



Section: General Administration

Subsection: Rights, Freedoms and Responsibilities

Procedure II-460: Institutional Review Board

The Lorain County Community College Institutional Review Board (IRB) is designed to be sufficiently qualified through the expertise, experience and diversity of its members, including race, gender and cultural background; to be sensitive to community issues and attitudes, and to promote respect for its advice and counsel in safeguarding the rights and welfare of those participating in research.

(A) Objective:

- (1) To ensure that Lorain County Community College properly and adequately discharges its responsibilities for protecting the rights and welfare of any and all human subjects of research, as “research” is defined in federal regulations and campus policies, that is conducted at or sponsored by the institution, regardless of whether the research is subject to federal regulation or funded, in whole or in part, by federal funds.
- (2) To ascertain the acceptability of the proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice.
- (3) Within the context of assuring these protections, the IRB has authority to approve, require modifications, or disapprove all research activities that fall within its jurisdiction as specified by the federal regulations and institutional policy. Research that has been reviewed and approved by and IRB may be subject to review and disapproval by officials of the institution. However, institutional officials may not approve research if it has been disapproved by the IRB [45 CFR Part 690 Sec. 101.112].

(B) Composition:

- (1) The Institutional Review Board will be comprised of no fewer than five (5) members.
- (2) Standing members shall include:
 - a. Vice President for Administrative Services, Treasurer
 - b. Associate Provost, University Partnership

- c. Dean of Research, Institutional Effectiveness and Public Services or her/his designee.
- (3) Additional members assigned to the Institutional Review Board will be appointed by the Office of the President. These appointments will be made after consultation with the Vice President for Administrative Services/Treasurer, who will provide the requisite balance required by the IRB in scientific knowledge; gender; ethnic and cultural balance and ability to serve and provide responses/reviewed in a timely manner. Faculty representation will be suggested through a communication from the Faculty Senate President to the Vice President for Administrative Services/Treasurer in the month of May for appointment beginning in the Fall.

The members shall include the following constituencies:

- a. One individual representing scientific disciplines
- b. One individual representing non-specific disciplines
- c. One individual not otherwise affiliated with the institution, and who is not part of the immediate family of a person who is affiliated with the institution

Standing Members' expertise may qualify them to satisfy the requirements of (3) a. – c

- (4) Additional members may be appointed as needed to ensure that the following conditions are also met:
- a. gender, ethnic and cultural balance
 - b. balance among social and physical sciences, humanities and other non-scientific expertise
 - c. balance among faculty and professional/technical staff
 - d. individual(s) capable of discerning potential risk to the human subject(s), including those from vulnerable populations/protected classes of individuals (children, prisoners, persons with disabilities, and/or pregnant women, etc.).
- (5) No selection or appointment to the IRB shall be made based solely on the basis of gender or profession.
- (6) No IRB member shall 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 by the IRB.

- (7) The IRB may, at its discretion, invite individuals with competence in special areas to assist in the review of issues requiring expertise beyond or in addition to that available within the IRB members. Such individuals may not vote on any research review application.

(C) Appointments:

Members are appointed by the Office of the President. Appointments will be made for three-year staggered terms and service will commence at the beginning of the Fall semester. The term will end at the conclusion of the Summer semester of the third year. The IRB secretary will be appointed by the Office of the President.

- (D) Meetings as scheduled by the Chairperson. The first meeting will be in September to communicate requisite certificates and training required of the membership. Monthly meetings will be recommended during the course of the academic year.

(E) Procedures:

- (1) The IRB Reviews shall be conducted as follows:
 - a. Review determinations can only be made by the Institutional Review Board upon receipt of a complete Request for IRB Review application form;
 - b. Exempt Review vs. Non-exempt Review determinations shall be made by the Chair and the Vice Chair within five business days of receipt of a complete Request for IRB Review application form;
 - c. In the event that the Chair and Vice Chair cannot agree on the determination, at least one additional member of the IRB shall be identified, and the decision made within five business days of the identification of the third member reviewer;
 - d. Expedited vs. Full Review determinations shall be made by the Chair, the Vice Chair and a third member of the IRB within five business days of the identification of the third member reviewer;
 - e. Full Reviews shall be made by the Full Board at the regular monthly meeting, using approved Operational Procedures for voting;
 - f. Annual (Continuing) Reviews shall be made using the same process of the original review and ruling (e.g., exempt, expedited or full), except in the event of change in the research design and/or

