

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)
 9. Evidence of completion of either the NIH or OHRP on-line training tutorial (see: <http://www.fresnostate.edu/academics/humansubjects/resources/training-modules.html>). In the case of faculty sponsored student research, both the student and faculty must complete a tutorial.

C. CONSENT FORM—for studies involving risk. It should be in language appropriate to subjects and include the following information (see Sample Informed Consent 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. COPY OF HUMAN SUBJECT ASSURANCE TRAINING

F. APPROVAL FROM PARTICIPATING INSTITUTIONS (where applicable)

Despite this seemingly long checklist, most protocols run several pages. Answer all of the points that pertain to your study, but be brief. Please submit one (1) copy of all material to the Committee for the Protection of Human Subjects, Frank W. Thomas Building Room 130, California State University, Fresno, M/S TA 51, Fresno, CA 93740-8014. If you have any questions, please call (559) 278-2448.

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.”