

Eastern Michigan University
University Human Subjects Review Committee (UHSRC)
ADVERSE EVENT REPORTING FORM

Adverse event: Any experience that has taken place during the course of a research project, which, in the opinion of the investigators, was harmful to a subject participating in the research, increased the risks of harm in the research, or had an unfavorable impact on the risk/benefit ratio.

Requirements: All adverse events must be reported to the UHSRC within **24** hours of the PI's knowledge of the adverse event. Full UHSRC Policies can be accessed at http://www.ord.emich.edu/downloads/downloads_subdir/humansubjects/HumanSub_emu_policy.pdf

Date Submitted: _____

Date of Adverse Event: _____

Title of Project: _____

Principal Investigator: _____

Phone Fax Email

1. Please attach a copy of the informed consent document(s) currently in use for this project. Check here to indicate that it is attached:

2. Describe the adverse event (include date, time, and location of event).

3. Are you submitting for approval a revised version of the informed consent document to include as risks the adverse events being reported?

If "no", check here , and please indicate the reasons for not revising the consent document (e.g., already included under risks, consent document no longer in use because subject recruitment has ended).

If "yes", check here , and please highlight the changes on your attached version for quick recognition.

4. Are you submitting, for approval, a revised version of the study protocol?

No Yes

If yes, please attach a revised version of you protocol and highlight the changes.
Check here if the revised version is attached:

5. Are you going to inform the subjects who are already enrolled in the study about the risk associated with the adverse event?

If “no”, check here , and please indicate why the subjects need not be informed of the information.

If “yes”, check here , and please indicate how and when the information will be conveyed to subjects. If it will be in writing, please submit the text for approval.

Principal Investigator:

(Sign, or type E-Signature, if submitting electronically)