



POLICY AND PROCEDURES

**FOR RESEARCH WITH HUMAN
SUBJECTS AT CALIFORNIA STATE
UNIVERSITY, FRESNO**



Committee on the Protection of Human Subjects

POLICY AND PROCEDURES FOR RESEARCH WITH HUMAN SUBJECTS
California State University, Fresno

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California State University, Fresno

BACKGROUND AND ACKNOWLEDGMENTS

The Committee on the Protection of Human Subjects (CPHS) was first formed in 1971 at the California State University, Fresno. The policy promulgated at that time has been in force until the adoption of the present **Policy and Procedures**.

During the fall and spring of 1986-87 the CPHS surveyed universities within and without the CSU system regarding human subjects' policy and procedures. Although the CPHS is not a senate committee, careful consultation with the Research Committee, Academic Policy and Planning, the Executive Committee and the Senate were undertaken. Open hearings on the present policy and procedures were held as well as consultation with the Vice President for Academic Affairs, the Dean of the Division of Graduate Studies and Research, and the Graduate Council.

The CPHS is grateful for the cooperation of the CPHS at San Diego State University for their advice and consultation. Certain parts of section 2.0 and some example forms are taken (mutatis mutandis) from the **Policy and Procedures** at San Diego State University with their permission.

Copies of the present document are available at the reserve desk of the Henry Madden Library. Permission to photocopy sections of this document for instructional use is granted.

Instructors of research methods courses in each discipline will want to review section 3.2.2.

For information, forms, assistance, consultation or transmittal, contact:

The Committee on the Protection of Human Subjects
Harold H. Haak Administrative Center, Madden Library, Room 4140
5200 N. Barton Ave., M/S ML 54
Fresno, California 93740-8014

Phone: (559) 278-6639

The Committee on the Protection of Human Subjects (CPHS) functions as the Institutional Review Board (IRB) at CALIFORNIA STATE UNIVERSITY, FRESNO.

Questions concerning the use of animals in research, radiation, toxic and radioactive substance storage, and use safety are handled by separate committees or officers of the University. For assistance in these matters, please call ext. 86639.

COVER: The Family
Clement Renzi

Photograph by Paulo Takahashi (Courtesy of the Fresno County Chamber of Commerce)

HISTORICAL DEVELOPMENTS LEADING TO INSTITUTIONAL REVIEW OR RESEARCH WITH HUMAN SUBJECTS:

With the growth of research during the first half of the twentieth century came increasing revelation of experimentation on human subjects. Subjects were often involved without informed consent. Sometimes they did not know they were being placed at excessive or inappropriate risk, at times without any compensating benefit.

The Tuskegee study was one that gained notoriety for ethical violations. This study, initiated by the United States Public Health Service in the 1930s, was a long-term investigation of untreated syphilis. Disadvantaged, rural black men unknowingly served as subjects. During the study, which lasted until 1973, participants with syphilis were examined periodically to follow the natural course of the disease, but treatment was withheld, even after penicillin therapy became available. Measures were even taken to keep subjects from obtaining treatment for syphilis from other sources.

In the 1960s, elderly patients at Jewish Chronic Disease Hospital in New York were injected with live cancer cells in a study of rejection responses. Subjects were not informed that the injected material contained live cancer cells because the investigators were afraid they would refuse participation. The study was not reviewed by a research committee, nor was approval obtained from several physicians providing care for the subjects.

In 1964, parents attempting to institutionalize their mentally disabled children at Willowbrook were told that admissions were closed. Shortly after, they were advised that there would be vacancies in the hepatitis unit if they were to volunteer their children for a study. They were not informed of the risks to their children. The children were inoculated with infectious hepatitis so that researchers could study the period of infectivity for the disease.

Mental patients at Milledgeville State Hospital were given investigational new drugs without their consent or the consent of their psychiatrist or representative. The practice was only stopped after the governor asked for an investigation.

In the Tea Room Trade study, a social scientist posed as a "watch queen" for homosexual encounters in public restrooms. He recorded the men's license plate numbers and located their names and addresses through motor vehicle registration files. The subjects were not told they were being studied. A year later the researcher went to the men's homes in disguise and interviewed them about their family and social life, supposedly for another type of study. In addition to the ethical questions concerning deception, this study placed subjects at risk of serious legal, social, and economic harm.

In another study, Chicano women seeking birth control were given placebo-contraceptives without informed consent and were then denied abortions because state laws prohibited it.

The most famous and perhaps most controversial studies in regard to the ethics of research with human subjects were conducted by Dr. Stanley Milgram at Yale University in the 1960s. In these studies, which were investigating obedience to authority, subjects were told to administer electroshocks to other persons. First pursued in order to try to understand the participation of the German citizenry in the Jewish holocaust, Dr. Milgram's work found unbelievably high compliance behaviors to authority among U.S. subjects. Although no actual electroshocks were administered to

the research confederates, the subjects were deceived into believing that they were administering electroshocks and were witnesses to the feigned reactions to the "shocks." The Milgram studies point out serious issues and conflicts implicit in the area of research with human subjects and are worthy of continuous reflection and debate.

