

POLICY CONCERNING RESEARCH INVOLVING HUMAN SUBJECTS FAM 845.72

Institutional Responsibility

California State University, San Bernardino and its auxiliary organization(s), will comply with the policies for protection of human participants 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 filed with the Office for Human Research Protections (number FWA00004865), this institution has established and will maintain an Institutional Review Board (IRB) competent to review projects and activities that involve human participants. The Board shall determine for each activity as planned and conducted whether participants will be placed at risk and, if risk is involved, whether:

1. the risks to the participant are so outweighed by the sum of the benefit to the participant and the importance of the knowledge to be gained as to warrant a decision to allow the participant to accept those risks;
2. the rights and welfare of any such participants will be adequately protected;
3. 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 investigator(s) as a means of safeguarding the rights and welfare of participants. 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 participants.

Institutional Review Board

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 46.107/revised January 15, 2009), and the

structure of the board will be modified as enacted revisions of the Code dictate. The quorum of the Board shall be defined as greater than 50% of the membership of IRB and must include at least one member whose primary concerns are in nonscientific areas.

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

1. Five tenure-track faculty appointed by the Executive Committee of the Faculty Senate in consultation with the Associate Provost for Research to include one member from each college representative of the campus community. The terms for each member will be three years and shall be staggered across the colleges. The Executive Committee of the Faculty Senate may, in consultation with the Associate Provost for Research, select additional faculty to the Board so long as each has varying backgrounds of expertise to promote complete and adequate review of research activities commonly conducted by the institution.
2. At least one member who is a current undergraduate or graduate student at the university to serve as a student research representative on the IRB committee, appointed by the Executive Committee of the Faculty Senate in consultation with the Associate Provost for Research and the Associated Students, Inc. for a term of one year.
3. One administrative member appointed by the President.
4. At least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution, appointed by the Associate Provost for Research in consultation with the Executive Committee of the Faculty Senate
5. When the IRB reviews research that involves a vulnerable category of participants, such as children, prisoners, pregnant women, or individuals with mental or physical disabilities, the Associate Provost for Research, in consultation with the Executive Committee for the Faculty Senate, shall appoint one or more individuals who are knowledgeable about and experienced in working with these participants if members qualified as such are not already serving on the board. A prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity, is required to be present and to vote when research involving prisoners/inmates is reviewed by the IRB.

6. The IRB Chair shall be sufficiently qualified through the experience and expertise and selected by and from the current IRB board. The IRB Chair will have the ability to conduct a full board meeting ensuring the board stays on track in the deliberations of human research protocols. The IRB Chair will promote respect for the IRB to the university and provide advice and counsel in safeguarding the rights and welfare of human participants. In addition to possessing the professional competence necessary to review specific research activities, the IRB Chair shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice.

All appointments to the board shall be consistent with the principles defined below in items (a) through (f).

- (a) The IRB shall have at least 5 members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, 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 participants. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas.
- (b) Every nondiscriminatory effort will be made to ensure that the IRB does not consist entirely of men or entirely of women, including the institution's consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender or sex. The IRB may not consist entirely of members of one profession.
- (c) The IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in a nonscientific area.
- (d) With the approval of the California State University, San Bernardino Institutional Review Board, Chairs of Departmental Subcommittees will be established to facilitate the approval of exempt (administrative) and expedited

review human participant applications within a department which will provide annual reports to the main IRB committee regarding the number of protocols submitted, resubmitted, declined and approved and other reports as needed for reporting purposes to campus officials and the Faculty Senate. The department IRB Chairs will ensure that their committees have sufficient staffing of faculty with sufficient expertise, knowledge and continuing IRB human participants training to review exempt and expedited human research applications. Department Subcommittee Chairs are also required to attend the full board committee meetings. The main IRB Chair reserves the authority to suspend Departmental Subcommittees that fail to comply with the Office of Human Research Protections policies and regulations and campus IRB policy in the protection of human participants in research.

- (e) The IRB may not have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.
- (f) An IRB 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 IRB. These individuals may not vote with the IRB.