Human Subjects Policy

Executive Memorandum 93-004

April 05, 1993

From: Robin S. Wilson, President

Subject: Human Subjects Policy

The attached policy replaces EM 84-003, the Policy on Unregulated Research Involving Human Subjects. This policy has been reviewed by the Human Subjects in Research Committee and the Research and Grant Development Council. Upon recommendation of the Provost, I approve it for immediate implementation.

POLICY FOR THE PROTECTION OF HUMAN SUBJECTS IN RESEARCH

California State University, Chico

California State University, Chico, hereinafter University, hereby provides policy to comply with federal and government regulations governing the use of human subjects in research. This policy is intended to cover all research involving human subjects conducted at or under the auspices of the University. By this policy, the University recognizes its obligation to protect human subjects and declares the intention to follow federal regulations in all research involving the use of human subjects.

Applicability

This policy is applicable to all research involving the use of human subjects that is conducted under the authority of the University and includes research conducted by individuals who are not members of the campus community but which uses university students, faculty, or staff as subjects. This policy is applicable to all research, whether funded or not by an agency of the federal government. Thus, covered research includes research activities engaged in as part of the instructional process, namely, course assignments and thesis projects using human subjects taking place off campus but conducted under the University's authority.

This policy is applicable to research activities as defined by federal regulations. Therefore, research means "a systematic investigation, including research, development, testing, and evaluation designed to develop or contribute to generalizable knowledge. " Research does not include the usual instructional testing and evaluation processes used to make judgments about student learning related to academic offerings of the University.
University Policy

The University will comply with all applicable federal laws and regulations governing the conduct of research involving human subjects. State and local laws will be taken into account in this process as applicable, including the California law prescribing provisions to be included in informed consent for human subjects involved in a medical experiment.

University policy will be implemented and further defined by the Human Subjects in Research Committee (HSRC), which will serve as the University's Institutional Review Board (IRB). The HSRC will determine and implement policy as required to carry out the charges provided by law and regulations. HSRC membership will conform to federal IRB requirements, including at least one member from each major academic unit (college), a student selected by the Council of Graduate Students, and at least one member who shall have no employee or student relationship with the University. The HSRC Chair will be the Vice Provost for Research or designee. The Office of Research and Sponsored Programs will have administrative responsibility for convening the HSRC and providing staff support.

The HSRC is charged with protecting human subjects involved in research. To fulfill this mandate, the HSRC will follow current federal regulations and law as a minimum set of standards in defining and determining what constitutes research involving human subjects, what research is exempt from coverage, what safeguards and restrictions to enforce for the protection of human subjects, and what processes and procedures to use in regulating such research. The HSRC is authorized to modify or amend existing implementation policies and procedures or to develop new implementation policies and procedures in order to ensure compliance with changing federal and state requirements.

Consistent with federal regulations, campus units--colleges, departments, programs--in which faculty conduct research involving human subjects may establish regulatory bodies to monitor and approve such research as long as the HSRC approves a written operating plan for each unit and as long as each reports annually to the HSRC on its activity. Such operating plans must conform to federal regulations and other policies and procedures deemed necessary by the HSRC. Campus units which do not wish to establish a unit regulatory body will work directly through the HSRC in protecting human subjects.

Any unit with an approved regulatory body will report to the HSRC each August on projects reviewed or monitored during the preceding year (July 1-June 30) and any other pertinent information.

Reports will include a description of the research, outcomes of the review or monitoring activities, and problems which may have occurred with any research projects covered by this policy. Any project experiencing significant problems involving risk to subjects should be reported immediately to the HSRC. The HSRC at any time may request additional information, call for a hearing before the HSRC on any or all projects, and require additional steps to protect human subjects. Any unit regulatory body may refer protocols to the HSRC when such review seems appropriate. However, any project which requests or involves federal funds must be reviewed by the HSRC as must any project (funded or unfunded) proposing research involving fetuses, pregnant women, human in vitro fertilization, prisoners, and children. Research involving children in usual instructional and typical school activities can be reviewed by approved unit
regulatory bodies. The HSRC may add to the list of projects subject to HSRC review based on new regulations and the HSRC's sense of what is appropriately subject to HSRC review.

No research involving human subjects will be conducted until a review of the project has been carried out and written approval given.

The HSRC will report each September to the Vice Provost for Research on activities involving the use of human subjects in research. The report, which will be forwarded to the Provost, will include a listing of all protocols reviewed during the preceding year (July 1-June 30). Also listed in the report will be projects monitored as required periodically by federal regulations due to their length continuing beyond one year or those which may experience problems or pose significant risks to warrant monitoring.

University policy recognizes that federal and other governing regulations and law may change over time. Thus, the HSRC is empowered to change or make new implementation policies and procedures in response to changing regulations and circumstances to ensure university compliance with federal and other pertinent regulations. These changes will be brought as recommendations to the Research and Grant Development Council for approval. This policy recognizes as current federal policy the Common Rule issued in the Federal Register (Vol. 56, No. 117, pp. 28012-28018, 6/18/91) and Subparts B, C, and D of the Public Health Service regulations (Code of Federal Regulations, 45 CFR 46, as revised 3/8/83) involving research related to fetuses, pregnant women, human invitro fertilization, prisoners, and children. Issues which may arise concerning the interpretation and implementation of federal regulations will be subject to final determination and interpretation by the HSRC.

**Guidelines for Research Approval and Monitoring**

The HSRC or unit regulatory bodies will approve research involving human subjects based on the determination that federal requirements related to subject risk are satisfied. For non-exempt categories of research, protocols will be approved that fully provide for informed consent of each subject as defined by the federal regulations and as interpreted on a case-by-case basis by the HSRC or unit regulatory bodies. As appropriate to the circumstances, the protocol will provide for monitoring the research activities and data collected to ensure safety and confidentiality of each subject. The HSRC will set monitoring provisions for each project as deemed necessary and appropriate by a majority of the HSRC membership.

The HSRC will exercise authority, as necessary, to withhold, suspend, or terminate approval of research not meeting established regulations and procedures, not conducted in accordance with HSRC decisions and conditions, or associated with bringing harm or undue risk to subjects. The HSRC will report within five working days to the Vice Provost for Research any incidents involving withholding, suspending, or terminating a research project. Any member of the campus community or public at large may report suspected problems or violations of regulations or approved protocols. Reports may be made to any member of the HSRC or to the Vice Provost for Research or referred thereto by university officials. The HSRC and Vice Provost for Research will investigate such reports and act appropriately. Principal investigators are charged with responsibility for reporting any unanticipated problems or risks to subjects and securing HSRC approval for any significant changes in the protocol as originally approved by the HSRC.