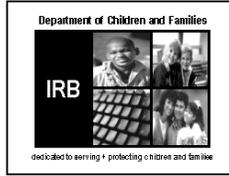




STATE OF CONNECTICUT DEPARTMENT OF CHILDREN AND FAMILIES



Institutional Review Board



REPORTING ADVERSE EVENTS

The principal investigator of approved research involving the use of humans subjects is responsible for reporting any significant harm, injuries, adverse events or unusual incidents experienced by a research subject that are associated with the research procedures. Any undesirable experience associated with the research procedures should be considered an adverse event. An event is considered **significant/serious** when the subject experiences an unusually strong response, recurring problems, unanticipated side effects and/or death.

This form should be used to report an adverse event to the IRB chair. This report should be submitted as soon as possible, but **NO LATER THAN FIVE (5) WORKING DAYS** after first awareness of the problem. The investigator should respond to the adverse event immediately, providing care in accordance with the protocol. The investigator should provide his/her opinion and support for any proposed changes in the protocol and/or consent form.

Please complete form electronically, then print out and submit signed copy. Report may be forwarded to the IRB chair electronically, but must be followed by a signed hard copy.

Date of Report:	Title of Study:
IRB number:	Principal Investigator:
Phone:	E-mail:

Type of Adverse Event: Submit report if the AE is (1) unanticipated AND (2) related or possibly related, AND (3) either serious or not serious.

- Unanticipated – the type or magnitude of the AE is NOT consistent with the risks outlined in the current protocol or consent document
- Related OR possibly related – there is a reasonable possibility the AE may have been caused by the study intervention OR it is possible that the AE may have been caused by the study intervention but there is insufficient information to determine the likelihood of this possibility.
- Serious – resulted in death or disability; is life threatening; resulted in hospitalization or other significant and unanticipated treatment; or other consequences deemed serious by the investigator.
- Not serious

Date of adverse event:	Date investigator became aware of event:
Event Location:	
Subject's ID #:	Age:



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Full description of adverse event:

Full description of actions taken:

Explanation of relationship of adverse event to study:

Describe action taken to ameliorate any discomfort or negative consequence related to the adverse event(s):

Does the adverse event suggest/require a change in study protocol and/or consent form? Yes No

Does the adverse event require that participants already enrolled be provided with any additional information? Yes No

If yes, please describe plan:

Description of any action planned or taken as a result of event such as internal procedural change; intervention with research staff; consent form change; protocol change; etc.:

Is IRB approval of a revision required with relation to any proposed changes? Yes No

NOTE: No new subjects may be entered until revisions in procedure or consent are approved.

THE IRB HAS THE RIGHT TO SUSPEND ANY STUDY PENDING A FULL REVIEW OF ANY ADVERSE EVENT(S) ASSOCIATED WITH THE STUDY

I assure the DCF IRB that this is a full and accurate account of adverse events associated with the above-named research protocol.

Signature
of Principal
Investigator:

Date:

Signature
of Faculty Advisor
(for student protocols):

Date:

Please submit your completed adverse event report form to:

Hard copy: Chair
DCF Institutional Review Board
c/o DCF Bureau of Continuous Quality Improvement
505 Hudson Street
Hartford, CT 06106

and E-mail: dcf.irb@ct.gov