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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Revised October 2001

California State University, Fresno

1.0 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 appendixes 5.5, 5.8, and 5.9 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. The CPHS has prepared **A Pocket Guide to Research with Human Subjects at CALIFORNIA STATE UNIVERSITY, FRESNO** to assist faculty and students in their classroom discussions. Permission to photocopy from this document is granted.

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

The Committee on the Protection of Human Subjects
Thomas Administration, Room 121
Mail Stop TA52
California State University, Fresno
Fresno, CA

Phone: (559) 278-2083

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. 82083.

COVER: The Family
Clement Renzi

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

2.0 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 1930's, 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 1960's, 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 1960's. 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 Nuremburg 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 "Nuremburg 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 Nuremburg 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. (Cf:appendix 5.15, sec. 46.101.)

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 (Appendix 5.3).

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. Instructors may secure copies of **A Pocket Guide to Research With Human Subjects** from the Committee on the Protection of Human Subjects, Thomas Administration-Room 121, ext. 2083, for classroom use.

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** (see Appendix 5.11).

"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. (See Appendix 5.15.)

Research involving prisoners must comply with subpart C section 46.301ff of the federal regulations. (See appendix 5.15.)

Research involving children must comply with subpart D section 46.401ff of the federal regulations. (See appendix 5.15.)

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 reasonable 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 given 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 are included in Appendixes 5.10, 5.11, and 5.12.

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 ten (10 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 Appendix 5.7 for 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 6 does not apply to research involving children. Category 5 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 5 and 6 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. (See Appendix 5.3 for a sample form). 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, (see Appendix 5.1);

B. A proposal or protocol (see Appendix 5.5) 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 (See Appendix 5.8) (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 Ten (10) 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 <u>which shall consist of three faculty members who are not involved in the research, will:</u>

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;

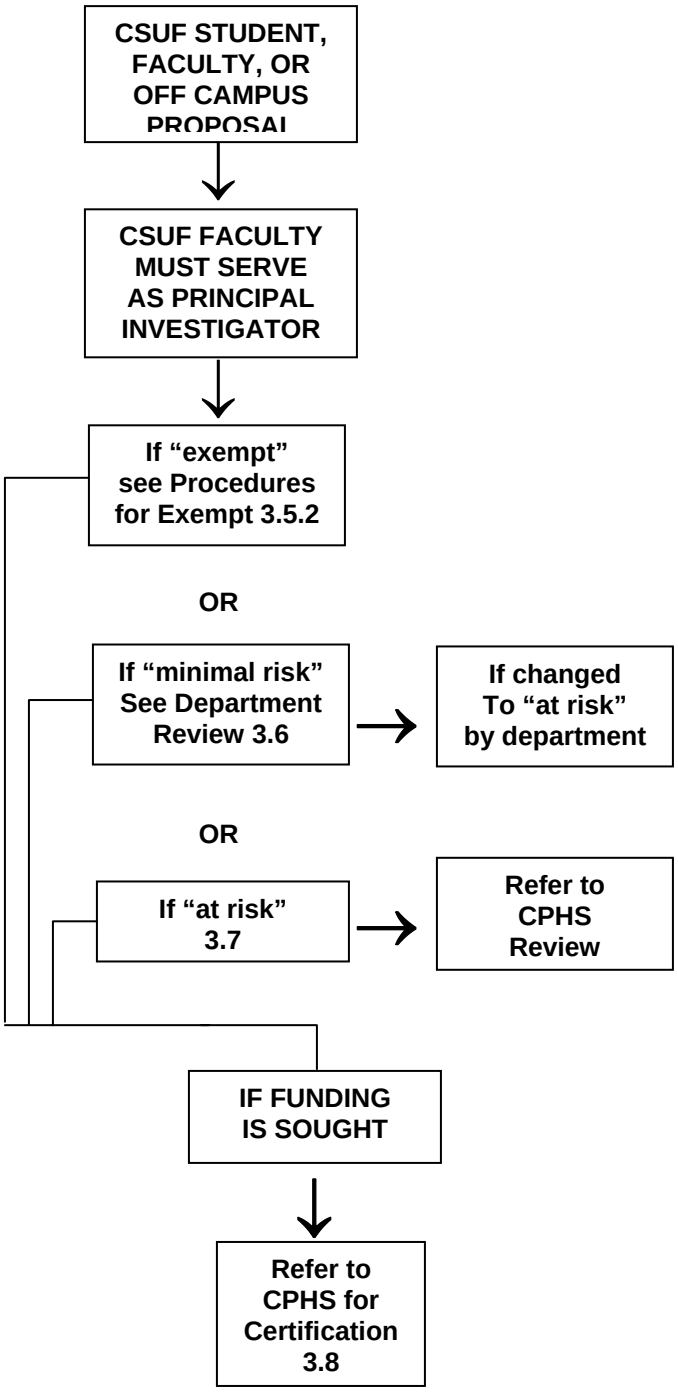
D. Invite the principal investigator to appear before it for clarification and possible modification before disapproving an application; and,

E. If indicated, forward ten (10) copies of the proposal to the CPHS and one additional copy to the Dean for information purposes.

