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 incapacity; 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* the event or outcome was related but not enough information is available at this time to assess the likelihood of this possibility. Complete and send this form to irb@millikin.edu and the IRB Chair within 5 days of discovery of the occurrence of the event.

3. **Participant Ethics Complaint** Such an event occurs when a participant has a negative experience, the nature, severity, or frequency of which is not consistent with the known or foreseeable risk of adverse events associated with the research procedures. These events, while unpleasant, do not result in death or hospitalization; do not produce a persistent or significant disability or incapacity; and are not life threatening. Usually the participant will report this concern directly to the IRB (using information provided in the consent form), however the responsible principal investigator should complete and send this form to irb@millikin.edu and the IRB Chair within 5 days of a participant complaining directly to any of the researchers involved in the study.

4. **Non-serious Adverse Events** Non-serious adverse events sometimes occur in studies when participants comment or behave inappropriately, negatively impact the experience of other study participant's during the study, etc. Non-serious adverse events are reported at the discretion of the Responsible Principal Investigator.

Proposal No.	**Date submitted:**
PI (name):	**PI Email:**
Phone (W):	**Phone** (H):
Project Supervisor (name):	**Phone & Email:**
CI:	

Research Project Title:					
Report Type (Mark an X)		Initial Report		Follow-up on Previously Reported Event	
Event Type (From categories 1-4 above)					
Event likelihood (Mark an X in a box)		Expected		Unexpected	
Date event Occurred:		**Date event discovered:**			
Date event reported to the IRB:					

Research Project Site -Where did the event occur?

Research Personnel - Who was present when the event occurred / was discovered?

Participant(s) information – For each participant involved, provide their age, gender, and indicate whether there were any know pre-existing conditions.

Describe the event (Mark an X in each box that applies)

	Life threatening experience		Psychological harm or injury occurred
	Required emergency treatment		Social harm or injury occurred
	Required transport to hospital		Economic harm occurred
	Required hospitalization		Breach of confidentiality occurred
	Prolonged current hospitalization		Increased psychological/social, or economic harm risk
	Persistent/significant disability/incapacity		Risk of confidentiality breach increased
	Congential anomaly / birth defect		Drug related problem:
	New disease / problem		Device related problem:
	Death – underlying or progressive disease		Biological related problem:
	Death – research related		Other:

Provide a brief narrative of the event

Describe any and all steps / actions taken in response to the handle or resolve the event

Indicate the participant's involvement in the study after the event occurred (Mark an X in each box that applies).

	Participant continued involvement in study		Participant continued involvement with follow-up only
	Participant could not complete the study		Participant withdrew from the study
	Participant had already completed study		Investigator withdrew participant from the study
	Other (please explain):		

Prognosis – Describe the participant's prognosis and source of information

Has any previous research produced this type of event or outcome? __ No ___ Yes If Yes, describe and reference previous reports.

Relationship to research – In the PI's judgment, was there a relationship between the event and the research project? (Mark an X in box that best fits the PI's judgment.)

	Definitely related to the research		Probably not related to the research
	Probably related to the research		Definitely not related to the research
	Possibly related, but information not yet available or unclear		

	No		**Yes**	**Relation to Stated Risks -** In the PI's judgment, is the 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.)
If Yes, attach and send copies of the research procedures, consent / assent forms with relevant sections highlighted to the IRB.				
	No		**Yes**	**Revision necessary?** In the PI's judgment, should the research procedures or consent / assent forms be revised?
If Yes, complete and submit the Research Amendment Request Form provide any necessary revised documents with the submitted request.				

Notification of participants or parents / guardians? In the PI's judgment, should any of the following participant groups or parents / legal guardians be notified? Place an X in every box that applies. If any box except "None" is marked, then provide your amended notification procedures in the Research Amendment Request Form to be filed with the IRB.

	New Participants		Current participants
	Participants that have completed the study		None

	No		**Yes**	**Re-consent / assent -** In the PI's judgment, is it necessary to obtain anew the consent /assent of participants or parents / legal guardians?
If Yes, complete and submit the Research Amendment Request Form provide any necessary revised documents with the submitted request.				

Effect on Research – In the PI's judgment, should the research: (Mark an X in all boxes that apply.)

	Continue research as planned with no changes to procedure or consent / assent		Suspend enrollment of new participants until further assessment of event outcomes
	Continue with changes to the procedures and / or consent /assent process		Terminate the study and remove all current participants from the study

Reports to be filed (Mark an X in the boxes that apply.)

Report filed with:		**Date reported**	**Report(s)** Mark an X all boxes that apply.			
	IRB (name):			Attached		Will Follow
	IRB (name):			Attached		Will Follow
	Food & Drug Administration			Attached		Will Follow
	Office of Human Research Protections			Attached		Will Follow
	Other (specify):			Attached		Will Follow

Investigator Assurance(s): I have reviewed the contents of this form, and I certify that the information I have provided is complete and accurate to the best of my knowledge.

_____ _____

PI signature Date Project Supervisor signature Date

_____ _____

Co-investigator signature Date Co-Investigator signature Date