




## Executive Memorandum 23-030

December 18, 2023

**From:** Stephen Perez, President 

**Subject:** New Institutional Review Board EM

Upon the recommendation of the Academic Senate and with the concurrence of the Provost, I approve New Institutional Review Board EM.

<b>Policy Title:</b>	Institutional Review Board EM 23-030
<b>Contact:</b>	IRB Program Administrator
<b>Supersedes:</b>	Supersedes and Decommissions EM 93-004
<b>Revision:</b>	
<b>Enabling Legislation or Executive Order:</b>	U.S. Department of Health and Human Services Policy for the Protection of Human Research Subjects, 45 CFR 46

### Institutional Review Board

#### Policy Statement:

The Policy of California State University, Chico (University) is to adhere to the U.S. Department of Health and Human Services *Policy for the Protection of Human Research Subjects* as codified at 45 CFR 46, regardless of funding or funding source. All research involving human subjects which is the responsibility of the University is reviewed by the Institutional Review Board (IRB) to ensure compliance with the highest ethical standards of research and federal regulations.

#### Who the Policy applies to:

This policy applies to University students, staff, faculty, and affiliates who engage the institution in human subjects research.

#### Why the Policy is necessary:

The federal policy at 45 CFR 46 has been widely adopted by federal, state, and non-governmental funding agencies that require institutions to have and uphold written procedures through which the institution carries out its mandate to protect human research participants. The California State University Sponsored Programs

Administration Policy states appropriate approval must be obtained in accordance with Campus policy and/or procedure either prior to award acceptance or before spending can begin on a particular segment of the award, whichever is applicable.

### **Responsibilities:**

The University, students, staff, faculty, and affiliates accept responsibility for assuring that research involving the use of human subjects is conducted in accordance with this policy, relevant federal regulations, and the Belmont Report's Ethical Principles and Guidelines for the Protection of Human Subjects in Research, which includes respect for persons, beneficence, and justice.

#### **A. Training Requirement:**

The University requires that all students, staff, faculty, and affiliates, including advisors of students conducting human subject research or instructional research activities, and any other University or auxiliary employees engaged in or reviewing human subjects research, successfully complete the Collaborative Institutional Training Initiative (CITI) Human Subjects course before receiving IRB approval. Training certification expires every three years at which point a refresher course is required.

#### **B. IRB Review**

All human subjects research must be reviewed by the IRB before obtaining informed consent, collecting data, and/or using private identifiable information for research purposes. The IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with this policy or relevant federal regulations. In some circumstances, IRB review will be a collaborative process if more than one institution is engaged in research.

#### **C. Shared Authority of the IRB and Institution**

The Institutional Official (IO) is designated by the University President and acts on behalf of the University to ensure adherence to the Federalwide Assurance with the U.S. Department of Health and Human Services Office of Human Subjects Research Protections (45 CFR §46.501). The IO is designated through the Office of Human Research Protections as the signatory official for the University's IRB and is responsible for providing resources for the IRB to function effectively and efficiently according to federal regulations. The IO appoints the IRB. The IRB Chair acts on behalf of the IRB and reports directly to the IO.

Research covered by this policy which has been approved by the IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. The institutional officials may not approve research involving human subjects that has not been approved by the IRB (45 CFR §46.112).

### **IRB Membership:**

#### **A. Composition**

As required by 45 CFR §46.107, the composition of the IRB will conform to the following federal requirements.

“The IRB shall have at least five members, with varying backgrounds to promote a 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 as members of one or more individuals who are knowledgeable about and experienced in working with these categories of subjects” (45 CFR §46.107).

1. The IRB shall include “at least one member whose primary concerns are in scientific areas.”
2. The IRB shall include “at least one member whose primary concerns are in nonscientific areas.”
3. The 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.”
4. “No IRB may have a member participate in the IRB’s initial or continuing review of any project in which the member has conflicting interest, except to provide information requested by the IRB.”
5. “The IRB may, at 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.” (45 CFR §46.107).

