

1 San José State University
2 Academic Senate
3 Organization and Government Committee
4 November 2, 2015
5 Final Reading

AS 1586

6
7 **Policy Recommendation**
8 **Modification of Human Subjects Institutional Review Board Membership**
9

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

17
18 Whereas: The Institutional Review Board – Human Subjects (IRB-HS) requested a
19 referral to the Organization and Governance Committee regarding
20 membership and voting, and

21
22 Whereas: Structural changes in Academic Affairs have an impact on titles and
23 representation on existing committees; and

24
25 Whereas: There is a clear need for members to have substantial experience and
26 knowledge in the administration of federal, state, and SJSU regulations
27 and policies that pertain to research with human subjects; therefore be it
28

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

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32
33 Rationale: Effective review of IRB protocols requires that the committee members have
34 significant training in, and knowledge of, federal, state, and SJSU regulations and
35 policies that pertain to research with human subjects. For that reason, the committee
36 functions more effectively (i.e., reviews protocols more consistently and more
37 accurately) when the board includes a substantial number of members who have been
38 on the committee for a longer period of time. The change to designation of the
39 physician member to a consultant (as needed) reflects the fact, grounded in experience,
40 that this person is not needed for the review of all protocols. Finally, for compliance
41 reasons the IRB coordinator needs to be a voting member of the IRB-HS. Federal
42 regulations for the Protection of Human Subjects allow for an expedited review
43 procedure for minor changes to previously approved research and for continuing review
44 of research if the original review was also conducted through an expedited review and
45 the research continues to be minimal risk. According to the regulations an expedited
46 review “may be carried out by the IRB chairperson or by one or more experienced

47 reviewers designated by the chairperson from among the members of the IRB.” In our
48 case, that person is the IRB coordinator. The implication is that the member carrying
49 out the review has voting status because they "can exercise all of the authorities of the
50 IRB except that the reviewer may not disapprove the research.” (45 CFR 46.110(b))
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52

53 **Proposed Changes** (to section VI.A.4 of S08-7):
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55 Delete Associate Dean of Graduate Studies

56 Add Associate Dean of Research

57 Make the IRB Coordinator Seat ex officio - voting

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

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

61 Recruitment and Appointment of Members.

62

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

68

69 (2) All applicants will submit a one page written statement describing their
70 qualifications to serve on the board. It is strongly recommended that applicants
71 attach their certificate verifying completion of one of the online CITI
72 (Collaborative Institutional Training Initiative) human subjects research courses
73 (see <http://www.sjsu.edu/research/irb/irb-researcher-training/index.html>). Upon
74 appointment members must complete one of the online CITI courses prior to
75 attending the first scheduled meeting.

76

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

79

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

86

87 Approved: 9/28/15

88 Vote: 8-0-0

89 Present: Grosvenor, Beyersdorf, Mathur, Curry, Gleixner, Shifflett, Becker,
90 El-Miaari

91 Absent: Laker

92 Financial Impact: None expected

93 Workload Impact: No change from current situation

94

95

96 **Complete membership list:**

97

98 IRB Coordinator (EXO)

99 Associate Dean of Research (EXO)

100 2 Faculty, Applied Sciences & Arts

101 1 Faculty, Business

102 2 Faculty, Education

103 1 Faculty, Engineering

104 1 Faculty, General Unit

105 1 Faculty, Humanities & the Arts

106 1 Faculty, Science

107 2 Faculty, Social Sciences

108 1 Student

109 1 Community-at-large (1 year appointment)

110 1 Physician or Licensed Health Professional

111 1 Physician (Kinesiological Consultant) (term: as needed)

112 1 Prisoner Advocate (term: as needed)

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