MILLIKIN UNIVERSITY

Research Amendment Request Form

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

Use this form to submit changes to previously approved by the Millikin IRB.

All modifications to human participant research must be reviewed and approved prior to implementation.

Minor modifications include those changes that: do not alter the risk/benefit ratio (e.g., investigator changes, minor changes in the consent / assent form, recruiting materials, measures, procedures, compensation, participation expectations, or the addition of a comparable new site. Minor modifications may also include changes in which the investigator provides participants with more accurate or complete information about the study. Minor changes are eligible for Expedited Review.

Major modifications include those changes that: substantial enough to cause participants to preform activities that were not previously approved, increase the level of physical or emotional risk, impact confidentiality, decrease a benefit of participation, or otherwise alter the risk/benefit ratio (e.g., adding a new participant pool, altering inclusion or exclusion criteria, changing the consent process, changing medication type or dosage, changing confidentiality, etc.). Depending on the nature of the major modifications the IRB may use either Expedited or Full Board Review procedures.

Submit this completed form with its supporting documents electronically to the IRB at irb@millikin.edu

Proposal No.		Date submitted:
Principal Investigator (name):		
Phone No. (W):	(H):	Email address:
Co-Investigators:		
Faculty Sponsor (name):		Email address:
Research Project Title:		

Minor or Major Modification? The Responsible Principal Investigator views the proposed modification as being:
___Minor ___ Major (mark with an X)

Amendment Description – In the box below, please describe the requested changes by providing the exact wording of the previously approved material (noted as OLD: approved text) followed by the exact wording of the new material that is being requested (noted as NEW: changed text). For each requested change, provide a clear rationale (Rationale & Impact:) for the change, and indicate how this change will affect such study features as risk, benefit, consent, inclusion / exclusion criteria, population studied, confidentiality, compensation, etc.

As needed, please provide the following documents as file attachments when you email the IRB with your Research Amendment Request form:

1. Copy of new Consent / Assent form
2. Copy of participant debriefing

3. Copy of new participant instructions 4. Other

Principal Investigator Assurances – The electronic or inked signature of the Responsible Principal Investigator is required before the IRB will review and process this request. Co-Investigators are also responsible to adhere to these assurances and encouraged, but not required to sign.

I certify that the information provided in this form, with supporting attachments, is complete and correct, and that the requested modifications have not yet been implemented, and will not be implemented until the IRB approves the requested changes and sends written notification of such.

_____ _____

Principal Investigator Signature Date Co-Investigator Signature Date

_____

Faculty/Staff Project Supervisor Signature Date

Millikin IRB Use Only

MU IRB Protocol No. _____ Date Submitted:_____

IRB Research Amendment Request Decision: __Approved ___ Resubmit ___ Denied

IRB Chair Signature _____ Date _____

Provost Notified _____ Date _____