An individual who meets the requirements of more than one of the categories may fulfill more than one requirement. However, the IRB may not consist of fewer than five members.

## **B. Selection/Member Appointments**

The IO appoints all IRB members. Upon any IRB member vacancy open to faculty, the faculty member will be appointed through the following procedures:

1. Each spring semester, depending on the Academic Senate calendar, the IRB program administrator will send a list of IRB faculty vacancies expected for the next academic year to the Chair of the Academic Senate.
2. In its annual spring call for faculty volunteers for service, the Academic Senate will include a call for faculty self-nominations to the IRB, noting special areas of member competence needed for the board.
3. Faculty interested in serving on the IRB will submit their Curriculum Vitae and any other required information to the Academic Senate.
4. The Academic Senate Office will submit the list of interested faculty to Faculty Affairs and Success. Faculty Affairs and Success will use criteria from the CSU Employment Policy Governing the Provision of Employee References to ensure interested faculty meet appropriate criteria. Faculty Affairs and Success will notify the Chair of the Academic Senate of the results of the reference check. Interested faculty who do not meet the policy’s criteria will be removed from consideration.

5. The Academic Senate will provide the recommended list of interested faculty who meet the appropriate criteria, along with their Curriculum Vitae and any other information, to the IO and IRB program administrator.
6. The IRB Chair, IRB Vice Chair, IO, and IRB program administrator will review the list of interested faculty and appoint members from the list. Under federal regulations, the IO has the responsibility to appoint members of the IRB.
7. Upon any IRB member vacancies open to faculty during the academic year, the IO will first make appointments from the recommended list of interested faculty sent by the Academic Senate. If there are no additional faculty on the list sent by the Academic Senate, the IO has the authority to open the call for nominations until the required number of qualified members, as determined by 45 CFR §46.107, are appointed. The names of faculty considered for appointment through this process will be submitted to Faculty Affairs and Success, which will use criteria from the CSU Employment Policy Governing the Provision of Employee References to ensure faculty meet appropriate criteria. If faculty do not meet the appropriate criteria, they will be removed from consideration.
8. Selection of the IRB Chair and Vice Chair is conducted via a call for nominations from the current board members to faculty from the IO and IRB program administrator. Current members can nominate others or self-nominate in person or by email to the IRB Chair and/or IRB program administrator. Consideration will be given to department release time and availability to serve in accordance with the IRB Chair and IRB Vice Chair descriptions in the IRB Standard Operating Procedures. The IO is responsible for appointing the IRB Chair and Vice Chair. Prior to appointment, the names of faculty considered for appointment to the Chair and/or Vice Chair positions will be submitted to Faculty Affairs and Success, which will use criteria from the CSU Employment Policy Governing the Provision of Employee References to ensure faculty meet appropriate criteria. If faculty do not meet the appropriate criteria, they will be removed from consideration for these positions. The IO and IRB program administrator may elect to conduct interviews with interested candidates. Positions are for three-year terms. Pending successful reference checks as described above, the Chair and Vice Chair can be reappointed every three years. Reappointment allows the IRB to call for new leadership or reinstate existing leadership. If no member is available or willing to serve as the Chair, the IO will serve as Interim Chair until a member becomes willing and properly trained. The IO will not participate in the vote due to a conflict of interest.

Faculty members of the IRB shall be appointed for staggered terms of three years. Nonaffiliate members shall be appointed for terms no less than one year. Members must be in good standing to remain a member, chair, or vice chair of the committee and/or to be reappointed to additional terms. The IRB Program Administrator will serve as the administrative support staff for the IRB.

#### **References:**

1. Federal Code of Regulations 45 Public Welfare Department of Health and Human Services, Part 46, Protection of Human Subjects: <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/>
2. The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research: <https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html>
3. California State University Sponsored Programs Administration Policy:

<https://calstate.policystat.com/policy/9401104/latest/>

4. Engagement of Institutions in Human Subjects Research (2008):

<https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html>