

SECTION: 01 GENERAL

SUBJECT: POLICY ON ETHICS IN RESEARCH WITH HUMANS

Background: This policy describes Lewis-Clark State College (LC State) policy and procedures for the protection of human participants in research consistent with 45 CFR 46. This policy applies to faculty and students conducting research with humans and delineates the roles and duties of the Institutional Review Board.

Point of Contact: Academic Affairs

Other LC State Offices directly involved with implementation of this policy, or significantly affected by the policy: Faculty Senate, IRB Committee

Date of Approval by LC State Authority: 11/1989

Date of State Board Approval: N/A

Date of Most Recent Review: March 2025

Summary of Major changes incorporated in this revision to the policy: Clarification of role and terms of service of IRB members. In addition, the process for submitting IRB applications has changed to electronic submissions to the IRB and the review process has changed from 3 members to various reviewer scenarios, depending on the classification of the research.

1. Policy

- A. It is the policy of LC State to actively protect the welfare and rights of subjects in research conducted under the auspices of the college, whether the research is conducted by a student, faculty member, staff member, or outside entity. It is further the policy of the college to support the ethical guidelines for conduct of research of the federal government and of respective disciplines represented in our college through the implementation of a collegial review procedure for all research associated with the college. Research involving human participants shall be subject to approval by the LC State Institutional Review Board in accordance with federal guidelines and LC State policies.
- B. Functions of the IRB are limited to:
 - i. certifying that ethical principles are adhered to in the approval of research with human participants, in accordance with 45 CFR 46 and other federal regulations;
 - ii. recommending modifications be made to uncertified research to bring into compliance with federal laws and college policy;
 - iii. maintaining confidentiality of all review proceedings between researchers and members of the Board;
 - iv. aligning the board review with the American Psychological Association (APA) Ethical Guidelines for Research with Human Subjects, OHRP, 45 CFR 46 and other federal regulations and the LC State IRB Guidelines.
- C. Institutional Review Board Composition and Leadership Responsibilities
Review of research at LC State shall be conducted by the Institutional Review Board for Research with Humans comprised of faculty and community volunteer members (in accordance with 45 CFR 46), and reporting to the Provost/Vice President for Academic Affairs.
 - i. Committee Composition
The IRB committee composition will comply with 46.107 (45 CFR 46) and will be comprised of a minimum of five (5) members. At least one (1) member of the committee will be a community member.

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Committee members will serve three-year terms and may be reappointed for multiple terms. Each incoming member must successfully complete the LC State IRB training or outside equivalent.

- a) IRB faculty members will represent a variety of disciplines. Once approved, committee members can serve indefinitely, with reapproval every three (3) years. IRB membership will be approved by a majority vote of the IRB committee, who reports to the LC State Provost/Vice President of Academic Affairs.
 - b) Members can be removed from the committee for non-participation. An IRB Member missing 50% of scheduled committee meetings per academic year may be removed from the IRB by majority vote of the IRB members.
 - c) Members can be reinstated on the committee upon approval by a majority vote of the IRB committee membership as soon as, but not before, the semester following the removal.
- ii. Committee Leadership
- a) The IRB chair will be selected by a plurality vote of the IRB committee members. Candidates for the IRB chair must be an LC State faculty member and have served a full academic year as an IRB member.
 - b) The LC State IRB chair will be granted one 3-credit course release by the Office of the Provost/Vice President for Academic Affairs in each fall and spring semester that they serve as chair.
 - c) The IRB committee will select a vice chair to fulfill the duties of the chair in his/her absence.
 - d) The role of the chair is to facilitate the work of the IRB in accordance with the functions listed below.
 - 1) provide an annual written report to the Provost/Vice President for Academic Affairs
 - 2) provide guidance to LC State students and faculty researchers
 - 3) ensure the IRB web pages are current
 - 4) ensure registration with U.S. Department of Health and Human Services (HHS) and the Office for Human Research Protections is current
 - 5) mentor IRB members
 - 6) report any adverse reactions to the Provost/Vice President for Academic Affairs immediately
 - 7) ensure the IRB Guidelines manual is current

2. Procedure

A. Applicants must complete IRB Training provided on the college's learning management system prior to submitting an Application for Research with Human Participants.

- i. For faculty or staff, email your request for IRB training to the LC State IRB to be added to the training course. This is a self-paced course that includes several modules covering ethical research with related content questions at the end of each module.
- ii. For students, the faculty research advisor must email the LCSC IRB with a request on the student's behalf, for access to the LC IRB training. Faculty must provide the students' LC email address for them to be added to the IRB training course.

B. Obtain an Application for Research with Human Participants from the LC State IRB webpage.

- i. Refer to the LC State IRB Guidelines on the LCSC IRB website for:
 - a) Criteria regarding exempt, expedited, and full board reviews
 - b) Research continuation forms and
 - c) Projects with outside IRB approval forms

C. Submit the application with the signed cover sheet to irb@lcsc.edu

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- D. Applications will be reviewed by members of the LC State Institutional Review Board. A majority vote of the Board is required for approvals of full board review applications. (A Board member may solicit input from a faculty member in the specific field of research, if that appears justified). The members' reviews and comments will be returned directly to the LC State IRB Chair to compile into a response to the applicant. The IRB Chair's response to applicants will notify~~ing~~ them of the Board's approval of their research proposal or provide guidance to the applicant on how to revise their research proposal so that it meets federally mandated protections of human participants in research. A review is expected to be completed within ten (10) working days.
- E. Applicants (and their advisor, if appropriate) will receive a copy of the Application for Research with Human Participants that includes IRB member feedback and approval status.
- F. If the research is not approved, the decision may be appealed in a meeting with the entire IRB and a decision will be made by majority vote at that meeting.
- G. A copy of the Application for Research with Human Participants form and IRB member feedback to participants will be retained by the LC State IRB Chair.