

*California State University, Sacramento*  
***Institutional Review Board***

**Campus Policy on the Protection of Human Subjects  
(DRAFT – December 10, 2010)**

California State University, Sacramento (hereafter, *the University* or *Sacramento State*) is committed to upholding ethical principles for the protection of human subjects in research, as set forth in the *Belmont Report* (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979). The University recognizes and accepts the responsibility, which it shares with its investigators and other researchers, for determining that research involving human subjects fulfills these ethical principles:

1. *Autonomy* means that each person shall be given the respect, time, and opportunity necessary to make his or her own informed decisions. Prospective participants will be given full and comprehensible information when asked to participate in research, and there will be no pressure to participate. The principle of autonomy requires that additional protection is given to potentially vulnerable populations such as children, the elderly, the mentally ill, the impoverished, prisoners, or others in relationships having differential status (e.g. student/teacher).
2. *Beneficence* obligates the researcher to secure the well-being of all research participants. The researcher must protect participants from potential sources of harm and explain any possible benefits of participation. The risk of harm must be as small as possible, and the sum of the benefits to participants and importance of knowledge to be gained must outweigh any remaining harm.
3. *Justice* requires that the selection of participants should be fair and equitable and that the risks and benefits of research should be distributed among participants in a fair and equitable manner. The researcher should avoid selecting some classes of persons simply because of their availability, compromised position, differential status, or manipulability.

Therefore, it is Sacramento State policy that the regulations of the U.S. Department of Health and Human Services (HHS) regarding implementation of the ethical principles outlined in the *Belmont Report*, as set forth in *45 CFR Part 46*, are applicable to all research involving human subjects for which the University is responsible, as defined by these regulations, regardless of whether the research is funded or the source of funding.

**Authority**

The Institutional Review Board (IRB) is the University's authorized body for the implementation of federal, state, and campus regulations and policies to safeguard the rights and welfare of human subjects participating in research activities by the University or its affiliates.

Any and all research conducted by Sacramento State faculty, staff, or students involving human subjects or any research-related activity involving human subjects that utilizes Sacramento State time, personnel,

facilities, resources, and/or students must be reviewed by the IRB to ensure compliance with applicable federal, state, and campus policies and procedures.

The IRB reports to the Provost and Vice President for Academic Affairs through the Assistant Vice President (AVP), Research Administration, and its charge is to review and approve, disapprove, or require amendment of protocols for research that involves the use of human subjects. The IRB is further charged with providing appropriate oversight for approved protocols, including heightened attention to “at risk” protocols. **The IRB has responsibility for and oversight of the departmental panels and subcommittees which engage in initial review of protocols involving human subjects.**

The IRB is authorized to take appropriate action to implement applicable human subjects regulations of any funding or regulatory agency covering the research activities under the IRB’s jurisdiction. To ensure campus-wide currency on issues related to the protection of human subjects and for federal compliance purposes, the IRB is charged with developing and coordinating, in concert with the Office of Research Administration, regular training opportunities for faculty, students, and staff to ensure continued compliance with state and federal regulations.

### **Administration**

The IRB establishes the policies and procedures for human subjects research on this campus consistent with federal, state, and university policy. These are documented in the *Policies and Procedures of the Committee for the Protection of Human Subjects (Revision in Spring 2011)*, available on the University’s human subjects website (<http://www.csus.edu/research/humansubjects/index.htm>), which also contains extensive guidance for researchers and the relevant application forms.

The Office of Research Administration maintains the records of the IRB’s activities, provides an Administrative Liaison, ensures an appropriate level of clerical assistance, and supports the IRB’s activities, including offering training to faculty, staff, and student researchers.

### **Membership**

In concert with *45 CFR 46* and its language on IRB membership, the IRB’s composition shall include at least nine (9) voting members and one non-voting member, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the University. 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 subjects.

If the IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.

