

**La Salle University
Research With Human Participants
Application**

Please type your information directly onto this form, print it, and submit to the Institutional Review Board Chair. Please use the checklist (<http://www.lasalle.edu/academ/irb/checklist.doc>) to make sure you have included everything necessary.

Faculty Member's Name(s)*:

Signature: _____

Address, Phone Number, and Email Address of Principal Investigator:

**As Faculty Sponsor you accept responsibility for the research described. You agree to be fully aware of all procedures to be followed, will monitor the research, and will discuss any problems or changes to the research protocol with other committee members and any outside reviewers.*

Student's Name (if any):

Signature: _____

Address, Phone Number, and Email Address of Student(s):

Title of Project:

Funding Agency (if any):

Date Submitted to IRB:

Category of Review: *(All proposals undergo a regular review of the full Institutional Review Board unless they meet the Federal requirements for exempt or expedited research. Please indicate which type of review you are requesting and add appropriate paragraph number to exempt and expedited applications. If you are uncertain about the categories, review:*

Exempt proposals: <http://www.lasalle.edu/academ/irb/exempted.pdf>

Expedited proposals: <http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm>

- Renewal (please submit copy of original IRB approval)**
- Exempt Review (Paragraph # _____)**
- Expedited Review (Paragraph # _____)**
- Regular Review**

Proposed Start Date of Project:

Proposed End Date of Project:

Please Answer All of the Following Questions

1. Does this study involve human subjects ____ Yes ____ No

2. Does this study involve an investigational (non-standard and/or unapproved) procedure?

____ Yes ____ No

If yes provide description of procedure and how it differs from current approved or accepted.

3. Will this study involve payment for participation?

____ Yes ____ No

If yes, indicate the amount of payment and partial payment in the event this study is not completed:

4. Will notices or advertisements be employed to recruit participants into this study?

____ Yes ____ No

If yes, such posters/advertisements must be attached for approval by the IRB.

5. Does this study involve warm-blooded (nonhuman) animals?

____ Yes ____ No

6. Does this study involve the use of pharmaceuticals in humans?

____ Yes ____ No

If yes, please list drugs:

Are these drugs approved by the FDA for the use indicated?

____ Yes ____ No

If no, provide IDN# & Sponsor for each drug.

7. Does this study involve the use of a medical device?

Yes No

If yes, list devices:

Has this device been approved by the PDA for the use indicated?

Yes No

If no indicated status of FDA Application for each device:

8. State objective of the research (including Research Questions/Hypotheses).

(Use clear language understandable to scholars outside your discipline; insert your description here, do not include attached pages.)

9. Describe the methodology of the research. Describe your protocol in sufficient detail to provide a sufficient and accurate description of the work when separated from the application. Make sure to describe characteristics of the subject population, such as their anticipated number, age ranges, sex, ethnic background, and health status. Identify the criteria for inclusion or exclusion. Explain the rationale for the use of special classes of subjects, such as fetuses, pregnant women, children, institutionalized, mentally disabled, prisoners, or others who are likely to be vulnerable. (Do not exceed 2 pages; Use clear language understandable to scholars outside your discipline; insert your description here, do not include attached pages.)

10. Identify the sources of research material obtained from individually identifiable living human subjects in the form of specimens, records, or data. Indicate to what extent these data have already been collected, and where and how they have been collected.

11. Describe plans for recruitment of subjects, including the consent procedures to be followed, including the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects and the methods of documenting consent. PLEASE ATTACH A COPY OF YOUR CONSENT/ASSENT FORMS IMMEDIATELY AFTER THIS APPLICATION.

12. Describe any potential risks—physical, psychological, social, legal, or other—and assess their likelihood and seriousness. Where appropriate, describe alternative treatment and procedures that might be advantageous to the subjects. Describe the procedures for protecting against or minimizing any risks to confidentiality, and assess their likely effectiveness. Where appropriate, discuss provision for insuring necessary medical or professional intervention in the event of adverse effects to the subjects. Also, where appropriate, describe the provisions for monitoring the data to be collected to insure the safety of the subjects.

13. Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and in relation to the importance of the knowledge that may reasonably be expected to result.

Please review the checklist; financial compensation is not considered a benefit.

14. Are the researchers receiving any financial compensation or other benefits for conducting the research? If so, please describe how potential conflicts of interest will be addressed.

*Immediately after this form, please submit a copy of the following things **in this order**: (a) your consent form(s)/assent form(s), (b) copies of scales/ measures/ procedures the participants will be asked to fill out/perform, and (c) vitae of all researchers.*