Instructions for Reporting Adverse Events

University of Hartford
Institutional Review Board

The IRB requires that the principal investigator report any adverse event related to the conduct of the research with human participants.

An ***anticipated adverse event*** is defined as an experience or reaction related to the conduct of the research that is identified or outlined in the research procedure and the noted in the informed consent form.

An ***unanticipated adverse event*** is defined as an experience or reaction related to the conduct of the research that is not identified or outlined in the research procedure and the informed consent form, including a change in the nature, severity or frequency of the experience or reaction; and/or any unanticipated problem associated with the conduct of the research related to the level of risk to the participants. The investigator will report unanticipated adverse events to the IRB ***within five business days of occurrence***.

Serious adverse events include, but are not limited to those that result in death; are life threatening or potentially life-threatening; result in disability; result in hospitalization or other significant and unanticipated treatment; or other events deemed to be serious by the investigator. ***The investigator must report serious adverse events in writing or by phone to the IRB within 24 hours***. If reported by phone, a written report must ***follow within three business days***.

The ***principal investigator*** will ***report adverse events*** to the IRB chair ***as delineated above***. Submit one copy (signed electronic PDF or hard copy – electronic preferred) of complete report to:

Jessica Pawlik-York
Chair, Institutional Review Board
Office of the Provost's
University of Hartford
200 Bloomfield Ave
West Hartford, CT 06117
Phone: 860.768-.5054
Email: irb@hartford.edu

For IRB Office Use Only

Date Received: _____

Date of IRB Review: _____

University of Hartford
Institutional Review Board
Adverse Event Report

I. General Information

Date of report: _____ Date of IRB Approval: _____

Project ID #: _____

Title of Project: _____

Funding agency/ sponsor: _____

Principal Investigator: _____ Advisor (if student): _____

Department and program or research agency/ university (if not U of H): _____

Address: _____

PI Phone: _____ PI Email: _____

Co-investigator(s): _____

Department and program or research agency/ university (if not U of H): _____

Address: _____

Total number of subjects enrolled in study: _____

Total number of subjects affected by adverse event: _____

Was this adverse event anticipated or not? _____

II. Description of Adverse Event

Provide a **detailed** description of all adverse events, participant complaints, and implications.

Describe any actions taken, and/or the likelihood of further risks to study subjects. Attach any additional documents showing actions taken.

I certify that the above information is correct and that the approved protocol and method for obtaining informed consent were followed during the period covered by this report.

Signature: _____ Date: _____
Principal Investigator

Signature: _____ Date: _____
Co-Investigator(s) (if any)

Signature: _____ Date: _____
Advisor (if student project)