Print Form

XAVIER UNIVERSITY

Institutional Review Board

ADVERSE EVENT REPORT

Submit this form immediately upon occurrence of an adverse event or subject injury.

Principal Investigator: _____

Address: _____

Phone: _____ Fax: _____ E-mail: _____

Faculty Advisor (if PI is a student): _____ ML: _____

IRB#: _____ **Title:** _____

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 signed consent form (if applicable) as soon as possible but no later than 10 (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.

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

_____

PI Signature **Date**

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