Martin Luther College

INSTITUTIONAL REVIEW BOARD APPLICATION

SECTION 1

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| **[ ]  NEW SUBMISSION****[ ]  RESUBMISSION****[ ]  REVISION OF PREVIOUSLY APPROVED APPLICATION** | **Date Received**: Click here to enter a date. **By**: Click here to enter text. |
| **Title of Study**:       |
| **Principal Investigator**: Last name:       First name: MLC staff [ ] ; Graduate student [ ] ; Undergraduate student [ ] ; Other:       |
| Address:      Phone number:       E-mail address:  |
| **List Co-Investigator(s), if any**: Last name:       First name: MLC staff [ ] ; Graduate student [ ] ; Undergraduate student [ ] ; Other:       |
| Address:      Phone number:       E-mail address:  |
| Where will the study take place? MLC campus [ ] ; High school [ ] ; Elementary school [ ] ; Other location [ ]  (specify):       |
| Approximate number of subjects to be studied:      **Gender**: Male [ ]  Female [ ]  **Subjects’ Age Range**:      **Each subject’s approximate time commitment**: **Estimated duration of entire study**:        |
| **\***Is a script attached that describes the study to the subject (if applicable) and includes basic elements of consent (e.g., risks and benefits, confidentiality of data, right to withdraw)? No [ ]  Yes [ ]  NA [ ]  |
| Will thestudy be conducted in a commonly accepted educational setting? No [ ]  Yes [ ] If yes, in what educational setting?      If no, see the Director of Graduate Studies before proceeding. |
| Will subjects under 18 years of age be studied? No [ ]  Yes [ ]  |
| Will study personnel interact with subjects? No [ ]  Yes [ ]  |
| Check type(s) of measures to be used [if applicable]:[ ]  Passive Observation of Behavior; [ ]  Educational Tests (cognitive, diagnostic, aptitude);[ ]  Survey; [ ]  Interview; [ ]  Other (describe)      \* Have copies of all measures or questions been attached? No [ ]  Yes [ ] . If no, why not?       |
| Will information be recorded anonymously (no identifiers)? No [ ]  Yes [ ] *If identifiers are recorded, provide justification*:       |
| Will “sensitive information” be recorded that could damage subjects’ reputation or employability, or place them at risk for criminal or civil liability? No [ ]  Yes [ ]  |

**If the research involves the use of human subjects please complete Section 2. If it does not involve human subjects, you may skip to Section 3 (page 3).**

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**SECTION 2**

1. **Research Objectives**

(a) What is the purpose of this research?

(b) What are your research question/s?

2. **Background and Significance**

1. What observations or prior scientific findings serve as the basis for this research?

(b) Why is it important to conduct this research?

1. **Subjects**

(a)Who will be studied?

(b) At what educational sites will this research be conducted?

(c) On what basis was this particular educational environment(s) selected?

 (d) Will sufficient numbers of subjects be studied to answer the scientific questions? Please elaborate.

 (e) If subjects under 18 years of age are included… [ ]  Not applicable

(i) Provide a rationale for the specific age ranges of subjects.

(ii) Describe the expertise of the investigative team for dealing with subjects of that
age range.

(iii) Describe the adequacy of the research facilities to accommodate subjects of that
age range.

1. **Recruitment**

(a) How will potential subjects be identified, and how and where will they be approached for participation?

(b) Describe recruitment materials (*ads, letters, recruitment script, etc.*) and enclose one copy of each.

1. How will the study be introduced to participants? (*Attach a script with information about this research project as well as about their rights as a research subject*). If applicable, how will parents or legal guardians be informed or involved with this project?

\*Attach a copy of any CONSENT FORMS that will be used.

 (d) Which institutional officials have agreed to provide access to the proposed research site(s)? Include letters of support, if appropriate.

5. **Methods**

(a) How will subjects be evaluated?

(b) Who will collect the data?

(c) What types of interactions will occur between investigators and subjects?

(d) How often will the subjects be contacted, and why?

(e) How will confidentiality of thedata be maintained?

(f) List the measures to be used (if applicable), and attach one copy of each (unless themeasure is a standard instrument).

1. **Analysis**

How will the results be analyzed to ensure that the research objectives have been met?

7. **Qualifications**

 Summarize the qualifications and experience of the Principal Investigator that are relevant to this research study:

8. **Additional Information**

Provide any clarifications or comments for the IRB reviewers:

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SECTION 3

**CERTIFICATION OF INVESTIGATOR RESPONSIBILITIES**

1. I am cognizant of, and will comply with, current federal regulations and IRB requirements governing human subject research, including adverse event reporting requirements.
2. I have reviewed this protocol submission in its entirety and I am fully aware of, and in agreement with, all submitted statements.
3. I will request and obtain IRB approval of any proposed modification to the research protocol prior to implementing such modification.
4. I will conduct this research study in strict accordance with all submitted statements except where a change may be necessary to eliminate an apparent immediate hazard to a given research subject, in which cases those changes will be promptly reported to the IRB.
5. I will ensure that all co-investigators and other personnel assisting in the conduct of this research study have been provided a copy of the entire current version of the research protocol.
6. I will not enroll any individual in this research study until IRB informs me in writing that the application for exempt status has been granted.
7. I will respond promptly to all requests for information or materials solicited by the IRB.
8. I will maintain adequate, current, and accurate records of research data.
9. I will not knowingly include prisoners.

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| Principal Investigator’s Name:       | Date: Click here to enter a date. |
| Signature: |

**Faculty Advisor Assurance**

I certify that the Principal Investigator named above will conduct this research under my supervision and guidance. I further certify that I assume responsibility for ensuring that the learner complies with all Martin Luther Collegepolicies and procedures regulating human research.

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| Advisor’s Name:       | Date: Click here to enter a date. |
| Signature:  |

**Director of Graduate Studies Assurance**

I certify that this research is in keeping with the standards set by the college and assure that the Principal Investigator has met all requirements for review and possible approval of this research.

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| Director’s Name:       | Date: Click here to enter a date. |
| Signature:  |

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| For IRB Use Only |
| Date Received:  | Reviewed by: [ ]  Director of Graduate Studies Date: [ ]  IRB Chairperson Date: [ ]  Full IRB Date:  |
| Included with Application:[ ]  Capstone Proposal[ ]  Committee Approval of Capstone Proposal[ ]  Signatures (PI, Advisor, DGS)[ ]  Informed Consent Form (if applicable)[ ]  Informed Assent Form (if applicable) |
| Review for Exemption |
| [ ]  Exempt[ ]  Not Exempt | Reason Not Exempt:  |
| Type of IRB Review for Not Exempt Research |
| [ ]  Expedited | Reason Type of Review:  |
|  | Date of Review: [ ]  Approved [ ]  Not ApprovedReason:  |
| [ ]  Full IRB | Reason Type of Review:  |
|  | Date of Review: [ ]  Approved [ ]  Not ApprovedReason:  |
| Date of Next Review: Click here to enter a date. |
|  | Further Review Action: |
| IRB Chair: |
| Signature: | Date:  |