

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 = 1 teaspoon. It is often useful to indicate the immediate purpose of procedures on the subjects.
- C. A description of any reasonably foreseeable 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 unforeseeable.
- 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.