3.8.2 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


CSUF STUDENT, FACULTY, OR OFF CAMPUS PROPOSAL
CSUF FACULTY MUST SERVE AS PRINCIPAL INVESTIGATOR
If "exempt" see Procedures for Exempt 3.5.2
OR
If "minimal risk" See Department Review 3.6
If changed To "at risk" by department
OR
If "at risk" 3.7
Refer to CPHS Review
IF FUNDING IS SOUGHT
Refer to CPHS for Certification 3.8

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 Vice President for Administration 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, a physician, 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 Appendix 5.15, sec. 46. 110) (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," including the procedures listed in appendix 5.9, 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.

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 Appendix 5.15, section 46. 112).

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 82083.

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

APPENDICES

Appendices 5.1—5.4 are available from the Form Template Page

Appendix 5.1—Unfunded Research – California State University, Fresno
Committee on the Protection of Human Subjects

Appendix 5.2—Funded Research – California State University, Fresno
Committee on the Protection of Human Subjects

Appendix 5.3—Departmental (Unit) Review Form – California State University, Fresno
Committee on the Protection of Human Subjects

Appendix 5.4—Annual Renewal – California State University, Fresno
Committee on the Protection of Human Subjects

APPENDIX 5.5

Checklist for Investigators Submitting Protocols

A. COVER SHEET APPLICATION AND ABSTRACT (one paragraph summary of the protocol, including potential benefits, potential risks, and risk management procedures)

B. PROTOCOL (for new applications it should include in the following order the information applicable to your study):

1. Purpose and Background
- ☐ a. Brief references to literature or statement of the problem
- ☐ b. Justification for study involving humans (medical research)
- ☐ c. Specific aims of research
  1) Hypothesis, questions to be answered, data to be tested or gathered
  2) Relevance to continuing work in the field

2. Subjects
- ☐ a. Number
- ☐ b. Source
- ☐ c. Criteria for inclusion and exclusion
- ☐ d. Rationale for using special groups whose capabilities to provide informed consent may be absent or limited
- ☐ e. Frank discussion of potential problems and risks involving the subject group

3. Methods
- ☐ a. Recruitment procedures which ensure voluntary participation
- ☐ b. Investigational or experimental procedures involving subjects
- ☐ c. Special procedures (IND, radioisotopes, electrical equipment, etc.)
- ☐ d. Frequency and duration of each procedure
- ☐ e. Location of study

4. Potential Benefits

- ☐ a. Benefits to the individual subject or patient, if any
- ☐ b. Benefits to the population from which the subject is drawn
- ☐ c. Benefits to science, society, humanity in general

5. Potential Risks

- ☐ a. Psychological
- ☐ b. Social
- ☐ c. Physical
- ☐ d. Economic
- ☐ e. Legal
- ☐ f. Violations of normal expectations

☐ 6. *Precautions Taken to Minimize Risks (If confidentiality is an issue, specify how it will be managed, i.e., coding procedures; storage of and access to identifying data, and when they will be destroyed.)

☐ 7. Compensation of Subjects

☐ 8. Academic Background and Experience of Investigator(s)

*NOTE: Management of risks does not change "at risk" classification to "no risk" or "minimal risk."

C. *CONSENT FORM—for studies involving risk. It should be in language appropriate to subjects and include the following information (see Appendix 5.8 for sample form):

- ☐ 1. Purpose of research (including larger social purpose, if appropriate)
- ☐ 2. Procedures (including time required and locale)
- ☐ 3. Potential risks and discomforts
- ☐ 4. Potential benefits
- ☐ 5. Where applicable, alternative treatments, their risks and benefits
- ☐ 6. Extent of confidentiality
- ☐ 7. Statement regarding voluntariness of participation and freedom to withdraw without jeopardy
- ☐ 8. Assurance of investigator's readiness to answer questions (including phone number)
- ☐ 9. Where applicable, terms of compensation
- ☐ 10. When risk is a possibility, phone number to call if injured from participation
- ☐ 11. Where applicable, provision for guardian or physician's consent

IF AN INTRODUCTORY STATEMENT WILL BE GIVEN BEFORE THE CONSENT FORM – submit both texts.

STUDIES NOT INVOLVING SIGNED WRITTEN CONSENT – submit cover letter or text of statement used to obtain voluntary participation of subjects.

☐ D. INSTRUMENTS

☐ E. APPROVAL FROM PARTICIPATING INSTITUTIONS (where applicable)

☐ F. FOR STUDENT RESEARCH, APPROVAL FROM DEPARTMENT'S HUMAN SUBJECTS COMMITTEE OR FROM FACULTY ADVISER IF DEPARTMENT DOES NOT HAVE A COMMITTEE

☐ G. MODIFICATIONS OF PREVIOUSLY APPROVED STUDIES: Submit

1. Modifications requested
2. Effect of modifications on benefits, risks, risk management, and consent process
3. New consent form, if applicable
4. When new personnel will execute the protocol, a description of their background appropriate to the work of the project
5. Agency approvals, when new agencies will participate in the study

☐ H. ANNUAL RENEWALS: One month before the expiration of your approval, the Vice President for Administration's office will send you a one-page form for completion and return. This form must be returned to the VPA's office within ten (10) working days.

