

Form E

Amendment to Previously Approved Research

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DATE

DATE OF INITIAL APPROVAL _____

CIRCLE TYPE OF REVIEW: E XEMPT EXPEDITED FULL IRB

Investigator(s): List all Faculty, Staff, and/or Students conducting this research:

Name	Location	Phone
P.I. _____	_____	_____
Co-P.I. _____	_____	_____
Co-P.I. _____	_____	_____
Co-P.I. _____	_____	_____
Co-P.I. _____	_____	_____

BEFORE YOU MAY INITIATE ANY CHANGES TO YOUR RESEARCH, THE INSTITUTIONAL REVIEW BOARD MUST REVIEW AND APPROVE THE CHANGES. PLEASE FOLLOW THESE INSTRUCTIONS CAREFULLY.

- I. Changes to the Research
 - A. Key Research Personnel: Are you requesting a change in key research personnel?
 - No
 - Yes. (Attach description)

 - B. Research Protocol and Instruments: Are you requesting any changes to the research protocol and/or instruments?
 - No
 - Yes. (Attach description. I am also submitting a revised protocol and revised instruments.)

 - C. Research Subjects: Are you requesting any changes to the type (for example: age, gender, race) and/or number of subjects being recruited and enrolled?
 - No
 - Yes. (Attach description. I am also submitting a revised protocol.)

D. Consent documents: Are you requesting any changes to the consent documents?

No

Yes. (Attach description. I am also submitting revised consent documents.)

E. Other changes: Are you requesting any other changes to the research?

No

Yes. (Attach description. I am also submitting supporting documents as needed.)

II. Research Compliance

A. Is this amendment being submitted in response to subject complaints, unanticipated problems, and/or serious adverse events?

No

Yes. (Attach description.)

B. Is the amendment being submitted to report and/or in response to the disapproval, suspension, termination, or administrative hold of this research by any non-Lewis University IRB?

No

Yes. (Attach description.)

III. Notification of Subjects

A. Will actively participating subjects that have already provided informed consent OR subjects that have completed participation be notified of the changes made in this amendment?

No. (Indicate reason why not.)

Yes. (Attach description.)

IV. Amendment Summary

Provide a summary here of the changes in this proposed amendment as indicated from questions above. I will also submit a revised research protocol and/or supporting documents pertinent to the changes described.

Investigator's Assurance

I certify that the information provided in this application for review is complete and correct. I understand that as Principal Investigator, I have ultimate responsibility for the protection of the rights and welfare of human participants, conduct of the study and the ethical performance of the project. I agree to comply with all IRB policies and procedures, as well as with all applicable federal, state and local laws regarding the protection of human participants in research, including, but not limited to, the following:

- The project will be performed by qualified personnel according to the Lewis University IRB certified protocol.
- No changes will be made in the protocol or consent form until approved by the Lewis University IRB.
- Legally effective informed consent will be obtained from human participants if applicable.
- Adverse events will be reported to the Lewis University IRB in a timely manner.

I further certify that the proposed research is not currently underway (except for those protocols of research previously approved and currently seeking renewal) and will not begin until approval has been obtained.

Principal Investigator's Signature _____ Date _____

Faculty Sponsor's Assurance for Student or Guest Investigators

By my signature as sponsor on this research application, I certify that the student or guest investigator is knowledgeable about the regulations and policies governing research with human participants and has sufficient training and experience to conduct this particular study in accord with the approved protocol. In addition,

- I agree to meet with the investigator on a regular basis to monitor study progress.
- Should problems arise during the course of the study, I agree to be available, personally, to supervise the investigator in solving them.
- I insure that the investigator will promptly report significant or untoward adverse effects to the Lewis University IRB in a timely manner.

If I will be unavailable, as when on sabbatical leave or vacation, I will arrange for an alternate faculty sponsor to assume responsibility during my absence and I will advise the Lewis University IRB by letter of such arrangements. I further certify that the proposed research is not currently underway and will not begin until approval has been obtained.

Faculty Sponsor's Signature _____ Date _____

The faculty sponsor must be a member of the Lewis University faculty. The faculty member is considered the responsible party for legal and ethical performance of the project.