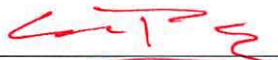




Executive Memorandum 23-032

December 18, 2023

From: Stephen Perez, President _____

Subject: Institutional Biosafety Committee

Upon the recommendation of the Academic Senate and with the concurrence of the Provost, I approve the new Institutional Biosafety Committee Executive Memorandum.

Policy Title:	Institutional Biosafety Committee EM 23-032
Contact:	IBC Program Administrator
Supersedes:	Supersedes and Decommissions EM 01-002
Revision:	
Enabling Legislation or Executive Order:	National Institutes of Health Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules

INSTITUTIONAL BIOSAFETY COMMITTEE

Policy Statement:

The policy of California State University, Chico (University) is to adhere to the National Institutes of Health (NIH) Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (*N*). To ensure the highest standard of research, it is University policy that all research, research training, and instructional activities involving recombinant and synthetic nucleic acid molecules or other potentially hazardous biological agents (as defined by NIH) are subject to review by the Institutional Biosafety Committee (IBC), regardless of funding or funding source.

Definitions:

Recombinant or Synthetic Nucleic Acid Molecules - (i) molecules that a) are constructed by joining nucleic acid molecules and b) that can replicate in a living cell, i.e., recombinant nucleic acids; (ii) nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally

occurring nucleic acid molecules, i.e., synthetic nucleic acids, or (iii) molecules that result from the replication of those described in (i) or (ii) above. (*NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*)

Potentially hazardous biological agents – A substance that (i) is made from a living organism or its products, (ii) is used in research and/or instruction, and (iii) could be hazardous to the immediate or surrounding community. (*NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*, Appendix B: Classification of Human Etiologic Agents based on Hazard. Pg. 42) Potentially hazardous biological agents also include select agents or toxins: <https://www.ecfr.gov/current/title-42/chapter-I/subchapter-F/part-73/section-73.3> The determination of whether or not a biological agent is potentially hazardous will be made by the Institutional Biosafety Committee.

Who the Policy applies to:

This policy applies to University students, staff, faculty, and affiliates conducting or participating in research or teaching activities conducted at the University involving recombinant and synthetic nucleic acid molecules or other potentially hazardous biological agents.

Why the Policy is necessary:

At a minimum, the University is expected to apply federal policy throughout research and educational activities as a recipient of federal funding. Under the *NIH Guidelines*, an IBC must be established specifically to review research involving recombinant or synthetic nucleic acid molecules and other potentially hazardous biological agents.

Responsibilities:

The University, students, staff, faculty, and affiliates accept responsibility for assuring that research and instructional activities involving the use of recombinant and synthetic nucleic acid molecules or other potentially hazardous biological agents are conducted per *NIH Guidelines* and IBC approval.

A. Training Requirement:

The University requires that students, staff, faculty, and affiliates, including advisors of students conducting research or instructional activities involving recombinant and synthetic nucleic acid molecules or other potentially hazardous biological agents, and any other University or auxiliary employees engaged in or reviewing research or activities successfully complete the Collaborative Institutional Training Initiative (CITI) Biosafety course before receiving IBC approval. Training certification expires every three years at which point a refresher course is required.

B. IBC Review

All research or instructional research activities involving recombinant and synthetic nucleic acid molecules or other potentially hazardous biological agents must be reviewed by the IBC in advance of initiation. The IBC has the authority to suspend or terminate approval of protocols that are not being conducted in accordance with this policy or relevant federal regulations.

C. Shared Authority of the IBC and Institution

IBC oversight rests collectively with the Institutional Official (IO) and the IBC. The IO is designated by the University President and acts on behalf of the University ensuring adherence to federal regulations. The IO is responsible for providing resources for the IBC to function effectively and efficiently and appoints the IBC. The IO and IBC are responsible for upholding federal regulations, state laws, and university policies through the prospective review of research and instructional research activities involving recombinant or synthetic nucleic acid molecules or other potentially hazardous biological agents under the *NIH Guidelines*. The IBC Chair acts on behalf of the IBC and reports directly to the Institutional Official.

The University Office of Environmental Health and Safety coordinates with the IBC and is an essential part of the overall program to ensure the safe use and disposal of biohazardous materials. For more information, please see the University Policy on [Hazardous Waste](#).

IBC Membership:

The composition of the IBC conforms to NIH Guide Section IV-B-2-a-(1). The IBC shall have at least five members who collectively possess the experience and expertise in recombinant DNA to assess the risks to public health associated with the use of recombinant DNA molecules, and potentially hazardous biological agents.

A. Composition

1. Of the required five members, the IBC shall include at least two faculty members from departments utilizing recombinant or synthetic nucleic acid molecules or other potentially hazardous biological agents in teaching and/or research.
2. The IBC shall include two members who are not otherwise affiliated with the institution and who are not part of the immediate family of a person who is affiliated with the institution.
3. The Director of Environmental Health and Safety or designee.
4. No IBC member may participate in the IBC's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IBC.
5. The IBC 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 IBC. These individuals may not vote with the IBC.

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

B. Selection/Member Appointments

The IO appoints all IBC members. Upon any IBC 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 IBC program administrator will send a list of IBC 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 IBC, noting special areas of member competence needed for the board.
3. Faculty interested in serving on the IBC 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 IBC program administrator.
6. The IBC Chair, IBC Vice Chair, IO, and IBC 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 IBC.
7. Upon any IBC 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 faculty members 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 IBC Chair and Vice Chair is conducted via a call for nominations from the current board members to faculty from the IO and IBC program administrator. Current members can nominate others or self-nominate in person or by email to the IBC Chair and/or IBC program administrator. Consideration will be given to department release time and availability to serve in accordance with the IBC Chair and IBC Vice Chair descriptions in the IBC Standard Operating Procedures. The IO is responsible for appointing the IBC 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 IBC 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 IBC 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 IBC 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 IBC Program Administrator will serve as the administrative support staff for the IBC.

References:

National Institutes of Health Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules: https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf