

**POLICY RECOMMENDATION**  
**Amendment D to University Policy F17-1, Amendment A to**  
**F18-3 on Institutional Review Board (IRB)**

**RATIONALE**

As per the Code of Federal Regulations (CFR) Title 45 Subtitle A Subchapter A Part 46 Subpart A § 46.107 on IRB Membership<sup>1</sup>:

(a) Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members (professional competence), and the diversity of its members, including 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. The IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments (including policies and resources) and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a category of subjects that is vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these categories of subjects.

(b) Each IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.

(c) Each IRB shall include at least *one member who is not otherwise affiliated with the institution* and who is not part of the immediate family of a person who is affiliated with the institution.

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<sup>1</sup> <https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-A/section-46.107>

(d) No IRB may have a member 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.

(e) An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

The main problem arising from SJSU's current IRB Board membership is that any research proposals submitted to the IRB which require a full board review have been delayed by an additional month because IRB protocols could not be approved in the absence of the Community-at-Large member, who must be present as per section (c) above.

On September 13, 2022, the Executive Committee of the Academic Senate passed a proposal to amend F18-3 temporarily. This amendment allows the IRB to have one alternate member appointed to serve on the IRB in the capacity of a Community-at-Large member in the absence of the primary Community-at-Large member. The alternate member may only vote when the primary Community-at-Large member is not present at the meeting, and the total number of Community-at-Large votes will only be one. The amendments proposed herein would make this change permanent, thereby enabling the IRB committee to more expeditiously approve IRB applications and make the approval process more efficient for faculty.

Two further improvements are offered in this recommendation. First, the seat for "Physician (Kinesiological Consultant) - as needed" has been removed. The reason for this is that the membership of the IRB already includes one physician or licensed healthcare professional as a voting member, making this additional seat redundant and unnecessarily raising the threshold for quorum.

Second, the "as needed" tag has been removed from the prisoner advocate slot, because no full member of the IRB should be participating on an "as needed" basis. If and when the IRB needs to bring in a consultant for occasional expertise on an as needed basis, they need not be included in the permanent membership of the board.

With this in mind, O&G therefore recommend that SJSU's IRB policies [F18-3](#) and [F17-1](#) be amended as described herein.

# F18-3

Institutional Review Board - Human Subjects [reporting to CR]

## 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

Physician (Kinesiological Consultant) – as needed

Prisoner Advocate – as needed

# F17-1

4.2.3 Convened Committee / Full Review – If the research is not eligible for an exempt or expedited review because it involves more than minimal risk to subjects, the protocol must be reviewed by the convened IRB membership at the monthly meeting. Full review will take place with a quorum of the IRB, defined as a majority of the total membership, including at least one member whose primary concerns are in a nonscientific area.

*Regarding the Community-at-large seat, the alternate shall vote only in the absence of the primary Community-at-large member, keeping the total number of votes for that seat at one.* Research protocols shall be distributed to the full membership at least one week in advance of the scheduled meeting. A protocol shall be approved if it receives the approval of a majority of those members present at the meeting. A primary reviewer is identified to present a specific protocol to other members in attendance. Following presentation and discussion, the committee will vote on a motion to either: 1) approve the protocol as it stands; 2) request revisions to the protocol to secure approval; 3) request that additional information be provided prior to further review by the convened committee; or 4) disapprove the protocol.

**Approved:** April 24, 2023

**Vote:** 5-0-1

**Present:** Andreopoulos, Hart, Higgins, Jochim, Muñoz-Muñoz,  
Nikalwala  
**Absent:** Baur, Han, Lee, Tan

**Financial impact:**

**Workload impact:**