Despite this seemingly long checklist, most protocols run several pages. Answer all of the points that pertain to your study, but be brief. For studies involving risk, please submit ten (10) copies of all material to the Committee on the Protection of Human Subjects, Room 121 Thomas Administration Building, California State University, Fresno, M/S TA52, Fresno, CA 93740-8027, and one additional copy to the Dean of the School. If you have any questions, please call (559) 278-2083.

PLEASE NOTE: YOU MUST OBTAIN CPHS APPROVAL BEFORE INITIATING ANY ACTIVITY WITH THE SUBJECTS.

*Note: Management of risks does not change "at risk" classification to "no risk" or "minimal risk."

APPLICATION PROCEDURES

Approval to use human subjects must be obtained **prior** to initiation of the research activity with the subjects. It is the responsibility of the principal investigator, faculty adviser (for student research), and the department chair to assure CPHS review. The Committee does not provide retroactive approval for research with human subjects that has been completed. Literature search and other work not involving human subjects may be initiated prior to CPHS review.

The following documents must be submitted for CPHS review:

1. Abstract

The abstract should be a one-paragraph summary of the protocol, including potential benefits, potential risks, and risk management procedures. A sample of the form is given in Appendix 5.4.

2. Protocol

The protocol is a statement of the objective of the proposed study, methods to obtain the stated objectives, and the investigator's responsibilities toward the human subjects involved in the research. The protocol should contain the following information, as applicable, in the given order. A protocol can usually be written in 2-3 single spaced pages.

A. Purpose and Background

This section contains information pertaining to the background of the study and the relation of the proposed research to previous scientific investigations in the field. The amount of background information depends on the nature of the study and the risks involved in participation. For interview and questionnaire procedures, a reference or two to the literature or a brief statement of the problem should be sufficient. For medical research, the section should include relevant laboratory and animal studies and clear justification for the participation of human subjects at this stage of the investigation.

The specific aims and hypotheses of the investigation should be discussed, along with the relevance of the hypotheses to previous work. If specific hypotheses are not being tested, then a brief description should be given of the questions to be answered or the possible information to be gained. Also, if the investigation is a pilot or exploratory one, this section should include a discussion of the way in which the information obtained will be used in future studies.

B. Subjects

This section should include an estimate of the number of subjects involved, as well as a statement describing the population from which they will be derived, and how they will be recruited. Criteria for inclusion and exclusion should be specified. Effects of sample size on risks and risk management will be considered by the CPHS.

Justification should be provided for the use of subject groups whose capacities to provide informed consent may be absent or limited. These include children, prisoners, residents or clients of institutions for the mentally ill or retarded, senile elderly, pregnant or nursing (breastfeeding) women and/or fetuses. A pregnant woman's ability to provide consent is limited insofar as she can participate only in activities which:

(1) The purpose is to meet the health needs of the mother, and the fetus will be placed at risk only to the minimum extent necessary to meet such needs, or

(2) The risk to the fetus is minimal.

A frank discussion of potential problems involving the subject groups should be given.

C. Methods

The Methods section should provide a detailed description of all procedures involving human subjects for the purposes of research. Recruitment procedures, which ensure voluntary participation, and experimental procedures should be specified. Tests, questionnaires, and interview guides should be identified and described, and a copy of each should be appended to the protocol. If the final instruments have not yet been developed, drafts or representative samples should be submitted. In cases where information given to subjects as to the procedures and purposes of the study would invalidate the objectives, the investigator should report to the Committee reasons for not informing subjects of the procedures. Alternatives to deception should be considered.

Devices or activities that are not customarily encountered by the subjects in their daily living, or unusual application of devices or activities, must be described in detail. Any special procedures involving radioisotopes or investigational new drugs (IND's) must also be described. Approval from appropriate campus and/or federal agencies must be obtained before CPHS approval can be granted. Unusual electrical devices must have approval from the California State University, Fresno Radiation Safety Committee. Research involving any source of radiation must be first approved by the Radiation Safety Committee. (Application can be obtained from the Radiation Safety Committee). Use of an investigational new drug must be first approved by the Federal Drug Administration (FDA).

A tentative time schedule for the procedures with human subjects should be provided. The schedule should include frequency and estimated duration of each procedure, as well as intervals between procedures. The precise location for each procedure should be specified.

D. Potential Benefits

Discussion of potential benefits should be an evaluation of the benefits to individual subjects, the population from which they are drawn, or society/humanity in general. Benefits are particularly important if participation places subjects at risk.

E. Potential Risks

Potential risks to human subjects must be identified and discussed. Deleterious effects may be psychological, social, physical, economic, or legal. Some research involves neither risks nor discomfort, but violations of normal expectations. Such violations should be specified. See Section 3.3 or the reverse of Appendixes 5.1, 5.2, 5.3 for examples of risk.) If no risks are anticipated, a statement to that effect should be made.

F. Management of Risk

If potential risks have been identified, procedures for minimizing the potential risks must be described. Risk management procedures range from those applicable to a group (such as the exclusion of pregnant or potentially pregnant women from a study involving a new drug) to those applicable to an individual subject.

Special attention should be given to issues of confidentiality. If it is important to collect identifiable information about subjects, the rationale should be provided in the protocol and the mechanism for maintaining confidentiality must be specified, including coding and reporting procedures, storage and access of identifiable data, and approximate date

identifying data will be destroyed. If confidentiality has been promised and case histories or anecdotes will be reported, explanation should be given on how narratives will avoid identifying subjects through description of unique information about them.

