Full Application for New Approval of a Study Involving Human Subjects
East-West Center Institutional Review Board
IRB00003085

Date: _____

Principal Investigator: _____ Email: _____

Phone: _____ [ ] Student - name of supervising professor: _____

Training in Human Subject Protection: When, where, & what? _____

_____

Project Title: _____

1. Summarize your proposed research. Outline objectives and methods.

2. Summarize all involvement of humans in this project (who, how many, age, sex, length of involvement, frequency, etc.) and the procedures they will be exposed to. Attach survey instrument, if applicable.

Check whether any subject of your research will be selected from the following categories:
[ ] Minors [ ] Pregnant Women [ ] Mentally Disabled [ ] Prisoners

[ ] Physically Disabled

3. Research involving humans often exposes the subjects to risks: For the purpose of this application, "risk" is defined as exposure of any person to the possibility of injury, including physical, psychological, or social injury, as a consequence of participation as a subject in any research, development, or related activity which departs from the application of those established and accepted methods necessary to meet his needs, or which increases the ordinary risks of daily life, including the recognized risks inherent in a chosen occupation or field or service.

   a. Describe all the risks to human subjects that apply to your project:

b. Describe procedures that will be used to protect human participants from risks (e.g., confideniality of subjects maintained via code numbers and protected files):

4. Describe mechanism for safety monitoring: How will you detect if greater harm is accruing to your subjects than you anticipated? What will you do if such increased risk is detected?

5. Briefly describe the benefits that will accrue to each human subject or to mankind in general, as a result of the individual's participation in this project, so that the committee can access the risk benefit/ratio.

6. **Participation must be voluntary: the participants cannot waive legal Rights, and must be able to withdraw at any time without prejudice.** Indicate how you will obtain informed consent:

[ ] Subject (or Parent/Guardian) reads complete consent form & signs ('written' form)

[ ] Oral briefings by PI or project personnel, with simple consent form ('oral' form). Explain below the reason(s) why a written consent form is not used

[ ] Other- explain

Signed: _____ Date: _____
Principal Investigator

Signed: _____ Date: _____
Supervising Professor (required if PI is a student)
Date of Human Subject Protection Training: _____

Submit the ORIGINAL plus 6 copies of this form with the following attachments:
Seven (7) copies of all consent forms
Seven (7) copies of any other information to be read or presented to the participants
Seven (7) copies of the survey instrument (Please consult with the IRB staff if providing the survey instrument is a problem.)