

**Child Development Department  
Policies and Procedures for Departmental Review for the  
Protection of Human Subjects**

**Departmental Human Subjects Review**

The Child Development Department human subjects review committee examines proposals for theses, projects, or course-based research assignments which involve the collection of data from human subjects. This review is in keeping with university policy that any research or related activity involving human subjects must be reviewed by a Committee for the Protection of Human Subjects. Reviews shall be conducted using the same criteria and standards established by the University Committee for the Protection of Human Subjects (CPHS). The department review committee has the authority to approve proposals identified as either “exempt” or “no risk.” If the department committee determines that a proposal is either “Minimal Risk” or “At Risk,” it must be forwarded to the university committee for their review.

The University CPHS has established clear guidelines for the Protection of Human Subjects. For complete information, including descriptions and examples of risk levels, please refer to the University CPHS document entitled: “Policies and Procedures of the Committee for the Protection of Human Subjects” which can be found at:

<http://www.csus.edu/rsp/HumanSubjects.htm>.

All student theses and any projects which involve the collection of data must obtain human subjects approval before data can be collected from any sources. The appropriate forms are posted on the department website (<http://edweb.csus.edu/departments/chdv>) as well as through the Office of Research and Sponsored Projects. Consistent with University policy, the Departmental Human Subjects Committee does not review faculty research. Proposals by faculty to engage in research involving human subjects must be submitted directly to the University’s CPHS Committee.

**Department Review Committee Structure**

The Departmental Human Subjects Committee shall consist of at least three members of the Graduate Committee and any other tenure track faculty members who wish to serve. The Human Subjects Committee will meet at least once a semester, with the meeting dates to be announced to faculty and students through the department office and on the website.

**Procedures for Submission of Proposals**

Any student who is aware that his or her research will involve contact with human subjects, or who receives advice from a faculty member that such research may involve such contact, must submit a proposal to the Departmental Human Subjects Committee.

Any faculty member who assigns a course project for students to conduct research with human subjects outside the classroom must submit a proposal to the Committee.

Proposals submitted to the Departmental Human Subjects Committee must include a signed original and two copies of all the following (forms can be downloaded from the department website as well as from the Office of Research and Sponsored Projects website listed above):

- 1) University's CPHS proposal form
- 2) Departmental Review Committee cover sheet (see below)
- 3) Thesis/project petition if applicable
- 4) The University's two required checklists
- 5) The proposed consent forms
- 6) Proposed instruments (i.e., questionnaires, etc).

All materials should be submitted to the department office, Brighton Hall 135, at least 10 days before the scheduled Departmental Review Committee meetings. The schedule of meetings for each semester shall be available in the department office and posted on the website.

### **Definitions of Consent and Risk:**

The Committee will use the following definitions of risk and consent as established by the University CPHS committee and federal regulations:

*Informed consent*- assures that prospective participants understand the nature of the research and can knowledgeably and voluntarily decide whether or not to participate. It is a continuing process, not just a piece of paper. It protects both the participant and the investigator, who otherwise faces legal hazards. When children and/or adolescents are participants in a research study, the investigator must solicit both the assent of the children and the permission of the parents or guardians. Also, the Buckley Amendment requires parental consent for release of records or identifiable information about children in public schools, and instructional materials to be used in connection with research must be available for inspection by parents or guardians.

*Exempt*- Some categories of research are considered "exempt" under federal regulations. (The research must still be reviewed.) For more specific information, see Federal Policy §46.101(b). Examples include:

- (1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as regular and special education instructional strategies, or the effectiveness of or comparison among instructional techniques, curricula, or classroom management methods.
- (2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless the information obtained is recorded in a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and any disclosure of the subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or damage the subjects' financial standing, employability, or reputation.
- (3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt

under paragraph (2) if the human subjects are elected or appointed public officials or candidates for public office; or federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

(4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers.

(5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine public benefit or service programs; procedures for obtaining benefits or services under those programs; possible changes in or alternatives to those programs or procedures; or possible changes in methods or levels of payment for benefits or services under those programs.

*No Risk*- Research is approved as “no risk” when no harm or discomfort is anticipated for participants.