Management of risk does not change the classification of a study from "risk" to "no risk"

G. Subject Compensation

Subjects may be reasonably reimbursed for their participation in an experiment. Compensation to subjects should never be such as to constitute coercive inducement.

H. Academic Qualifications

The final section of the protocol should indicate the academic qualifications of student and/or faculty investigators. For procedures requiring special skills on the part of the investigators, licensure, accreditation, and/or experience qualifying the investigators for the performance of these procedures should be indicated. A complete curriculum vitae is not required.

3. The Consent Form

Legally effective informed consent must be obtained and documented for the participation of any individual who will be placed at risk. Informed consent means the knowing consent of an individual, or his or her legally authorized representative, so situated as to be able to exercise free power of choice without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion. Legally authorized representative means an individual, judiciary, or other body authorized under applicable law to consent on behalf of the prospective subject to such subject's participation in the activity. When the proposed investigation involves a subject who is a minor, uncomprehending, or legally incompetent to give consent, the consent form must clearly indicate the procedures are being consented to on behalf of the subject by his or her legally authorized representative. (See Appendix 5.8 for a sample consent form.)

Basic Elements of Informed Consent Includes:

A. A statement that the proposed activity involves research, and an explanation of the research purpose, including the larger social purpose, if applicable. (When elements of purpose cannot be disclosed without biasing the behavior of subject in a way that would invalidate the objectives of the study, the investigator may request that modified informed consent be obtained.) The investigator's name and affiliation with California State University, Fresno should also be provided.

B. A fair explanation of the procedures, including frequency, duration, site of administration, and identification of any procedures that are experimental. The explanation of the procedures and purposes must be given in terms comprehensible to the intended subject, e.g., 5cc = I teaspoon. It is often useful to indicate the immediate purpose of procedures on the subjects.

C. A description of any reasonably forseeable risks or discomforts to the subject. It is appropriate to estimate the degree of risk and to be especially candid about high risk procedures.

D. A description of any benefits to the subject or to others which may reasonably be expected from the research. A distinction should be made between personal benefits and social benefits.

E. A disclosure of any appropriate alternative procedures that might be advantageous for the subject, including their risks and benefits. Disclosure of alternative procedures is only applicable in certain circumstances, particularly when a new diagnostic or therapeutic procedure is being used. The discussion of the alternative must be fair and should attempt to balance the alternatives against the experimental therapy or procedures. The risks and benefits of the alternatives should, therefore, be discussed.

F. A statement describing the extent to which confidentiality of the subject will be maintained.

G. When applicable, the amount and nature of compensation to be given to the subject.

H. A statement that participation is voluntary; refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled. If the subject decides to participate, he or she is free to discontinue participation at any time without penalty.

I. An offer to answer questions, with a resource to contact for later questions regarding the research.

Additional Elements of Informed Consent

When required by the CPHS, the research investigator must provide one or more of the following elements of information to the subjects:

A. How the subject's name and address or phone number were obtained.

B. The possibility that the particular treatment or procedure may involve risks to the subject (or the embryo or fetus, if the subject is or may become pregnant) that are currently unforseeable.

C. Description of compensation for participation and conditions under which it will be paid.

D. Any additional costs to the subject that may result from participation in the research.

E. Consequences of a subject's decision to withdraw from the research, and circumstances under which the subject's participation may be terminated by the research investigator without regard to the subject's consent.

F. Findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject.

G. The approximate number of subjects involved in the study.

Informed Consent as a Process

Informed consent should not be thought of as a form to be signed, but as an ongoing educational process between the research investigator and the prospective subject. The investigator should attempt to view the activity from the subject's perspective to consider what the subject might want to know before deciding whether or not to participate in the research. Information must be presented to the prospective subject in language he or she can easily understand and a dialog of questions and explanations should be encouraged. The investigator should talk with the subject until he or she feels confident that the subject understands what is being asked.

If the information is so complex or possibly disturbing that it may require some time to be absorbed and evaluated by the subject, the investigator should consider using a multi-stage consent process. The investigator might present the information and discuss the issues on more than one occasion or allow a

period of time to elapse between presenting the information and requesting a signature on the consent form. For procedures that are very stressful or otherwise involve substantial risk, the investigator might also ask for reaffirmation of the subject's consent at various stages of his or her participation.

Cross-Cultural Consideration

Informed consent should be obtained in the native language of the subject if English is not readily understood. If the research is done in cultures where signed statements are mistrusted, or where the concept of experimentation itself is unfamiliar, the investigator's protocol should clearly indicate how the project will be explained, how the consent of the subject will be obtained, and who will validate the act of consent.

Oral Consent

If approval for the use of oral consent is sought, the information to be conveyed to the potential subjects must be submitted to the CPHS with the protocol. The rationale for the use of the oral consent procedure rather than the written consent procedure should be included.

Exculpatory Clauses

No consent form may contain exculpatory language through which the subject is made to waive, or appear to waive, any of his or her legal rights, or to release the institution or its agents from liability for negligence.

