

Institutional Review Board

Research Proposal Checklist

College policy requires that the Institutional Review Board (IRB) review all research involving human subjects **before** the research procedures are implemented and data is collected.

In order to protect subjects and student investigators, the IRB requires that the *Principal Investigator* **must** be an LSC faculty member.

There are three types of proposals: Exempt Status, Expedited Review, and Full Review. Please see the Planning and Institutional Effectiveness website for details regarding types of proposals. In completing the application, be aware that the persons reviewing it may be unfamiliar with the field of study involved. Present the request in non-technical terms.

Use the checklist below to insure that all steps have been completed and all required documentation is attached. Submit completed application and attachments to the Institutional Research Office.

Requests for Exempt Status:

- Complete *Human Research Approval Form*.
- Complete *Request for Exempt Status* form.
- Attach a 100-150 word abstract or summary of the proposed study.
- Submit original **and** one copy of required information for **Exempt Status**.

Request for Expedited and Full reviews:

- Complete *Human Research Approval Form*.
- Complete *Ethical Compliance Questionnaire*.
 - Attach a complete statement of the research methods, including copies of the instrument(s) being used to collect data. **Do not include literature review chapters or proposals.**
 - Attach *Informed Consent Form* (Section III).
 - Attach signed letter of permission from an institutional representative, if research is to be conducted in an institution such as a school, hospital, etc.
 - Attach *Debriefing Statement* when applicable (Section IV).
- Attach a 100-150 word abstract or summary of the proposed study.
- Submit original **and** one copy of required information for **Expedited Review**.
- Submit original **and** ten copies of required information for **Full Review**.

Lake Superior College Request for Exempt Status

Name of Principal Investigator

Title of study

- | | | |
|--|-----|----|
| 1. Are the subjects at more than minimal risk? | Yes | No |
| 2. Will the researcher obtain Informed Consent? | Yes | No |
| 3. Will the researcher maintain the confidentiality of the subjects? | Yes | No |

4. The following types of research are exempt from the required review. Select the type of research that applies to your proposal and provide a brief explanation.

- Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
- Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
- Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior that is not exempt under paragraph 2 of this section, if (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
- Research involving the collection or study of existing data, documents, records, pathological specimens or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
- Research and demonstration projects which are conducted by or subject to the approval of federal department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) public benefits or services programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.
- Taste and food quality evaluation and consumer acceptance studies, (1) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environment contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

5. How does your proposal meet the Exempt Status requirements that you selected above? (Please attach a separate sheet with your response.)

Lake Superior College Human Research Approval Form

Principal Investigator (must be LSC faculty):

Name:

Address where you want to receive IRB correspondence:

Telephone:

E-mail address:

Signature:

Co-Investigator: Attach separate sheet if more than two

Name:

Telephone:

E-mail address:

Signature:

Co-Investigator: Attach separate sheet if more than two

Name:

Telephone:

E-mail address:

Signature:

Title of study:

Date submitted:

Project starting date:

Project ending date:

Request:

- Exempt Status (complete *Request for Exempt Status*)

Submit original and 1 photocopy

- Expedited Review (include reasons below)

Submit original and 1 photocopy

- Full Review

Submit original and 10 photocopies

Reason for requesting Expedited Review:

Institutional Review Board Recommendation:

Exempt Status Approval: Yes No Revise and Resubmit (see attached)

Expedited Review Approval: Yes No Revise and Resubmit (see attached)

Full Review Approval: Yes No Revise and Resubmit (see attached)

IRB Chair's Signature Date

Ethical Compliance Questionnaire

Name of Principal Investigator

Title of study

Complete all items on this form and/or on separate sheets of paper attached to this form.

I. Subject Population, Recruitment and Requirements

1. How many human subjects will participate in the research? Who will the subjects be? (gender, location, affiliation, special characteristics, estimated number required) What are the ages of the potential subjects?

0-7 requires parental informed consent form

8-17 required child assent form and parental consent form

18-64 requires adult informed consent form

65+ requires adult informed consent form

2. Some populations are considered "vulnerable" to coercion or undue influence. Will any of these populations be invited to participate in the research? (Check all that apply)

children (under age 18)

prisoners

pregnant women

mentally disabled individuals

elderly individuals (over the age of 65)

non-English speakers

economically/educationally disadvantaged individuals

no vulnerable populations

3. Provide rationale for using these vulnerable populations and explain, in full, the safeguards that will be included in the research to protect their rights and welfare.

4. Where and how do you propose to identify and recruit potential subjects?

5. If your study involves subjects in institutions (schools, hospitals, other agencies), how will institutional consent be obtained? A signed letter of permission from an institutional representative is required. Attach copy to proposal.

6. How much time will be required of each subject?

II. Methods and Procedures

7. Describe the research procedures and list tasks/activities that subjects will be asked to complete.

8. What materials and/or equipment will be used? What questionnaires, inventories, tests, or other instruments will be used? Attach copies of investigator-prepared materials or a description of commercially prepared or copyrighted materials.

9. Will the data include names or other identifiers? Is confidentiality assured? Yes No
If yes, how? If no, why not?

III. Subject Risk

10. Certain practices are generally to be avoided. If any are included in the proposed study, check the blank next to the appropriate category and justify with attachments.

___ Deception

___ Pain, threat, or aversive stimulation

___ Embarrassment

___ Invasion of privacy

11. What benefits do subjects obtain by participating?

12. Will subjects be compensated for participation? Yes No
If yes, please specify:

III. Informed Consent

A copy of the signed Informed Consent form must be given to subjects or guardians. For surveys and questionnaires that do not involve sensitive topics or minors, return of the questionnaire can be taken as implying consent. However, a cover letter must be included which contains the elements of consent and gives enough information about the survey that the subjects can choose to participate or not. Attach copy of cover letter if appropriate.

Minors and/or Adults Incapable of Giving Consent

13. Will your study use minors or adults legally incapable of giving consent? Yes No

If yes, how will permission be obtained from parents or guardians and assent from the subject?
Attach copies of all documents to be used.

Consenting Adults

1. If subjects are of legal age and capable of giving consent, how will consent be obtained?
Attach copy of documents.

IV. Debriefing

1. Will subjects be provided with feedback about the study? Yes No

If yes, when and how?

2. Is a debriefing form attached? Yes No

Include debriefing statement when applicable.

3. If deception has been used, how will the subjects be informed?

4. What follow-up supports will be available if subjects experience undesirable consequences of participation?

V. Materials

1. Will you make audio-tapes, video-tapes, or photographs of subjects? Yes No

Consent must be obtained from subjects in the informed consent form for these types of materials. Include statements about assurance of confidentiality, the planned use and eventual disposition of these materials (i.e., use of materials at conferences, published research, posting to the internet).

3. What electrical, electronic, or mechanical equipment will be used? If any have been specially constructed or modified for use in this study, provide a description with sufficient detail so that any physical danger may be assessed. Supplementary documents may be attached if necessary.

Federal guidelines require that *all* materials related to the research be retained for at least three years.

See current copy of *Code of Federal Regulations* for details.