

INSTITUTIONAL REVIEW BOARD
CALIFORNIA STATE UNIVERSITY, LOS ANGELES

REQUEST FOR REVIEW OF A PROJECT INVOLVING HUMAN SUBJECTS
(Please type)

This document is to be completed by the person with the primary responsibility for conducting the research: generally, the Principal Investigator (PI). If the PI is not a full-time staff or faculty member of CSLA, a full-time faculty or staff member must take responsibility for the use of human subjects. A copy of this document should be submitted at least 10 working days prior to the next scheduled meeting of the Institutional Review Board and prior to the involvement of human subjects. For requests involving funding from outside agencies, or any questions regarding this document, please contact the Research and Sponsored Programs Office, ext. 3-5366.

1. Name of principal investigator: _____
2. Phone _____ Email _____
3. Name of faculty/staff adviser for student or non-CSLA PIs: _____

4. Phone _____ Email _____
5. Department/Division: _____
6. Phone _____ Email _____
7. Title of project _____
(Include course number if applicable)
8. External funding source (if any): _____
New _____ Continuation _____ Renewal _____ Modification _____ Denied _____
7. Project period under review: _____ - _____ - _____ to _____ - _____ - _____
(One year maximum)
9. Entire project period: _____ - _____ - _____ to _____ - _____ - _____
10. Request for expedited review _____. If you believe you qualify for expedited review, please submit an explanation with this form. (See guidelines for expedited review.)

FOR OFFICE USE ONLY

Application No.: _____ Approved _____ Denied _____

Chair of IRB: _____
(Type name) (Signature)

Minutes of Meeting # _____ Date: _____

11. Indicate with an "X" which of the following apply to your project.

A. Purpose of Research

Student-conducted activity

B. Subject Characteristics

- Minors (less than 18 years of age)
- Hospitalized persons
- Prisoners and/or parolees
- Pregnant women
- Mentally and/or physically disabled persons
- Persons not competent in English
- Exercising subjects

C. Research Material

- Fluids, tissues, organs removed from persons living or dead
- Public behavior
- Documents, data banks or other records
- Survey instruments including interviews and questionnaires
(Attach a copy of the survey instrument to be used)
- Excreta and/or external excretions
- Data collected using sensors applied to the surface of the body or
at a small distance (e.g., electrocardiogram, thermograph)
- Film, videotape or voice recordings
- Fetuses (in utero, ex utero, dead)
- Human in vitro fertilization

D. Subject Recruitment

- Written consent forms would place subjects at risk (as in the study
of illegal or stigmatized behavior characteristics)
- Fully informed consent would imperil the validity of research
findings
- Use of procedures for which written consent is normally required even of
outside of the research context (e.g., physical intrusion into the body)
- Subject to be paid
- Subject not to be paid

E. Risks

- Hazardous materials (must also be reviewed by the Biohazards)
- Drugs
- Use of placebo(s) or other deceptive research methodologies
- Use of unproved or experimental devices, materials, or procedures

F. Preliminary review

- Use of human subjects is expected, but the specific nature of
their involvement will not be known until sometime after the project
start date (For projects seeking external funding which must reviewed
prior to submission.)

PLEASE ATTACH THE FOLLOWING TO THIS APPLICATION:

- A. Project Abstract: In a brief abstract, cover each of the following topics. In topics 1-5 include an explanation of any procedures marked in the corresponding sections of Question 11. If F Preliminary review) was marked in Question 11, please include an explanation here.
1. **Introduction:** Introduction to the area and issues of the field, leading to the statement of the problem, justification of the study, purpose of the study, and hypothesis (1 -2 pages).
 2. **Methods and Procedures:** The following areas should be covered:
 - a. **Subject Characteristics and Recruitment:** Describe the 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. Describe plans for the recruitment of subjects and the consent procedures to be followed, including the circumstance 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 method of documenting consent.
 - b. **Research Instrumentation/Material:** Identify the type(s) of instrumentation used in obtaining data (e.g., questionnaire, interview, electrocardiograph, blood pressure monitor, syringes). If questionnaires are used, indicate if they are modifications of standard scales (cite references) or self-developed. Identify the sources of research material obtained from individually identifiable living human subjects and the form (specimens, records, or data). Indicate if use is existing specimens, records, or data or whether the material or data will be obtained specifically for this research project.
 - c. **Analysis of Data:** Briefly describe the different types of statistical treatment or methods to be used to analyze the data and how the results will be reported (e.g., thesis, journal article).
 3. **Risks:** Describe any potential risks—physical, psychological, social, legal, biological, environmental, chemical, radiological or other--and assess their likelihood and seriousness. Where appropriate, describe alternative treatments and procedures that might be advantageous to the subjects.
 4. **Risk Reduction:** Describe the procedure for protecting against or minimizing any potential risks, including risks to confidentiality, and assess their likely effectiveness. Indicate where data (e.g., surveys, video tapes, audio tapes) will be stored, who will have access to the data, and the length of time data will be kept. Where appropriate, describe the provisions for monitoring the data collected to ensure the safety and confidentiality of the subject. Also, where appropriate, discuss provisions for ensuring necessary medical or professional intervention in the event of adverse effects to the subject.
 5. **Risk/Benefit Ratio:** 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.

- B. A legally effective *Informed Consent* form, if applicable. (See *Procedures and Guidelines for Obtaining Institutional Approval for Research and Research-Related Activities Involving Human Subjects*.) Provide translations and back translations if necessary (e.g., from English to Chinese and from Chinese back to English, done by two different translators). It is the Principal Investigator's responsibility to make sure that each participant gets one copy and the Principal Investigator retains one copy.
- C. Any additional information that would allow the IRB to make a complete assessment of your project, e.g., data collection instruments, translations and back translations of documents, letters from external sites (e.g., school or agency) indicating that the researcher has permission to conduct the research.

The Principal Investigator must assure the Institutional Review Board that all procedures performed under the protocol will be conducted by individuals legally and responsibly entitled to do so, and that any deviation from the protocol will be submitted, in writing, to the Institutional Review Board for its approval prior to implementation.

Signature of Principal Investigator

Date

Signature of Faculty/Staff adviser (If PI is student or non-CSLA PI)

Date

Signature of Department Chair/Dean

Date

Revised 6/5/98