series of training requirements to ensure that they meet all of the membership requirements articulated in the Sections above. The HRP Director is responsible for ensuring that this training is available to all incoming and existing members of the IRB. The content of the training must be sufficient to ensure that IRB members are able to successfully complete protocol reviews in line with federal, state, local, institutional and professional standards that apply to the research.

Before beginning their terms, IRB members will sign an IRB Member Role Statement that contains the expectations for the position, and certifies that the training requirements articulated above have been provided to them.

After joining the IRB, IRB members must engage in continuing education efforts to ensure that the Human Research Protection Program is continuously improving. This might include attending IRB meetings where training topics of interest are to be discussed; engaging with training materials distributed by the HRP Director; attending conferences, sessions, or seminars dedicated to research ethics involving human participants; or seeking out additional information and research regarding human subjects research ethics. Any training needs that IRB members identify during their term should be communicated to the IRB Chair and/or the HRP Director for consideration in the development of future training materials.

IRB Members should be assessed annually by the Chair and Vice Chair. The IRB Chair and Vice Chair engage in a self-assessment at an annual meeting to review the IRB. The results of those self-assessments are delivered to the Institutional Official either verbally or in writing during the Annual Review of the HRPP. Training objectives, areas of improvement, and areas of strength are noted by the IRB Chair, Vice Chair, and IO during each of these reviews, and delivered to the HRP Director for implementation.