

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

**Amendment D to University Policy F17-1, A-3 on the Institutional  
Review Board (IRB) presented by Senator Hart for the Organization**

**ACTION BY UNIVERSITY PRESIDENT:**

**Approved and signed by President  
Cynthia Teniente-Matson,  
San José State University on June 20, 2023.**

**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

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.

(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

## **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

Prisoner Advocate

## **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