*Minimal Risk*- Research is approved at “minimal risk” when the probability and magnitude of harm or discomfort anticipated for participants is no greater than what might be encountered in daily life or during the performance of routine physical or psychological examinations or tests [Federal Policy §46.102(i)]. (Note that only “minimal risk” is defined in the federal regulations.)

*At Risk*- Research is approved as “at risk” when the probability and/or the magnitude of possible harm (physical, psychological, social, or economic) from participation in a research study is more than minimal.

*Psychological Harm*- An example of psychological harm would be stress or feelings of guilt or embarrassment from thinking or talking about one’s own behavior or attitudes on sensitive topics such as drug use, sexual orientation, selfishness, or violence. These feelings may be aroused from being interviewed or from filling out a questionnaire. Another kind of risk would be invasion of privacy, for example, from covert observation (even in a public place) of behavior that participants would likely consider private. Still another risk of psychological harm occurs when there is inadequate protection for the confidentiality of data that has been given voluntarily.

*Social and Economic Harm*- Some invasions of privacy or breaches of confidentiality could result in embarrassment or harm to a participant’s reputation within his or her business or social group, a loss of employment, or criminal prosecution. Areas of particular sensitivity include such topics as alcohol or drug abuse, child or partner abuse, and sexual behavior

### **Procedures and Standards for Review**

Committee members will review proposals independently prior to the scheduled meeting. In accordance with this policy and with University guidelines, the Committee will make a review decision for each proposal submitted. This decision will be recorded in writing and

communicated to the submitter and, where applicable, the faculty sponsor, by letter or electronic mail. Records of the Committee's actions, including copies of correspondence and electronic mail messages, will be maintained in the departmental files.

Proposals will be evaluated in accordance with the following five criteria:

- Does the proposal adequately explain the research project?
- Does the proposal include any "protected classes" of subjects (i.e., minors, prisoners, pregnant women, fetuses, elderly people, patients of hospitals or mental facilities, or any other person who may be legally unable to give consent)?
- Can the project be classified as "exempt" by Federal regulations?
- To what extent does the project pose risk to subjects or the researcher?
- To what extent does the research design protect human subjects?

In its review, the Committee may make any of the following decisions:

- Approve a proposal if it finds no risk to the subjects or researcher *and* that no members of "protected classes" are subjects, *or* if the research qualifies for "exempt" status under Federal regulations.
- Approve a proposal contingent on specified changes.
- Request a resubmission based on specific changes or the need for further information.
- Forward the proposal to the University Committee if it finds that the proposal poses some risk to the subjects and/or the researcher *or* if the proposal uses subjects who are members of "protected classes."

Approval for research involving human subjects expires after a one year period and if necessary must be resubmitted for review.

It is the responsibility of the researcher to notify the Committee of changes to the research proposal subsequent to approval, if such changes might affect human subjects.

At the end of the academic year the Departmental Committee will report to the University Committee about the number and disposition of proposals considered during that year. This annual report shall include the following information for each proposal reviewed:

- name of the researcher
- title of the project
- date of review
- level of risk assigned by the department committee
- action taken by the department committee

**Requests for information or any other questions may be directed to the Graduate Coordinator through the Child Development Department Office, BRH 137, 916-278-7192.**

Human Subjects Committee Review Cover Form  
Child Development Department

Project/Thesis Title \_\_\_\_\_

Student Researcher \_\_\_\_\_

Student's email address: \_\_\_\_\_

Faculty Sponsor name: \_\_\_\_\_

Faculty Sponsor Signature \_\_\_\_\_

(Faculty signature indicates that your sponsor has read and approved this application and the thesis/project petition.)

FOR COMMITTEE USE ONLY:

- 1. Proposal adequately explains the research project
- 2. Proposal includes any "protected classes" of subjects     Yes     No
- 3. Project can be classified as "exempt"     Yes     No
- 4. What level of risk does project pose risk to subjects or the researcher?
- 5. How does the research design protect confidentiality and anonymity of human subjects?

COMMITTEE ACTION:

- Approved
- Forward to University Committee
- Approved Contingent (see below)
- Not approved - resubmit (see below)

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_  
Committee Chair

\_\_\_\_\_  
Date