State of Connecticut Department of Developmental Services
Office of the Commissioner Institutional Review Board

Reporting Adverse Events

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 informed consent form. Anticipated adverse events will be ***reported at the time of the continuation review***.

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[1]; 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 ***investigator*** will ***report adverse events*** to the IRB chair ***as delineated above***. Submit one copy of complete report to:

Office of the Commissioner Institutional Review Board
Department of Developmental Services
460 Capitol Avenue
Hartford, CT 06106
Attn: IRB Chair

[1] ***Immediate notification is required in the case of client deaths.***

For IRB Office Use Only
Date Received: _____

Date of IRB Review: _____

_____
IRB Authorized Signature

For IRB Office Use Only

Application #: _____

State of Connecticut Department of Developmental Services
Office of the Commissioner Institutional Review Board
Adverse Event Form

I. General Information

Date of Report: Date of Original IRB Approval:

Title of Project:

Principal Investigator (or Major Advisor, if student project):

Department/Agency/University:

Address:

Phone: Fax: E-mail:

Co-Investigator(s) (or student):

Department/Agency/University:

Address:

Phone: Fax: E-mail:

II. Description of Unanticipated Adverse Event

- ✓ Number of subjects entered since last continuation report:
- ✓ Total number of study subjects enrolled (since initiation of the study):
- ✓ Number of subjects withdrawn _____ and reasons for withdrawal (since the initiation of the study):

- ✓ Total number of study subjects effected (since initiation of the trial):

Provide a **detailed** description of all adverse events, participant complaints, implications, actions taken, and the likelihood of further risks to study subjects.

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 (or Major Advisor, if student project)

Signature: _____ Date: _____
Co-Investigator(s) (or student)

Signature: _____ Date: _____