Pursuant to 45 CFR 46

# CONTINUATION FORM

# Submit with signatures to the

# Lewis-Clark State College Institutional Review Board

**E-mail application as an attachment to the** **IRB Chair**

**Please submit at least** **three weeks before the expiration date**. Please note: You may not recruit new human participants or continue your activity with previously enrolled participants beyond the expiration date unless you have received approval for the continuation of the project.

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

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

Current IRB Approval Number Expiration Date

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

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

Name of Primary PI Signature of PI Date

|  |
| --- |
|  |

Additional Researchers’ Names

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

Mailing Address Division

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Telephone Number |  | E-mail address (If student, use lcmail 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 participants are properly protected.

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

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

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

***I. Research Activity Status*** (please check as applicable):

 \_\_\_ New participant enrollment still in progress

 \_\_\_ Enrollment closed, but participants are still undergoing study procedures

 \_\_\_ Enrollment closed, participants have completed study procedures, but are still in follow-up

 \_\_\_ Participant involvement completed, need approval for continued use of identifiers for data analysis only

1. ***Participant Status:***

|  |  |
| --- | --- |
| Number of participants approved in original IRB application |  |
| Number of participants actively enrolled in the study |  |
| Number of additional participants needed to complete the study |  |

***III. Research Progress Report:***

1. Provide a summary of the **purpose** of this research activity, the study population, sample procedure, and methodology.

2. Provide a summary of your progress to date, to include any changes you have made to the methodology during the last period of approval which were approved with a modification.

3. Describe any changes in the risks or benefits to participants over the last period of approval.

4. If you propose changes to this activity for the next period of approval, summarize the changes. Also attach copies of the revised consent or assent forms and any other revised study materials, if applicable.

5. Have there been any changes in key personnel? \_\_\_Yes \_\_\_No If yes, explain why the changes were made.

***IV. Adverse Events:***

1. Did any adverse effects occur? \_\_\_Yes \_\_\_No

2. If yes, provide the number of adverse events: \_\_\_\_\_ Explain how you handled each adverse event.

3. Were any of these adverse events unexpected or more serious than expected? \_\_\_Yes \_\_\_No

4. If yes, did you send us an Adverse Event report? \_\_\_Yes \_\_\_No

5. If not, please complete the Human Participants Adverse Effect Report and send it to the IRB Chair immediately with this continuation form.

6. Number of complaints: \_\_\_\_\_\_\_\_ Explain how you handled each one.

7. Number of participant withdrawals: \_\_\_\_\_\_\_\_ For each, explain why the participant chose to withdraw or why you withdrew the participant from the study.

8. Number of protocol violations: \_\_\_\_\_\_\_\_ Explain how you handled each one.

1. ***Grant Status***

Funding: Please review and update the grant and contract information listed below, if applicable.

Is there new funding proposed for this activity? \_\_\_Yes \_\_\_No If yes, send us one complete copy of the proposal and explain if there are any differences between this new proposal and what is approved in this application.

Please include all funding, current and pending, for this Continuation/Renewal application.

**Funding Type:**

\_\_\_Research Grant \_\_\_Fellowship \_\_\_Training Grant \_\_\_Contract \_\_\_Other, specify:

Funding Agency: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Principal Investigator (on proposal): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Agency Number (if known): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Proposal Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Status: \_\_\_New \_\_\_Competing \_\_\_Non-Competing

Start Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ End Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Funded? \_\_\_Yes \_\_\_No