INSTITUTIONAL REVIEW BOARD FOR THE PROTECTION OF HUMAN PARTICIPANTS IN RESEARCH

Adverse Events Report Form for the Study Participant

Section I: General Information

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

Participant Name: _____

Study Title: _____

Principal Investigator or Faculty Advisor: _____

Department: _____

Campus Address: _____

Email Address: _____ Phone: _____

Research Sponsoring Agency (if applicable): _____

Section II: Event Information

Adverse Events (**AE**) and Serious Adverse Events (**SAE**) can be reported to the Institutional Review Board submitting this form if an adverse event has taken place in the context of a study in which you have participated. **AE** is defined as any circumstance that has caused you to suffer physical or psychological/emotional injury as a result of your participation in your study. **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: _____
3. AE/SAE Site: _____
4. Did event result in (check all that apply):
   - ☐ Death
   - ☐ Injury
   - ☐ Hospitalization
   - ☐ Prolongation of Hospitalization
   - ☐ Disability
   - ☐ Congenital anomaly/birth defect
5. Required Care:
   - ☐ Emergency Room/Physician _____
   - ☐ Clinic _____
   - ☐ Counseling/Referral _____
   - ☐ No additional care sought _____

ADVERSE EVENT SUMMARY: Attach a detailed summary describing the circumstances of the adverse event. Please be as specific as possible and attach any additional documentation that will be helpful.

☐ Yes ☐ No Did you report the adverse event to the experimenter?

Please return the completed form to the Chair of the IRB.

Participant: 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