Lake Superior State University Human Subjects Institutional Review Board Administrative Policy and Procedures (Revised August 2015)

**Implementation of the Policy**

The Board of Trustees of Lake Superior State University delegates responsibility for the implementation and administration of the Human Subjects Policy to the Provost and Vice President for Academic Affairs. The Provost is responsible for appointing the members of the University Human Subjects Institutional Review Board and giving them direction. The Provost is also responsible for promulgating and enforcing the procedures to be used in the implementation of this Policy.

**B. Authority of the Lake Superior State University Human Subjects Institutional Review Board**

The Lake Superior State University Human Subjects Institutional Review Board (HSIRB) shall review and have authority to exempt, approve, require modifications in, or disapprove all research activities covered by the Human Subjects policy. It shall review proposed research at convened meetings at which a majority of the members of the Board are present, or it may use an expedited review procedure if the research involves no more than minimal risk or if it is reviewing minor changes in previously approved research during the period in which approval is authorized.

If during an expedited review, any member of the expedited review committee determines that there is greater than minimal risk, the proposal shall be referred to the full Board for consideration. The HSIRB would be given 10 business days, when University classes are in session, to review the document(s) and discuss the protocol at their next meeting.

The HSIRB may establish college-level committees, composed of representative faculty and administrators, to review student research, using procedures approved by the HSIRB, when the volume, type or timing of research in a particular college necessitates it, and when students initiate the research. College-level committee structures that are equivalent to the University HSIRB structure as stated in Section: Administrative Procedures – A. Membership, of this document. In such instances, the student’s faculty advisor shall be considered the Principal Investigator and shall be responsible for obtaining HSIRB approval and for enforcing any conditions of such approval. The Chair of the HSIRB will review decisions made by college level committees and recommend any modifications to the study protocol or refer to the HSIRB.

The LSSU Human Subjects Institutional Review Board shall conduct continuing review of research covered by the Policy at intervals appropriate to the degree of risk, but not less frequently than once per calendar year, and shall have authority to observe or have a third party observe the consent process and the research itself. The Board shall have the authority to suspend or terminate approval of research that is not being conducted in accordance with the Policy or that has produced unexpectedharm to subjects. In cases where the Board disapproves of research, notification will promptly be sent to the investigator, appropriate institutional officials and the funding agency, if applicable, along with a statement of the reasons for the disapproval. The Board may also recommend that the University impose sanctions upon any investigator who does not conform to this Policy.

Research covered by the Policy that has been approved by the LSSU Human Subjects Institutional Review Board (HSIRB) may be subject to further appropriate review and approval or disapproval by officials of the University. However, those officials cannot approve the research unless the HSIRB has also approved it.

**C. Applicability of the Policy**.

The Human Subjects review process applies to all research involving the use of human subjects for one or more of the following criteria:

1. Whether funded or unfunded

2. Participated in, or directed by, any faculty, staff or students at Lake Superior State University

3. Done on the property of, or using the facilities ofLake Superior State University

4. Using university personnel or students as subjects

All faculty and staff must, prior to the commencement of research, using procedures promulgated by the Human Subjects Institutional Review Board, submit research proposals for review by the Committee. Securing prior approval for research is the responsibility of the project director, principal investigator or similarly designated person who has responsibility for leading or supervising the project, or students within the project.

**D. Student Research**

In the case of research involving human subjects that is conducted by undergraduate students as part of a course assignment, the instructor of the class will be considered a principal investigator. Undergraduate students are prohibited from conducting research in which there would be greater than minimal risk to human subjects.

# E. Course-Related Activities

Course-related activities that use human subjects are exempt from review if the purpose of the activity is purely pedagogical and the results are intended solely for use within the classroom setting (see LSSU Protocol Packet for Institutional Review Board (IRB) for the Protection of Human Subjects for further discussion). Faculty who are involved is such research will need to submit a syllabus or written descriptions to the chair of the HSIRB of how the subjects are being used and that safe guards are followed that assure that the research conducted maintains exempt status.

**F. Cooperative Research**

In the event that a research project’s director or co-director is from another institution, the University Human Subjects Institutional Review Board may accept a statement of approval from the Human Subjects Review Committee at the project director's home institution in lieu of review by the LSSU Committee when and only when:

1. The policy guidelines of another domestic Human Subjects Review Committee are certified as meeting at least the U. S. federal regulations

2. The other Human Subjects Review Committee certifies that it has approved the research

3. The project is approved by the Chair of Lake Superior State University’s Human Subjects Review Committee.

If the project director of a collaborative research project is a faculty or staff member of Lake Superior State University, the Lake Superior State University Human Subjects Institutional Review Board must review the project.

