Charge of the Institutional Biosafety Committee (IBC)

Authorization: San José State University shall have an Institutional Biosafety Committee established under the authority of the Office of Research in the Research and Innovation Division.

Purpose: The purpose of the SJSU Institutional Biosafety Committee (IBC) is to review research and teaching activities performed by agents of the University (i.e., faculty, staff, and students) involving recombinant or synthetic nucleic acid molecules and other hazardous biological agents or toxins at SJSU. The IBC provides oversight for biological safety at SJSU and ensures compliance pursuant to the *NIH Guidelines for Research Involving Recombinant DNA Molecules* and University policies as per: [https://osp.od.nih.gov/biotechnology/nih-guidelines/].

Membership

Committee members are recommended to the Associate Vice President for Research (AVPR) by the IBC chair and appointed for a term of three years. The IBC shall be comprised of no fewer than six (6) individuals including two non-affiliated community members. Alternate members may be appointed to serve and participate on the IBC as a substitute for the primary member. Alternate members may voluntarily attend and participate in IBC business. When the primary member and alternate are both present, only one vote may be cast among them. The critical members shall have titles and expertise in the following areas:

IBC Chair

The IBC chair shall be a University member appointed to the IBC by the AVPR and will serve as the committee chair. The chair will be responsible for the following tasks:

1) Convene at minimum an annual meeting and any additional meetings as needed
2) Call for full proposal reviews as needed
3) Report to the IBC and the Institution any NIH Guidelines violations within 30 days
4) Investigate accidents involving use of synthetic or recombinant nucleic acid molecules and/or incidents involving hazardous biological agents
5) Submit an annual report to the AVPR for submission to the NIH/OBA consisting of:
    a. A current member roster
    b. Biographical Sketches

Biosafety Officer (BSO)

The University shall appoint a staff member to be the Institution's Biosafety Officer (BSO) to serve as both a point of contact with the University's Environmental Health and Safety (EHS) department, and to provide additional expertise in the area of laboratory safety, Cal/OSHA, EPA, and other applicable regulations. Working with the chair, the BSO will be responsible for the following tasks:

1) Develop emergency response plans for spills and personnel exposure/contamination
2) Provide technical advice to PI and IBC on safety procedures
3) Provide training for PI, faculty, staff, and students where needed
4) Oversee and review lab safety inspections
5) Report to the IBC and the Institution any NIH Guidelines violations within 30 days

6) Investigate accidents involving use of synthetic or recombinant nucleic acid molecules and/or incidents involving hazardous biological agents

If the BSO is unable to perform duties, the responsibilities will be delegated to the IBC Chair.

Technical Staff Representative

The University shall appoint a staff member who has expertise in biohazardous agent use. Ideally, the staff member would also have experience in the handling, processing, and tracking of biohazardous waste for shipment, treatment and/or disposal.

Molecular Biology Expert(s)

The University shall appoint at least one expert (faculty or staff member) who has expertise in the molecular basis of biological activity in and between cells including understanding the implications of recombinant and synthetic nucleic acid molecules to professionally address the research or teaching activities that require IBC approval in accordance with NIH Guidelines.

Animal Containment Expert

The University shall appoint at least one individual (faculty or staff member) with expertise in animal containment principles to address research or teaching activities with animals that require IBC approval in accordance with NIH guidelines.

Community Members (Non-Affiliated Members)

The University shall appoint two volunteers from the community (within 100 miles) who are unaffiliated with the University and have expertise in biosafety-related matters. These members will represent the community with respect to health and protection of the environment.

Other Members Needed Pending Specific Biological Hazard Usage

1. *Plant Expert.* Should recombinant or synthetic nucleic acid molecule research or teaching activities involving plants (subject to Appendix L of the NIH Guidelines) be started on campus, a plant expert must also be appointed to the committee.
2. *Human Gene Therapy Expert*. Should work involving the transfer of recombinant or synthetic nucleic acid molecules to humans be started on campus, a human gene therapy expert must also be appointed to the committee (ad hoc is acceptable)

Responsibilities

Reporting to the AVPR, the SJSU IBC primary responsibilities lie in reviewing two areas of teaching and research: 1) programs involving recombinant or synthetic nucleic acid molecules and 2) programs that pose potential risk to the environment and public health due to activities listed in the general charge below. Within these areas, the committee also provides oversight on institutional and investigator compliance, and teaching or research plans to ensure conformity with NIH Guidelines, which includes assigning proper containment levels, adequacy of facilities, PI and personnel training, and standard operating procedure (SOP) review. At least one meeting open to SJSU personnel will be called annually to discuss the charter and any concerns regarding safety, training and/or operating procedures. Minutes will be kept for all meetings including reviews, and records will be maintained for three years.

