INSTITUTIONAL REVIEW BOARD FOR THE PROTECTION OF HUMAN PARTICIPANTS IN RESEARCH

Adverse Events Report Form for the Principal Investigator

Section I: General Information

Date: _____ **IRB Number** (*Assigned by IRB office*): _____

Study Title: _____

Principal Investigator or Faculty Advisor: _____

Department: _____

Campus Address: _____

Email Address: _____ Phone: _____

Co-Principal Investigator: _____

Department: _____

Campus Address: _____

Email Address: _____ Phone: _____

Type of research, check all that apply:

☐ Faculty Research ☐ Dissertation/Thesis/Honor's Thesis

☐ Product of Learning/Capstone Research ☐ Class Project – Course Number: _____

☐ Other (describe): _____

Research Sponsoring Agency (if applicable): _____

Section I: Event Information

Adverse Events (**AE**) and Serious Adverse Events (**SAE**) must be reported to the IRB by the Principal Investigator (PI) as soon as possible after the event has been discovered. PIs should advise all research personnel of the proper procedures for reporting such events as described in Section 5.3.5 of the IRB Procedures Manual. **AE** is defined as any circumstance that has caused a participant to suffer physical or psychological/emotional injury as a result of their participation in your study. This event could be undesirable and unintended. **SAE** is defined as an adverse event that results in death or is life threatening, results in serious injury or disability/incapacity, requires hospitalization or prolongation of an existing hospitalization, or results in congenital anomaly/birth defect.

1. Description of Event: ☐ Adverse Event (AE) ☐ Serious Adverse Event (SAE)
2. Event Date: _____ Discovery Date: _____
3. Study Site: _____ AE/SAE Site: _____
4. Did event result in (check all that apply):
   - ☐ Death ☐ Hospitalization ☐ Disability
   - ☐ Injury ☐ Prolongation of Hospitalization ☐ Congenital anomaly/birth defect
5. Required Care: ☐ Emergency Room/Physician _____
   ☐ Clinic _____

☐ Counseling/Referral _____
☐ No additional care sought _____

6. ☐ Yes ☐ No Is the risk of this adverse event contained in the consent form?
7. In your judgment, how likely was the AE caused by procedures in the protocol?
   ☐ Not likely ☐ Unlikely ☐ Possibly ☐ Probably ☐ Definitely ☐ Unknown

ADVERSE EVENT SUMMARY: Attach a detailed summary describing the circumstances of the adverse event. Include responses given by subject(s) (include name) and the investigator; what measures were taken to address the participant's situation; and procedures taken to prevent similar incidents. Attach any additional documentation that will be helpful.

Section III: Impact on Study

1. In your judgment, is a change in the protocol necessary to reduce or eliminate the risk?
   ☐ Yes - Attach the Request for Revision Status IRB form
   ☐ No - Provide brief rationale
2. Are any changes required in the informed consent document(s) to better inform and protect the rights of subjects enrolled hereafter?
   ☐ Yes - Attach revised consent form(s)
   ☐ No - Provide brief rationale
3. Will participants currently enrolled in the study be notified of this new information?
   ☐ Yes - Attach information sheet or consent addendum
   ☐ No - Provide brief rationale

NOTE: This form must be completely filled out. Please return the completed form to the Chair of the IRB.

Principal Investigator/Faculty Advisor: Printed Name	Signature	Date
Co-Principal Investigator: Printed Name	Signature	Date
Individual Reporting Event: Printed Name	Signature	Date

FOR IRB OFFICE USE ONLY

- ☐ Continue study as submitted and approved by IRB. No changes needed.
- ☐ Discuss with Principal Investigator
- ☐ Changes recommended in protocol or consent form
- ☐ Place the study on hold. Discuss with Principal Investigator
- ☐ Report to Institutional Officials: Date: _____

Comments:

IRB Chair:	Printed Name	Signature	Date