

Pursuant to 45 CFR 46

HUMAN SUBJECTS ADVERSE EFFECT REPORT
Lewis-Clark State College Institutional Review Board
Social Sciences – SPH 101A
E-mail application as an attachment to the [IRB Chair](#)

Send two (2) copies of this form, and one (1) copy of the consent form signed by the subject, to the IRB Office. Keep one copy of this form for your files. **MUST BE TYPED.**

Current IRB Approval Number

Expiration Date

Principal Investigator(s): *I acknowledge that this represents an accurate and complete description of my research.*

Name of Primary PI

Signature of PI

Date

Additional Researchers' Names

Mailing Address

Division

Telephone Number

E-mail address (Student's lmail account)

Adviser (complete if PI is a student): I agree to provide the proper surveillance of this project to ensure that the rights and welfare of the human subjects are properly protected.

Name of Adviser/Chair (typed)

Signature of Adviser/Chair

Date

Adviser's Address

Adviser's E-mail address

Telephone

Title of Project

Did this event occur to a subject enrolled in your study? ___ Yes ___ No

Was the event attributable to a study procedure? * ___ Cannot be ruled out ___ Yes ___ No

Was the event unexpected or more serious than expected? ___ Yes ___ No

Is this kind of adverse event described in the currently approved
consent form? ___ Yes ___ No

Will the event require changes in the consent form or in the research procedures? Yes No

If yes, attach a copy of the revised consent form with the changes highlighted.

Have you reported this event to the study sponsor? Not applicable Yes No

Have you reported this event to the FDA? Not applicable Yes No

Have you reported this event to the NIH Office Not applicable Yes No

Has this kind of event happened before in connection with this study? Yes No

If yes, explain below.

Who is financially responsible for treatment of this adverse event? Not applicable

Sponsor: _____

Subject/subject's insurer: _____

Other - - please explain

Estimate of cost for treatment: _____ Not applicable

Where was care provided: _____ Not applicable

Subject's name: _____ Not applicable

Address: _____ Not applicable

Date(s) of occurrence: _____ Location of event: _____ Time (am, pm): _____

Description of adverse effect and action take (use additional pages, if necessary):

*If any relationship between the event and the study can be ruled out, do not submit this form.

Signature of Investigator _____ **Date** _____

Signature of IRB Chair _____ **Date** _____