Aurora University

**Institutional Review Board**

**ADVERSE EVENT REPORT**

**Submit this form to the Chair of the IRB committee immediately upon occurrence of an adverse event or subject injury. Please see** [**https://aurora.edu/academics/resources/irb/index.html**](https://aurora.edu/academics/resources/irb/index.html) **for current chair of the IRB committee.**

 **Researcher (provide contact information for primary contact person if more than one researcher):**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Phone: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Fax: \_\_\_\_\_\_\_\_\_\_\_\_\_\_ AU E-mail: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Faculty Advisor (if PI is a student): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ AU Email: \_\_\_\_\_\_\_\_\_\_\_\_

**IRB#:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Title:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date of IRB approval: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Injury to subjects, breaches of confidentiality, and unapproved deviations from the protocol are examples of adverse events that must be reported to the IRB and the research halted if necessary.**

Submit this form and a copy of the original signed consent form (if applicable) as soon as possible but no later than ten working days after first awareness of the event.

Describe the injury or adverse event, the date and place of occurrence, the action taken in response to the event, and the relationship of the adverse event to the research. Include any additional information that you believe may be beneficial to the IRB in their review of the event. Please use as much space as necessary below:

**I certify that the information on this form is accurate to the best of my knowledge.**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Researcher Signature Date**

**The IRB will review this information and notify the researcher (and faculty advisor for student research) in writing of the appropriate action required in response to the adverse event.**