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| Proposal Number |
| _____ |
| Date Received |
| _____ |

IRB Review Request

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

Submit this form to instreviewboard@calu.edu or Campus Box #109

Project Title: _____

Researcher/Project Director _____

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

Faculty Sponsor (if researcher is a student) _____

Department _____

Anticipated 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

All researchers must complete an approved Human Participants Protection training course. The training requirement can be satisfied by completing the CITI (Collaborative Institutional Training Initiative) online course at <http://www.citiprogram.org> New users should affiliate with "California University of Pennsylvania" and select the "All Researchers Applying for IRB Approval" course option. A copy of your certification of training must be attached to this IRB Protocol. If you have completed the training within the past 3 years and have already provided documentation to the IRB, please provide the following:

Previous Project Title _____

Date of Previous Project IRB Approval _____

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. All items in the Review Request Checklist, (see below) must be addressed.*
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.
(text boxes will expand to fit responses)*

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 target.*

| | |
|---|--|
| <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 or interview, ensure that it meets the requirements indicated in the Survey/Interview/Questionnaire checklist.

California University of Pennsylvania Institutional Review Board
Survey/Interview/Questionnaire Consent Checklist (v021209)

This form **MUST** accompany all IRB review requests

Does your research involve **ONLY** a survey, interview or questionnaire?

YES—Complete this form

NO—You **MUST** complete the “Informed Consent Checklist”—skip the remainder of this form

Does your survey/interview/questionnaire cover letter or explanatory statement include:

- (1) Statement about the general nature of the survey and how the data will be used?
- (2) Statement as to who the primary researcher is, including name, phone, and email address?
- (3) **FOR ALL STUDENTS:** Is the faculty advisor’s name and contact information provided?
- (4) Statement that participation is voluntary?
- (5) Statement that participation may be discontinued at any time without penalty and all data discarded?
- (6) Statement that the results are confidential?
- (7) Statement that results are anonymous?
- (8) Statement as to level of risk anticipated or that minimal risk is anticipated? (NOTE: If more than minimal risk is anticipated, a full consent form is required—and the Informed Consent Checklist must be completed)
- (9) Statement that returning the survey is an indication of consent to use the data?
- (10) Who to contact regarding the project and how to contact this person?
- (11) Statement as to where the results will be housed and how maintained? (unless otherwise approved by the IRB, must be a secure location on University premises)
- (12) Is there text equivalent to: “Approved by the California University of Pennsylvania Institutional Review Board. This approval is effective nn/nn/nn and expires mm/mm/mm”? (the actual dates will be specified in the approval notice from the IRB)?
- (13) **FOR ELECTRONIC/WEBSITE SURVEYS:** Does the text of the cover letter or explanatory statement appear before any data is requested from the participant?
- (14) **FOR ELECTONIC/WEBSITE SURVEYS:** Can the participant discontinue participation at any point in the process and all data is immediately discarded?

**California University of Pennsylvania Institutional Review Board
Informed Consent Checklist (v021209)**

This form **MUST** accompany all IRB review requests

Does your research involve **ONLY** a survey, interview, or questionnaire?

YES—DO NOT complete this form. You **MUST** complete the “Survey/Interview/Questionnaire Consent Checklist” instead.

NO—Complete the remainder of this form.

1. Introduction (check each)

- (1.1) Is there a statement that the study involves research?
- (1.2) Is there an explanation of the purpose of the research?

2. Is the participant. (check each)

- (2.1) Given an invitation to participate?
- (2.2) Told why he/she was selected.
- (2.3) Told the expected duration of the participation.
- (2.4) Informed that participation is voluntary?
- (2.5) Informed that all records are confidential?
- (2.6) Told that he/she may withdraw from the research at any time without penalty or loss of benefits?
- (2.7) 18 years of age or older? (if not, see Section #9, Special Considerations below)

3. Procedures (check each).

- (3.1) Are the procedures identified and explained?
- (3.2) Are the procedures that are being investigated clearly identified?
- (3.3) Are treatment conditions identified?

4. Risks and discomforts. (check each)

- (4.1) Are foreseeable risks or discomforts identified?
- (4.2) Is the likelihood of any risks or discomforts identified?
- (4.3) Is there a description of the steps that will be taken to minimize any risks or discomforts?
- (4.4) Is there an acknowledgement of potentially unforeseeable risks?
- (4.5) Is the participant informed about what treatment or follow up courses of action are available should there be some physical, emotional, or psychological harm?
- (4.6) Is there a description of the benefits, if any, to the participant or to others that may be reasonably expected from the research and an estimate of the likelihood of these benefits?
- (4.7) Is there a disclosure of any appropriate alternative procedures or courses of treatment that might be advantageous to the participant?

5. Records and documentation. (check each)

- (5.1) Is there a statement describing how records will be kept confidential?
- (5.2) Is there a statement as to where the records will be kept and that this is a secure location?
- (5.3) Is there a statement as to who will have access to the records?

6. For research involving more than minimal risk (check each),

- (6.1) Is there an explanation and description of any compensation and other medical or counseling treatments that are available if the participants are injured through participation?
- (6.2) Is there a statement where further information can be obtained regarding the treatments?
- (6.3) Is there information regarding who to contact in the event of research-related injury?

7. Contacts.(check each)

- (7.1) Is the participant given a list of contacts for answers to questions about the research and the participant's rights?
- (7.2) Is the principal researcher identified with name and phone number and email address?
- (7.3) FOR ALL STUDENTS: Is the faculty advisor's name and contact information provided?