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, to include at least one group member whose primary concerns are in scientific areas and at least one member whose primary concerns are in non-scientific areas:

1. Six (6) faculty members from varying disciplines who possess the professional competence to review research and instruction activities;
2. One (1) member from the community who is not affiliated with Sacramento State and who is not part of the immediate family of a person who is affiliated with Sacramento State; and,
3. **Two (2) additional voting members:**
  - a. **An at-large clinical, medical, or student-welfare oriented member recruited from the campus community based in IRB needs by the AVP Research Administration and IRB Chair;**
  - b. **A member designated by the CFO/Vice President for Administration and Business Affairs to represent the University's Department of Environmental Health and Safety.**
4. An Administrative Liaison to the IRB from the Office of Research Administration shall be designated by the Provost and Vice President for Academic Affairs. The Administrative Liaison shall serve on the IRB in an *ex-officio, non-voting* capacity to advise the IRB on federal, state and research community compliance matters and other aspects involving institutional liability or concern.
5. The IRB may, at its discretion, invite individuals with competence in special areas to assist in the review of issues **or protocols** which require expertise beyond, or in addition to, that available on the IRB. These individuals may not vote with the IRB.

IRB members shall represent a diversity of gender and ethnic/cultural backgrounds. To assure representation for departments that have historically conducted substantial amounts of human subjects research, the IRB shall include at least one faculty member each from the College of Education, the College of Health and Human Services, **the College of Natural Sciences and Mathematics**, and the College of Social Sciences and Interdisciplinary Studies.

**To ensure broad faculty representation, the faculty seats shall be filled via nominations from the Faculty Senate following an open call. The AVP Research Administration and IRB Chair shall send to the Chair of the Senate Executive Committee a request for nominations, based on the nature of the opening, for either particular College representation or needed areas of expertise. The Senate Executive Committee shall issue its call through the Senate with the IRB's indicated requirements, and shall advance to the AVP Research Administration and IRB Chair the names of faculty meeting the stipulated criteria. The AVP Research Administration will consult with the IRB Chair on candidates and their credentials and forward names to the Provost for approval and appointment.**

All appointments are for a period of three years and may be renewed by the Provost upon recommendation of the IRB Chair and AVP Research Administration. **Given the importance of training and experience for IRB members, continuity of membership is of particular concern to the IRB and its deliberations. However, in light of the Faculty Senate role in the faculty nomination process, a**

**member's second renewal appointment, if desired, shall be initiated via re-nomination through the Faculty Senate.** The Chair and Vice Chair of the IRB shall be a faculty member elected by and from the IRB and approved by the Provost.

The Chair of the IRB is delegated to act on routine matters on behalf of the IRB and is normally the person who communicates with researchers about their research protocols. The Vice Chair will assist the Chair by reviewing protocols that may qualify as exempt research, coordinating oversight of departmental human subjects committees, providing educational support for the members of those committees and the campus, and other activities as the IRB and the AVP Research Administration consider appropriate.

Effective 7/1/2011, all IRB members, and all researchers submitting applications (protocols) for the IRB's review, must provide evidence of training on the protection of human subjects. Such training is intended to meet any applicable federal or state requirements. The length and frequency of any required training shall be such as to avoid any undue burden on researchers and IRB members.

#### **Protocol Procedures and Process**

Protocols submitted by faculty, students, or staff must be signed by the researcher and the department chair or supervisor. After IRB approval, a copy of the protocol will be sent by the Office of Research Administration to the appropriate college dean or vice president. Protocols submitted by students must be signed by the student's faculty advisor and the department chair.

At its discretion, the IRB may authorize department committees to do an initial review of student protocols, with limited authority to approve some kinds of student research. If the proposed research does not fall within the authority of the department committee to approve, the student should then submit a protocol to the University IRB for review. The department committees are considered sub-committees of the University IRB, which provides guidance and training for the department committees.

It is the policy of the IRB that no member of the committee shall 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. In the event that a perceived conflict of interest is determined to exist, the Chair is responsible for ensuring that the relevant member of the IRB is not present for deliberations or voting on the affected protocol.

#### **Minimal Risk and Above Protocols**

All protocols determined to be at a risk level higher than "Minimal Risk" shall be issued with re-affirmed obligations to report adverse events and a required six-month progress report (or issued, alternatively, for six months duration) for each six month period that the protocol remains active. Deans and chairs will be copied on progress reports and failure to submit an acceptable report may result in the protocol being suspended. The faculty member/PI would be responsible for any consequential impact on ongoing research, as well as any actions taken by funding agencies in response to the protocol suspension.

#### **Policy Review**

This policy is to be reviewed and updated as needed, but at least bi-annually, by the IRB and the Office of Research Administration.