4. Instruments

A copy of each questionnaire, interview guide, or test should be submitted. If the instruments have not yet been developed, drafts or representative sample questions should be submitted. CPHS approval without complete instrumentation will depend on the sensitivity of the research topic and the vulnerability of the subjects; approval will be conditional upon submission of the final instruments when they are available.

5. Approval From Participating Institutions, if Applicable

If approvals from participating agencies, institutions, or organizations have not been received at the time of submission, they may be placed on file when available, but prior to initiation of the activity.

6. For Student Research, Approval From the Department's Human Subjects Committee

If the department does not have a committee that reviews research involving human subjects, approval from the faculty adviser should be submitted.

Deadlines for Submission of Protocols

Whenever possible, submitters should make submission to the CPHS during regular semester periods. Delays may be expected on submissions made during "breaks" and summer.

Number of Copies to Submit

If risks are identified in the protocol, ten (10) copies of all materials must be submitted to the CPHS and one additional copy to the Dean of the School.

APPENDIX 5.6

EVALUATION CRITERIA FOR PROPOSALS SUBMITTED TO THE COMMITTEE ON THE PROTECTION OF HUMAN SUBJECTS CALIFORNIA STATE UNIVERSITY, FRESNO

TITLE OF STUDY: _____

PRINCIPAL INVESTIGATOR: _____

COLLABORATORS: _____

DATE REVIEWED: _____

LEVEL OF RISK (AS ASSESSED BY THE PI): _____ Minimal Risk _____ At Risk

Criteria for IRB Approval of Research:

- ☐ Risks to subjects are minimized
- ☐ Risks to subjects are reasonable in relation to anticipated benefits
- ☐ Selection of subjects is equitable
- ☐ Informed consent is sought from each prospective subject or the subject's legally authorized representative
- ☐ Informed consent is appropriately documented and is adequate
- ☐ Where appropriate, research plan makes adequate provision for monitoring the data collected to insure the safety of subjects
- ☐ Adequate provisions to protect the privacy of subjects and maintain the data collected to insure the safety of subjects
- ☐ Where appropriate, safeguards are included in the study to protect the rights and welfare of vulnerable subjects

Elements of Informed Consent Present:

- ☐ Information given to the subject or legal representative is in understandable language
- ☐ Purpose of research (including larger social purpose, if appropriate)
- ☐ Procedures (including time involved and locale)
- ☐ Potential risks and discomforts
- ☐ Potential benefits
- ☐ Where applicable, alternative treatments contemplated (with risks and benefits)
- ☐ Extent of confidentiality
- ☐ Statement regarding voluntariness of participation and freedom to withdraw without jeopardy
- ☐ Assurance of investigator's readiness to answer questions (including phone number)
- ☐ Where applicable, terms of compensation
- ☐ When risk is a possibility, phone number to call if injured from participation
- ☐ Where applicable, provision for guardian or physician's consent

Decision: ☐ Approved ☐ Disapproved ☐ Convene a Meeting

APPENDIX 5.7

SAMPLE

March 5, 1996

MEMORANDUM

TO: Chair, Committee on the Protection of Human Subjects

FROM: Principal Investigator

Subject: **NOTICE OF "EXEMPT" RESEARCH ACTIVITY**

I will be administering the PRCA (Personal Report of Communication Anxiety) to 47 inmates of the Fresno City Jail in April, 1996.

Pursuant to Section 3.5 of the ***Policy and Procedures for Research with Human Subjects*** at California State University, Fresno, I am notifying you of this research and my judgment that it is **exempt** from further review because it is within categories 2 and 4.

Attached is a brief outline of my research.

Please verify my judgment in this matter.

Thank you.

****

SAMPLE RESPONSE

March 10, 1987

MEMORANDUM

TO: Principal Investigator

FROM: Chair, Committee on the Protection of Human Subjects

Subject: **VERIFICATION OF EXEMPT STATUS - PRCA-Inmates-Fresno Jail**

I hereby verify that your proposed research *is **exempt*** from further human subjects review.

Alternate Response: *I* am withholding verification of your research and forwarding it to the departmental committee because you are dealing with a special class of human subject, *prisoners. (cf.* Section 3.3.5 of *Policy and Procedures)*

(The Committee will report to you as soon as possible.)

Thank you.

APPENDIX 5.8

SAMPLE CONSENT FORM

The following sample is provided as a skeleton from which a consent form can be developed. It is not provided with the intention that it be precisely emulated. The detailed description of the basic elements of the consent form is presented in the CPHS Policy and Procedures manual. **REMINDER: The consent form should be written in terms comprehensible to the intended subject.**

You are invited to participate in a study conducted by [name of investigator and affiliation]. We hope to learn [state what the study is designed to discover or establish]. You were selected as a possible participant in this study because [state why the subject was selected].

If you decide to participate, we [or: Dr. (blank space) and his associates] will [describe the procedures to be followed, including their purposes, how long they will take, and their frequency]. [Describe the risks, discomforts, inconveniences, and benefits reasonably to be expected. If benefits are mentioned, add:] We cannot guarantee, however that you will receive any benefits from this study.

[Describe appropriate alternative procedures that might be advantageous to the subject, if any. Any standard treatment that is being withheld must be disclosed.]

Any information that is obtained in connection with this study and that can be identified with you will remain confidential and will be disclosed only with your permission or as required by law. If you give us your permission by signing this document, we plan to disclose [state the persons or agencies to whom the information will be furnished, the nature of the information to be furnished, and the purpose of the disclosure].

