5.94 Research-General Principles (See Also Chapter 3 for Ethics and Conduct Policies)

B. Protections in Research Involving Human Subjects. It is the policy of the university to protect the rights, well being, and personal privacy of individuals participating in research projects, while also maintaining a favorable climate for the conduct of scientific inquiry and protecting the interests of the university. The university has established the Institutional Review Board to regulate the participation of human subjects in research, consistent with federal law. (*See* 5.94.30 D. below.) All research conducted at or by the university, regardless of funding source, shall adhere to the requirements of the Institutional Review Board and the following tenets:

1. The university, including its faculty, staff, contractors and student body shall be responsible for the protection of the rights and welfare of human subjects.

2. No human subject involved in a research activity shall be exposed to unreasonable risk to health or well-being, in order to ensure the subject's physical and mental safety and well-being.

3. All participation by human subjects shall be voluntary; no subject will be coerced in any way to participate in a research project. A request by any subject to withdraw from a research activity shall be honored promptly without penalty or loss of benefits to which the subject is otherwise entitled, within the limits of the research.

4. The confidentiality of information received from subjects in experiments or respondents to questionnaires shall be protected, both during and after the conduct of a research activity, consistent with applicable law.

5. In research which involves more than minimal risk, or which involves substantial stress or discomfort, such risk, stress or discomfort shall be carefully explained in advance to the subject. The researcher(s) shall be satisfied that the explanation has been understood by the subject, and that the written consent of the subject, is obtained and kept as a matter of record. The researcher(s) shall be responsible for ensuring that method used to obtain informed consent (written, audio-recorded, witnessed) is the most appropriate for the participant, and for providing appropriate evidence of informed consent consistent with the approval granted by the Institutional Review Board and with applicable federal law.

6. Research involving special subject populations (e.g., persons under the age of 18, or mentally disabled or disadvantaged persons) may be conducted as long as a qualified guardian signs the consent form.

5.94.30 Research Oversight and Risk Management [*Proposition 22-08/09 Amending University Research Council Charter Passed by Faculty Senate 04.03.09; Amendment to Institutional Review Board procedures Adopted by Administrative Council 07.14.09; Ratified by Board of Regents 07.29.09*]

D. Institutional Review Board.

Administrative authority for the protection of human subjects at New Mexico State University has been delegated by the president to the vice president for research. The Office of the Vice President for Research oversees the Institutional Review Board, which has been established to regulate university research involving human subjects, consistent with federal law and university policy. Prior to submitting an application to the Institutional Review Board, principal investigators shall familiarize themselves with Policy 5.94 and all subparts, any supplemental procedures issued by the Institutional Review Board, and guidance available online from the Office of Compliance and the federal Office of Human Research Protections. Procedures may be amended from time to time by the Institutional Review Board with the approval of the vice president for research.

1. Membership.

a. Institutional Review Board members are appointed by the vice president for research for renewable three-year terms, upon recommendation from, but not limited to, the institutional review board chair and the compliance director. All members of the Institutional Review Board appointed by the vice president for research will be voting members. A list of the current officers and membership of the Institutional Research Board as well as detailed application procedures are available from the Office of Compliance.
b. The Institutional Review Board chair is appointed by the vice president for research and serves as the link between the Office of the Vice President for Research and the Institutional Review Board. A vice chair will be appointed to conduct business if the chair is unavailable, or has a conflict of interest.
c. The composition of the Institutional Review Board will consist of individuals sufficiently qualified through their experience, expertise, and diversity, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. The Institutional Review Board will not consist entirely of men or entirely of women, or entirely of members of one profession.
d. The Institutional Review Board will primarily be composed of representatives from the colleges and departments most concerned with projects involving human subjects. It will include at least:
   - one member whose primary concerns are in scientific areas,
   - one member whose primary concerns are in nonscientific areas, and
   - one individual who is not employed by or otherwise officially affiliated with the university and who is not part of the immediate family of a university employee.
e. If the Institutional Review Board regularly reviews research protocols that involve a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, the Institutional Review Board will

include one or more individuals whose background is in protecting the welfare of these subjects.

f. The vice president for research or his/her designee and the compliance director will be ex-officio non-voting members of the Institutional Review Board. A representative from the Office of the University General Counsel will serve as a non-voting consultant to the Institutional Review Board as necessary.
g. The Institutional Review Board may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the Institutional Review Board. These individuals will be non-voting members. Such non-voting members may include, but not be limited to, expert consultants external to the university and/or additional representatives of the university.

2. Functions and Responsibilities.

a. The Institutional Review Board will assure complete and adequate review of research activities involving human subjects, and will be able to determine the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice.
b. No member of the Institutional Review Board will participate in the initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the Institutional Review Board.
c. The Institutional Review Board shall recommend to the vice president for research, and review on a continuing basis, university policies and procedures regarding the use of human subjects in research.
d. The Institutional Review Board shall review and have authority to approve, require modifications to secure approval, or disapprove all research activities involving human subjects or data related to human subjects.
e. Research activities shall be reviewed by the Institutional Review Board for compliance with established federal regulations related to the protection of human subjects, as issued by the U.S. Department of Health and Human Services and the U.S. Food and Drug Administration, and contained in the Code of Federal Regulations 45, Part 46.
f. Research covered by these regulations that has been approved by the Institutional Review Board may be subject to further appropriate review and approval or disapproval by officials of the university. However, those university officials may not approve the research if it has not been approved by the Institutional Review Board.
g. The Institutional Review Board shall provide advice and guidance to investigators regarding the protection of the rights and welfare of human subjects.
h. The Institutional Review Board shall ensure that investigators have been certified in the ethical principles of using human subjects in research.
i. Where necessary, the Institutional Review Board shall serve as a referral board for complaints from subjects of research.
j. The Institutional Review Board shall require that information given to subjects as part of informed consent is in accordance with federal regulations as indicated in the Code of federal Regulations 45, Part 46. The Institutional Review Board may require that information in addition to that specifically mentioned in Code of Federal Regulations

45, Part 46, be given to the subjects when, in the Institutional Review Board's judgment, the information would meaningfully add to the protection of the rights and welfare of the subjects. Documentation of that process shall also be required. The Code of Federal Regulations outlining requirements for the protection of human subjects is available by contacting the Office of the Vice President for Research.

k. The Institutional Review Board shall notify investigators in writing of its decision to approve or disapprove the proposed research activity or of modifications required to secure Institutional Review Board approval. If the Institutional Review Board decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.
l. The Institutional Review Board shall conduct continuing review of research covered by these regulations at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research.
m. The Institutional Review Board shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the Institutional Review Board's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the Institutional Review Board's action and shall be reported promptly to the principal investigator, to appropriate university officials, and to the federal Office of Human Research Protections.
n. If a research subject registers a complaint, the investigator shall attempt to relieve the complaint by explanation or by a change of procedure. Written Institutional Review Board approval is required for procedural changes.
o. It is the responsibility of the Institutional Review Board to determine whether applications that involve more than minimal risk to human subjects are of sufficient scientific merit to answer the proposed research questions or hypotheses.