Proposal # _____ Date Received by IRB _____New ___ Revised ___

Application for Exemption from Review for Research Involving Human Participants Form

Institutional Review Board Office
Attn: Provost office, 1184 W Main St
Millikin University IRB, Decatur, IL 62522
Tel: 217-424-6220 fax: 217-424-6653
E-mail: irb@millikin.edu

Please review the six categories of exemption listed below and indicate the category or categories that apply to your research. [Note: Exempt status does not apply for prisoners, or for research that specifically targets persons who are cognitively impaired or persons who are economically or educationally disadvantaged.]

☐ 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 number 2 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. [**Note: to be eligible for this exemption, all data, documents, records or specimens must exist prior to IRB review and must have been collected for purposes other than the proposed research. To qualify for an exemption in this category, the proposed research must be strictly retrospective.]**

☐ 5. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads. The program must deliver a public benefit or service (e.g., Social Security Act or Older American Act). Such research or demonstration projects must be conducted pursuant to specific federal statutory authority; there must be no statutory requirement that the project be reviewed by an Institutional Review Board and the project must not involve significant physical invasions or intrusions upon the privacy of participants.

☐ 6. Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration (FDA) or approved by the Environmental Protection Agency (EPA) or the Food Safety and Inspection Service of the U.S. Department of Agriculture (USDA).

If the proposed research does not qualify in any of these categories, please complete the "Review Request for Research Involving Human Participants" found on the Millikin IRB web site.

For proposed studies that you believe qualify for exemption, please complete the following questions:

1. **Principal Investigator (PI):** The PI is the faculty, staff, or student who conducts the project at Millikin. If a student is the PI, then a Millikin **Project Supervisor (PS), who is either Millikin faculty or a staff member must be designated.**

PI Information –Attach Required CITI Certification		
Last name:	First Name:	Dept:
Office address:	Phone:	Email:
Street address:	City:	State/Zip:
PS Information –ONLY IF PI is a student. Attach CITI Certification		
Last name:	First Name:	Dept:
Office address:	Phone:	Email:
Street address:	City:	State/Zip:

Co-Investigator(s) (CI): List all co-investigators, including those from other institutions, who will: 1) be directly responsible for the project's design or implementation, 2) obtain informed consent, or 3) be involved in data collection, data analysis, or follow-up. List additional Co-Investigators at the end of this form.

☐ **No Co-Investigators.** Check box and go to Question 2.

Co-PI 1 Information - Attach CITI Certification		
Last name:	First Name:	Dept:
Office address:	Phone:	Email:
Street address:	City:	State/Zip:

2. **PROJECT TITLE**

3. **Research Summary:** Please summarize, in lay terms, the aims/objectives and significance of the research.

4. Participants: Describe who will participate in the research and how they will be recruited and if they will be compensated in any way.

5. Research Procedure: Specifically describe what the participants will do and where the activities will take place. Outline the approximate dates and durations for specific activities, including the total number of treatments, visits, or meetings required and the total time commitment. The IRB must review all measurement instruments participants will complete for the study including surveys and psychological tests. It is the researcher's responsibility to obtain any necessary permission to use copyrighted materials. Include a copy of each measurement instruments as attachments and evidence of permission to use copyrighted materials.

6. Data Collection & Confidentiality Please explain how confidentiality will be maintained during and after data collection. If applicable, address confidentiality of data collected via e-mail, web sites, computer servers and other networked information.

7. Individually identifiable information: Will any individually identifiable information, including images of subjects, be published, shared, or otherwise disseminated?

☐ No ☐ Yes

If yes, subjects must provide explicit consent or assent for such dissemination. Provide appropriate options on the relevant consent/assent documents.

8. Consent Process: Describe when and where voluntary consent will be obtained, how often, by whom, and from whom. Attach copies of all consent and assent forms.

9. Funding: Describe any funding sources for your study

10. Expected Completion Date:

INVESTIGATOR ASSURANCES:
I certify that the project described above, to the best of my knowledge, qualifies as an exempt study. I agree that any changes to the project will be submitted to the Institutional Review Board for review prior to implementation. I realize that some changes may alter the exempt status of this project. **The original signatures of the PI (and PS if applicable) is required before this application may be processed (scanned or faxed signatures are acceptable).**

_____ _____
Principal Investigator Date

_____ _____
Co-Investigator Date

_____ _____
Project Supervisor Date

Millikin IRB Use Only

MU IRB Protocol No. _____ Date Submitted:_____

IRB Determination: ___ Exempt ___ Non-Exempt PI/PS Notified (Date) _____

IRB Chair Signature _____ Date_____

Provost Notified _____ Date_____