

Interim Policy for Human Subjects Review
Department of Social Work Education, California State University, Fresno

(Refer to Committee on the Protection of Human Subjects. [1987]. *Policy and procedures for research with human subjects at California State University, Fresno*. Fresno, CA: California State University, Fresno, for university policies/procedures.)

ALL STUDIES INVOLVING HUMAN PARTICIPANTS OR PERSONAL INFORMATION ABOUT/FROM INDIVIDUALS FROM ANY SOURCE MUST DEVELOP HUMAN SUBJECTS PROCEDURES AND BE REVIEWED, AT MINIMUM, BY THE DSWE HUMAN SUBJECTS REVIEW COMMITTEE (RESEARCH SEQUENCE FACULTY).

1. Human subjects review is required by the university for all student research in social work. This includes observational studies, survey research, interviews, and analyses of secondary data (e.g., case records, existing data files/sets)
2. You and your chair will designate the level of risk (“exempt,” “minimal risk,” or “at risk”) involved in your project and submit the study protocol for department review. Reviewers will determine the final level of review that is required. Refer to Committee on the Protection of Human Subjects. (1987). *Policy and procedures for research with human subjects at California State University, Fresno*. Fresno, CA: California State University, Fresno, for full definitions of risk levels.
 - a. “Exempt” is limited to studies e.g., 1) using publicly available information (e.g., census data published by the government or public documents like newspapers, print ads, totally public documents); 2) public behaviors where there is no expectation of privacy and those observed can not be identified; 3) surveys where there is no psychological stress and respondents are legally competent; and 4) focus is on accepted/common educational techniques and tests. In all situations, identification of respondents is not possible (with exception of public statements by public officials).
 - b. “Minimal risk.” Risks of harm anticipated are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during performance of routine physical or psychological exams or tests. Even if you are conducting an analysis of SECONDARY DATA, you must demonstrate that respondents agreed to the use of their information for purposes like your study and that you are maintaining confidentiality or anonymity.
 - c. “At risk.” Participant is exposed to the possibility of harm – physical, psychological, sociological, or other as a consequence of any activity of the research.

3. You must receive human subjects clearance and file the clearance form with the Department Secretary **BEFORE** you may proceed with your research/data collection. If you are using existing data (secondary data), you may not begin your “selection” and “analysis” of these data until cleared.

PROCEDURE FOR OBTAINING A DEPARTMENT REVIEW FOR HUMAN SUBJECTS

1. Submit a request for human subjects review to the DSWE office by completing the information on the University Human Subjects Clearance form - see attached example listing your chair as the Principal Investigator and your name under “student or collaborative research” - and study documentation. Documentation that should be submitted with your request should include a brief paragraph describing your study question, a copy of your METHODS CHAPTER (your “study protocol”), and copies of any study documents, e.g., information letters, informed consent document(s), assent document(s). **NOTE: Informed consent documents, recruitment letters etc. will not be required and/or relevant for every study. The student should work with his/her chair to identify the appropriate documents to include for review (see “Documentation to include with your request” at the end of this policy.)**
2. If you and your chair designate your study as “exempt,” you should explain the reasons for this designation in a memo to the Research Sequence.
3. Two tenure/tenure-track faculty members from the DSWE research sequence will be assigned to review your study protocol. Reviews will be discussed for approval at the next scheduled research sequence meeting. (The research sequence generally meets every other week.) Any issues of concern will be discussed during the meetings. If indicated, chair and student will be invited to participate in the discussion.
4. If concerns are not resolved after the initial review/discussion, a third faculty member from the research sequence will review the protocol. If, after the third review and consultation with chair and student, concerns remain, the study will be referred to the University Human Subjects Committee.
5. All studies deemed “at risk” must be reviewed by the University Human Subjects Committee; the student will be assisted regarding the procedures for submitting a request for review by the university human subjects committee.
6. **Note that your chair is the “principal investigator” of record and CAN NOT SIGN OFF on your study for purposes of the departmental human subjects review.**
7. **KEEP COPIES OF ALL WRITTEN APPROVALS FROM DSWE AND ANY AGENCIES TAKING PART IN YOUR STUDY AND PLACE COPIES IN AN APPENDIX IN YOUR FINAL REPORT.**

DOCUMENTATION TO INCLUDE IN YOUR REQUEST

1. A brief statement/paragraph describing the purpose of the study/project, research question(s), and any hypotheses. What is the benefit/contribution of this study? This content may be covered in a brief introductory paragraph as part of your Methods Chapter.
2. The Methods Chapter - describes all procedures in your study AND how you have addressed any human subjects issues
 - a. Describe all procedures involved in the study, e.g., sampling, data collection plans.
 - i. **Describe the target sample and sampling plan.** Who will be the subjects/participants in the study? Why is this population appropriate to the study? Note any ethical issues in singling this population/group out for study. **SECONDARY DATA ANALYSES:** proposal should describe the rationale and strategy for selecting the data that will be analyzed.
 - ii. **Describe the study procedures.** What are you expecting the subjects/participants to do (or what will you do to or with them)? **SECONDARY DATA ANALYSES:** proposal should explain how the data will be extracted from the source format.
 - iii. **Describe the data collection instruments.** List and operationalize study variables. Attach copies of data collection instruments and/or interview guide as addendum. **SECONDARY DATA ANALYSES:** proposal should list and define the variables that will be extracted/requested and used in the study.
 - iv. **Describe data analysis plan.**
 - b. Provide a full explanation of human subjects issues in the study and steps taken to protect human subjects/address these issues. Reviewers will want to be able to determine if the “risks/costs” to participants is warranted by the potential benefits/answers to be gained by the study. Studies involving **SECONDARY DATA ANALYSES** also have to consider the issues noted below. Human subjects discussion should include (as applicable):
 - i. Procedures that will be used to inform participants about the nature of the study. **SECONDARY DATA ANALYSES:** explain how informed consent was obtained when the data were initially gathered **AND** that consent covers secondary analyses.

- ii. What are the provisions for obtaining informed consent from subjects/participants? Are there any limitations to subjects/participants being able to give informed consent? How will you deal with this?
- iii. What necessary special provisions are you proposing because you seek to study members of a special class and/or vulnerable population? (If applicable). You need to consider who/what groups would be considered to be vulnerable, the reasons for vulnerability, and how you will address this procedurally to obtain adequate informed consent. This may also mean getting assent from minor subjects/participants and consent from a guardian.
- iv. Plans to protect the confidentiality of participants or maintain anonymity. What exceptions may there be to confidentiality? When will it be broken and how will those situations be handled?
- v. Plans to secure/safeguard records and data during and after the study; disposition/destruction of data and other data collection materials after completion of the study.
- vi. What are the benefits to subjects/participants of participating in the study? (What do they get [any compensation?], what do they contribute etc.)
- vii. What are the risks to subjects/participants of participating in the study? Describe plans to minimize physical or emotional risks, social stigma, revelations or behaviors that create potential for liability and to address any adverse effects of participation in the study e.g., seek outside referral to deal with any adverse reaction or distress experienced by the participant as a result of participation in the study.
- viii. What are the provisions for receiving approvals from IRBs/administrations in agencies (if work is taking place under auspices of an agency) to conduct the study? You will need WRITTEN approval on agency letterhead from the appropriate administrator.

3. Additional documents to include (as applicable to your study):

- a. Data collection instruments, surveys, scales, interview guides
- b. (Where applicable) If you have received permission from an agency/data source, include this WRITTEN documentation. You must have written authorization before you may begin recruitment/data collection.

- c. Informed consent document (where applicable)
- d. Recruitment letters, letter of introduction/information etc. (where applicable)