



Proposal Number

Date Received

**PROTOCOL for Research Involving
Human Subjects**

Institutional Review Board (IRB) approval is required before beginning any research and/or data collection involving human subjects

(Reference IRB Policies and Procedures for clarification)

Project Title _____

Researcher/Project Director _____

Phone # _____ **E-mail Address** _____

Faculty Sponsor (if required) _____

Department _____

Project Dates _____ **to** _____

Sponsoring Agent (if applicable) _____

Project to be Conducted at _____

Project Purpose: *Thesis* *Research* *Class Project* *Other*

Keep a copy of this form for your records.

Required IRB Training

The training requirement can be satisfied by completing the online training session at <http://cme.nci.nih.gov/>. A copy of your certification of training must be attached to this IRB Protocol. If you have completed the training at an earlier date and have already provided documentation to the California University of Pennsylvania Grants Office, please provide the following:

Previous Project Title _____

Date of Previous IRB Protocol _____

Please attach a typed, detailed summary of your project AND complete items 2 through 6.

1. *Provide an overview of your project-proposal describing what you plan to do and how you will go about doing it. Include any hypothesis(es) or research questions that might be involved and explain how the information you gather will be analyzed. For a complete list of what should be included in your summary, please refer to Appendix B of the IRB Policies and Procedures Manual*

2. *Section 46.11 of the Federal Regulations state that research proposals involving human subjects must satisfy certain requirements before the IRB can grant approval. You should describe in detail how the following requirements will be satisfied. Be sure to address each area separately.*
 - a. *How will you insure that any risks to subjects are minimized? If there are potential risks, describe what will be done to minimize these risks. If there are risks, describe why the risks to participants are reasonable in relation to the anticipated benefits.*
 - b. *How will you insure that the selection of subjects is equitable? Take into account your purpose(s). Be sure you address research problems involving vulnerable populations such as children, prisoners, pregnant women, mentally disabled persons, and economically or educationally disadvantaged persons. If this is an in-class project describe how you will minimize the possibility that students will feel coerced.*
 - c. *How will you obtain informed consent from each participant or the subject's legally authorized representative and ensure that all consent forms are appropriately documented? Be sure to attach a copy of your consent form to the project summary.*
 - d. *Show that the research plan makes provisions to monitor the data collected to insure the safety of all subjects. This includes the privacy of subjects' responses and provisions for maintaining the security and confidentiality of the data.*

3. *Check the appropriate box(es) that describe the subjects you plan to use.*

<input type="checkbox"/> <i>Adult volunteers</i>	<input type="checkbox"/> <i>Mentally Disabled People</i>
<input type="checkbox"/> <i>CAL University Students</i>	<input type="checkbox"/> <i>Economically Disadvantaged People</i>
<input type="checkbox"/> <i>Other Students</i>	<input type="checkbox"/> <i>Educationally Disadvantaged People</i>
<input type="checkbox"/> <i>Prisoners</i>	<input type="checkbox"/> <i>Fetuses or fetal material</i>
<input type="checkbox"/> <i>Pregnant Women</i>	<input type="checkbox"/> <i>Children Under 18</i>
<input type="checkbox"/> <i>Physically Handicapped People</i>	<input type="checkbox"/> <i>Neonates</i>

4. *Is remuneration involved in your project? Yes or No. If yes, Explain here.*

5. *Is this project part of a grant? Yes or No. If yes, provide the following information:*
Title of the Grant Proposal _____
Name of the Funding Agency _____
Dates of the Project Period _____

6. *Does your project involve the debriefing of those who participated? Yes or No*
If Yes, explain the debriefing process here.

7. *If your project involves a questionnaire interview, ensure that it meets the requirements of Appendix __ in the Policies and Procedures Manual.*

Project Director's Certification
Program Involving HUMAN SUBJECTS

The proposed investigation involves the use of human subjects and I am submitting the complete application form and project description to the Institutional Review Board for Research Involving Human Subjects.

I understand that Institutional Review Board (IRB) approval is required before beginning any research and/or data collection involving human subjects. If the Board grants approval of this application, I agree to:

1. Abide by any conditions or changes in the project required by the Board.
2. Report to the Board any change in the research plan that affects the method of using human subjects before such change is instituted.
3. Report to the Board any problems that arise in connection with the use of human subjects.
4. Seek advice of the Board whenever I believe such advice is necessary or would be helpful.
5. Secure the informed, written consent of all human subjects participating in the project.
6. Cooperate with the Board in its effort to provide a continuing review after investigations have been initiated.

I have reviewed the Federal and State regulations concerning the use of human subjects in research and training programs and the guidelines. I agree to abide by the regulations and guidelines aforementioned and will adhere to policies and procedures described in my application. I understand that changes to the research must be approved by the IRB before they are implemented.

Professional Research

Project Director's Signature

Department Chairperson's Signature

Student or Class Research

Student Researcher's Signature

Supervising Faculty Member's
Signature if required

Department Chairperson's Signature

ACTION OF REVIEW BOARD (IRB use only)

The Institutional Review Board for Research Involving Human Subjects has reviewed this application to ascertain whether or not the proposed project:

1. provides adequate safeguards of the rights and welfare of human subjects involved in the investigations;
2. uses appropriate methods to obtain informed, written consent;
3. indicates that the potential benefits of the investigation substantially outweigh the risk involved.
4. provides adequate debriefing of human participants.
5. provides adequate follow-up services to participants who may have incurred physical, mental, or emotional harm.

Approved Disapproved

Chairperson, Institutional Review Board

Date

Approved, September 12, 2005