Public disclosure of these and many other unacceptable projects contributed to the support of governmental monitoring of research, resulting in a variety of regulations. One of the first major efforts to deal with unethical biomedical research was the prosecution of Nazis who had conducted medical experiments on inmates in concentration camps. The Nuremberg Military Tribunal established a set of ethical and legal principles for the conduct of experiments as a basis to judge the guilt of the defendants and to be used as future standards for research involving human subjects. The "Nuremberg Code," developed in 1947, was refined later by national and international organizations and became a useful guide for evaluation of research activities. According to the Nuremberg Code, informed consent of a research subject was essential.

In 1962 physician members of the World Medical Association gathered at Helsinki, Finland, and developed standards for clinical research. The standards were revised in 1964 and became known as the Declaration of Helsinki.

United States federal guidelines were established in 1953 when the National Institute of Health began requiring that research involving human subjects at its clinic in Bethesda, Maryland, be approved by a committee for the protection of human subjects. In 1966 the Surgeon General extended the review requirement to all research and training funded by the United States Public Health Services. In 1971 the Department of Health, Education and Welfare published the Institutional Guide to DHEW Policy on the Protection of Human Subjects for research funded by the Department. The National Research Act of 1974 combined with the DHEW regulations to extend the need for committee approval of all research involving human subjects at any institution that ever receives federal DHEW (now HHS) support for such work.

The State of California enacted regulations governing research on prisoners in 1977. In 1978 the California Legislature passed the Protection of Human Subjects in Medical Experimentation Act. This bill required, in addition to informed consent, that subjects of medical experiments be given a Bill of Rights. The CPHS has worked with the CALIFORNIA STATE UNIVERSITY, FRESNO research community since 1971.

COMMITTEE ON THE PROTECTION OF HUMAN SUBJECTS (CPHS)

3.0 POLICY AND PROCEDURES

3.1 PURPOSE

The purpose of this policy and procedures is to protect the rights and health of human subjects used in research investigations while promoting free inquiry and research at this University, and to assure compliance with governmental regulations by establishing:

- A. The appropriate institutional review boards (IRB's) (herein called "Committees") as required by federal regulations;
- B. Procedures to ensure that the rights and dignity of human subjects are not violated by research projects at California State University, Fresno; and
- C. Procedures to protect the principal investigator, the investigative staff, and the University from potential liability in research projects involving human participants.

3.2 APPLICABILITY

All research involving human subjects (defined below) conducted under the auspices of the University, any of its auxiliary organizations, or any cooperative project with researchers outside of the University is covered under this policy.

A specific determination must be made in each instance whether the research is "exempt," "minimal risk," or "at risk" (defined below), and thus covered by different aspects of policies and procedures delineated in this document. No research methodology (e.g., survey, questionnaire) is **per se "not at risk."** Each principal investigator must provide each review committee with sufficient information for an informed judgment about risk level.

Instructional activities that take place in the classroom are not governed by this policy. However, research activities that involve classroom groups or individuals in any way are governed. Should a researcher have doubt about whether an activity is covered, the "departmental" committee should be consulted.

Exemptions

Certain kinds of research are "exempt" from review. A summary of those is found in section 3.5.2.

3.2.1 Student Research.

Research conducted by students solely for a class project is usually not reviewed by the Committee on the Protection of Human Subjects. However, if such student research may be reasonably foreseen to involve any aspect of the ethical dimensions of this policy, the instructor must submit the project for "departmental" review.

3.2.2 Discussion in Research Courses.

Although research training activities are not reviewed by the CPHS, it is the policy of the California State University, Fresno, that all graduate and undergraduate courses that deal with research procedures include an appropriate discussion of the ethics and procedures for the protection of human subjects.

3.3 DEFINITIONS FOR THE PURPOSES OF THIS POLICY

3.3.1 "Principal Investigator"

A principal investigator is the individual in charge of a research project and must be a California State University, Fresno "faculty" member (Cf:sec. 3.3.9) qualified in the area of the proposed research. The principal investigator must assume the responsibility for compliance with the present policy. A student may not serve as a principal investigator.

3.3.2 "Investigator."

An investigator is a person working on a research project who is neither a subject nor the principal investigator. A student or collaborator may be an investigator.

3.3.3 "Research. "

Research is investigation or experimentation aimed at the demonstration, discovery or interpretation of new facts, revision of accepted theories or laws in the light of new facts, or practical application of new or revised theories or laws. Research includes, but is not limited to, investigations conducted by faculty members, University associates, and graduate and undergraduate students, and includes collaboration with researchers outside the University. So called "pilot studies" are defined as research.

