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://ohsr.od.nih.gov/guidelines/45cfr46.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 research plans must be submitted to the IRB through 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 investigator or 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 as needed. A listing of members and their representative capacity is found in Appendix A of these guidelines.

Which Capstone Projects Require Approval from the IRB?

All projects that will be making use of human subjects as part of the research will need to submit a proposal to the IRB. Most capstone projects associated with the Master of Science degrees 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, all capstone projects will need to submit an application to the IRB.

Types of Review

Research projects are reviewed at one of two levels according to the IRB's determination of the project's potential risk to the human subjects and the federal guidelines that define the categories of review.

- Exemption - screening for exemption from full IRB review, or
- Full-Review - fully convened IRB review

The level of review is determined only by the IRB chairperson.

Exempt Research

The decision for exemption is made by the IRB or its chairperson. All research 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). Any research deemed by the IRB to be exempt from full review is approved for three years from the date of approval. Any research extending beyond three years or undergoing any changes must be resubmitted for approval.

In general, the federal guidelines for research on human subjects allow a project to be exempt from full review 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.

Full IRB Review

A project that involves *greater than no risk* requires approval by the full IRB. Research that requires full committee review includes

- research that involves greater than no risk,
- non-exempt research that involves children or other vulnerable populations, or
- 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; and
- 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.

Submission Guidelines

1. Students must receive approval of the capstone project or internship proposal from the capstone committee.
2. Students must complete an application for IRB approval and all informed consent materials.
3. The advisor must review, approve, and sign the proposal and IRB application as complete.
4. 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
5. The application will be screened by the IRB chairman with input from the director of graduate studies to determine if the proposed activity
    i. involves no risk to the subject according to exempt criteria in 45 CFR 46.101, and so is exempt from full IRB review, or
    ii. requires full IRB review because it involves greater than no risk or non-exempt research.
6. If required, the full IRB will meet to make a determination regarding the proposed activity.
7. 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.
8. Complete documentation of IRB action will be sent to the researcher and a copy kept on file.
9. 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.

For additional information tips regarding the role of the advisor and the student see Moodle resource "Tips for Working with Human Subjects."

Role of the 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 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

Research Within A Course

In an MLC sponsored class that teaches research methods or assigns research to be completed with human subjects, an IRB approval is required. This applies to assignments that do not seem to qualify as "true research" where results are not intended for publication, will not advance work in another area, or will not contribute to generalized knowledge. The IRB will review the research for risk assessment and informed consent. The instructor may apply for course level IRB approval and he or she is responsible for reviewing and approving individual student work. Students may not gather data on subjects outside the purpose of the class. If they do, then each student must receive individual IRB approval.

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APPENDIX A

IRB Membership

August 30, 2016

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