MLC Institutional Review Board (IRB)

Purpose

Martin Luther College's Institutional Review Board (IRB) exists to assure compliance with federal law and professional ethics in all research conducted by or for the college and its students. The federal law affecting such research is Title 45, Code of Federal Regulations, Part 46, Protection of Human Subjects (1991). This law specifically refers to educational research in section 46.101. (The complete document is available at http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html). These statutes will be used by the IRB to fulfill its charge to protect human subjects involved in research at or through MLC from inappropriate risk, and to ensure that human subjects consent to their research participation.

All IRB applications are submitted to the IRB chair except for graduate student research, which is submitted to the director of graduate studies. Interpretation of the IRB guidelines and determination of the research approval is made exclusively by the IRB or its approved representative, not by the student, instructor, investigator, or student's advisor. Written approval must be received from the IRB before any research or recruitment of subjects is begun. Applications should be submitted to the IRB in sufficient time for the application to be approved before research is to begin (6 weeks is suggested).

Membership and Structure of the IRB

The board is appointed by the director of graduate studies and includes two graduate faculty members, an undergraduate faculty member, the MLC human resource director, and a member of the general public. A listing of members and their representative capacity is found in Appendix A of these guidelines.

Which Types of Research Require Approval from the IRB?

Any research conducted by representatives of the institution (faculty, staff, students) acting on behalf of or under the authorization of the college may require IRB approval. IRB approval is needed if the research activity meets either one or both of the following conditions:

1. It involves *research* designed to develop or contribute to *generalizable knowledge*.
2. It involves *human subjects*.

Research is a systematic investigation of a phenomenon.

Generalizable Knowledge represents conclusions drawn from research which are disseminated beyond the local setting.

Examples of generalizable knowledge

- Thesis or capstone project
- Any published reports of the research
- Presentation or dissemination of the research outside of a classroom

Examples of non-generalizable knowledge

- Activities used to train students in the use of particular research methods or devices, for which information will not be shared outside of class
- Research shared only within a department group, such as a program evaluation

Human Subject research involves data collection about identifiable, living people through some sort of intervention or interaction.

Examples of human subject research

- All research with children under age 18.
- Interviews, surveys, etc. to gain personal information about living people
- Interventions introduced to see how people react
- Interactions with individuals being studied
- Research in which the data and the individual are identifiable

Examples of non-human subject research

- Use of existing, previously gathered data to which all individual identity has been stripped
- Research for departmental, school, or other institutional administrative purposes only (i.e. teaching evaluations, customer service surveys) and for which there is no desire to share or publish
- Information gathered from individuals rather than about them personally or about their thoughts

A Special Note About Graduate Student Capstone Projects

Most capstone projects associated with the Master of Science in Education degree from MLC will involve working with human subjects, especially children, and publication of the results is encouraged. The IRB will need to ensure that provisions for obtaining consent are made and carried out. It is important to plan for parental consent and student assent when working with children. For good order, graduate students will need to submit an application to the IRB for all capstone projects.

Types of Review

Research projects are reviewed in one of two ways based upon the IRB's determination of the project's potential risk to the human subjects and the federal guidelines that define the categories of review.

- *Expedited Review* - screening by one or more IRB representatives. Research that is either exempt from IRB oversight or presents minimal risk to subjects may qualify for expedited review.
- *Full Review* – full IRB review. Research that is not exempt and poses greater than minimal risk will be reviewed by the entire IRB.

The level of review is determined by the IRB chairperson.

Types of IRB Determinations

Upon application review, the IRB will determine whether the proposed research is *exempt* or *non-exempt* from IRB monitoring and regulation.

Exempt Research

The decision for exemption is made by the IRB or its chairperson. All research with human subjects must be submitted for such approval regardless of whether the researcher believes it fits within a category for exemption. All exempt research involving children under 18 years of age is required to have documented provisions for informed consent (see section on informed consent).

In general, the federal guidelines for research on human subjects allow a project to be exempt from IRB monitoring and regulation only if the research involves *no risk* to the subject and the procedures are limited to the following criteria:

1. 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.

