

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

**F18-3, University Policy, Charge and Membership of the
Institutional Review Board (Also Amendment B to F17-1)**

Amends: F17-1

Legislative History:

This proposal amends the membership of the Institutional Review Board Committee to remove the Associate Dean, Research. This would supersede the charge/membership section of F17-1 (Protection of Human Research Subjects) and re-establish in this policy, membership details that were contained in F15-8 (Modification of Human Subjects Institutional Review Board Membership). This policy amendment was approved and signed by President Mary A. Papazian on October 15, 2018.

On May 8, 2023, the Academic Senate approved Amendment A to University Policy F18-3 presented by Senator Hart for the Organization and Government Committee. On June 20, 2023, President Cynthia Teniente-Matson approved and signed Amendment A to University Policy F18-3. Amendment A modifies the membership of the Institutional Review Board. Amendment A is incorporated below.

Whereas: There are presently two administrative representatives from the same office serving on IRB, and

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

Resolved That the Ex-Officio position for the Associate Dean, Research be removed, and be it further

Resolved That the charge and membership provided here replaces the section of F17-1 pertaining to the charge and membership of IRB.

Rationale: O&G this past year invited all committees to review their charge and membership. The IRB committee proposed the change in membership and the AVP for Research concurred noting that in the past, from the Office of Graduate Studies and Research, the AVP had a seat on the IRB committee. We received feedback (from OHRP, Office of Human Research Protection, a federal office) that it was a conflict to

have the AVP sit on the committee and also at the end of the process approve the protocols for the institution.

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

It is not necessary to have the Associate Dean on the IRB - two seats from the same office. The AVP stays informed of issues through Chair and the IRB Coordinator.

Finally, policy pertaining specifically to the charge and membership of committees is best contained in its own document rather than embedded in other policies (e.g., F17-1 (Protection of Human Research Subjects). F17-1 rescinded S08-7 which had been modified by F15-8. However, the details regarding IRB membership contained in F15-8 were not carried forward. This update corrects that oversight and puts information related to the charge and membership of the IRB in its own policy.

Approved: 9/24/18
Vote: 8-0-0
Present: Bailey, Capizzi, French, Gallo, Higgins, Ormsbee,
Rodan, Shifflett
Absent: Curry, Grosvenor, Saldami

Financial Impact: None
Workload Impact: None

Charge and Membership of Institutional Review Board – Human Subjects Committee

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

Recruitment and Appointment of Members.

1.0 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.

Membership:

IRB Coordinator [EXO]
1 Faculty, College of Business
2 Faculty, College of Education
1 Faculty, College of Engineering
1 Member, General Unit
2 Faculty, College of Health and Human Sciences
1 Faculty, College of Humanities & Arts

1 Faculty, College of Science
2 Faculty, College of Social Science
1 student

1 Community-at-large member who is not otherwise affiliated with SJSU

For this Community-at-large seat, the IRB may appoint one alternate community-at-large member who may serve in the absence of the primary Community-at-Large seat holder.

Physician or licensed health professional

Prisoner Advocate

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

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