Form E

Amendment to Previously Approved Research

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DATE

DATE OF INITIAL APPROVA L_____

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.			_____

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?
‘ 1 R
‘ Yes. (Attach description)

B. Research Protocol and Instruments: Are you requesting any changes to the research protocol and/or instruments?
‘ 1 R
‘ 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?
‘ 1 R
‘ < H V $ W W D F K H G Y H U V L R Q L D P D O V R V X E P L W W L Q J D U H Y L V H G S U R W R F R O .)

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

- ○
- ○ ISWWDKFKHEULSWLRQ . I am also submitting revised consent documents.)

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

- ○
- ○ 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?

- ○
- ○ . (Attach description.) 1D DÞÌÍL• E ÍL• F G H I P ÍL• Q Q T

Investigatorôs 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 Signature _____ Date _____