**G. Independent Research**

Research involving the use of human subjects that is conducted independently of the University is not covered by this Policy. However, to consider research as independent, the investigator cannot use his/her affiliation with the University, any University facilities, nor other University resources in the conduct of the research, nor may the research be pursued under University auspices in any way.

**H. Use of Secondary Data**

Research projects proposing to analyze secondary data fall under this policy and therefore require HSIRB approval. The term “secondary data” includes all archival forms of clinical records, medical charts, correctional institution records, personnel or human resource records, financial records, or records from educational institutions. Prior consent for medical treatment, psychological counseling, or other informed consent for treatment or service is neither a substitute for nor an *a priori* equivalent to HSIRB review. “Secondary data analysis” as defined as further statistical analysis of data after the original research project with the data is completed would fall under the general consent that participants in these studies had originally provided.

**I. Use of Technology (online data collection)**

Researchers who use online data collection must explain in their protocol security precautions, data storage procedures, and anonymity issues relative to safeguarding sample identity.

If data are collected manually and subsequently converted to an electronic/digital format for storing and analysis, the researcher needs to explain in the protocol safeguards to protect data through such measures as encryption, password protection, de-identifying the data, deletion of files, etc.

**J. Exempt Activities**

As described in the Code of Federal Regulations (Title 45, Part 46, Protection of Human Subjects, Subpart A), research activities in which the only involvement of human subjects will be in one or more of the following categories may be determined through the expedited review process of the University Human Subjects Review Committee to be exempt from this policy and accompanying procedures.

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (a) research on regular and special education instructional strategies, or (b) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

a) Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; AND

b) 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.

**NOTE**: This exemption does not apply to research involving children~~.~~

3. 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 Criterion 2, above, if:

a) The human subjects are elected or appointed public officials or candidates for public office; OR

b) Federal statute(s) require(s), without exception, that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

4. 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 in such a manner that subjects cannot be identified, directly or indirectly.

5. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:

a) Public benefit or service programs;

b) Procedures for obtaining benefits or services under those programs;

c) Possible changes in or alternatives to those programs or procedures; or

d) Possible changes in methods or levels of payment for benefits or services under those programs.

6. Taste and food quality evaluation and consumer acceptance studies, if:

a) Wholesome foods without additives are consumed, or

b) A food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or an agricultural chemical or environmental 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.

**Exempt Research -- Program Review**

**1.** **Federal Regulations Exemptions**. Research and demonstration projects that are conducted by or subject to the approval of department or agency heads, and that are designed to study, evaluate, or otherwise examine: 1) Public benefit or service programs; 2) Procedures for obtaining benefits or services under those programs; 3) Possible changes in or alternatives to those programs or procedures; or 4) Possible changes in methods or levels of payment for benefits or services under those programs.

**2. LSSU Program Review Data**. Data collected for the purpose of evaluation, review, and improvement of LSSU academic and extra-curricular programs is exempt from review under the federal regulations exemptions listed above. Specifically, these areLSSU educational programs administered by LSSU, by its associated accrediting agencies, and by other related educational bodies. Educational Program Review proposals that meet the criteria for exemption from review do not need to be sent to the LSSU- HSIRB.

**K. Ethical Standards for Research Involving Human Subjects**

The decision to undertake research rests upon a considered judgment by the individual investigator. The investigator carries out the investigation with respect and concern for the dignity and welfare of the people who participate and with cognizance of federal and state regulations, University policy and professional standards governing the conduct of research with human participants.

In order to approve research covered by this Policy, the Human Subjects Institutional Review Board shall determine that all of the following requirements are satisfied:

1. Risks to the subjects are minimized

a) By using procedures that are consistent with sound research design and that 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, and the importance of the knowledge that may reasonably be expected to result.

3. Selection of subjects is equitable considering the purposes of the research, the setting in which the research will be conducted, and the population from which subjects will be recruited.

4. Informed consent will be sought from each prospective subject or the subject's legally authorized representative. The written informed consent statement shall be in language that is understandable to the subject or his/her representative and shall include a statement about a subject's right to withdraw from a study at any time without prejudice.

5. Informed consent will be appropriately documented.

6. Where appropriate, the research plan makes adequate provision to protect the privacy of subjects and to maintain the confidentiality of data.

7. Where some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as persons with acute or severe physical or mental illness, or persons who are economically or educationally disadvantaged, appropriate additional safeguards have been included in the study to protect the rights and welfare of these subjects.

