

Institutional Review Board Application for Research Using Humans

Part 1: Administrative Information

1. Title of protocol

2. Contact information

Applicant's Full Name _____ ID# _____ Dept. _____

Address _____ City _____ State _____ Zip _____

E-mail _____ Phone _____

Applicant Status: Undergraduate Student Graduate Student Faculty Staff
 Others: specify _____

Faculty Supervisor (if student project) _____ Dept. _____

E-mail _____ Phone _____

Dates of Entire Project Period from _____ to _____

3. Funding Information

Indicate if your project is funded by an external (non-La Sierra) sponsor, including a gift or a sponsored award.

- Federal Funding Agency
- Student projects funded fully or in part by Federal funds received by a Faculty Advisor
- Non Federal sponsor that requires compliance with Federal IRB regulations
- Other Funding source
- My research is not funded by any outside funding agency
(this option should be available only if none of the above are selected)

Name of the external funding agency:

Provide the Sponsor's Project ID number

Part 2: Study Design, Methods and Procedures

1. Type of project/study: Please select ALL of the categories of work that apply to this proposed project.

- Active collection of data (not human biological materials or physiological data)
- Active collection and use of human biological materials or physiological data
- Use of physiological or biomedical devices, or drugs, biological, or chemical agents
- Use of existing data (not human biological materials)
- Use of existing human biological materials

2. Please provide a lay summary of the study, including the purpose, research questions and hypotheses to be evaluated. (If you need more space for your answer, please attach separately.)

3. Please describe briefly how this study will contribute to existing knowledge in the field.
(If you need more space for your answer, please attach separately.)

4. Will your research involve a questionnaire, interview, or both? _____
(If instruments will be used, please attach a copy of each to your protocol.)

Part 3: Participants, Recruitment and Compensation

1. Please provide the estimated number of participants you plan to recruit.

2. Please provide the age range of the participants.

3. Please select all the categories of participants that will be included in your study.

- Healthy adult volunteers
 - Children or minor individuals under 18
 - La Sierra students
 - La Sierra employees
 - Cognitively impaired persons
 - Pregnant or nursing women
 - Prisoners or individuals under detention or on probation
 - People in foreign countries
 - People unable to read, speak or understand English
 - People with limited literacy
 - People with specific health conditions
 - Other category of participants not listed above
- Please explain below:

None of the above

4. Please select all of the tools that you plan to use to recruit your participants.

- Flyers
- Notices
- Mailers (U.S. Post)
- Online Advertisements
- Email
- Use of Internet social media or online networking sites
- TV, radio, print advertisements
- La Sierra participant pool recruiting methods (such as Sona Systems or other La Sierra-affiliated web-based participant pool management software)
- Face to face public intercept
- Presentations at meetings
- Other (Please describe below)

5. Please describe each recruitment method to be used.

6. Describe the inclusion or exclusion criteria for participants as applicable in this study.

7. Will participants be compensated for their participation? ___ Yes ___ No

If yes, please describe the type and amount of compensation.

8. Please describe the tasks that the participants will be asked to perform for each phase of the study.

9. Please provide an estimate of the time commitment from each participant for each phase of the study.

Part 4: Risks and Benefits

1. From the list below, please select ALL of the potential risks that are involved in your study.

- Use of deceptive techniques
- Use of private records (such as educational or medical records)
- Manipulation of psychological or social state such as sensory deprivation, social isolation, psychological stress
- Probing for personal or sensitive information in surveys or interviews (e.g.: private behaviors, sexual activities, employer assessments)
- Presentation of materials which some participants may consider sensitive, offensive, threatening or degrading
- Possible invasion of privacy of subject or subject's family
- Social or economic risk (reputational, cultural, employability, etc.)
- Identification of child, spousal, or elder abuse
- Identification of illegal activity (e.g. drug use)
- Risk of injury or bodily harm
- Other (Please specify)

if none of the risks above are selected.

There are no risks of any kind to any participants enrolled in this study. *This option is valid only*

2. Describe the nature and degree of the risks or harm selected above. All of the risks/harms must be disclosed in the consent form.

3. Describe the steps that will be taken to minimize risks or harms and to protect the welfare of participants. Include a description of how you will handle an adverse or unexpected outcome that could be potentially harmful (e.g., suicidal ideation). If the study will include protected populations, identify each group and provide an explanatory paragraph for each group.

4. Describe any benefits that individuals may reasonably expect from participation. If there are none, state "None."

. Describe the anticipated benefits of this study to society, academic knowledge or both.

Part 5: Privacy and Confidentiality

1. Will you or any member of your research team collect or have access to any of the personal identifiers listed below? Select all that apply.

- Name
- Date of birth
- Mailing or email address
- Phone or fax numbers
- Social Security number
- Medical records
- License, certificate or Vehicle ID
- IP (internet protocol) address
- Biometric identifiers
- Photos/images/audio/video recording
- Signatures, handwriting samples
- Any unique identifier not mentioned above: _____
- No member of the research team will have access to any personal identifiers.
This option is valid only if none of the other options in this question are selected.

Part 6: Consent Process

1. Informed Consent:

Will you use a written informed consent document?

- Yes
- No, I am requesting a waiver of written informed consent
- Not applicable

Will you use a verbal informed consent?

- Yes
- No, I am requesting a waiver
- Not applicable

2. Written assent for individuals under 18:

Will you obtain written assent for children and individuals under 18?

- Yes
- No, I am requesting a waiver of written assent
- Not applicable

3. Written parental permission:

Will you obtain written parental or guardian permission for children and individuals under 18?

- Yes
- No, I am requesting a waiver of written parental or guardian permission
- Not applicable

Part 7: Triennial Review

This project may be eligible for Triennial review, which means that this project will be reviewed every three years instead of annually. No changes to the study can be implemented however, before an amendment is submitted to the IRB and the PI receives written approval from the IRB office. The IRB policy on Triennial Review is on the IRB website at www.lasierra.edu/irb

Indicate if you would like to proceed with Triennial review or request an Annual review (recommended if you are expecting to receive Federal funding for some part of this study).

Options:

- Proceed with Triennial Review
- Request Annual Review

Reminder Check List

You have now completed this form. Please review it to ensure that it is filled out completely and accurately. Please save this form and proceed to the signature page for submission instructions.

Please include (attach) informed consent form(s) with this application. If your research does not use a consent form, please indicate how you will obtain participant consent.

In case of research involving children include both forms used to solicit the assent of the children and the permission of their parent(s) and/or guardian(s).

Please include (attach) all the questionnaires, surveys, or any other data collection protocols with this application.

Please include (attach) the certificate of completion of free online FHI Research Ethics Training that can be found at <https://www.fhi360.org/sites/all/libraries/webpages/fhi-retc2/RETCTraditional/intro.html> (if you are a student of a class and need an IRB approval for your class project (i.e. PSYC 323, EXSC 364, etc.), ask your instructor about this training requirement.)

If you have any questions or need assistance, please contact the IRB office.

Phone: (951) 785-2099
Office: Ambs Hall 150
Email: irb@lasierra.edu

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 _____

Updated 01/17