3.3.4 "Human Subject."

Any person who is studied in any research investigation is considered to be a human subject. Subjects may include, but are not limited to, classroom participants or voluntary participants in behavioral studies or oral or written interviews, donors of fluid and tissues, participants in a clinical setting (the "unborn" are human subjects), or students registered in a course for which academic credit is given for participation in research projects. The use of a departmental pool of subjects does not exempt the principal investigator from compliance with this **Policy and Procedures**.

"Human subject" also includes any living individual about whom an investigator obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information. "Intervention" includes both physical procedures by which specimens are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

"Interaction" includes communication or interpersonal contact between investigator and subject. "Private information" includes information about behavior that occurs in a context in which an individual can reasonably expect no observation or recording to be taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is known or may readily be ascertained by the investigator) in order to constitute research involving human subjects (or in a format in which the individual can be identified).

3.3.5 "Special Classes of Human Subjects."

Research involving pregnant or nursing (breast feeding) women and **in utero or ex utero** fetuses, including nonviable fetuses, must comply with the provisions of section 46.207ff of the federal regulations.

Research involving prisoners must comply with subpart C section 46.301ff of the federal regulations.

Research involving children must comply with subpart D section 46.401ff of the federal regulations.

3.3.6 "Subject 'At Risk'."

"A subject is considered to be 'at risk' if he or she is exposed to the possibility of harm -physical, psychological, sociological, or other - as a consequence of any activity which goes beyond established and accepted methods for meeting his needs. The determination of when an individual is at 'risk' requires sound professional judgment of the circumstances of the activity in question and the ethical principles contained herein. Responsibility for this determination resides at all levels of institutional and departmental review." (**The Institutional Guide to DHEW Policy on Protection of Human Subjects**, Washington, D.C., 1971, p. 2.)

An illustrative, but not inclusive, list of "at risk" procedures would include experiments involving any aspect, degree, quality or amount of any of the following:

Deception, mental stress, including subjection to public embarrassment, humiliation, discomfort, irritation, or harassment, hypnosis, sensory deprivation, sleep deprivation, normally ingested or inhaled materials in excess of or less than normal amounts, injection, ingestion or inhalation of toxic materials, including all drugs, alcohol or placebos; strenuous physical exertion; use of physical stimuli in abnormal amounts (e.g., noise, vibration, shock, heat, magnetic fields, radiation); violation of anonymity or confidentiality of subjects and data; observations recorded about the individual which, if they became known outside the research, could make the subject liable to criminal or civil action or damage the subject's financial or employment status; or abrogation of any civil right.

3.3.7 "Minimal Risk" Research.

Research in which the risks of harm anticipated are not greater, probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. No research utilizing any procedure listed in paragraph 3.3.6 can be determined to be minimal risk. A research proposal submitted as "minimal risk" in the judgment of the principal investigator, may be determined "at risk" in the department's judgment.

3.3.8 "Certification. "

"Certification" means a written signed statement to a funding source by the CPHS that the proposed research has been reviewed and approved by the CPHS in accordance with the present **Policy and Procedures**.

3.3.9 "Department," "Chair," "Faculty."

"Department" means any current organizational unit of the University or first level review echelon (in some cases "school" review). Non-academic units are expressly included.

The term "chair" refers to the supervisor of any department, program, or non academic unit of the University.

"Faculty" refers to any principal investigator in any unit of the University

3.3.10 "Funded" refers to grants, contracts or other funding obtained from the federal government.

3.4 ETHICAL GUIDELINES FOR RESEARCH PROJECTS WITH HUMAN SUBJECTS

3.4.1 Decision for or Against Conducting a Research Investigation

It is the personal responsibility of the principal investigator to evaluate the ethical acceptability of each study and to ensure that no one is subjected to unreasonable risk to health, well-being, or dignity. Responsibility for this determination resides at the "departmental" and CPHS levels. No assumption exists that "at risk" research is more or less ethical. The standards of care and review are stringent for each class of research proposal.

3.4.2 Individual Informed Consent

The investigator must obtain the informed consent of the prospective subject, or in the case of an individual who is not capable of giving informed consent, the proxy consent of a properly authorized guardian or representative.

