POLICY CONCERNING RESEARCH INVOLVING HUMAN SUBJECTS

FAM 565

Statement of Compliance

California State University, San Bernardino and its auxiliary organization, The Foundation for The California State University, San Bernardino, will comply with the policies for protection of human subjects participating in activities supported directly by grants or contracts from the various agencies of the Federal Government, State Government, and California State Universities. In fulfillment of its assurance, this institution has established and will maintain an Institutional Review Board competent to review projects and activities that involve human subjects. The Board shall determine for each activity as planned and conducted whether subjects will be placed at risk and, if risk is involved, whether:

1. the risks to the subject are so outweighed by the sum of the benefit to the subject and the importance of the knowledge to be gained as to warrant a decision to allow the subject to accept those risks;
2. the rights and welfare of any such subjects will be adequately protected;
3. legally effective informed consent will be obtained by adequate and appropriate methods.

This institution assures that the committee reviews are conducted objectively and in a timely fashion, and in a manner to ensure the exercise of independent judgment of the members. Members are excluded from reviews of projects or activities in which they have an active role or conflict of interest. This institution encourages constructive communication between the committee and the project director(s) as a means of safeguarding the rights and welfare of subjects. This institution will maintain appropriate and informative records of committee reviews of applications and active projects, of documentation of informed consent, and of other documentation that may pertain to the selection, participation, and protection of subjects.

To further fulfill this assurance, this institution provides the following general guidelines of institutional standards. The decision to undertake research should rest upon a considered judgment by the individual investigator about how best to contribute to science and to human welfare. The responsible investigator weighs alternative directions in which personal energies and resources might be invested. Having made the decision to conduct research, the investigators must carry out their investigations with respect for the people who participate and with concern for their dignity and welfare. The individual investigator is personally responsible for being informed of all ethical codes from federal, state, local, university, and professional sources. Any research conducted utilizing human subjects which has not been formally reviewed and accepted by the university wide committee is to be considered a purely private venture without any sponsorship by the University or its associates.

1. In planning a study the investigator has the personal responsibility to make a careful evaluation of its ethical acceptability. To the extent that this appraisal, weighing scientific and humane values, suggests a deviation from any Principle, the investigator incurs an increasingly serious obligation to seek ethical advice and to observe more stringent safeguards to protect the rights of
the human research participant.

2. Responsibility for the establishment and maintenance of acceptable ethical practice in research always remains with the individual investigator. The investigator is also responsible for the ethical treatment of research participants by collaborators, assistants, students, and employees, all of whom, however, incur parallel obligations.

3. Ethical practice requires the investigator to inform the participant of specific features of the research that reasonably might be expected to influence willingness to participate. Failure to make appropriate disclosure gives added emphasis to the investigator's responsibility to protect the welfare and dignity of the research participant.

4. Openness and honesty are essential characteristics of the relationship between investigator and research participant. When the methodological requirements of a study necessitate concealment or deception, the investigator is required to ensure the participant's understanding of the reasons for this action and to restore the quality of the relationship with the investigator.

5. Ethical research practice requires the investigator to respect the individual's freedom to decline to participate in research or to discontinue participation at any time. The obligation to protect this freedom requires special vigilance when the investigator is in a position of power over the participant. The decision to limit this freedom increases the investigator's responsibility to protect the participant's dignity and welfare.

6. Ethically acceptable research begins with the establishment of a clear and fair agreement, which is often in written form, between the investigator and the research participant that clarifies the responsibilities of each. The investigator has the obligation to honor all promises and commitments included in that agreement.

7. The ethical investigator protects participants from physical and/or mental discomfort, harm, and danger. If the risk of such consequences exists, the investigator is required to inform the participant of that fact, secure consent before proceeding, and take all possible measures to minimize distress. A research procedure may not be used if it is likely to cause serious and lasting harm to participants.

8. After the data are collected, ethical practice requires the investigator to provide the participant with a full clarification of the nature of the study and to remove any misconceptions that may have arisen. Where scientific or humane values justify delaying or withholding information, the investigator acquires a special responsibility to assure that there are no damaging consequences for the participant.

9. Where research procedures may result in undesirable consequences for the participant, the investigator has the responsibility to detect and remove or correct these consequences, including where relevant, long-term aftereffects.

10. Information obtained about the research participants during the course of an investigation is confidential. When the possibility exists that others may obtain access to such information, ethical research practice requires that this possibility, together with the plans for protecting confidentiality, be explained to the participants as a part of the procedures for obtaining informed consent.
The Institutional Review Board (IRB) shall be the official committee of the institution charged with determination of compliance as outlined above. The structure of the board as defined below is designed to meet the current Code of Federal Regulations (45 CFR 46/ Revised January 11, 1978), and the structure of the board will be modified as enacted revisions of the Code dictate.

The membership of the board shall consist of the following persons:

A. Three qualified tenure track faculty appointed by the Executive Committee of the Faculty Senate in consultation with the Director of Sponsored Programs. The members shall serve four year terms. These terms are to be staggered.

B. One administrative representative appointed by the President.

C. All Chairs of Departmental Subcommittees of the Institutional Review Board (IRB) called Human Subject Review Board (HSRB).

D. One Graduate Student appointed by the Executive Committee of the Faculty Senate in consultation with the Dean of Graduate Studies and Associated Students, Inc.

The quorum of the Board shall be defined as a majority of the total membership duly convened to carry out the Board's responsibilities under the terms of the assurance.