

FORM B

Guidelines for preparing a Proposal for IRB Review

CSUDH Institutional Review Board for the Protection of Human Subjects

Note to Investigators – All words in blue italics are instructions and should be deleted from the form that is submitted to the IRB office.

First, fill in the information requested on a Cover Sheet (Form A)

Then, create a document that addresses each of the items identified, uses these categories as headings, and presents them in this order. Number the pages.

1. Study Abstract

Provide a one-paragraph summary of the study, including its potential benefits, risks and risk management procedures. You may find that this is easier to write after you have completed the rest of the proposal.

2. Statement of Purpose and Background

In one or two paragraphs, discuss relevant background information to provide a rationale for the proposed research. Cite references if appropriate. Include information about the purpose and design of the study—what it is that you will actually do. Provide a justification for the use of humans in the research if the project could conceivably use some other source of data.

3. Subjects

Discuss how you will identify, recruit, and assure informed consent from the subjects. Use the following categories to structure your description:

- a) **Characteristics of the subjects:** *How many, their gender, age range, ethnicity, etc. Use the list on the cover sheet to remind you of the main categories.*
- b) **Selection Criteria:** *How will you determine who is included or excluded? Who makes the decision?*
- c) **Special or vulnerable populations:** *If you will use special groups where ability to provide informed consent may be limited, provide a rationale for including them. Special populations might include children, pregnant women, prisoners, cognitively impaired individuals, frail elderly persons, etc.*
- d) **Recruitment source:** *Identify the institutions from which you will recruit subjects. If appropriate, include a letter from that institution/organization indicating support of the study.*
- e) **Recruitment Methods:** *Describe how you will identify and recruit subjects. Submit a copy of the flyer or advertisement if you will be advertising for subjects. (If subjects will be identified through private records, the holder of the records must make the initial contact with the subject.) Include a statement about how the recruitment will ensure voluntary participation and not single out or embarrass individuals who choose not to participate.*
- f) **Informed Consent Process:** *Describe who will make the initial contact with potential subjects and how the research will be explained to them. Include information about how you will introduce the informed consent agreement and note any other measures you will use to assess the potential subject's understanding of what will be asked of him/her. Be sure to build in adequate time for prospective subjects to reflect on whether or not they want to participate. (To prepare the actual consent documents, consult Form C "Guidelines for Assuring Informed Consent." There are also templates and sample consent forms available: Forms D, E, and F.) Include wording that signed consents will be kept for a minimum of three years (as per OHRP regulations)*
- g) **Study Location:** *Identify the location and setting where subjects will participate in this research and address any special considerations. For example, if the subjects are school children, will the research take place during class time or after school? Will alternative activities be available for children who do not agree to participate?*
- h) **Potential Problems:** *If appropriate, address any potential problems involving subject identification, recruitment of data collection.*

4. Research Design and Methods

- a) **Research Design:** Describe the general methodology and design of the proposed research. Indicate the amount of time that a subject will spend on each aspect of the study.
- b) **Devices, Tests, Questionnaires, and Interview Guides:** Include interview questions or formats and a copy of any survey instruments that will be administered. If appropriate, identify any medical devices or equipment that will be used with the subjects.
- c) **Deception or Incomplete Disclosure:** If applicable, fully describe and justify the use of deception in this research. Include a description of the debriefing practices that are proposed.

5. Potential Benefits

Describe the anticipated benefits to (a) the subject, (b) the population from which the subject is drawn, and (c) society/science expected to result from this research. (Do not include compensation or incentives that might be offered to subjects.)

6. Risks

- a) **Identify Risks:** Consider potential or known physical, psychological, social, and economic or legal risks that might be associated with participation in the research. These might be direct risks or the result of a subject's name accidentally being linked to his/her responses. Discuss whether the risks are minimal (no greater than normal daily risks) or significant.
- b) **Management of Risks:** Describe precautions, safeguards, or other steps incorporated into the research activity to reduce or limit the severity or likelihood of harm. These might include extra precautions in storing data or coding personal identifiers.
- c) **Confidentiality:** Describe provisions made to maintain confidentiality of data. Who will have access to the collected data, where will it be stored, and for how long? Remember, confidentiality refers to recording but concealing the subject's identity or codes linked to the individual's identity. Anonymity means that the identity of the subject is not known to the researchers, and is never recorded or associated with the data collected. Note: All computer files must be password-protected. For more information, see IRB webpage at <http://www.csudh.edu/RF/rfpro3.html>.
- d) **Data Monitoring:** For clinical and medical trials, when applicable, discuss any process used to monitor data collected to ensure the ongoing safety of subjects.
- e) **Assessment of Risk:** Assess whether the risks and inconveniences associated with a subject's participation in the research are reasonable in relation to the anticipated benefits to the subjects or in relation to the knowledge that may reasonably be expected to result from the research.

7. Costs

Describe any costs that the subject may incur as a result of participation (charges for tests, travel, parking charges, etc.) Please do not include costs to the investigator.

8. Compensation and Incentives

If compensation or an incentive is offered for participation, provide details of this payment. Indicate whether the subject is compensated for the number of procedures, the time involved, or some other basis for payment. Indicate whether payment is made by check, cash, or money order, and whether the amount is prorated if the subject decides to discontinue participation. Indicate how the value of the incentive was determined. Compensation/incentives should be appropriate but not excessive to a degree that would unduly influence a potential subject's decision to participate.

9. Investigator Experience

Provide a brief summary of the primary investigator's and co-investigator's research or training as related to the proposed project (do not include a vitae). If the investigator is a student, also include a summary of the relevant expertise of the faculty member who is supervising the research.

The responses to these items should be submitted along with a cover sheet (Form A) and copies of consent form(s) by attaching to an email sent to irb@csudh.edu. For further information, contact IRB Coordinator in the Office of Graduate Studies and Research, WH D-445, Phone 310-243-2136.

Reminder: Subject recruitment and data collection may not be initiated prior to Formal written approval from the California State University, Dominguez Hills Institutional Review Board.