**ADMINISTRATIVE PROCEDURES**

**A. Membership**

1. The LSSU Human Subjects Institutional Review Board (hereafter HSIRB) shall be composed of a minimum of ten voting members.

a) No fewer than eight members shall be selected from the ranks of the faculty. At least one person from each of the colleges shall be selected.

b) At least one person shall be from professions or vocations that are in a non-scientific area. This person may be a member of the faculty if he or she meets the vocational requirement.

c) A representative appointed by the Associate Provost and Associate Vice President (AVP) will serve as the Administrative Chair.

d) At least one person who is not otherwise affiliated with the institution or a part of the immediate family of one who is affiliated.

e) The HSIRB will function as a committee of the whole with a minimum of 6 members needed to conduct business.

2. The Provost and Vice President for Academic Affairs shall approve HSIRB membership, based on the recommendation of the HSIRB Chair.

a) Candidates for faculty positions on the HSIRB shall be selected by the Chair from the lists of names recommended by the academic Deans in consultation with their constituent departments/schools and programs.

b) The selection of faculty to serve on HSIRB shall take into account such factors as the prospective member’s experience and expertise in matters that fall within the purview of the HSIRB, the degree to which the faculty member’s discipline involves research likely to be in the domain of the HSIRB, and representation from among the colleges.

c) The following additional criteria should be considered in selecting HSIRB membership:

i. The HSIRB shall be sufficiently qualified through the experience and expertise of its members, and the gender, professional, racial and cultural diversity of the members’ background to assure sensitivity to community attitudes, and that decisions reflect consideration of an appropriate diversity of perspectives in safeguarding the rights and welfare of human subjects.

ii. The HSIRB shall possess the professional competence necessary to review specific research activities.

iii. In order to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice, the HSIRB shall include persons knowledgeable in these areas.

d) There shall annually be public notice of vacancies on the HSIRB.

3. The HSIRB may, at its discretion, invite individuals with competence in special areas to assist in the review of complex issues that require expertise beyond that available on the HSIRB. These individuals may not vote with the HSIRB.

4. No member of the HSIRB may participate in the committee’s initial or continuing review of any project in which the member has a direct conflicting interest, except to provide information requested by the HSIRB. Due to the small size of the institution, indirect conflict of interest –real or apparent- may occur. This potential conflict will be addressed by transparency of process.

5. New members of the HSIRB, within the first semester of their appointments, shall obtain training in the protection of Human Research Subjects by completing a certification program or equivalent training. Because the availability and suitability of these programs may vary over time, appropriate training options for meeting this expectation will be delineated and periodically revised by the HSIRB. If new members have received training prior to joining the Committee, the nature and extent of such training will be taken into consideration, and the training requirement may be waived or reduced. The HSIRB Chair will be responsible for communicating with committee members about training options and monitoring adherence to this policy.

**B. Term of Service**

1. The term of service on HSIRB shall be three years and may be repeated.

2. All new appointments shall become effective at the beginning of the academic year.

3. Members who do not fulfill the training requirement in human subjects protection, who do not return protocol review documents in a timely fashion, or who do not regularly attend the Committee meetings will be removed and replaced by the Chair if there is the consensus of the HSIRB.

**C. Officers of the** HSIRB

1. There shall be a chairperson for the HSIRB appointed by the Provost.

**D. Voting**

Except when an exempt or expedited review procedure is used, the HSIRB shall review proposed research at meetings at which a majority of the members of the HSIRB are present, including at least one member whose primary professional background is in a non-scientific area. In order for the research to be approved, it must receive the approval of a majority of those members present at the meeting. All documents that require consideration for a vote at the meeting of the full committee shall be distributed at least one week in advance of the meeting.

**E. Research Approval and Oversight**

1. Only research approved by the means set forth in this document shall be considered authorized.

2. Notification of HSIRB Action

The HSIRB shall notify investigators in writing of its decision to approve or disapprove the proposed research activity, or of the modifications required to secure HSIRB approval ofthe project. If the HSIRB decides to disapprove a research activity, it shall include in its notification a statement of the reasons for its decision and shall give the investigators an opportunity to respond to the Committee in person or in writing. The chair will also notify the appropriate dean of any proposal that has been disapproved.

3. Continuing Review of Research Projects

The Federal Office for Human Research Protections (OHRP) requires that “an IRB shall conduct continuing review (research that has been deemed minimal risk or greater) … at intervals appropriate to the degree of risk, but not less than once per year. ” OHRP interprets “not less than once per year” review to mean on or before the one-year anniversary date of the previous IRB review, even if the research activity began some time after the IRB approval date. Continuing review must be substantive and meaningful. Review by the convened USIRB, with recorded vote, is required unless the research is otherwise appropriate for expedited review.

