

**SAN JOSE STATE UNIVERSITY
ONE WASHINGTON SQUARE
SAN JOSE, CA 95192**

**F15-8, University Policy, Modification of Human Subjects
Institutional Review Board Membership**

Legislative History: Amends S08-7

At its meeting of November 2, 2015, the Academic Senate approved the following policy recommendation presented by Senator Shifflett for the Organization and Government Committee.

Amends S08-7 - Policy for Protection of Human Research Subjects. SM-F05-1 created an IRB-HS task force whose work culminated in S08-7. SM-F05-2 added members (CASA, Social Sciences, Education) to the Institutional Review Board - Human Subjects. SM-S05-3 added to the IRB-HS charge that the Board may also provide information to the campus on IRB_HS procedures, compliance, rules and regulations. SM-S00-1 provided for one faculty member from each Senate representative unit.

**Approved and signed by
Interim President Susan W. Martin on
November 5, 2015.**

**University Policy:
Modification of Human Subjects Institutional Review Board
Membership**

Whereas: The Institutional Review Board – Human Subjects (IRB-HS) requested a referral to the Organization and Governance Committee regarding membership and voting, and

Whereas: Structural changes in Academic Affairs have an impact on titles and representation on existing committees; and

Whereas: There is a clear need for members to have substantial experience and knowledge in the administration of federal, state, and SJSU regulations and policies that pertain to research with human subjects; therefore be it

Resolved: That University Policy S08-7 be amended to reflect the revisions detailed below.

Rationale: Effective review of IRB protocols requires that the committee members have significant training in, and knowledge of, federal, state, and SJSU regulations and policies that pertain to research with human subjects. For that reason, the committee functions more effectively (i.e., reviews protocols more consistently and more accurately) when the board includes a substantial number of members who have been on the committee for a longer period of time. The change to designation of the physician member to a consultant (as needed) reflects the fact, grounded in experience, that this person is not needed for the review of all protocols. Finally, for compliance reasons the IRB coordinator needs to be a voting member of the IRB-HS. Federal regulations for the Protection of Human Subjects allow for an expedited review procedure for minor changes to previously approved research and for continuing review of research if the original review was also conducted through an expedited review and the research continues to be minimal risk. According to the regulations an expedited review “may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among the members of the IRB.” In our case, that person is the IRB coordinator. The implication is that the member carrying out the review has voting status because they “can exercise all of the authorities of the IRB except that the reviewer may not disapprove the research.” (45 CFR 46.110(b))

Proposed Changes (to section VI.A.4 of S08-7):

Delete Associate Dean of Graduate Studies

Add Associate Dean of Research

Make the IRB Coordinator Seat ex officio - voting

Modify physician seat to reflect the need for a Kinesiological Consultant with a term of ‘as needed’

Add a section VI.A.4.e that reads:

Recruitment and Appointment of Members.

(1) Each faculty member serves a 3-year term renewable for one additional 3-year term. Student and community members serve 1-year terms. Recruitment of faculty and student members to serve on the IRB-HS will be done through the normal Committee on Committees process for the seats designated for faculty and student members.

(2) All applicants will submit a one page written statement describing their qualifications to serve on the board. It is strongly recommended that applicants attach their certificate verifying completion of one of the approved human subjects research courses (see <http://www.sjsu.edu/research/irb/irb-researcher-training/index.html>). Upon appointment

members must complete an approved IRB reviewer course prior to voting at their first scheduled meeting.

(3) Recommendations for a physician to serve as Kinesiological Consultant will be solicited from the SJSU Kinesiology Department Chair.

(4) When there are multiple applications for any seat, the Executive Committee of the Academic Senate will select individuals to serve. In considering potential IRB-HS members, attention should focus on the person's research skills and experience and careful consideration of the balance of new and continuing members so the board retains experienced members yet also brings on new members.

Approved: 9/28/15
Vote: 8-0-0
Present: Grosvenor, Beyersdorf, Mathur, Curry, Gleixner, Shifflett, Becker, El-Miaari
Absent: Laker
Financial Impact: None expected
Workload Impact: No change from current situation

Complete membership list:

- IRB Coordinator (EXO)
- Associate Dean of Research (EXO)
- 2 Faculty, Applied Sciences & Arts
- 1 Faculty, Business
- 2 Faculty, Education
- 1 Faculty, Engineering
- 1 Faculty, General Unit
- 1 Faculty, Humanities & the Arts
- 1 Faculty, Science
- 2 Faculty, Social Sciences
- 1 Student
- 1 Community-at-large (1 year appointment)
- 1 Physician or Licensed Health Professional
- 1 Physician (Kinesiological Consultant) (term: as needed)
- 1 Prisoner Advocate (term: as needed)