

Department of Public Policy and Administration

Departmental Policy and Procedures with Respect to Protection of Human subjects

Academic Year 2005-06

DEPARTMENTAL HUMAN SUBJECTS COMMITTEE

To protect human subjects involved in student research and meet University requirements in this area, the PPA Department has established a Human subjects Committee. Ordinarily the Committee will consist of the Chair of the Department (who will also serve as Committee Chair) and two others elected from among the full time faculty; elections for Committee positions will occur in the summer prior to each academic year or early in the fall semester. For Academic Year 2005-06, Committee Members were chosen in a summer, 2005 election and consist of the following faculty.

Assistant Professor Miguel Ceja, Chair
President Emeritus Don Gerth
Assistant Professor Mary Kirlin

COMMITTEE CHARGE

The Human subjects Committee is charged with reviewing student research that involves contact with human subjects, including but not limited to: 1) student initiated research related to Master's projects or theses; and 2) collaborative projects between faculty and students in which students are involved in project development and contact with human subjects outside the classroom, and/or students who present their findings outside the classroom (e.g., at a professional conference).

Pursuant to University policy, the departmental Human subjects Committee does **not** include oversight of faculty's own research, with the exception of faculty-student collaborative projects discussed in the prior paragraph. Proposals by faculty to engage in other research involving human subjects bypass this Committee and go directly to the University's IRB Committee. Projects in which the only subjects are other students in the same course and the only reporting of results is in that course do not require review. It should be noted that faculty-student projects in which the student role is limited to data collection are considered faculty research for the purpose of this document.

COMMITTEE PROCEDURES

- The Human subjects Committee will meet at least once a semester, with the meeting date to be announced to faculty and students early in the semester. The Committee Chair will call the meeting. The Chair may cancel the semester meeting if no proposals are submitted.

- 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 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.
- When submitting a proposal to the Human subjects Committee, a student or faculty member should: 1) complete three copies of the University's IRB proposal form found at the Research and Sponsored Projects Web site (www.csus.edu/rsp/HumanSubjects.htm); 2) complete three copies of the departmental "cover sheet" that distills the crucial information into one page (see Appendix); and 3) submit the above materials (stapled together) in hard copy to the PPA office.
- Human subjects Committee members will review proposals independently and discuss them when the entire Committee meets.
- The individual submitting a proposal may attend the Human Subjects Committee meeting but it is not required that he or she do so.
- In accordance with standards set forth in the subsequent section, the Human subjects Committee will make a decision about the need for further review of each proposal submitted. Each such decision will be recorded in writing.
- As soon as is convenient after the Human Subjects Committee meeting, the Committee Chair will inform the individual submitting the proposal of the Committee's decision. The proposer may be notified either by letter or by electronic mail.
- Records of the Committee's actions, including copies of correspondence and electronic mail messages, will be maintained in the PPA office.

CRITERIA AND STANDARDS FOR REVIEW

Proposals are to be evaluated in accordance with the following five criteria:

- 1) Does the proposal adequately explain the research project?
- 2) 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)?
- 3) Can the project be classified as "exempt" by Federal regulations?
- 4) To what extent does the project pose risk to subjects or the researcher?
- 5) To what extent does the research design protect human subjects?

The Committee may make any of the following decisions with respect to a proposal:

- It may **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.
- It may **approve a proposal contingent on specified changes to the research protocols**.
- It may **return the proposal for further information** if Committee members find that aspects of the proposal are unclear.
- It may **forward the proposal to the University Committee** if Committee members find 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.”

NOTES REGARDING RESEARCH USING SECONDARY DATA

Our expectation is that the vast majority of projects using only secondary data sets (e.g., Field Polls, the General Social Survey) will be exempt from the University approval process because they pose no danger to human subjects, as the researcher is not in direct contact with individuals and it is not possible even to identify individual participants. Nevertheless, secondary data sets may occasionally pose the danger of violating individual privacy, especially if the data set in question is small and makes it possible to identify individuals through a combination of variables. For this reason, students using secondary data sets should complete a proposal describing the variables to be used and means of protecting individual privacy. If the researcher expects that the research is exempt, it should indicate why they believe so in their proposal. A distinguishing factor that is likely to make research exempt is if the database is freely available to the general public. The situation is different when only users with certain credentials, or by paying a certain fee, can access a human subject database.

APPROVAL PERIOD AND MODIFICATIONS TO RESEARCH PLAN

Unless the Committee specifically indicates otherwise, approval for research involving human subjects shall be in effect for one year.

It is the responsibility of the researcher to notify the Committee chair of changes to the research proposal subsequent to approval, if such changes might affect human subjects. Upon being notified of any such changes the Committee chair may:

- 1) approve them if in his or her judgment the changes do not substantially increase the potential of the research to cause harm to human subjects; or
- 2) call another meeting of the Committee to consider the revised plan.

END OF THE ACADEMIC YEAR REPORT

At the end of the academic year the Chair of the Human subjects Committee will report to the University Committee about the number and disposition of proposals considered during that year. The report may also contain recommendations for improving consideration of proposals within the PPA Department.

Department of Public Policy and Administration
**Cover Page for Proposals Submitted to the
Department's Human subjects Committee**

Instructions: If your research project involves contact with human subjects or data previously collected from human subjects please complete the original and two copies of this form, and attach each of the three to completed copies of the University's proposal form.

Project Title _____

Name of Researcher _____

E-Mail Address _____

Faculty Sponsor (if applicable) _____

Sponsor's Signature _____ Date _____

(This signature indicates the faculty member has read and approved the research plan)

1. Is the research for a class? Yes No
 If "yes," for what class and in what semester? _____

2. Have you attached copies of the University forms, including your consent form(s) and instrument(s)?
 Yes No (If no, STOP: only complete packets will be considered)

3. Does this project use members of any *protected class*? (i.e., Does it involve minors, prisoners, pregnant women, elderly people, patients of hospitals or mental facilities, or any person who may be legally unable to give consent?)
 Yes No

4. Is this project *exempt* according to University standards? (Exempt research includes that conducted as part of an established course on the effectiveness of instructional technique, observational research of adults that does not allow individual participants to be identified; a review of prior anonymous records or surveys; and evaluation of a public service program.)
 Yes No (If yes, STOP)

5. Does the research pose the risk of any physical or psychological harm to the subjects and/or the researcher?
(Note: studies that use deception are considered to pose potential psychological harm.)
 Yes No
 If yes, please explain _____

Committee Use Only

This proposal is: approved, requires more information, referred to the University Committee , approved with the following revisions _____

Signature of HSC Chair _____ Date _____