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.)