To comply with federal policy, if a project is being renewed, it should be submitted using the full *Request for Human Subjects Approval Form* to the LSSU HSIRB

Ordinarily, if a research study did not qualify for expedited review at the time of initial review, it would not qualify for expedited review at the time of continuing review. It is also possible that research activities that were previously judged as exempt or those that qualified for expedited review might have changed or will change, such that full committee review would be required.

Documents used for research approval are retained by the HSIRB for three years post study closure.

4. Adverse Event Reporting

If an adverse event occurs during a research project that has been approved by the LSSU- HSIRB, it is the responsibility of the project investigator to report this event to the Chair of the HSIRB as soon as possible, but no later than 24 hours after the PI learned of the event (see *Adverse Event Report* form).

An adverse event is defined as anyincident that has taken place during the course of a research project, which, in the opinion of the investigators, was harmful to a subject participating in the research, increased the risks of harm in the research, or had an unfavorable impact on the risk/benefit ratio. Note that the investigator does not necessarily have to determine that an adverse event was *caused by* research participation in order for it to merit reporting to the HSIRB.

All adverse events must be reported to the HSIRB within 24 hours of the PI’s knowledge of the adverse event, using the *Adverse Event Report* form. If the research is being funded by an external agency, the project investigator must also report the adverse event to the head of the Office of Research Development, whose responsibility it is to inform the agency in conformance with agency rules or regulations. The HSIRB Chair is responsible for immediately sending a copy of this report to the University’s attorney.

The HSIRB will review the *Adverse Event Report* and determine what actions might be necessary to protect human subjects and continue the study, if risks can be adequately managed. Upon approval by the HSIRB committee, a newly dated version of a protocol change for approved research above minimal risk shall be provided for HSIRB files. The HSIRB may halt the research or take other appropriate action as necessary.

Subsequent to an *Adverse Event Report*, for studies that continue to involve more than minimal risk and/or a high risk/potential benefit ratio, the HSIRB may require additional oversight such as:

a) a six-month review or a review at the completion of 20% (not less than five participants) of the sampling based upon the type and level of risk. (The length of this oversight period shall be documented. Two members of the HSIRB shall serve as the primary reviewers with a full report to be voted upon by the full committee. )

b) direct or third-party observation of the consent process or aspects of the research protocol

c) Committee review of a protocol summary and status report on the progress of the research, including:

i. a report of the number of subjects recruited

ii. a summary of adverse events and any unanticipated problems involving risks to subjects or others

iii. a summary of subject withdrawal from the research or complaints about the research since the last HSIRB review

iv. a summary of any relevant recent literature, interim findings, and amendments or modifications to the research since the last review

v. any relevant multi-center trial reports

vi. other relevant information, especially information about risks associated with the research

vii. a copy of the current informed consent document and any newly proposed consent document.

5. Protocol Changes

Project investigators are responsible for notifying the HSIRB when there are changes to their research protocol. For minor changes, submission of a letter to the Chair of the HSIRB that explains the minor modifications and rationale is necessary. Minor modifications would include items such as the addition or deletion of researchers or research partners, change in source of sample but type of source is the same (e. g., different high school), change in contact information on informed consent, minor changes to the language of the survey instrument or interview questions, etc. When the changes address sample composition to include special populations or when data collection procedures change, use the *Request for Human Subjects Approval* form checking the modification section.

Upon approval by the HSIRB, a dated version of a protocol change for approved research shall be provided for the HSIRB files. This approval must be obtained in advance of implementation, except in those cases in which an immediate change is made in response to an adverse event or new information that demonstrates an unnecessarily high risk to subjects. In these cases, the chair of the HSIRB must be notified immediately of the change, and reasons for it, and an application for approval shall be submitted with documentation of the appropriateness of the change. (As stated in E. 7, it is within the purview of the Chair to halt the research if they deem it necessary, prior to implementation of a protocol change.)

6. Ongoing Research Not Approved by the HSIRB

Research otherwise falling under the purview of the HSIRB but that has not been approved by the HSIRB shall not be conducted at the University or under its auspices. When such research becomes known to the committee, the HSIRB chair shall immediately notify the investigators, , the Provost and Vice President for Academic Affairs and the University Attorney in writing that if the research is not halted, the Provost and the Vice President for Academic Affairs shall notify the investigator and University’s attorney of the continuing infraction. These University representatives shall specify the disciplinary actions that the University has at its disposal. Should the research not be halted, the Provost shall take appropriate action in consultation with the University’s attorney to resolve the matter.

