

**Ohio University
Institutional Review Board
Adverse Event Reporting Form**

Proposal #: _____ Date: _____

Proposal Title: _____

Principal Investigator Information

Name _____ Department _____

Address _____
(If off-campus, include city, state and zip code)

Email _____ Phone _____

Study is: **Multi-site** **Ohio University only**

Did this event occur at OU? **Yes** **No**

Is this a follow-up report? **Yes** **No**
If yes, date of original report: _____

Is this protocol open to enrollment at OU? **Yes** **No**

In the judgement of the OU principal investigator, was the event caused by the therapy or procedures associated with this protocol?
Not related **Unlikely** **Possibly** **Probably** **Definitely related**

Is the risk of this adverse event included in the current, approved version of the consent form? **Yes** **No**

Should the consent form or any portion of the study be revised as a result of this event?

Yes - If yes, file a Project Amendment form and revised documents

No - If no, explain why not if the risk is related (possibly, probably, or definitely) and the risk is not currently listed in consent form.

Will currently enrolled participants be notified of this event?

Yes No

If yes, describe notification procedures.

Provide a summary of the adverse event.

Principal Investigator

Date

Please return this form to: Office of Research Compliance, 117 Research & Technology Center, Ohio University, Athens, OH 45701-2979