

1 San José State University
2 Academic Senate
3 Organization and Government Committee
4 October 1, 2018
5 Final Reading

AS 1708

6
7 Senate Management Resolution
8 Charge and Membership of the Institutional Review Board
9

10 Legislative History: This proposal amends the membership of the Institutional Review
11 Board Committee to remove the Associate Dean, Research. This would supersede the
12 charge/membership section of F17-1 (Protection of Human Research Subjects) and re-
13 establish in this policy, membership details that were contained in F15-8 (Modification of
14 Human Subjects Institutional Review Board Membership).
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17 Whereas: There are presently two administrative representatives from the same
18 office serving on IRB, and
19

20 Whereas: The IRB-HS Committee recommends eliminating the Associate Dean for
21 Research seat, therefore, be it
22

23 Resolved That the Ex-Officio position for the Associate Dean, Research be
24 removed,
25 and be it further
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27 Resolved That the charge and membership provided here replaces the section of
28 F17-1 pertaining to the charge and membership of IRB, and be it further
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30 Resolved That the charge and membership provided here reinstates the section of
31 F15-8 pertaining to the recruitment and appointment of IRB members.
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34 Rationale: O&G this past year invited all committees to review their charge and
35 membership. The IRB committee proposed the change in membership and the AVP for
36 Research concurred noting that in the past, from the Office of Graduate Studies and
37 Research, the AVP had a seat on the IRB committee. We received feedback (from
38 OHRP, Office of Human Research Protection, a federal office) that it was a conflict to
39 have the AVP sit on the committee and also at the end of the process approve the
40 protocols for the institution.
41

42 The senate then passed a change to replace the AVP with the Associate Dean, but as a
43 non-voting member. Over time, we were able to hire an Analyst Exempt III with Human
44 Protections Analyst as her title. The senate then changed the policy to move the IRB
45 coordinator to a voting member.
46

47 It is not necessary to have the Associate Dean on the IRB - two seats from the same
48 office. The AVP stays informed of issues through Chair and the IRB Coordinator.
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50 Finally, policy pertaining specifically to the charge and membership of committees is
51 best contained in it's own document rather than embedded in other policies (e.g., F17-1
52 (Protection of Human Research Subjects). F17-1 rescinded S08-7 which had been
53 modified by F15-8. However, the details regarding IRB membership contained in F15-8
54 were not carried forward. This update corrects that oversight and puts information
55 related to the charge and membership of the IRB in its own policy.
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59 Approved: 9/24/18
60 Vote: 8-0-0
61 Present: Bailey, Capizzi, French, Gallo, Higgins, Ormsbee,
62 Rodan, Shifflett
63 Absent: Curry, Grosvenor, Saldami
64
65 Financial Impact: None
66 Workload Impact: None
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68 Charge and Membership of Institutional Review Board - Human Subjects Committee

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70 Charge: Facilitates the responsible conduct of inquiry by reviewing all proposals for
71 human subject research to be conducted under the direction of University personnel,
72 including University students; ensures that, before data collection is begun, all
73 appropriate measures have been taken to protect the safety, personal rights and dignity
74 of all individuals and social groups involved as participants in the project. The Board
75 may also provide information to the campus community on IRB-HS procedures and
76 compliance with applicable rules and regulations.

77

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79 Recruitment and Appointment of Members.

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81 1.0 Each faculty member serves a 3-year term renewable for one additional 3-year
82 term. Student and community members serve 1-year terms. Recruitment of faculty and
83 student members to serve on the IRB-HS will be done through the normal Committee
84 on Committees process for the seats designated for faculty and student members.

85

86 (2) All applicants will submit a one page written statement describing their qualifications
87 to serve on the board. It is strongly recommended that applicants attach their certificate
88 verifying completion of one of the approved human subjects research courses (see
89 <http://www.sjsu.edu/research/irb/irb-researcher-training/index.html>). Upon appointment
90 members must complete an approved IRB reviewer course prior to voting at their first
91 scheduled meeting.

92

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

95

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

101

102 Membership

103

104 Assoc. Dean, Research

105 IRB Coordinator

106 1 faculty, Business

107 2 faculty, Education

108 1 faculty, Engineering

109 2 faculty, Health and Human Sciences

110 1 faculty, General Unit

111 1 faculty, Humanities & Arts

112 1 faculty, Science

113 2 faculty, Social Science

- 114 1 student
- 115 1 Community-at-large
- 116 Physician or licensed health professional
- 117 Physician (Kinesiological Consultant) - as needed
- 118 Prisoner Advocate - as needed

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121 Note: To be compliant with federal regulations, the IRB must have a Physician or Nurse
122 Practitioner, a student, and a community member. Link to the relevant portion in the
123 regulations - see 46.107c

124

125 [https://www.ecfr.gov/cgi-](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1107)
126 [bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1107)
127 [pt45.1.46&r=PART&ty=HTML#se45.1.46_1107](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1107)