COLUMBUS STATE
INSTITUTIONAL REVIEW BOARD

Adverse Event Report

This form should be used to report a single adverse event. Reports of problems involving the conduct of the study or subject participation, including problems with recruitment and/or consent processes and any deviations from the approved protocol should be described in a letter. Send to IRB Administrator, Office of Institutional Effectiveness (irb@cscc.edu).

This form must be submitted within 10 days of the occurrence of the adverse event.

Project Coordinator/ Principal Investigator		Phone Number	
Research Title		IRB Log #	
Adverse Event (3-4 words)			
Date of Adverse Event		Subject's Initials or Study ID #	

Additional details/description of event and response, if any. (A detailed report may be attached.)

Research involved:
- ☐ Human Subjects
- ☐ Animals
- ☐ Biohazards
- ☐ Other:

Adverse event appears to be: (check one)
- ☐ Directly related to the research
- ☐ Indirectly related to the research
- ☐ Unrelated to the research

Was event intended to benefit subject directly?	☐ Yes	☐ No
Was subject enrolled at a CSCC site?	☐ Yes	☐ No
Has this type of adverse event been reported before?	☐ Yes	☐ No
Is this type of event likely to occur again?	☐ Yes	☐ No
Is the event adequately described in the protocol and consent form?	☐ Yes	☐ No*
*If not, are changes needed in the protocol form?	☐ Yes**	☐ No
**If so, a modification application should accompany this report.		

What other entities (e.g., sponsors) have been notified of this adverse event?

Signature of Project Coordinator/Principal Investigator

Date