

**INSTITUTIONAL REVIEW BOARD**

**ADVERSE EVENT REPORTING FORM**

Investigators: SUSPEND RESEARCH ACTIVITY with participants until the IRB reviews the adverse event and notifies you that your research is approved to recommence.

The IRB requires the Principal Investigator (or faculty advisor if PI is a student) to report to the IRB **within 24 hours** of becoming aware of any adverse event that occurs in association with a research study in which there is harm or other unanticipated problems involving risks to participants or others. Adverse events include but are not limited to:

* Significant change in the risks associated with the study
* Serious and unexpected events
* Unexpected negative events that are not described in the study’s Informed Consent Form
* Death occurring while the participant is involved with the study, regardless of whether the death was related to the study
* Any event that requires prompt or urgent reporting to the sponsor (if the study is externally funded)

To report an adverse event, please complete the following and submit to Mary Hoehn, IRB Chair, at mhoehn@skidmore.edu within 24 hours of the event.

1. Study Title:
2. Protocol #:
3. Principal Investigator:
4. Faculty Advisor (if PI is a student):
5. Sponsor of Study:
6. Date of Adverse Event:
7. Date Report Submitted to IRB:
8. Location of Adverse Event:
9. Was the adverse event unexpected? [ ]  Yes [ ]  No

Please explain:

1. Was the adverse event serious? [ ]  Yes [ ]  No
* Results in death
* Is life-threatening
* Requires inpatient hospitalization or prolongation of existing hospitalization
* Results in persistent or significant disability or incapability
* Results in a congenital anomaly or birth defect

Please explain:

1. Describe the adverse event:
2. Is the adverse event related to the research?

[ ]  Related

[ ]  Probably related

[ ]  Possibly related

[ ]  Unlikely related

[ ]  Not related

[ ]  Unknown

Please explain:

1. What treatment, if any, for the adverse event was provided to the participant?
2. Date of treatment for adverse event:
3. Describe the participant’s prognosis:
4. Is the study closed to enrollment? [ ]  Yes [ ]  No
5. Have similar adverse events been reported previously? [ ]  Yes [ ]  No

If yes, please explain:

1. Are participants placed at greater risk than they were before? [ ]  Yes [ ]  No
2. Is a change in protocol necessary to reduce or eliminate risk? [ ]  Yes [ ]  No
3. Are any changes required in the informed consent document(s) to

better inform and protect the rights and welfare of participants?

If yes, you must submit an amendment. [ ]  Yes [ ]  No

**Principal Investigator Certification**

**I certify that I have assessed the information concerning the adverse event and that in my judgment the risks of this research are minimized to the greatest extent possible and continue to be outweighed or balanced by the potential benefits.**

Investigator Name:       Date: