

APPENDIX 5.1

Application Form for

UNFUNDED RESEARCH—CALIFORNIA STATE UNIVERSITY, FRESNO COMMITTEE ON THE PROTECTION OF HUMAN SUBJECTS

Please type

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

Telephone Number Dept. Telephone Number

Student's name or collaborator(s) _____
(if applicable) (if a graduate school thesis, so indicate) (affiliation if collaborative research)

Telephone Number Telephone Number

TITLE _____

The Principal Investigator is responsible for fully understanding the **Policy and Procedures** of the CPHS. Below indicate your judgment as Principal Investigator as to the RISK category of the present study. (See definitions on the reverse of this sheet.) (If exempt see 3.52)

Minimal Risk _____

PROCEDURES

1. Attach your protocol and submit to your department chair for review by your human subjects committee.
2. Your departmental committee will review the protocol status and if it agrees with the determination of "minimal risk" status (see Appendix 5.3), then
3. Your department chair will keep the forms for 5 years.
4. Your responsibilities have been satisfied.

HOWEVER,

(If the departmental review changes the determination to "At Risk," follow the procedure to the right of this page.)

At Risk _____

PROCEDURES

1. Attach your protocol and submit to your department chair for review by your human subjects committee. (A sample informed consent must be included.)
2. Submit the department review form(s) with this form to the CPHS.
3. Transmit all reviews and ten (10) copies of the protocol to the CPHS for review. Send one additional copy to the Dean.
4. Allow two weeks during the school year for your response from the CPHS.

"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.