INSTITUTIONAL REVIEW BOARD RESEARCH PROPOSAL FORM

This form is required by the Institutional Review Board (IRB) of Meadville Lombard Theological School in its review of research projects that involve human participants. This form must be completed by the Principal Investigator (PI). To best complete this form, you should have your research project fully planned out, step by step. Your answers should be in-depth but succinct, using full-sentence narrative explanations when necessary to fully explain your research to members of the IRB who may not be familiar with your project. If you need more space for answers, write "See Attached" in the answer block and attach a document with your longer response, noting the relevant question number.

When completed, please submit this form with other documentation, such as the consent form, instruments, and recruitment messages to irb@meadville.edu. **You may not begin your project until you have received approval from the IRB.** Depending on staff availability and type of review required, review can require several weeks.

SECTION ONE: INVESTIGATOR INFORMATION

1.1 Your name: _____ 1.2 Date: _____

1.3 Email: _____ 1.4 Phone: _____

1.5 Title of your Project: _____

1.6 Date you completed CITI SBE Exam: _____
If you have not already shared a copy of your certificate of completion, you must send a copy with this application to irb@meadville.edu.

1.7 Name of your faculty advisor (if applicable): _____

1.8 Will there be other researchers working with you on this study? ☐ Yes ☐ No
If you answered Yes*, then you must list the names, emails, institutional affiliations, and CITI SBE exam completion dates. The IRB may request copies of these researchers' SBE certificates.*

1.9 Please describe your level of experience and/or training in the conduct of human research.

1.10 Do you declare any conflict of interest regarding this research? ☐Yes ☐No

If you answered Yes*, please describe below.*

SECTION TWO: RESEARCH PROCEDURES

2.1 Synopsis: Describe the scientific purposes of the project, including study aims and hypotheses to be tested. For most projects, a summary of about 200 words is sufficient.

2.2 Summary of Research Procedures: Describe the research methods that you will use, including research design, type of measures, procedures, and locations. For most projects, a summary of about 200 words is sufficient. If the project uses self-report methods, such as surveys, questionnaires, and interviews, copies of the actual items used must be submitted to the IRB with this application.

2.3 Participants: Describe the study participants (i.e., the human subjects that you will be studying), including approximate anticipated number of subjects, their age, and any specific characteristics. Note if they are members of any identified vulnerable population, any factors that may affect the ethical acceptability or conduct of this research for this population, and describe steps taken to minimize the possibility of coercion or undue influence.

2.4 Recruitment: Describe how you will recruit subjects. Will you use emails, phone calls, word or mouth, posters, etc.? You must include with this application the full text or script of your email/phone call/etc.

2.5 Dissemination Plans: Describe how the findings will be disseminated, such as presented to external audiences (e.g., presentations at such-and-such conference), submitted for publication, posted on the Internet, etc. If this study is for a D.Min. Project, note that your study will be disseminated in your final submitted D.Min. Project.

SECTION THREE: PARTICIPANT PROTECTIONS

3.1 Direct benefits: Describe the benefits of the proposed research for those who take part in the research. (Indicate if there are "no direct benefits"; if compensation is provided, describe the compensation amount and distribution process.)

3.2 General benefits: Describe the general benefits of the research, other than the direct benefits to participants listed above.

3.3 Identification of Risks and Steps taken to Minimize Risk: Describe any possible risks to participants in this study, including physical, psychological, or emotional harm, and steps taken to minimize those risks. Any risks noted here must be included in the consent form for this study.

3.4 Risk level: Indicate if, in your judgment, the study's risks are greater than minimal, where "Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests" (Code of Federal Regulations, 45 CFR 46).

☐Yes, the risks are greater than minimal ☐No, the risks are minimal

3.5 Privacy Protections: Describe precautions that will be used to ensure subject privacy is protected.

3.6 Data Safety: Describe precautions that will be used to maintain the confidentiality of identifiable information.

3.7 Outside funding: Is this project funded by an outside group or individual (such as a government agency, a MLTS department, or a private donor)?

☐ Yes ☐ No

If you answered Yes *above, specify the name of the funder(s):*

_____

3.8 Check the box for any statement below that applies to your research project:

☐ Participants are specifically recruited from an identified vulnerable population (e.g., less than 18 years of age, employees, prisoners)

☐ You request a waiver of an element of consent or documentation of consent

☐ This project includes international sites

☐ This project is a multisite study

☐ This project requires an authorization agreement with one or more external agencies or institutions

☐ The project qualifies as a clinical trial and so must be registered on ClinicalTrials.gov

If you checked any of the boxes in 3.8, please elaborate.

SECTION FOUR: DOCUMENTATION OF CONSENT

4.1 Elements of Consent: Submit as a separate document the consent form to be used for this project. Before submitting it, verify it includes all required elements of consent (as covered in the CITI SBE course) or provide justification for the absence of any required elements of consent.

4.2 Verify (by checking each statement below) that the consent form—which must be included with this research proposal—includes:

☐ A statement that the study involves research

☐ An explanation of the purposes of the research and the expected duration of the subject's participation

☐ A description, in language understandable by a layperson, of what the subjects will do as participants in the study (e.g., reports of personal information or experiences, complete of self-assessments, making judgments, solving memory problems, reporting their opinions), including identification of any procedures that are novel or untested

☐ Contact information for the investigator(s)

☐ Contact information for the IRB

☐ A description of any reasonably foreseeable risks or discomforts to the subject

☐ A description of any benefits to the subject that may reasonably be expected from the research

☐ A description of the use of information and data collected

☐ A description of how confidentiality of records identifying the subject will be maintained; participants should be told if identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies

☐ An explanation of whom to contact for answers to questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject

☐ 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 the subject may discontinue participation at any time without penalty or loss of benefits to which they are otherwise entitled.

☐ A means to indicate understanding and acceptance of the conditions of consent

Provide justification for any waiver of an element of consent:

4.3. Additional elements: Indicate, if required, other elements included in the consent:

☐ For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained

☐ For treatment studies only: A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject

SECTION FIVE: AFFIRMATION

5.1 Please check the following indicating your acceptance of these statements:

☐ To the best of my knowledge, the answers in this form are accurate.

☐ I will include with this proposal copies of the following documents (check all that apply):

- ☐ CITI SBE Exam certificate of completion (if not already submitted)
- ☐ Research subject recruitment form(s) and/or script(s)
- ☐ Research subject consent form(s)
- ☐ Interview or survey questionnaires (if applicable)
- ☐ Extended answers/explanations to any of the above questions (if applicable)
- ☐ Any other relevant instruments or documents (if applicable)

☐ For students: My Faculty Advisor/Mentor will review and approve this study's protocol prior to submission to Meadville Lombard IRB.

☐ I will read and abide by all of the Notices of Actions and Conditions of Approval from the IRB that I receive.

☐ If one or more of the Board's requirements are not acceptable, I understand that I may ask the Board to reconsider its requirements but may not enroll subjects until the issue is resolved in a manner acceptable to the Board.

☐ I understand that if I need to make any meaningful changes to my project after I have received IRB approval, then I must notify the IRB at irb@meadville.edu of these changes in a timely manner. I understand that the IRB has the right to approve or disapprove of these changes.

Name: _____

Signature: _____ Date: _____

When completed, submit this form, as well as other required documents files (pdf, doc, or docx; no zipped folders, please) directly to the MLTS IRB at irb@meadville.edu.

This form has been adapted from the University of Richmond IRB Proposal Form.