[If the subject will receive compensation, describe the amount or nature.] [If there is a possibility of additional cost to the subject because of participation, describe it.] (If there are risks to the subjects, state them explicitly.)

Your decision whether or not to participate will not prejudice your future relations with California State University, Fresno [and the named cooperating agency or institution, if any], If you decide to participate, you are free to withdraw your consent and to discontinue participation at any time without penalty. The Committee on the Protection of Human Subjects at California State University, Fresno has reviewed and approved the present research.

If you have any questions, please ask us. If you have any additional questions later, Dr. (state name) [give a phone number or address] will be happy to answer them.

You will be given a copy of this form to keep.

YOU ARE MAKING A DECISION WHETHER OR NOT TO PARTICIPATE. YOUR SIGNATURE INDICATES THAT YOU HAVE DECIDED TO PARTICIPATE, HAVING READ THE INFORMATION PROVIDED ABOVE.

_____	_____
Date	**Signature**
	_____
	Relationship to Subject **(This line should not appear on forms that will be given to subjects consenting for themselves)**
_____	_____
Signature of Witness (if any)	**Signature of Investigator**

APPENDIX 5.9

RESEARCH ACTIVITIES THAT MAY BE REVIEWED THROUGH EXPEDITED PROCEDURES

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 3, 4, 5, and 6 must be performed by qualified and/or licensed professionals.

1. Ongoing or previously approved research, in which no change is proposed from previous submission to the CPHS.

2. Collection of: Hair and nail clippings, in a nondisfiguring manner; deciduous teeth; and permanent teeth if patient care indicates a need for extraction.

3. 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.

4. 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).

5. 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.

6. 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.

7. Voice recording made for research purposes, such as investigations of speech defects.

8. Moderate exercise by healthy volunteers.

9. The study of existing data, documents, records, pathological specimens, or diagnostic specimens.

10. 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.

11. Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required.

APPENDIX 5.10

ETHICAL PRINCIPLES OF THE BELMONT REPORT

The Committee is in part guided by the ethical principles set forth in the *Belmont Report. These principles are Respect for Persons, Beneficence, and Justice.

In consideration of Respect for Persons, investigators should obtain voluntary, informed consent of potential human subjects. Voluntary, informed consent means that subjects are given explicit assurances of the voluntary nature of their participation and adequate information about the study in order to decide whether to participate, in terms that are easy to understand. Respect also means honoring an individual's privacy and maintaining confidentiality when appropriate. Respect for immature or incapacitated persons may require taking extra precautions to protect them while they mature or are incapacitated, perhaps even to the extent of excluding them from participation in the research. The extent of protection should depend on the risks and the benefits of the research.

The principle of Beneficence requires that potential benefits to the subjects are maximized and potential risks of harm are minimized. Benefits to the subjects, or from knowledge to be gained, should, outweigh the risks.

Justice means that subjects are selected fairly and that the risks and benefits are distributed equitably among subjects. Care should be taken not to systematically select subjects simply because of their easy availability, their compromised position, or their manipulability, rather than for reasons directly related to the research problem.

*The complete Belmont Report can be consulted at the CPHS Office, Room 121, Thomas Administration Building.

APPENDIX 5.11

THE ETHICAL PRINCIPLES OF THE AMERICAN PSYCHOLOGICAL ASSOCIATION

The decision to undertake research rests upon a considered judgment by the individual psychologist about how best to contribute to psychological science and human welfare. Having made the decision to conduct research, the psychologist considers alternative directions in which research energies and resources might be invested. On the basis of this consideration, the psychologist carries out the investigation with respect and concern for the dignity and welfare of the people who participate and with cognizance of federal and state regulations and professional standards governing the conduct of research with human participants.

A. In planning a study, the investigator has the responsibility to make a careful evaluation of its ethical acceptability. To the extent that the weighing of scientific and human values suggests a compromise of any principle, the investigator incurs a correspondingly serious obligation to seek ethical advice and to observe stringent safeguards to protect the rights of human participants.

B. Considering whether a participant in a planned study will be a "subject at risk" or a "subject at minimal risk," according to recognized standards, is of primary ethical concern to the investigator.

C. The investigator always retains the responsibility for ensuring ethical practice in research. The investigator is also responsible for the ethical treatment of research participants by collaborators, assistants, students, and employees, all of whom, however, incur similar obligations.

D. Except in minimal-risk research, the investigator establishes a clear and fair agreement with research participants, prior to their participation, that clarifies the obligations and responsibilities of each. The investigator has the obligation to honor all promises and commitments included in that agreement. The investigator informs the participants of all aspects of the research that might reasonably be expected to influence willingness to participate and explains all other aspects of the research about which the participants inquire. Failure to make full disclosure prior to obtaining informed consent requires additional safeguards to protect the welfare and dignity of the research participants. Research with children or with participants who have impairments that would limit understanding and/or communication requires special safeguarding procedures.

E. Methodological requirements of a study may make the use of concealment or deception necessary. Before conducting such a study, the investigator has a special responsibility to (1) determine whether the use of such techniques is justified by the study's prospective scientific, educational, or applied value; (2) determine whether alternative procedures are available that do not use concealment or deception; and (3) ensure that the participants are provided with sufficient explanation as soon as possible.

