

Lane Education Service District Administrative Rule

Code: **IFA-AR**
Adopted: 8/17/94
Readopted: 6/26/01
Orig. Code(s): IFA-AR

Research Guidelines

To assist in keeping research focused on the needs of Lane ESD, the superintendent will appoint a Research Review Committee. The purpose of the Research Review Committee is to advise the superintendent regarding proposals to do research in the district and to monitor approved research projects.

The Research Review Committee will review each research proposal. The following criteria shall be used in considering each proposal:

1. The privacy and dignity of all individuals (i.e., students, parents, teachers, administrators) must be assured in the study;
2. The study must comply with federal and state law and ESD policy and administrative rules;
3. The study must not be detrimental, either physically or psychologically, to any of the participants;
4. The study must contain full disclosure of the treatment to which the participants will be subjected;
5. The study must be designed so as to pose a question and to present a tenable solution;
6. The study is in an area of inquiry in which the resulting information is relevant to ESD programs;
7. The proposal must meet generally accepted criteria for quality research within the field of inquiry;
8. The proposal must adequately protect the rights of individuals who may be involved in the research.

Consent of students' parents shall be obtained for any testing beyond that which is normally required for all similar students in the district.

Student records and data reported in any study shall be handled in such a way that the information shall not be personally identifiable.

All instructional materials to be used in connection with a study - including teacher manuals, films, tapes and other supplementary items - shall be made available to and by the ESD for inspection by the parents of students engaged in the study.

Participation of ESD staff and students in any non-ESD originated study shall be voluntary. In studies initiated by the district, full staff participation may be necessary and cooperation of all ESD personnel may be required.

In order to facilitate review of the proposal by all members of the committee, one complete, formal copy of the proposal, as well as five summaries (as outlined in items 1.-11. below) should be submitted. The committee will establish a regular time to meet once each month for the purpose of reviewing new proposals and for receiving a status report on projects in progress. The committee will make a determination at each meeting on the status of each approved project. The status designation will be: (1) continuing; (2) completed; (3) recommendation for termination.

All initial proposals must be processed by the Research Review Committee before any action is taken. After the committee has reviewed the study, its recommendation will be forwarded to the superintendent. The superintendent will notify the person who has submitted the proposal in writing whether or not approval has been granted to conduct the study. Once this written approval is given, the researcher may conduct the research, filing a monthly status report with the Research Review Committee.

Individuals interested in doing research through Lane ESD are to observe the following format in submitting their proposal:

1. Name, address, telephone number and affiliation of person submitting the proposal;
2. Title of proposed research;
3. Statement of purpose (the questions proposed to be answered by the study);
4. Design and implementation:
 - a. Statement of problem;
 - b. Experimental hypotheses to be tested;
 - c. Dependent variables;
 - d. Independent variables;
 - e. How the variables are to be measured;
 - f. Design;
 - g. Experimental procedure:
 - (1) Apparatus to be used;
 - (2) Steps necessary to complete the study (State in clear sequence);
 - (3) Process for gathering and analyzing results.
 - h. Other related research in this field.
5. If any nonstandard instrument is to be used, a sample must accompany the request. If instrument is standardized, supporting documentation must be provided;
6. If direct involvement of students will be required, restrictions or qualifications relative to type of students must be noted. The proposal must also describe how the project will comply with district policy on protection of human subjects;

7. If direct involvement of staff of Lane ESD is required, specific staff members must be identified, as well as the amount of time each is to be involved, extent of involvement and any other information helpful to understanding the approach and how the project will comply with district policy on protection of human subjects;
8. A statement detailing how the results of the study could be valuable to Lane ESD;
9. If ESD funds are to be used, the amount and the period of time during which they will be spent must be specified;
10. If ESD facility space is to be used, the amount, location and duration of use must be specified;
11. All proposals must follow the style of the American Psychological Association as presented in the Publication Manual of the APA, 2nd Edition, 1974, or other style manual appropriate to the content area.

No names of individuals or schools will be permitted to be published in studies approved by the district unless permission is granted in writing by the individual or school district. It is also understood that the director of any project that is approved will, upon termination of the project, send a final copy of the completed research project, including a summary report of no more than three pages, to the chairperson of the Research Review Committee for submission to the members of the committee.

Following a determination by the Research Review Committee, all proposals must also be approved by the ESD superintendent and any participating district(s).

Additional information may be obtained by contacting the Chairperson, Lane ESD Research Review Committee:

Send research requests to:

Chair, Research Review Committee
Lane Education Service District
1200 Highway 99 North
P.O. Box 2680
Eugene, OR 97402
Telephone: (503) 461-8200

BACKGROUND INFORMATION, RESEARCH REVIEW COMMITTEE

**Sections Taken From: Department of Health and Human Services,
Part 46 - Protection of Human Subjects**

§46.111 Criteria for Research Review Committee (RRC) approval of research.

- (A) In order to approve research covered by this policy the RRC shall determine that all of the following requirements are satisfied:
- (1) Risks to subjects are minimized: (a) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (b) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
 - (2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.
 - (3) Selection of subjects is equitable. In making this assessment the RRC should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, mentally disabled persons, or economically or educationally disadvantaged persons.
 - (4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative.
 - (5) Informed consent will be appropriately documented.
 - (6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
 - (7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

§46.116. General requirements for informed consent.

No investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the

subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

§ 46.117 Documentation of informed consent.

- (A) Informed consent shall be documented by the use of a written consent form approved by the RRC and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

§46.408 Requirements for permission by parents or guardians and for assent by children

Definitions:

- (1) *Children* are persons who have not attained the legal age for consent to treatments or procedures involved in the research.
 - (2) *Assent* means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.
 - (3) *Permission* means the agreement of parent(s) or guardian to the participation of their child or ward in research.
 - (4) *Parent* means a child's biological or adoptive parent.
 - (5) *Guardian* means an individual who is authorized to consent on behalf of a child to general medical care.
- (A) The RRC shall determine that adequate provisions are made for soliciting the assent of the children, when in the judgment of the RRC the children are capable of providing assent. In determining whether children are capable of assenting, the RRC shall take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved in research under a particular protocol, or for each child, as the RRC deems appropriate. If the RRC determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted, the assent of the children is not a necessary condition for proceeding with the research.
- (B) The RRC shall determine that adequate provisions are made for soliciting the permission of each child's parents or guardian. Where parental permission is to be obtained, both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

- (C) Permission by parents or guardians shall be documented in accordance with procedures established by the RRC.
- (D) When the RRC determines that assent is required, it shall also determine whether and how assent must be documented.