

# Policy on Research on Human Subjects



The Meadville Lombard Internal Review Board (MLIRB) is chaired by the Provost and comprised of two members of the faculty, elected annually.

As an institution committed to the upholding the worth and value of every human being and the interconnected web of life, Meadville Lombard Theological School requires all research impacting human beings meet the standards that follow.

## **MLTS Standards for Conducting Research on Human Beings<sup>1</sup>**

### Honesty

Strive for honesty in all scientific communications. Honestly report data, results, methods and procedures, and publication status. Do not fabricate, falsify, or misrepresent data. Do not deceive colleagues, granting agencies, or the public.

### Objectivity

Strive to avoid bias in experimental design, data analysis, data interpretation, peer review, personnel decisions, grant writing, expert testimony, and other aspects of research where objectivity is expected or required. Avoid or minimize bias or selfdeception. Disclose personal or financial interests that may affect research.

### Integrity

Keep your promises and agreements; act with sincerity; strive for consistency of thought and action.

### Carefulness

Avoid careless errors and negligence; carefully and critically examine your own work and the work of your peers. Keep good records of research activities, such as data collection, research design, and correspondence with agencies or journals.

### Openness

Share data, results, ideas, tools, resources. Be open to criticism and new ideas.

### Respect for Intellectual Property

Honor patents, copyrights, and other forms of intellectual property. Do not use unpublished data, methods, or results without permission. Give credit where credit is due. Give proper acknowledgement or credit for all contributions to research. Never plagiarize.

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<sup>1</sup> Adapted from Shamoo A and Resnik D. 2009. *Responsible Conduct of Research*, 2nd ed. (New York: Oxford University Press).

### Confidentiality

Protect confidential and/or private communications, such as papers or grants submitted for publication, personnel records, trade or military secrets, and patient records.

### Responsible Publication

Publish in order to advance research and scholarship, not to advance just your own career. Avoid wasteful and duplicative publication.

### Responsible Mentoring

Help to educate, mentor, and advise students. Promote their welfare and allow them to make their own decisions.

### Respect for colleagues

Respect your colleagues and treat them fairly.

### Social Responsibility

Strive to promote social good and prevent or mitigate social harms through research, public education, and advocacy.

### Non-Discrimination

Avoid discrimination against colleagues or students on the basis of sex, race, ethnicity, sexual orientation, gender identification, socioeconomic class or other factors that are not related to their scientific competence and integrity.

### Competence

Maintain and improve your own professional competence and expertise through lifelong education and learning; take steps to promote competence in science as a whole.

### Legality

Know and obey relevant laws and institutional and governmental policies.

### Animal Care

Show proper respect and care for animals when using them in research. Do not conduct unnecessary or poorly designed animal experiments.

### Human Subjects Protection

When conducting research on human subjects, minimize harms and risks and maximize benefits; respect human dignity, privacy, and autonomy; take special precautions with vulnerable populations; and strive to distribute the benefits and burdens of research fairly.

## Who Must Gain Permission to Conduct Human Research

Formal approval is needed for any research where data is gathered from human subjects with the intent to publish or convey research findings publicly. Students must consult with their advisers about securing this approval from the MLIRB before beginning research. IRB approval is not required for class assignments that inquire into the role, experience, efficacy or outcomes of ministry reported out to other students, faculty or staff in the context of said class. Likewise, approval is not required for research by students, faculty or staff that uses data such as grades, course work, surveys, interviews, etc., if it is intended to provide feedback to improve a course or program.

IRB approval is required for circumstances when:

1. data will be disseminated outside of the seminary (e.g., publication, presentation of findings at a conference, general assembly, professional meeting, or a granting agency);
2. research projects involve intervention with people and communities outside the seminary and will be published/made public;
3. the potential for conflict of interest is present (see section below)
4. data is being collected for Master's theses and doctoral dissertations.

### Conflict of Interest

A conflict interest is said to exist whenever the researcher, his or her marital partner, or dependent child falls under any of the following conditions and/or meets the criteria below;

1. Is an investigator on the protocol (only applicable to IRB members);
2. Has entered into a financial arrangement with the sponsor or agent of the sponsor, whereby the outcome of the study could influence the value of the economic interest;
3. Acts as an officer, director, or agent of the sponsor;
4. Has any equity interest in the sponsor exceeding \$5,000 or 3% of the equity of the sponsor;
5. Has received any payments or other incentives from any sponsor that total in excess of \$5,000;
6. Has identified him or herself for any other reason as having a conflicting interest.

### Use of Private Information in Research

Private Information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a counseling session, grade, health status). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

## **Responsibilities of Conducting Research**

1. Accepting personal responsibility for protecting the rights, welfare, health and safety of human research subjects and for complying with the applicable regulations.
2. Acknowledge the authority and responsibility of the IRB to make the final approval (or disapproval) of research involving human subjects.
3. Fully inform subjects of the risks, benefits, subjects' expectations, compensation and other aspects of the research in which they are being asked to participate.
4. Use only the IRB approved consent document.
5. Obtain Informed Consent from each human subject in a non-coercive manner. Provide each subject a copy (or duplicate original) of his/her signed Consent form. All signed Consent documents are to be retained in a secure and confidential manner.
6. During the retention period, data, signed consent forms, and other documentation related to human subjects must be stored in a safe area for three years. Access to data, signed consent forms, and other documentation related to human subjects must be limited to the researcher or identified agents.
7. Report promptly proposed changes in previously approved human subject research activities to the IRB. The proposed changes will not be initiated without IRB review and approval, except where necessary to eliminate apparent immediate hazards to the subjects.
8. Report promptly to the IRB any injuries or other unanticipated or adverse events involving risks or harms to human research subjects or others.

## ***Approved Sample Consent Form***

### **RESEARCH PROCEDURES**

The study paper explores the question of....

We will be asking you to tell us about your opinions about (insert topic of the research project) each interview will take (insert amount of time) to finish.

### **RISKS AND BENEFITS**

You will not lose any rights by being in the study. However, you may feel nervous talking about your opinions on (topic). You can drop out of the study at any time. There are no direct benefits to you for participating in the study. But the things we find out may help (insert person/group) understand more about (insert topic).

### **CONFIDENTIALITY**

We may audiotape and/or videotape focus group interviews. We will keep the tapes in a very safe place. Everything that we all say on the tapes will be transcribed, but your name, the name of your place of employment and even the city where you live and work will be changed so that no one will be able to identify you. We may use some of your words when we write our report, but we will never tell anyone your name. We will destroy the tapes after (insert time period), after we have written about your opinions about (insert topic).

### **PARTICIPATION**

You do not have to talk to us if you do not want to. If you change your mind after we start talking and want to stop that is OK. We will not get angry and nothing will happen to you if you decide to no longer participate.

### **CONTACT**

My name is (insert name), and I am (insert professional title). You can call me at (insert phone #) if you have any questions about this study. This research process falls within national standard and ethics about research. If you have questions or concerns about this process, please contact (IRB chair, provost) to register your concern.

### **CONSENT**

I have read this form and I agree to be part of this study

Print Name \_\_\_\_\_

Title \_\_\_\_\_ Date \_\_\_\_\_

Signature \_\_\_\_\_