Pursuant to 45 CFR 46

## **HUMAN SUBJECTS ADVERSE EFFECT REPORT**

# Lewis-Clark State College Institutional Review Board

**E-mail application as an attachment to the** [**IRB Chair**](mailto:irb@lcsc.edu)

Send two (2) copies of this form, and one (1) copy of the consent form signed by the participant, to the [Lewis-Clark State College IRB](mailto:irb@lcsc.edu). Keep one copy of this form for your files. MUST BE TYPED.

|  |
| --- |
| Title of Project |

|  |  |  |
| --- | --- | --- |
|  |  |  |

Current IRB Approval Number Expiration Date

**Principal Investigator(s):** *I affirm that this represents an accurate and complete description of the adverse effect(s) related to this research.*

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| --- | --- | --- | --- | --- |
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Name of Primary PI Signature of PI Date

|  |  |  |
| --- | --- | --- |
|  |  |  |

Mailing Address Division

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Telephone Number |  | E-mail address (If student, use lcmail account) |
|  | | |

Additional Researchers’ Names

**Adviser (complete if PI is a student):**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
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Name of Adviser/Chair (typed) Signature of Adviser/Chair Date

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |

Adviser’s Address Adviser’s E-mail address Telephone

1. Did this event occur to a participant enrolled in your study? \_\_\_Yes \_\_\_No
2. Was the event attributable to a study procedure? \*Cannot be ruled out \_\_\_Yes \_\_\_No
3. Was the event unexpected or more serious than expected? \_\_\_Yes \_\_\_No
4. Is this kind of adverse event described in the currently approved

consent form? \_\_\_Yes \_\_\_No

1. Will the event require changes in the consent form or in the  
    research procedures? \_\_\_Yes \_\_\_No
2. If yes, attach a copy of the revised consent form with the changes highlighted.
3. Have you reported this event to the study sponsor? \_\_\_Not applicable \_\_\_Yes \_\_\_No
4. Have you reported this event to the FDA? \_\_\_Not applicable \_\_\_Yes \_\_\_No
5. Have you reported this event to the NIH Office \_\_\_Not applicable \_\_\_Yes \_\_\_No
6. Has this kind of event happened before in connection with this study? \_\_\_Yes \_\_\_No

**If yes, explain below**.

1. Who is financially responsible for the treatment of this adverse event?

\_\_\_Not applicable

\_\_\_Sponsor: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_Participant/participant’s insurer: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_Other - - please explain \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Estimate of cost for treatment: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_Not applicable

Where was care provided: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_Not applicable

Participant’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 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**