3.4.3 Essential Information for Prospective Research Subjects

Before requesting an individual's consent to participate in research, the investigator must provide the individual with the following information, in language that he or she is capable of understanding:

- A. That each individual is invited to participate as a subject in research, and the aims and methods of the research;
- B. The expected duration of the subject's participation;
- C. The benefits that might reasonably be expected to result to the subject or to others as an outcome of the research;
- D. Any foreseeable risks or discomfort to the subject, associated with participation in the research;
- E. Any alternative procedures or courses of treatment that might be as advantageous to the subject as the procedure or treatment being tested;
- F. The extent to which confidentiality of records in which the subject is identified will be maintained;
- G. The extent of the investigator's responsibility, if any, to provide medical services to the subject;
- H. That therapy will be provided free of charge for specified types of research-related injury;
- I. Whether the subject or the subject's family or dependents will be compensated for disability or death resulting from such injury; and
- J. That the individual is free to refuse to participate and will be free to withdraw from the research at any time without penalty or loss of benefits to which he or she would otherwise be entitled.

3.4.3.1 Assuring Freedom From Coercion to Participate.

The investigator shall respect the individual subject's freedom to choose to participate and to discontinue participation at any time. Refusal to participate must not carry an academic penalty; conversely, participation must not carry an academic reward.

3.4.3.2 Fairness and Freedom From Exploitation in the Research Relationship.

Before research begins, all subjects must have a clear understanding of the procedures to be used, including, but not limited to, the amount of time involved. The investigator has an obligation to honor all commitments in that understanding.

3.4.3.3 Confidentiality of the Data and Anonymity of the Individual Participant.

The investigator should keep confidential all personal information obtained. When any possibility exists that the anonymity of the subject will not be protected, this possibility must be explained to the subjects or their parents or legal guardians as part of the informed consent procedure (see section 3.7.4). When the researcher needs to identify the subject for research reasons, such disclosure should be made clearly and explicitly.

3.4.4 Obligation of Investigators Regarding Informed Consent

The investigator has a duty to:

- A. Communicate to the prospective subject all information necessary for adequately informed consent;
- B. Give the prospective subject full opportunity and encouragement to ask questions;
- C. Exclude the possibility of unjustified deception, undue influence and intimidation;
- D. Seek consent only after the prospective subject has adequate knowledge of the relevant facts and of the consequences of participation, and has had sufficient opportunity to consider whether to participate;
- E. As a general rule, obtain from each prospective subject a signed form as evidence of informed consent; and
- F. Renew the informed consent of each subject if there are material changes in the conditions or procedures of the research.

3.4.5 Research Involving Children as Research Subjects

Before undertaking research that involves children, the investigator must ensure that:

- A. Children will not be involved in research that might equally well be carried out with adults;
- B. The purpose of the research is to obtain knowledge relevant to the health needs of children;
- C. A parent or legal guardian of each child has given proxy consent;
- D. The consent of each child has been obtained to the extent of the child's capabilities;
- E. The child's refusal to participate in research must always be respected unless according to the research protocol the child would receive therapy for which there is no medically acceptable alternative;
- F. The risk presented by interventions not intended to benefit the individual child-subject is low and commensurate with the importance of the knowledge to be gained; and
- G. Interventions that are intended to provide therapeutic benefit are likely to be at least as advantageous to the individual child-subject as any available alternative.

3.4.6 Research Involving Persons with Mental or Behavioral Disorders

Before undertaking research involving individuals who by reason of mental or behavioral disorders are not capable of giving adequately informed consent, the investigator must ensure that:

- A. Such persons will not be subjects of research that might equally well be carried out on persons in full possession of their mental faculties;
- B. The purpose of the research is to obtain knowledge relevant to the particular health needs of persons with mental or behavioral disorders;

C. The consent of each subject has been obtained to the extent of that subject's capabilities, and a prospective subject's refusal to participate in non-clinical research is always respected;

D. In the case of incompetent subjects, informed consent is obtained from the legal guardian or other duly authorized person;

E. The degree of risk attached to interventions that are not intended to benefit the individual subject is low and commensurate with the importance of the knowledge to be gained; and

F. Interventions that are intended to provide therapeutic benefit are likely to be at least as advantageous to the individual subject as any alternative.

3.4.7 Research Involving Prisoners as Research Subjects

Prisoners with serious illness or at risk of serious illness should not arbitrarily be denied access to investigational drugs, vaccines or other agents that show promise of therapeutic or preventive benefit.

3.4.8 Selection of Pregnant or Nursing (Breastfeeding) Women as Research Subjects

Pregnant or nursing women should in no circumstances be the subjects of non-clinical research unless the research carries no more than minimal risk to the fetus or nursing infant and the object of the research is to obtain new knowledge about pregnancy or lactation. As a general rule, pregnant or nursing women should not be subjects of any clinical trials except such trials as are designed to protect or advance the health of pregnant or nursing women or fetuses or nursing infants, and for which women who are not pregnant or nursing would not be suitable subjects.

3.4.9 Additional Ethical Principles include the Belmont Report, the American Psychological Association Bill of Rights, and the Medical Bill of Rights.

3.5 PROCEDURES FOR APPROVAL OF PROPOSALS IN WHICH HUMAN SUBJECTS WILL PARTICIPATE

Review Sequence. Each researcher shall have access to a review body at the "departmental" level (see definition section 3.3.9).

