OWENS
COMMUNITY COLLEGE

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. Provide this form to the IRB Administrator located in the OSCC Office of Institutional Research, Administration Hall 227.

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

Principal Investigator/ Project Director		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 an OSCC 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 no, are changes needed in the protocol form?	☐ Yes**	☐ No
**If yes, a completed Modification Request form should accompany this report.		

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

Signature of Principal Investigator/Project Director

Date