

For Office Use Only:

Date Reviewed:

IRB Case No:

Action: ☐ Exempt ☐ Full Review
☐ Not Approved

IRB Reviewer:

LOGOS EVANGELICAL SEMINARY INSTITUTIONAL REVIEW BOARD (IRB) RESEARCH PROPOSAL FOR HUMAN PARTICIPANTS

The Logos IRB reviews requests to conduct research involving human participants. It is the investigator's responsibility to give complete information regarding procedures and the informed consent process. If the principal investigator is a student, the application must be approved and signed by the applicant's first mentor or the academic dean.

After completing the application and obtaining required signatures, one original copy of the application and all supporting materials must be forwarded to Dr. Amy Lin, Chair of the IRB. The IRB will notify each applicant of the IRB's decision. If you have questions, please contact Professor Amy Lin by email: amylin@les.edu or 626-571-5110 ext. 154.

The Principal Investigator must supply the required documentation listed below:

- ☐ A copy of all questionnaires or survey instruments
- ☐ Informed consent document(s)
- ☐ Letters of approval from cooperating institutions (if appropriate)
- ☐ All required signatures

Please type or print responses. Failure to provide all required information will result in the return of this application for correction prior to IRB review.

PROJECT TITLE:

1. Principal Investigator's Name: _____
 Phone: _____
 Mailing Address: _____
 Email: _____

For Students Only

- First Mentor: _____
 Second Mentor: _____
 If the mentors are not Logos full-time faculty, please provide mentor's:
 Email: _____ Phone: _____

Is this a Thesis/Dissertation? ____ yes ____ no

Other? _____

2. Project Start Date: _____ Project End Date: _____

3. Is this a continuation/revision of an IRB project? ____ yes ____ no

If yes, previous IRB case number: _____

4. **PROJECT DESCRIPTION:** *The IRB must have sufficient information about what will happen to the subjects in order to evaluate and estimate possible risks. Assurance from the investigator, no matter how strong, will not substitute for a description of the transactions between the investigator and subject. Provide a brief, nontechnical summary of the proposed research.*

5. **SUBJECT SELECTION:**

All individuals involved will be informants.

Will subjects be less than 18 years of age? ____ yes ____ no

Age range of subjects: From _____

Will subjects be students at Logos? ____ yes ____ no

How many subjects will participate? _____

How will subjects be selected, enlisted or recruited?

6. **INFORMED CONSENT PROCESS:** Describe the informed consent process and attach a copy of all consent documents. Describe the process of both consent & withdrawal. If appropriate, describe how assent will be obtained from children and/or developmentally delayed persons. When the consent of a legally authorized representative is substituted for consent of the adult participant, explain why this is necessary. If non-English-speaking participants will be enrolled, a consent form should be prepared in their native language. Someone who is fluent in the participants' language must be available to interpret. Attach a copy of all written informed consent documents.

7. **PROCEDURES:** Provide a step-by-step description of each procedure, including the frequency, duration, and location of each procedure. Include kinds of data to be collected;

primary outcome measurements; and follow-up procedures, if any. Attach relevant materials and add extra pages as needed.

8. **CONFIDENTIALITY AND ANONYMITY:** How will subjects' privacy be maintained and confidentiality be guaranteed?

9. **RISKS:** Describe all known and anticipated risks to the subject, paying close attention to the potential physical, emotional, and psychological effects of all procedures. Include risk of psychosocial harm (e.g., deception, emotional distress, embarrassment, breach of confidentiality, etc.) economic harm (e.g. loss of insurability) and legal jeopardy (e.g., disclosure of illegal activity) and risk of pain or physical injury. *State clearly EITHER 1) that an individual's participation in the project is completely anonymous; OR, 2) that an individual's participation in the project is confidential. If the latter, state how confidentiality will be ensured and maintained, including where data will be kept & who will have access to it during & after the study.*

10. **BENEFITS:** Describe what benefits, if any, the subjects may derive from participation in your study. The possibility of benefits to society should be clearly distinguished from the possibility of benefit to the individual participant, if any. If there is no direct benefit to the individual participant, say so. Do not list monetary payment as a benefit.

RESPONSIBILITIES OF THE PRINCIPAL INVESTIGATOR:

- *Any additions to or changes in procedures in this protocol must be submitted to the IRB for written approval prior to the changes being put into practice.*
- *Any problems connected with the use of human subjects once the project has begun must be brought immediately to the attention of the IRB Chair.*
- *The principal investigator and his or her designee(s) are responsible for retaining informed Consent Documents for a period of **five** years after the completion of the project.*

The principal investigator may not initiate any research involving human subjects until written notification of IRB approval of this research protocol has been received. Formal approval by the IRB may include specific directives concerning the responsible conduct of research for particular aspects of the project, or may specify steps necessary for compliance in certain contingencies. The investigator must indicate to the IRB Chair the acceptance of such modifications before research may begin.

