

Request for Continuing IRB Approval

La Sierra University Institutional Review Board

Part 1: Administrative Information

1. Protocol Information

IRB Protocol #: _____

Title: _____

Expiration date of the last IRB approval: _____

2. Contact Information

Principal Investigator (PI): _____

ID#: _____

E-mail: _____ Phone: _____

Department: _____ College: _____

Status: Undergraduate Student Graduate Student Faculty Staff

Others: Specify _____

Faculty Supervisor (if student project) _____ Dept. _____

E-mail _____ Phone _____

Part 2: Study Overview

1. Please summarize the research activities since last IRB approval (excluding amendment approvals):

2. Since the last IRB approval (excluding amendment approvals),

a. were there any participant withdrawals from the study or complaints about the research activities? Yes ___ No ___

If yes, explain

b. were there any unexpected problems or adverse events involving risks to participants?
Yes ___ No ___

If yes, explain

- c. were there any changes to your study (including with recruitment, informed consent, study design and/or research procedures, research personnel, study location, etc.)?

Yes ___ No ___

If yes, explain

3. Research activities planned for the next year or more

- a. Do you plan to recruit new participants? Yes ___ No ___

- b. Do you plan to collect new or additional data from current research participants?

Yes ___ No ___

Part 3: Amendment Information (Check here ___ if it is not applicable.)

1. Please select ALL the categories of amendment(s) you are requesting.

- Change in Study Title
- Change in Principal Investigator
- Addition of/change in research personnel
- Addition of/change in funding source
- Change to research/study design, methods or procedures (e.g., observations, interventions, collection of biological samples or biometric information, participant tasks, etc)
- Addition of/change to study population
- Addition of/change to recruitment or compensation procedure(s)
- Addition of/change to survey(s), questionnaire(s), or other research instruments – *please attach the revised instrument(s)*
- Addition of/change to the identifiers collected in the study, or any others that would impact the privacy and confidentiality of the study participants
- Addition of/change to informed consent/assent document(s) and/or procedures – *please attach all related documents*
- Other changes

2. Please describe the changes you are proposing.

3. Please state the reasons you are making amendments to the study.

4. Will the proposed changes have an impact on the risks or benefits to research participants? Please explain.

5. Do these changes involve information that might relate to a subject's willingness to continue to take part in the research? Yes No

If yes, explain

Signature

This page is to be signed by the principal investigator. If the principal investigator is an undergraduate or graduate student, the faculty supervisor must also sign in the lower box.

OPTIONAL: You may submit an electronic copy of this application by clicking on the attestation box below and entering your name and today's date. After clicking on the attestation box, please save a copy of the form before emailing it to irb@lasierra.edu. If you are a student, send this file to your faculty supervisor (in addition to your sending this to the IRB office), and ask your faculty supervisor to send his/her approval to irb@lasierra.edu. The email submission must come from your La Sierra email account. (If you don't have a La Sierra email account, contact the IRB office.)

Principal Investigator

I certify that the information I provide in this application is correct and complete. I also pledge that I will not change any of the procedures, forms, or protocols used in this study without first seeking review and approval from the Institutional Review Board for Human Participants.

___ Attestation of Principal Investigator (*for email submissions*)

Applicant's Name _____ Date _____

Applicant's Signature _____ Date _____

Faculty Supervisor (if student project) _____ Date _____