3.5.1 Each department shall maintain a review committee for the implementation of this policy or designate an existing committee to comply with the present policy. Should a situation arise in which no committee has been created or designated, the "chair" shall request three "faculty" to serve on an **ad hoc** basis.

The participation of human subjects in projects and research at California State University, Fresno, is authorized only when approved in advance.

As indicated in the Flow Guide (see page 12), proposals considered to be at "minimal risk" are reviewed at only the departmental level (unless funded). All "funded" research and "at risk" research has two reviews. After the unit review, the proposal is forwarded along with two (2 copies) directly to CPHS with one additional copy to the unit Dean for informational purposes.

3.5.2 Exempt Research

If a principal investigator has determined research to be exempt because it is wholly within one or more of the categories listed below, the researcher shall address a memo to his chair stating that the proposed research is to be undertaken and is exempted by policy, indicating the specific category by number. The principal investigator shall attach a brief but sufficient description of the research. The chair shall give the researcher written verification that the research is exempt. See Sample Memos.

If the exempt research is funded, the chair shall forward the protocol and memos to the CPHS for "certification."

The following research projects are exempt from full review by the Committee on the Protection of Human Subjects; however, there are some exceptions for special populations. Category F does not apply to research involving children. Category E is applicable to research involving pregnant or nursing (breastfeeding) women or fetuses, prisoners, or the institutionalized mentally disabled and is not exempt; a standard protocol must be submitted for those reviews. Additionally, some instructional activities may contain an element of risk. If any degree of risk exists, the proposal must be processed as "minimal risk" or "at risk" research.

A. Research conducted in established or accepted educational settings using standard educational practices, such as comparison among instructional techniques, curricula, or management methods.

B. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), if information taken from these sources is recorded in such a manner that makes identification of the subjects impossible.

C. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are routinely available to the investigator, and are recorded by the investigator in such a manner that makes identification of the subjects impossible.

D. Research involving survey or interview procedures when the respondents are elected or appointed public officials or candidates for public offices.

E. Research involving the observation (including observation by participants) of public behavior in places where there is no recognized expectation of privacy.

F. Research involving survey or interview procedures that do not produce psychological stress, the subjects are legally competent, and the investigator identifies him or herself and states that he or she is conducting a research survey or interview.

Categories E and F are not exempt if responses or observations are recorded in such a manner that the subjects can be identified and the information, if it became known outside the research, could reasonably place

the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability, or the research deals with a sensitive aspect of a subject's behavior, such as illegal conduct, sexual behavior, or use of alcohol or controlled substances.

3.6 "MINIMAL RISK" RESEARCH OR RESEARCH REQUIRING LIMITED REVIEW (UNFUNDED)

No individual researcher can make the determination that a research project is "minimal risk. " The principal investigator may state his or her judgment on the application form.

The "departmental" review is conducted by at least three faculty who are not involved in the research under consideration. If the review confirms the judgment that the proposal is of "minimal risk" and written notice to the effect has been given to the chair, the principal investigator may consider the professional obligations regarding human subjects to have been satisfied and the research can begin. The chair shall keep this form for 5 years.

3.7 RESEARCH REQUIRING REVIEW BY THE UNIVERSITY COMMITTEE ON THE PROTECTION OF HUMAN SUBJECTS (CPHS) "AT RISK" (UNFUNDED)

Investigators have an obligation to protect their research subjects from risk conditions. If a potential risk exists, the subject is "at risk," and the investigator must take all possible and reasonable measures to minimize such risk by:

- A. Searching for alternative procedures to avoid the risk;
- B. Using stringent safety precautions to minimize the risk;
- C. Screening out participants who might be particularly susceptible to the risk;
- D. Continuous monitoring of the subject during the procedures;
- E. Minimizing the level and duration of the risk;
- F. Using appropriate measures to detect and correct any consequences of the risk;
- and,
- G. Consulting with colleagues on and off campus for techniques of minimization.

3.7.1 In order to obtain approval of proposals which are not supported by government grants or contracts, the principal investigator shall submit to his "department" committee:

- A. An Application form;
- B. A proposal or protocol detailing the procedures to be employed, potential risks to subjects, and precautions taken to deal with the risks and to protect the welfare and civil rights of the subjects;

C. The Informed Consent Form (in the native language of the subjects and in English) to be provided to the subjects, which describes in detail the procedures to be performed and potential risks.

3.7.2 The investigator must inform the subject of all features of the investigation which might influence his or her willingness to participate, including:

- A. A complete explanation of the procedures to be followed;
- B. A description of possible discomforts and risks;
- C. An offer to answer any questions about procedures;
- D. Instruction that the subject is free to withdraw his or her consent and to discontinue participation in the investigation at any time without prejudice or penalty; and,
- E. A statement that the research procedures have been approved by the Committee on the Protection of Human Subjects at California State University, Fresno.