F. The investigator respects the individual's freedom to decline to participate in or to withdraw from the research at any time. The obligation to protect this freedom requires careful thought and consideration when the investigator is in a position of authority or influence over the participant. Such positions of authority include, but are not limited to, situations in which research participation is required as part of employment or in which the participant is a student, client, or employee of the investigator.

G. The investigator protects the participant from physical and mental discomfort, harm, and danger that may arise from research procedures. If risks of such consequences exist, the investigator informs the participant of that fact. Research procedures likely to cause serious or lasting harm to a participant are not used unless the failure to use these procedures might expose the participant to risk of greater harm

or unless the research has great potential benefit and fully informed and voluntary consent is obtained from each participant. The participant should be informed of procedures for contacting the investigator within a reasonable time period following participation should stress, potential harm, or related questions or concerns arise.

H. After the data are collected, the investigator provides the participant with information about the nature of the study and attempts to remove any misconceptions that may have arisen. Where scientific or humane values justify delaying or withholding this information, the investigator incurs a special responsibility to monitor the research and to ensure that there are no damaging consequences for the participant.

I. Where research procedures result in undesirable consequences for the individual participant, the investigator has the responsibility to detect and remove or correct these consequences, including long-term effects.

J. Information obtained about a research participant during the course of an investigation is confidential unless otherwise agreed upon in advance. When the possibility exists that others may obtain access to such information, this possibility, together with the plans for protecting confidentiality, is explained to the participant as part of the procedure for obtaining informed consent.

APPENDIX 5. 12

MEDICAL RESEARCH SUBJECT'S BILL OF RIGHTS

The faculty and staff of California State University, Fresno, wish you to know:

Any person who is requested to participate as a subject in a medical experiment, or who is requested to consent on behalf of another, has the right to:

1. Be informed of the nature and purpose of the experiment.

2. Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be used.

3. Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment.

4. Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.

5. Be given a disclosure of any appropriate alternative procedures, drugs, or devices that might be advantageous to the subject, and their relative risks and benefits.

6. Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.

7. Be given the opportunity to ask any questions concerning the experiment or the procedures involved.

8. Be instructed that the consent to participate in the medical experiment may be withdrawn at any time, and the subject may discontinue participation in the medical experiment without prejudice.

9. Be given a copy of a signed and dated written consent form when one is required.

10. Be given the opportunity to decide to consent or not to consent to a medical experiment without intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.

CALIFORNIA MEDICAL RESEARCH SUBJECT'S BILL OF RIGHTS

Under California law, any person who is requested to participate as a subject in a medical experiment, or who is requested to consent on behalf of another, must be given a copy of a specified Bill of Rights written in a language in which the person is fluent. Medical experiment is defined in the law as:

I The severance or, penetration or damaging of tissues of a human subject or the use of a drug or a device as defined in the California Health and Safety Code, use of electromagnetic radiation, heat or cold, or use of a biological substance or organism, in or upon a human subject in the practice of research or medicine, in a manner not reasonably related to maintaining or improving the health of such subject or otherwise directly benefiting such subject.

2. The investigational use of a drug or device licensed by the Federal Food and Drug Administration or the California Department of Health Services.

3. Withholding medical treatment from a human subject for any purpose other than maintenance or improvement of the health of such subject.

A Spanish version can be obtained from the CPHS Office, Room 121, Thomas Administration Building (278-2083).

APPENDIX 5.13

The Human Subjects Bibliography is available at the Reference Desk at the Henry Madden Library.

APPENDIX 5.14

WORLD MEDICAL ASSOCIATION DECLARATION OF HELSINKI

NOTE: This document was adopted by the 18th World Medical Assembly, Helsinki, Finland, June 1964 and by the American Medical Association in 1966. It was amended by the 29th World Medical Assembly, Tokyo, Japan, October 1975; 35th World Medical Assembly, Venice, Italy, October 1983; and the 41st World Medical Assembly, Hong Kong, September 1989.

INTRODUCTION

It is the mission of the physician to safeguard the health of the people. His or her knowledge and conscience are dedicated to the fulfillment of this mission.

The Declaration of Geneva of the World Medical Association binds the physician with the words, "The health of my patient will be my first consideration," and the International Code of Medical Ethics declare that, "A physician shall act only in the patient's interest when providing medical care which might have the effect of weakening the physical and mental condition of the patient."

The purpose of biomedical research involving human subjects must be to improve diagnostic, therapeutic and prophylactic procedures and the understanding of the aetiology and pathogenesis of disease.

In current medical practice most diagnostic, therapeutic or prophylactic procedures involve hazards. This applies especially to biomedical research.

Medical progress is based on research that ultimately must rest in part on experimentation involving human subjects.

In the field of biomedical research a fundamental distinction must be recognized between medical research in which the aim is essentially diagnostic or therapeutic for a patient, and medical research, the essential object of which is purely scientific and without implying direct diagnostic or therapeutic value to the person subjected to the research.

Special caution must be exercised in the conduct of research that may affect the environment, and the welfare of animals used for research must be respected.