8. General Considerations (check each)

- (8.1) Is there a statement indicating that the participant is making a decision whether or not to participate, and that his/her signature indicates that he/she has decided to participate having read and discussed the information in the informed consent?
- (8.2) Are all technical terms fully explained to the participant?
- (8.3) Is the informed consent written at a level that the participant can understand?
- (8.4) Is there text equivalent to: "Approved by the California University of Pennsylvania Institutional Review Board. This approval is effective nn/nn/nn and expires mm/mm/mm"? (the actual dates will be specified in the approval notice from the IRB)

9. Specific Considerations (check as appropriate)

- (9.1) If the participant is or may become pregnant is there a statement that the particular treatment or procedure may involve risks, foreseeable or currently unforeseeable, to the participant or to the embryo or fetus?
- (9.2) Is there a statement specifying the circumstances in which the participation may be terminated by the investigator without the participant's consent?
- (9.3) Are any costs to the participant clearly spelled out?
- (9.4) If the participant desires to withdraw from the research, are procedures for orderly termination spelled out?
- (9.5) Is there a statement that the Principal Investigator will inform the participant or any significant new findings developed during the research that may affect them and influence their willingness to continue participation?
- (9.6) Is the participant is less than 18 years of age? If so, a parent or guardian must sign the consent form and assent must be obtained from the child
- Is the consent form written in such a manner that it is clear that the parent/guardian is giving permission for their child to participate?
- Is a child assent form being used?
- Does the assent form (if used) clearly indicate that the child can freely refuse to participate or discontinue participation at any time without penalty or coercion?
- (9.7) Are all consent and assent forms written at a level that the intended participant can understand? (generally, 8th grade level for adults, age-appropriate for children)

California University of Pennsylvania Institutional Review Board
Review Request Checklist (v021209)

This form **MUST** accompany all IRB review requests.

Unless otherwise specified, **ALL** items must be present in your review request.

Have you:

(1.0) **FOR ALL STUDIES:** Completed **ALL** items on the Review Request Form?

Pay particular attention to:

(1.1) Names and email addresses of all investigators

(1.1.1) **FOR ALL STUDENTS:** use only your CalU email address)

(1.1.2) **FOR ALL STUDENTS:** Name and email address of your faculty research advisor

(1.2) Project dates (must be in the future—no studies will be approved which have already begun or scheduled to begin before final IRB approval—**NO EXCEPTIONS**)

(1.3) Answered completely and in detail, the questions in items 2a through 2d?

2a: **NOTE:** No studies can have zero risk, the lowest risk is “minimal risk”. If more than minimal risk is involved you **MUST**:

i. Delineate all anticipated risks in detail;

ii. Explain in detail how these risks will be minimized;

iii. Detail the procedures for dealing with adverse outcomes due to these risks.

iv. Cite peer reviewed references in support of your explanation.

2b. Complete all items.

2c. Describe informed consent procedures in detail.

2d. **NOTE:** to maintain security and confidentiality of data, all study records must be housed in a secure (locked) location **ON UNIVERSITY PREMISES**. The actual location (department, office, etc.) must be specified in your explanation and be listed on any consent forms or cover letters.

(1.4) Checked all appropriate boxes in Section 3? If participants under the age of 18 years are to be included (regardless of what the study involves) you **MUST**:

(1.4.1) Obtain informed consent from the parent or guardian—consent forms must be written so that it is clear that the parent/guardian is giving permission for their child to participate.

(1.4.2) Document how you will obtain assent from the child—This must be done in an age-appropriate manner. Regardless of whether the parent/guardian has given permission, a child is completely free to refuse to participate, so the investigator must document how the child indicated agreement to participate (“assent”).

(1.5) Included all grant information in section 5?

(1.6) Included **ALL** signatures?

(2.0) **FOR STUDIES INVOLVING MORE THAN JUST SURVEYS, INTERVIEWS, OR QUESTIONNAIRES:**

(2.1) Attached a copy of all consent form(s)?

(2.2) **FOR STUDIES INVOLVING INDIVIDUALS LESS THAN 18 YEARS OF AGE:** attached a copy of all assent forms (if such a form is used)?

(2.3) Completed and attached a copy of the Consent Form Checklist? (as appropriate—see that checklist for instructions)

(3.0) FOR STUDIES INVOLVING ONLY SURVEYS, INTERVIEWS, OR QUESTIONNAIRES:

(3.1) Attached a copy of the cover letter/information sheet?

(3.2) Completed and attached a copy of the Survey/Interview/Questionnaire Consent Checklist? (see that checklist for instructions)

(3.3) Attached a copy of the actual survey, interview, or questionnaire questions in their final form?

(4.0) FOR ALL STUDENTS: Has your faculty research advisor:

(4.1) Thoroughly reviewed and approved your study?

(4.2) Thoroughly reviewed and approved your IRB paperwork? including:

(4.2.1) Review request form,

(4.2.2) All consent forms, (if used)

(4.2.3) All assent forms (if used)

(4.2.4) All Survey/Interview/Questionnaire cover letters (if used)

(4.2.5) All checklists

(4.3) **IMPORTANT NOTE:** Your advisor's signature on the review request form indicates that they have thoroughly reviewed your proposal and verified that it meets all IRB and University requirements.

(5.0) Have you retained a copy of all submitted documentation for your records?

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 (Faculty/Staff) Research

Project Director's Signature

Student or Class Research

Student Researcher's Signature

Supervising Faculty Member'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