Before the research commences, an Informed Consent Form containing the above information must be signed by the subject or, if the subject is a minor or otherwise legally incompetent, by his parent(s) or legal guardian(s). When possible, written consent should also be obtained from subjects who are minors. The investigator must be sure that the subject, or his parent or legal guardian, has understood the explanation and that the consent was obtained without deception or coercion. If the subject is "at risk" the informed consent signature must be witnessed.

3.7.3 Copies of questionnaires or other materials that cannot be fully described in the proposal.

3.7.4 Two (2) copies of the completed proposal will be submitted to the Committee on the Protection of Human Subjects for action. The principal investigator also will send one copy to the appropriate Dean for informational purposes. If the subjects are deemed to be at "minimal risk," the proposal need not to be submitted to the University Committee.

3.8 FUNDED RESEARCH

In order to obtain approval of any proposal that is supported by government grants or contracts: The principal investigator shall submit to the University Committee through the departmental committee all documents and materials delineated in Appendix 5.5. If the subjects are deemed "at risk," the principal investigator must include in the proposal a discussion of all measures listed in paragraphs 3.7 to 3.7.4.

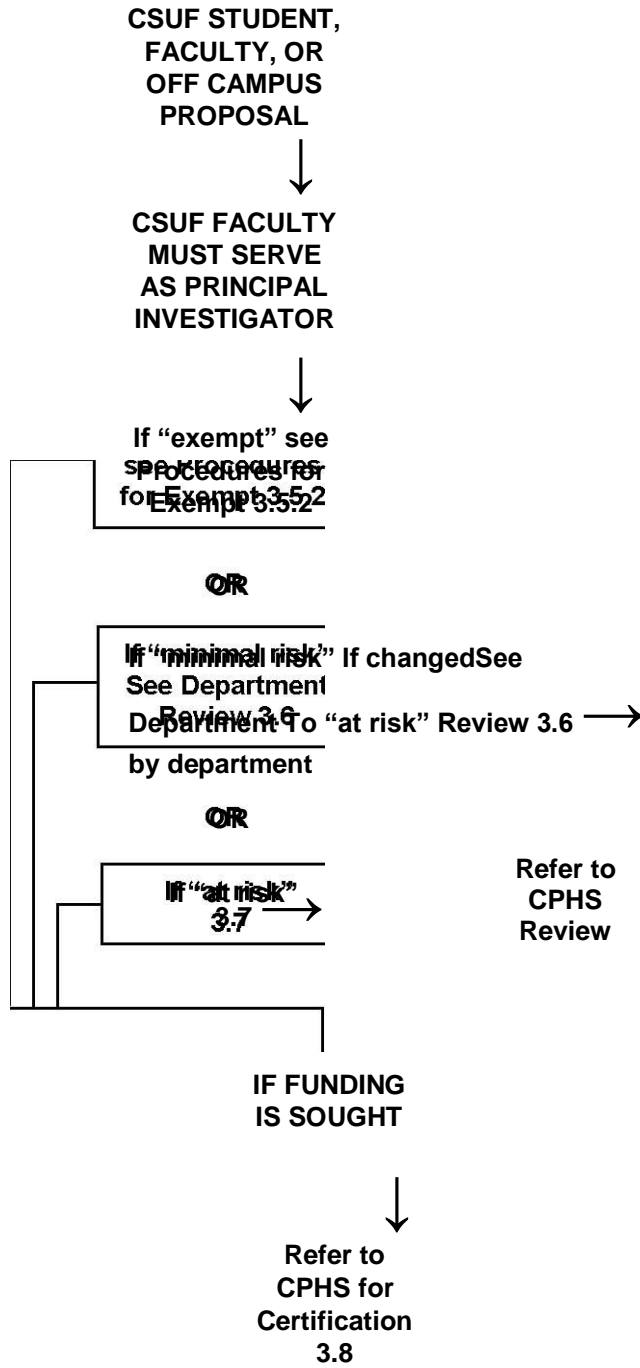
3.8.1 The "departmental" review committee which shall consist of three faculty members who are not involved in the research, will:

- A. Use this document as a guide in its deliberations: review submissions for risk, methodology, and adequate consent. Submissions which are federally funded or are judged to be at risk must be forwarded to the California State University, Fresno Committee on the Protection of Human Subjects. If a submission is unfunded and judged to be of minimal risk, the departmental review committee may:
- B. Approve with or without modification or disapprove the submission with an explanation of the reasons for disapproval;
- C. The departmental review committee may arrange for qualified consultants when needed;
- D. Invite the principal investigator to appear before it for clarification and possible modification before disapproving an application; and,
- E. If indicated, forward two (2) copies of the proposal to the CPHS and one additional copy to the Dean for information purposes.