2. 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.

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 paragraph (b)(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.

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 by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

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: (i) Public benefit or service 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.

Non-Exempt Research

All research that involves *greater than minimal risk* requires approval and monitoring by the IRB. Review may be expedited or full. Research that is non-exempt includes:

- research that involves greater than minimal risk
- research that involves children under any of these conditions
    - survey or interview procedures;
    - educational tests or observations of public behavior if the investigator participates in the observed activities.
- research that involves deception.

Survey research that involves sensitive questions or information about sexual practice or illegal behavior is subject to full review, in keeping with federal guidelines. Any survey or interview that is likely to be stressful for the subject requires full committee review. IRB staff will make this determination.

All non-exempt research is subject to continuing review at least annually. If research involves significant risk to subjects, the IRB may require more frequent review and may ask to be kept apprised of all research activity.

Informed Consent*

Researchers must submit consent forms when they first apply for IRB review and approval, and when they apply for continuing review. Any revisions made to a previously approved consent form must be submitted to the IRB for approval before use. Written parental or legal guardian permission is required for studies involving children under the age of 18. If the research involves potential risk to the child, signatures from both parents are required unless the second signature is not reasonably available. A single signature is sufficient if only one parent has legal responsibility for the care and custody of the child or if one parent is deceased, unknown, or incompetent. Parental permission is documented in a form similar to an adult subject consent form but modified to indicate it gives permission for the child. Consent forms should include the following information:

- explain the purposes of the research;
- report the expected duration of the subject's participation;
- describe the procedures to be followed;
- identify any procedures or products that are experimental;
- explain why the subject is eligible to participate;
- describe any foreseeable risks or discomforts that the subject will bear;
- describe any benefits to the subject or to others that can reasonably be expected;
- disclose appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
- explain the confidentiality of any records that identify the subject;
- explain, for research that involves physical contact or physical activity, whether compensation or medical treatment will be available if the subject is injured and where to get further information about this;

- identify people who can answer questions about the research, including the principal investigator.
- State that participation is voluntary and that no penalty or loss of benefits will occur if one chooses to not participate or to discontinue once the study has begun.

Once parental permission has been obtained, non-exempt research must also obtain the agreement of the child. The child's agreement is documented with an "assent form," a child-friendly document that outlines the essential information about the research. All children 8 years through 17 years old should be given an opportunity to assent. Some children under the age of 8 may also be capable of granting and withholding assent, and the IRB asks researchers to be sensitive to the needs of these children on an individual basis. Researchers should try to draft a form that is age-appropriate and study-specific, taking into account the typical child's experience and level of understanding, and composing a document that treats the child respectfully and conveys the essential information about the study. The form should:

- tell why the study is being conducted;
- describe what will happen and for how long or how often;
- say it's up to the child to participate and that it's okay to say no or withdraw;
- explain if it will hurt and for how long and how often;
- say what the child's other choices are;
- describe any good things that might happen;
- say whether there is any compensation for participating; and
- ask for questions.

Waiver of consent *

On rare occasions, the federal regulations for human subjects research allow a waiver of the requirement for informed consent. For example, a waiver is possible if a study investigates certain aspects of public benefit or service programs (see 45 CFR 46.116[c]). Also, either a waiver or a consent process that omits or modifies the essential elements of informed consent is possible if the IRB finds that:

- the research involves no greater than minimal risk to the subjects;
- the waiver or alteration will not adversely affect the rights and welfare of the subjects;
- the research could not practicably be carried out without the waiver or alteration; and
- whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Only the IRB can waive or modify the consent process. Researchers are not authorized to make this decision.

*portions of these guidelines were borrowed from or based upon the document “Protecting Human Subjects Guide” produced by the Research Subject’s Protection Program Staff at the University of Minnesota (2004) and used by permission.

