

Protocol Number 10-11-____
(Assigned by Office of Research)

**Request for Review by the Sacramento State
Committee for the Protection of Human Subjects (Revised 09/2010)**

Submit 11 copies of this form and any attachments to the Office of Research Administration,
Hornet Bookstore, Suite 3400, mail code 6111. Please **type** your responses or use a word processor.
Handwritten forms will be returned without review.

Project Title: _____

Funding Agency (if any): _____

Name(s) and affiliation(s) of Researchers: _____

Mailing address (or Department and campus mail code): _____

Telephone and e-mail address for researcher

Anticipated starting date

Name of faculty sponsor (for student research)

E-mail address of sponsor

1. Who will participate in this research as subjects (e.g., how many people, from what source, using what criteria for inclusion or exclusion)? How will you recruit their participation (e.g., what inducements, if any, will be offered)? How will you avoid any conflict of interest as a researcher?

2. How will informed consent be obtained from the subjects? Attach a copy of the consent form you will use. If a signed written consent will not be obtained, explain what you will do instead and why. (See Appendix C in *Policies and Procedures* for examples of consent forms, an example of an assent form for children, and a list of consent form requirements. Also see the section on *Informed Consent* in *Policies and Procedures*.)

3. How will the subjects' rights to privacy and safety be protected? (See the section on *Level of Risk in Policies and Procedures*. For online surveys, also answer the checklist questions at the end of Appendix B in *Policies and Procedures*.)

4. Summarize the study's purpose, design, and procedures. (Do not attach lengthy grant proposals, etc.)

5. Describe the content of any tests, questionnaires, interviews, etc. in the research. Attach copies of the questions. What risk of discomfort or harm, if any, is involved in their use?

6. Describe any physical procedures in the research. What risk of discomfort or harm, if any, is involved in their use? (The committee will seek review and recommendation from a qualified on-campus medical professional for any medical procedures.)

7. Describe any equipment or instruments and any drugs or pharmaceuticals that will be used in the research. What risk of discomfort or harm, if any, is involved in their use? (The committee will seek review and recommendation from a qualified on-campus medical professional for the use of any drugs or pharmaceuticals.)

8. Taking all aspects of this research into consideration, do you consider the study to be "exempt," "no risk," "minimal risk," or "at risk?" Explain why. (See the section on *Level of Risk in Policies and Procedures*.)

For protocols approved as “at risk”, the researcher is required to file semiannual reports with the committee that describe the recruiting of subjects, progress on the research, interactions with the sponsor, and any adverse occurrences or changes in approved procedures. In addition, the committee reserves the right to monitor “at risk” research as it deems appropriate. Failure to file the required progress reports may result in suspension of approval for the research.

Signature of Researcher

Date

Signature of Faculty Sponsor
(for student research)

Date

Signature of your department or division chair confirms that he or she has had an opportunity to see your human subjects application.

Signature of Department/Division Chair

Date

Questions about the application procedures for human subjects approval may be directed to the Office of Research Administration, (916) 278-7565, or to any member of the committee. Questions about how to minimize risks should be directed to a committee member. Applicants are encouraged to contact a committee member whose professional field most closely corresponds to that of the researcher. See www.csus.edu/research/humansubjects/ for a list of committee members and the current year’s due dates for submitting an application.

*To assure prompt review of your application,
ALL researchers should complete this checklist:*

- Have you written an appropriate answer for each question on the application form? (Please do not attach research proposals, grant applications, etc. as the committee cannot read such documents.)
- Have you answered all of the questions on the application form? (Please enter “N/A” if a particular question does not apply to your research.)
- Have you provided an e-mail address and a phone number where you can be reached on the application?
- Have you (and all co-researchers) signed the application form? Has your department or division chair also signed the application form?
- Have you included your consent form with your application? Does that consent form identify you as the researcher and your department?
- Does your consent form clearly describe what participants will be asked to do in your research? Does it clearly describe any direct benefit they will receive as a result of their participation? Does it clearly describe any risks they will be exposed to during their participation, and what you will do to minimize those risks?
- Have you included with your application any screening forms that will be used to determine the eligibility of participants for your research?
- Have you described in your application any potential conflict of interest between your role as a researcher and any other relationship you may have with the participants or with an organization that is a source of your participants? This could occur if some or all of the participants are your students, employees, co-workers, friends, etc. Have you also described how you will avoid any such conflict of interest?
- Have you included with your application all tests, questionnaires, surveys, interview questions, focus group questions, etc. that will be used in your research?
- Have you checked the grammar and spelling throughout all of your documents?
- Have you prepared 11 copies of your complete application packet, including all attachments, for the committee? Does one of those copies have original signatures?
- Have retained an electronic copy of your application that can be edited and resubmitted with any changes requested by the committee? (This will be forwarded to your Dean.)

STUDENT researchers must also complete this checklist:

- Have you met with your faculty advisor before preparing your application? Has your faculty advisor thoroughly reviewed all of your materials before you submitted your application?
- Have you provided an e-mail address and a phone number where you can be reached on the application? Did you also include your home address on the application?
- Have you included the name of your faculty advisor and that person's e-mail address on your application?
- Has your application been signed by you, any co-researchers, and your faculty advisor? Did you submit an original copy of your application with all of those signatures?
- Does your department have an approved Human Subjects committee that reviews student research projects? (As of July 2009, the approved departments are Child Development; Communication Studies; Criminal Justice; Economics; Educational Leadership & Policy Studies; Kinesiology & Health Science; Nursing; Psychology; Public Policy & Administration; Social Work; Sociology; Special Education, Rehabilitation & School Psychology; and Teacher Education.) If your research is in one of these departments, it must be reviewed and approved by that department's committee first. Has your department's committee completed the following form?

DEPARTMENT HUMAN SUBJECTS COMMITTEE APPROVAL

Project Title: _____

Student Researcher: _____

Faculty Sponsor: _____

The _____ Department's human subjects committee has reviewed and approved this application. It requires review by the CPHS because the research is considered (*circle one*) Minimal Risk or At Risk.

Name of department's human subjects chairperson

E-mail address of chairperson

Signature of department committee's chairperson

Date