Appeal From "Departmental" Review.

A principal investigator, a chair, or a "departmental" committee may request the CPHS to review any decisions made during the "departmental" review.

FLOW GUIDE



COMMITTEE ON THE PROTECTION OF HUMAN SUBJECTS (CPHS)

4.0 MEMBERSHIPS, PROCEDURES, AND AUTHORITY

4.1 MEMBERSHIP

California State University, Fresno has maintained the Committee on the Protection of Human Subjects (CPHS) since 1971. This committee functions as the Institutional Review Board (IRB.) required by Federal regulations. The Committee always is composed of members of both genders, and in the nomination of new members gives consideration to racial and cultural backgrounds, community attitudes, and the promotion of respect for its role in safeguarding the rights and welfare of human subjects. The Committee, an independent committee of the University, reviews proposals submitted pursuant to the Policy and Procedures of the University.

The following members are nominated by the Committee to the Provost and Vice President for Academic Affairs for appointment for three-year terms and may serve multiple terms.

At least three faculty members from different schools nominated from a pool of interested faculty maintained by the Committee.

A community member, with no employment relationship to California State University, Fresno, nominated by the Committee.

The Vice President for Administration or designee shall serve as a permanent **ex officio** member.

The Director of University Health and Psychological Services is a traditional, permanent, voting member of the Committee.

One member of the Committee must be nominated specifically because he or she does not possess a scientific background (e.g., lawyer, minister, ethicist). No action of the CPHS can be official without the participation of this member.

The Chair of the CPHS is elected by the Committee annually. The Chair may serve multiple terms.

4.2 PROCEDURES

The Committee has adopted the following procedures.

Upon receipt of a complete proposal, the chair will send copies to each Committee member for independent review. If any member disapproves of the proposal or requests a meeting to discuss the proposal, the chair must call a meeting. A quorum (defined as 50% of the voting membership plus one), must be present to conduct business.

All decisions require a majority vote of those present and the participation of the Committee member with a non-scientific background. The chair votes in all cases, except when acting as a principal investigator or when otherwise involved in the research protocol under

consideration. The Committee may invite consultants at will. Members may not vote on proposals that they have reviewed at any other level.

Minutes of meetings, correspondence, and copies of submissions are retained by the Office of the Vice President for Administration for five years.

The Chair of the Committee may grant "expeditious approval" of submissions. (See section 4.9)

The Chair, California State University, Fresno Committee on the Protection of Human Subjects, is authorized by the Committee to transmit "Certification" to the Department of Health and Human Services (HHS), unless the Committee has denied approval.

4.3 AUTHORITY

The CPHS has the responsibility for reviewing and the authority to approve, require modification, or disapprove all research and related activities involving human subjects under the auspices of California State University, Fresno, including previously approved activities.

The CPHS will approve research after the Committee has determined that the following requirements have been satisfied: (Approval will normally expire, one (1) year from the date of CPHS action.)

A. Risks to subjects are minimized:

- 1 By using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk, and
- 2 By using procedures already being performed on the subjects for diagnostic or therapeutic purposes.

B. Risks to the subjects are reasonable in relation to anticipated benefits, if any, to the subjects, and the value of information that may reasonably be expected. In evaluating risks and benefits, the CPHS will consider only those risks and benefits that may result from research and not the risks and benefits of therapy the subjects would receive if not participating in the research. The CPHS may consider the long-range benefits of information gained in the research as among the risks or benefits that fall within its purview.

C. Selection of subjects is appropriate. In making this assessment the CPHS will take into account the purpose of the research, the setting in which the research is to be conducted, and the population from which subjects are to be recruited.

D. Informed consent will be obtained from each prospective subject or the subject's legally authorized representative, and will be appropriately documented. If the documentation would impair the validity of the results of the investigation, the CPHS may allow the investigator to provide subjects with only a written statement describing the research.

E. The research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

F. The research plan contains adequate provisions for protecting the privacy of subjects and for maintaining the confidentiality of data.

G. If some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as persons with acute or severe physical or mental illness, or persons who are economically or educationally disadvantaged, appropriate safeguards have been included in the study to protect the rights and welfare of these subjects.

4.4 OBSERVATION OF THE CONSENT PROCESS AND THE RESEARCH

The CPHS has the authority to observe or have a third party observe the consent process and the research.

4.5 CONTINUING REVIEW

The CPHS will conduct continuing review of research at intervals appropriate to the degree of risk, but not less than once each year.

4.6 VERIFICATION OF CHANGE

The CPHS can determine that projects require verification from sources other than the investigator, and that no significant changes have occurred since the previous CPHS review.