Because it is essential that the results of laboratory experiments be applied to human beings to further scientific knowledge and to help suffering humanity, the World Medical Association has prepared the following recommendations as a guide to every physician in biomedical research involving human subjects. They should be kept under review in the future. It must be stressed that the standards as drafted are only a guide to physicians all over the world. Physicians are not relieved from criminal, civil and ethical responsibilities under the laws of their own countries.

I. BASIC PRINCIPLES

1. Biomedical research involving human subjects must conform to generally accepted scientific principles and should be based on adequately performed laboratory and animal experimentation and a thorough knowledge of the scientific literature.

2. The design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental protocol which should be transmitted for consideration, comment and guidance to a specially appointed committee independent of the investigator and the sponsor, provided that this independent committee is in conformity with the laws and regulations of the country in which the research experiment is performed.

3. Biomedical research involving human subjects should be conducted only by scientifically qualified persons and under the supervision of a clinically competent medical person. The responsibility for the human subject must always rest with a medically qualified person and never rest on the subject of the research, even though the subject has given his or her consent.

4. Biomedical research involving human subjects cannot legitimately be carried out unless the importance of the objective is in proportion to the inherent risk to the subject.

5. Every biomedical research project involving human subjects should be preceded by careful assessment of predictable risks in comparison with foreseeable benefits to the subject or to others. Concern for the interests of the subject must always prevail over the interests of science and society.

6. The right of the research subject to safeguard his or her integrity must always be respected. Every precaution should be taken to respect the privacy of the subject and to minimize the impact of the study on the subject's physical and mental integrity and on the personality of the subject.

7. Physicians should abstain from engaging in research projects involving human subjects unless they are satisfied that the hazards involved are believed to be predictable. Physicians should cease any investigation if the hazards are found to outweigh the potential benefits.

8. In publication of the results of his or her research, the physician is obliged to preserve the accuracy of the results. Reports of experimentation not in accordance with the principles laid down in the Declaration should not be accepted for publication.

9. In any research on human beings, each potential subject must be adequately informed of the aims, methods, anticipated benefits and potential hazards of the study and the discomfort it may entail. He or she should be informed that he or she is at liberty to abstain from participation in the study and that he or she is free to withdraw his or her consent to participation at any time. The physician should then obtain the subject's freely given informed consent, preferably in writing.

10. When obtaining informed consent for the research project the physician should be particularly cautious if the subject is in a dependent relationship to him or her or may consent under duress. In that case the informed consent should be obtained by a physician who is not engaged in the investigation and who is completely independent of this official relationship.

11. In case of legal incompetence, informed consent should be obtained from the legal guardian in accordance with national legislation. Where physical or mental incapacity makes it impossible to obtain informed consent, or when the subject is a minor, permission from the responsible relative replaces that of the subject in accordance with national legislation.

    Whenever the minor child is in fact able to give a consent, the minor's consent must be obtained in addition to the consent of the minor's legal guardian.

12. The research protocol should always contain a statement of the ethical considerations involved and should indicate that the principles enunciated in the present Declaration are complied with.

II. MEDICAL RESEARCH COMBINED WITH PROFESSIONAL CARE (Clinical research)

1. In the treatment of the sick person, the physician must be free to use a new diagnostic and therapeutic measure, if in his or her judgment it offers hope of saving life, reestablishing health or alleviating suffering.
2. The potential benefits, hazards and discomfort of a new method should be weighed against the advantages of the best current diagnostic and therapeutic methods.

3. In any medical study, every patient – including those of a control group, if any – should be assured of the best proven diagnostic and therapeutic method.

4. The refusal of the patient to participate in a study must never interfere with the physician-patient relationship.

5. If the physician considers it essential not to obtain informed consent, the specific reasons for this proposal should be stated in the experimental protocol for transmission to the independent committee (**I**,2).

6. The physician can combine medical research with professional care, the objective being the acquisition of new medical knowledge, only to the extent that medical research is justified by its potential diagnostic or therapeutic value for the patient.

III. NON-THERAPEUTIC BIOMEDICAL RESEARCH INVOLVING HUMAN SUBJECTS (Non-clinical biomedical research)

1. In the purely scientific application of medical research carried out on a human being, it is the duty of the physician to remain the protector of the life and health of that person on whom biomedical research is being carried out.

2. The subjects should be volunteers – either healthy persons or patients for whom the experimental design is not related to the patient's illness.

3. The investigator or the investigating team should discontinue the research if in his/her or their judgment it may, if continued, be harmful to the individual.

4. In research on man, the interest of science and society should never take precedence over considerations related to the well being of the subject.

Appendix 5.15

The Federal Regulations HHS 2000 are available at this web link.

RESEARCH ACTIVITIES THAT MAY BE REVIEWED THROUGH EXPEDITED PROCEDURES

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 3, 4, 5, and 6 must be performed by qualified and/or licensed professionals.

1. Ongoing or previously approved research, in which no change is proposed from previous submission to the CPHS.

2. Collection of: Hair and nail clippings, in a nondisfiguring manner; deciduous teeth; and permanent teeth if patient care indicates a need for extraction.

3. 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.

4. 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).

5. 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.

6. 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.

7. Voice recording made for research purposes, such as investigations of speech defects.

8. Moderate exercise by healthy volunteers.

9. The study of existing data, documents, records, pathological specimens, or diagnostic specimens.

10. 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.

11. Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required.