Adverse Event & Ethics Complaint Report

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

When to Use this Form - The Principal Investigator (PI) should complete and sign this form and submit it electronically with related attachments for any event that falls into Categories 1, 2, or 3 listed below. Category 4 may be reported at the discretion of the Responsible Principal Investigator.

1. Serious Adverse Event that occurs within 48 hours of participation in the research project. Serious adverse events include those resulting in death; a life-threatening experience; hospitalization; creation of a persistent or significant disability or in capacity; or a congenital anomaly or birth defect. Every serious adverse event must be reported on this form, even if the event does not appear to be associated with the research protocol. If applicable, the researcher must also file an FDA Adverse Event Report (http://www.fda.gov/cder/aers/). In addition, the Millikin IRB Office should be notified within 24 hours of discovery of any serious adverse event by electronically submitting this completed form to irb@millikin.edu and the IRB Chair.

2. Adverse Event for which *all three* of the following are True: (1) An event or outcome has occurred that has *resulted in harm* to the participant, has *affected the participant detrimentally* , has *worsened* the participant's condition as a result of their participation, or that has resulted in *increased risk to the participant or to others,* whether or not the risk has actually resulted in harm (for example, misplacing a subject's research records would constitute an increased risk event that should be reported); and (2) the event or outcome *was not described as a risk* of participation in the research, or, though described as a risk, the event or outcome has occurred with *unexpected severity or frequency;* and (3) the event or outcome was *definitely related* to participation in the research or it's *reasonable to conclude* that the event or outcome was related to participation, or *it's possible*

Research Project Title:				
Report Type (Mark an X)		Initial Report		Follow-up on Previously Reported Event

No	Yes	Relation to Stated Risks - In the PI's judgment, is th e probability, magnitude, and reversibility of this event consistent with the risk information present in the IRB proposal and informed consent / assent documents previously provided to and reviewed by the IRB? (Type an X in one of the boxes to the left.)