7. Suspension or Termination of Research

The HSIRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the HSIRB’s requirements, that has resulted in unexpected serious harm to subjects, or where new information indicates an increase in the level of risk to subjects. Any suspension or termination of approval shall include a statement of the reasons for the HSIRB’s action and shall be reported promptly to the investigator, and the Provost. Should compliance with a notice of suspension or termination not occur immediately, the Provost will take appropriate action in consultation with the University’s attorney to resolve the matter.

# F. Expedited Review

1. An expedited review may be conducted for research involving no more than minimal risk. (See Appendix A of this document for the definition of "minimal risk.")

2. An expedited review is conducted by two members of the HSIRB selected by the administrative chair.

3. Full details of the project being reviewed shall be available for examination by all HSIRB members. Any HSIRB member may call for a full review, which will then be held in accordance with the procedures contained in this document.

4. If one or both of the expedited reviewers recommend disapproval, the research proposal must be given a full review in accord with the guidelines set forth in this document.

**G. Informed Consent**

No investigator may involve a human being as a subject in research covered by these regulations unless the investigator has obtained the appropriate informed consent of the subject or the subject’s legally authorized representative. An investigator shall seek informed 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 at an appropriate understandable level 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. Copies of the HSIRB -approved informed consent form with approval and expiration dates must be used by the investigator to obtain consent, and these records must be maintained throughout the life of the project.

In conducting research with children, procedures must be in place for obtaining both the informed consent of the parent or legal guardian and the assent of the child, obtained in a developmentally appropriate fashion. Ideally, parents will provide written informed consent, but in some cases, it may be permissible to request a “passive consent” process, wherein parents are asked to provide written refusal if they do not want their child to participate, but need to do nothing if they are agreeable to the child participating. Typically, approval for passive consent would only be granted in cases where the research involved minimal risk and there is no practical way to obtain written informed consent.

In seeking informed consent, the following information shall be provided to each subject:

1. A statement that the study involves research, an explanation of the purpose of the research and expected duration of the subject’s participation, a description of the procedures to be followed, identification of any procedures that are experimental, that may result in public dissemination;

2. A description of any reasonably foreseeable risks or discomforts to the subject;

3. A description of any benefits to the subject or to others that may reasonably be expected from the research;

4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that may be advantageous to the subject;

5. A statement describing the extent to which confidentiality of records identifying the subject will be maintained and how participant confidentiality will be maintained in the dissemination of results;

6. For research involving more than minimal risk, information must be made available regarding medical treatments, counseling or other personal assistance that will be provided should personal injuries or problems occur;

7. A list of contacts who can answer pertinent questions about the research and research subject’s rights, and whom to contact in the event of a research-related physical or psychological injury to the subject;

8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time;

9. Statements of significant new findings developed during the course of the research that may relate to the subjects’ willingness to continue participation will be provided to all subjects.

A waiver of **signed** informed consent may be requested if either of the following two conditions apply.

1. The only record linking the subject and the research would be the consent document AND the principal risk is potential harm resulting from a breach of confidentiality

2. The research presents no more than minimal risk of harm to subjects AND involves no procedures for which written consent is normally required outside of the research context.

Regardless of whether informed consent is obtained on a signed document or more informally, the above delimited elements of informed consent must be in place.

**H. Record Keeping**

The HSIRB shall maintain a file of records. These shall be retained for at least three years after the completion of the research, and the records shall be accessible for inspection and copying by authorized representatives of the University at reasonable times and in a reasonable manner. These records shall include:

1. Copies of all research proposal reviews, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of adverse events;

2. Minutes of HSIRB meetings, which shall be in sufficient detail to show attendance at the meetings, actions taken by the HSIRB, the vote on these actions including (the number of members voting for, against, and abstaining) the basis for requiring changes in or disapproving research, and a written summary of the discussion of controversial issues and their resolution;

3. Records of continuing review activities;

4. Copies of all correspondence between the HSIRB and the investigators;

5. A list of HSIRB members as required by federal guidelines;

6. Written procedures which the HSIRB will follow for (a) conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution; (b) determining which projects require review more often than annually and which projects need verification from sources other than investigators that no material changes have occurred since previous HSIRB review; (c) reporting changes that have occurred since previous HSIRB review; (d) ensuring prompt reporting to the HSIRB of proposed changes in research activity, and for ensuring that changes in approved research, during the period for which approval has already been given, may not be initiated without HSIRB review and approval except where necessary to eliminate apparent immediate hazards to the subjects; and (e) ensuring prompt reporting to the Secretary of Health and Human Services of unanticipated problems involving risks to subjects or others.

**I. Institutional Support**

The Division of Academic Affairs shall provide administrative and financial support for the operation of the HSIRB, including support for faculty training.