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 us

**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