Research Within a Course

MLC classes, either undergraduate or graduate, that include research with human subjects must obtain approval from the IRB. The instructor may apply for course level IRB approval and he or she is responsible for reviewing and approving individual student work. The IRB will review the research for risk assessment and informed consent. Such approval is needed in the following circumstances:

- The classroom assignment is designed to contribute to generalizable knowledge and / or will be disseminated beyond the class.
- The data being collected is *about* living individuals.
- The data will be collected through intervention (manipulation of a variable) or interaction (survey, focus group, interviews) with individuals.
- The data contains individually identifiable information.
- The data collected is considered private.

MLC classes, either undergraduate or graduate, that include research that is not with human subjects, that conducts research-type activities for the sole purpose of teaching research methods, or that will not disseminate the findings does not require approval from the IRB.

Submission Guidelines

Submission process for **faculty, staff, or undergraduate students**:

1. Obtain an appropriate IRB application form from the network G: drive. Students will need faculty assistance.

2. Complete the entire application.

3. Include all informed consent, parental consent, or participant assent forms as needed.

4. Submit completed application form and additional documentation to the IRB chairman.

5. Allow at least 6 weeks before research begins.

Submission process for **graduate students** working on a capstone project:

1. Student must receive approval of the capstone project or internship proposal from the capstone committee.

2. Obtain an appropriate IRB application form from the graduate studies website: https://mlc-wels.edu/graduate-studies/institutional-review-board/

3. Students must complete an application for IRB approval and include all informed consent materials.

4. The advisor must review, approve, and sign the proposal and IRB application as complete.

5. Two copies of the proposal, the IRB application, and all consent or assent forms are submitted to the Director of Graduate Studies for initial review by the following individuals:

    i. IRB chairman,

    ii. Director of Graduate Studies

6. The application will be screened by the IRB chairman with input from the Director of Graduate Studies to determine if the proposed activity is exempt, can receive expedited review, or requires full IRB review.

7. If required, the full IRB will meet to make a determination regarding the proposed activity.

8. After review, the IRB may:

    i. approve the proposal as submitted,

    ii. approve with minor suggestions for changes,

    iii. approve with stipulations to be met before final approval is given, or

    iv. not approve.

9. Complete documentation of IRB action will be sent to the researcher and a copy kept on file.

10. All non-exempt research is subject to continuing review at least annually, but possible more frequently as determined by the level of risk to the subjects.

Role of the Course Instructor / Advisor

As appropriate within courses and when advising for the capstone project, the course instructor/advisor should make use of opportunities to instruct students in ethical conduct of research and help them prepare applications for IRB approval. It is helpful to instruct students concerning the following:

- Understanding of the elements of informed consent,
- Developing readable (8th grade level) consent forms,
- Planning appropriate recruitment strategies when needed,
- Establishing and maintaining strict guidelines for protecting anonymity and confidentiality, and
- Allowing sufficient time (six weeks) for IRB review and completion of the project.

Tips for Graduate Students

- Carefully plan the ethical aspects of your study from the very beginning.

- Submit your IRB application and research proposal at least six weeks prior to the start of research.
- Include your capstone/internship proposal with special attention to human subject interactions to demonstrate clearly how anonymity, confidentiality, and informed consent will be obtained.
- Ask yourself if you would honestly want someone you love to participate in your study.
- Work hard to ensure that recruitment materials yield equitable and noncoercive results.
- Write consent forms at an eighth-grade reading level.
- Overestimate risks and underestimate benefits in your consent forms.
- Educate and debrief subjects on the nature, purpose, and findings of your study.
- Establish procedures to delink identifying information from main data sets and sources.
- Establish procedures to encrypt any and all identifying information and destroy it as soon as possible.
- Remember that research is not a right but a privilege and IRB's are peer review groups.

Adopted from:
Oakes, J. Michael (2002). Risks and Wrongs in Social Science Research. *Evaluation Review*, 26 (5), 443-479

Revised 1/26/2010
Revised 7/2/2010
Revised 7/17/2010
Revised 11/8/16

APPENDIX A
IRB Membership

March 2022

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