	UNIVERSITY RESEARCH POLICY: Composition and Membership of the Institutional Review Board Responsible Office: Research Integrity			
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I. Policy Statement

This policy describes the policy and procedures for appointing Institutional Review Board (IRB) members and maintaining the Office of Human Research Protections (OHRP) membership roster.

II. Reason for Policy

This policy addresses the university's commitment to maintaining an effective, well-functioning, and compliant human research protections program, including an IRB committee that meets all regulatory requirements.

III. Entities Affected By This Policy

This policy applies to all faculty, staff, and students of the university conducting human subjects research; the IRB committee members and chairs; the Institutional Official (IO); Research Integrity office staff.

IV. Who Should Read This Policy

- New and re-appointed IRB committee members
- New and re-appointed IRB committee co-chairs
- Research Integrity office staff

V. Web Address For This Policy

<https://research.cc.lehigh.edu/irb>

VI. Related Resources


University Policies and Documents <i>Lehigh University IRB website: https://research.cc.lehigh.edu/irb</i>

VII. Contacts

Subject Matter	Office Name	Telephone Number	E-mail/Web Address
Policy Clarification and Interpretation	Manager of Research Integrity	610-758-2985	https://research.cc.lehigh.edu/contact-us-0

VIII. Responsibilities

Responsible Party <i>(alphabetical order)</i>	List of Responsibilities
Institutional Official (IO) or designee	Collaborate with the IRB co-chairs and/or the Research Integrity office staff to appoint, evaluate, re-appoint, and remove IRB members.


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IRB committee alternate member	<p>Submit CVs/resumes and complete new member trainings at the direction of the Research Integrity office.</p> <p>Maintain knowledge to consistently apply the ethical principles of the Belmont Report and of the federal regulations and IRB policies governing human research protections.</p>
IRB committee co-chair	<p>Ensure the proper review, approval, and disapproval or determination of exemption from further review of research protocol submissions to the IRB committee.</p> <p>Maintain knowledge to enforce consistent application of the ethical principles of the Belmont Report and of the federal regulations and IRB policies governing human research protections.</p> <p>Respond to the concerns of IRB committee members, manage the efficient and effective conduct of IRB meetings, and demonstrate consistent attendance at meetings and participation in reviews.</p> <p>Regularly participate in continuing education and training efforts.</p>
IRB committee member	<p>Submit CVs/resumes and complete new member trainings at the direction of the Research Integrity office.</p> <p>Maintain knowledge to consistently apply the ethical principles of the Belmont Report and of the federal regulations and IRB policies governing human research protections.</p> <p>Regularly participate in continuing education and training efforts.</p> <p>Consistently attend meetings and participate in reviews.</p>
Non-voting consultant	<p>Provide assistance to the IRB committee in the review of issues that require expertise beyond or in addition to that available on the committee</p>
Research Integrity office staff	<p>Collaborate with the IO or designee and the IRB co-chairs to appoint, evaluate, re-appoint, and remove IRB members.</p> <p>Solicit new committee members and direct new member training.</p> <p>Establish and maintain records of IRB committee members' and co-chairs' qualifications, performance, contribution, and IRB meeting attendance. Share information with the IO/designee and/or IRB committee co-chair as needed.</p> <p>Maintain and update the OHRP IRB registration and roster.</p> <p>Serve as alternate IRB committee member.</p>

IX. Principles

The IRB committee at Lehigh University has a minimum of five voting members sufficiently qualified through experience and expertise to promote complete and adequate review of research activities commonly conducted by the institution. The membership includes two co-chairs, who are directly responsible for overseeing the protection of research participants by ensuring the proper review, approval, and disapproval or determination of exemption from further review of research protocol submissions to the IRB committee. The IRB committee includes regular members and alternate members. Alternate members are appointed to the committee in general and do not serve as alternates to specific individual committee members. Each member is appointed to a three-year renewable term. Student member terms are one year.

The IRB shall be sufficiently qualified through the experience, expertise, and diversity of its members, including race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its

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advice and counsel in safeguarding the rights and welfare of human subjects. The IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments (including policies and resources) and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas.

The IRB has at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas. The IRB has at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

The IRB may, at its discretion, invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the committee. Non-external consultants may not vote with the IRB.

Except when expedited review or exempt determination procedures are used, an IRB must review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting. No IRB member may participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested to the IRB. All IRB committee members and consultants are subject to the IRB Conflict of Interest Policy.

X. Procedures

- The IO or designee, in collaboration with the IRB co-chairs and/or the Research Integrity office staff appoints, evaluates, re-appoints, and removes IRB members to ensure that the IRB committee meets all applicable composition requirements.
- Solicitation of new committee members is based on need as well as expertise and knowledge required for conducting regulatory and ethical review of protocols.
- Individuals being considered as IRB members must submit a current CV or resume and complete new member training at the direction of the Research Integrity office.
- Appointment letters will be sent to the member (with a copy to their department chair or dean, as applicable), and will include the term of their appointment.
- The standard appointment term is three years. Student member terms are one year. Members may request to serve additional terms. Decisions regarding re-appointment of existing members will be based on the member's history of good performance, contribution, and attendance at IRB meeting.
- IRB committee co-chairs are appointed by the IO or designee in consultation with the Research Integrity office staff. IRB committee co-chairs are typically Lehigh University faculty with previous experience on the committee. The appointment term is three years with the option to serve additional terms.
- IRB committee co-chairs will have knowledge to enforce consistent application of the ethical principles of the Belmont Report and of the federal regulations and IRB policies governing human research protections. Responsiveness to the concerns of IRB committee members, ability to manage the efficient and effective conduct of IRB meetings, attendance and/or participation in Lehigh University's human research protections program are factors that may be used to make appointment, re-appointment, and removal decisions. The co-chairs will have standard voting privileges as members of the IRB.
- Appointment, re-appointment, and removal of IRB committee members and co-chairs is at the discretion of the IO or designee, as appropriate.