

APPENDIX 5.3

COMMITTEE ON THE PROTECTION OF HUMAN SUBJECTS DEPARTMENTAL (UNIT) REVIEW FORM CALIFORNIA STATE UNIVERSITY, FRESNO

Please type

PRINCIPAL INVESTIGATOR _____
Name Dept. (unit) Mail Stop Number
Telephone Number Dept. Telephone Number

If student or collaborative research: _____
Name Affiliation
Telephone Number Telephone Number

TITLE OF STUDY _____

If funding is sought, from what agency? _____

How did the Principal Investigator designate the research? Minimal risk _____ At risk _____

REVIEWER 1

Name _____
At risk _____ Minimal risk _____

COMMENTS:

Place your signature in the category of your judgment

APPROVED

DISAPPROVED

REVIEWER 2

Name _____
At risk _____ Minimal risk _____

COMMENTS:

Place your signature in the category of your judgment

APPROVED

DISAPPROVED

REVIEWER 3

Name _____
At risk _____ Minimal risk _____

COMMENTS:

Place your signature in the category of your judgment

APPROVED

DISAPPROVED

The department may wish to route this form to the 3 reviewers or send each reviewer a form. If the review is done on three separate forms, the Chair ought to give each reviewer the comments of the other reviewers as well as the Principal Investigator. If all three reviewers judge the proposal as "minimal risk," the Department Chair notifies the Principal Investigator and keeps this form(s) for 5 years. If funding is sought for this study or it is "at risk," ten (10) copies of the protocol and this form are forwarded to the university CPHS, Thomas Administration, Room 121, M/S TA52, with one additional copy to the dean's office. (See sections 3.7 or 3.8.)

"Exempt" Research.

If "exempt", see Section 3.5.2.

"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 involving any item listed as being "at risk" can be determined to be minimal risk. A department or other unit review committee may determine that a research proposal submitted, in the judgment of the principal investigator as "minimal risk," is actually "AT RISK."

"At Risk" Research.

"A subject is considered to be 'at risk' if he/she is exposed to the possibility of harm- physical, psychological, sociological, or other as a consequence of any activity that goes beyond the application of those established and accepted methods necessary to meet his/her needs. The determination of when an individual is 'at risk' requires application of sound professional judgment 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 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.