4.7 SUSPENSION OR TERMINATION OF APPROVAL

The CPHS has the authority to suspend or terminate approval of research that is not being conducted in accordance with the Committee's decisions and requirements, or that has resulted in unexpected injury to subjects.

4.8 INFORMATION DISSEMINATION AND REPORTING

The CPHS has the authority and the responsibility for promptly reporting the following information to the Dean of the Graduate Studies, the Provost and Vice President for Academic Affairs, Associate Vice President for Grants and Research, University Risk Manager, and the Department of Health and Human Services (for HHS funded studies):

- A. Any noncompliance by research investigators with the requirements of the CPHS
- B. Any injury to human subjects
- C. Any unanticipated risks to subjects or others
- D. Suspension or termination of CPHS approval, including reasons for the Committee's actions

4.9 EXPEDITED REVIEW

Research that involves no more than “minimal risk” will be afforded “expedited” review. A member conducting expedited review may exercise all of the authorities of the CPHS except disapproval, which requires action of the full Committee. The reviewer may ask for the opinions of one or more additional CPHS members. The reviewer will refer any research protocols to the full Committee whenever the reviewer considers full committee review to be warranted. When the expedited review procedure is followed, the CPHS member(s) conducting the review will inform the full CPHS of research protocols that have been approved. At a convened CPHS meeting, any member may request that a proposal that has been expeditiously approved be reviewed by the CPHS. Members will vote on the request and a majority will decide the issue. When research activities initially approved under expedited procedures are subsequently reviewed, the decisions reached at the convened meeting will supersede any decisions made by the expedited review

Research activities involving no more than minimal risk and in which the only involvement of human subjects will be in one or more of the following categories (carried out through standard methods) may be reviewed by the CPHS through the expedited review procedure authorized in 46.110 of 45 CFR 46. Categories C, D, E, and F must be performed by qualified and/or licensed professionals.

- A. Ongoing or previously approved research, in which no change is proposed from previous submission to the CPHS.
- B. Collection of: Hair and nail clippings, in a nondisfiguring manner; deciduous teeth; and permanent teeth if patient care indicates a need for extraction.
- C. Collection of excreta and external secretions including sweat, uncannulated saliva, placenta removed at the time of rupture of the membrane prior to or during labor.
- D. Recording of data from subjects 18 years of age or older using noninvasive procedures routinely employed in clinical practice. This includes the use of physical sensors that are applied to either the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the subject or an invasion of the subject’s privacy. It also includes such procedures as weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, diagnostic echography, and electroretinography. It does not include exposure to electromagnetic radiation outside the visible range (for example, x-rays, microwaves).
- E. Collection of blood samples by venipuncture, in amounts not exceeding 450 milliliters in an eight-week period and no more often than two times per week, from subjects 18 years of age or older and who are in good health and not pregnant.
- F. Collection of both supra-and subgingival dental plaque and calculus, provided the procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques.
- G. Voice recording made for research purposes, such as investigations of speech defects.
- H. Moderate exercise by healthy volunteers.
- I. The study of existing data, documents, records, pathological specimens, or diagnostic specimens.
- J. Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the investigator does not manipulate subjects’ behavior and the research will not involve stress to subjects.
- K. Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required.

4.10 APPEAL OF THE CPHS decision

If an investigator believes that his proposal has been disapproved as the result of incorrect, unfair, or improper evaluation by the CPHS, he or she may appeal to the Vice President for Academic Affairs and to the President (or to the Graduate Dean if the research is a thesis). The CPHS will reconsider any aspect of its decision upon request by the Vice President for Academic Affairs or the President (or the Graduate Dean if the research is a thesis). The records of CPHS are to be available for such appeal.

No office or officer of the University may reverse the CPHS's decision (See section 46.112 of the federal regulations).

4.11 CONSULTATION FOR RESEARCH INVESTIGATORS AND DEPARTMENTS

Investigators and department units may call upon the CPHS for consultation regarding the protection of human subjects in research. The CPHS will maintain a panel of consultants for this purpose. The panel will consist of current and previous members of the CPHS in addition to other individuals approved by the CPHS.

Any researcher may receive a roster of members of the CPHS by calling extension 84468.

4.12 THE CPHS SHALL ENSURE THE POLICIES CONFORM WITH FEDERAL REGULATIONS, SHALL NOTIFY THE ACADEMIC SENATE OF ANY CHANGES, AND SHALL PUBLISH REVISION OF THE POLICY WHEN NEEDED.

NOTE: THE MOST RECENT GOVERNING REGULATIONS ARE THOSE OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES, 45 CFR, SUBTITLE A, Part 46, Subpart A, Oct. 1, 1986, as amended October 1, 2000.

The CPHS complies with and commences implementation of the federal guidelines upon their receipt. The CPHS considers the federal guidelines as superseding California State University, Fresno's Policy and Procedures whenever conflicts in interpretations arise.