General Charge: The Institutional Biosafety Committee (IBC) is a standing committee responsible for reviewing all proposed University research and teaching activities under IBC purview conducted by faculty, staff, students and/or visiting scientists and ensuring that they are aware of the responsibility to register the use or handling of biological agents or activities as described below:

A. Activities involving recombinant or synthetic nucleic acid molecules or recombinant or synthetic nucleic acid-containing organisms/viruses/cell cultures

B. Biological agents above biosafety level 1 (BSL-1), including field activities that collect environmental samples (e.g., soil, water) from areas likely to harbor such agents, or that collect/use animals that harbor zoonotic agents;

C. Unfixed materials derived from human and nonhuman primates;

D. Activities that collect or cultivate exotic plants;

E. Work with biological toxins (e.g., cholera toxin, snake venom toxins, tetrodotoxin, etc.)

F. Select agents or toxins subject to 42 CFR Part 73, 9 CFR Part 121, or 7 CFR Part 331 [https://www.selectagents.gov/sat/index.htm];

G. Proposed research or teaching activities subject to the United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern [https://osp.od.nih.gov/biotechnology/dual-use-research-of-concern/].

The purpose of these Biological Use Authorization (BUA) reviews is to ensure that all activities involving biological agents and the facilities used to conduct such work are in compliance with all external regulations, and applicable University policies. The committee will function to ensure that investigators handle biological agents in a safe and responsible manner, and meet criteria as described by the NIH Guidelines for use of synthetic or recombinant nucleic acid molecules (*specifically those defined in section IV-B-2*); the CDC/NIH publication Biosafety in the Microbiological and Biomedical Laboratories; applicable regulations defined by the state of California; the OSHA Bloodborne Pathogens Standard; HHS and USDA final rules for the possession, use, and transfer of select agents and toxins; and other applicable requirements.

Foremost, the IBC's objective shall be to ensure that such activities meet the standards of good biological safety practice emphasizing protection of personnel, the public and the environment. To this end, the IBC shall assist principal investigators and instructors in meeting their responsibilities, impose requirements, review and approve policies, proposals, procedures, programs, and facilities pursuant to the safe and legally compliant use of biological agents.

Meetings: The Institutional Biosafety Committee shall gather at a convened meeting at least once per semester to review submissions and address other business items. The IBC Chair will ensure that any and all members recuse themselves from committee business if they are involved in the research project under review, or have a direct conflict of interest, except to provide specific information requested by the committee.

Meeting schedules, submission deadlines, and committee membership must be made readily available to the University community. Meeting agendas, minutes, documentation, and other meeting and coordination efforts will be arranged by the IBC. At least fifty-one percent of the voting membership is necessary to establish a quorum for conducting business.

Support: The AVPR shall provide resources necessary to support IBC operations. This may include staffing, database services, support for member education, clerical equipment or materials, and other resources necessary to support committee operations.

Appeals: In cases of dispute with respect to procedures or decisions of the IBC, appeals must be made to the IBC in writing or in person. Appeals unresolved through IBC channels may be subsequently presented to the AVPR for resolution.

Sanctions and Enforcement: An approved Biological Use Authorization (BUA) must be in place to conduct research or teaching activities involving biohazards under IBC purview. The IBC must investigate suspected or alleged violations of protocols, external regulations, or University policies that involve biological agents. If violations are insufficiently resolved through normal channels of communications with the Principal Investigator, the Department Chair will be notified of the violation and a timeline for resolution will be established. Matters that remain unresolved will be forwarded to the relevant Dean and AVPR for resolution. The IBC can suspend research or teaching activities involving biological agents. The IBC may also authorize access restriction, or removal of personnel from a BUA.

Accidents or Breach of Containment:
The IBC will provide emergency procedures to investigators covering accidental spills and personnel contamination resulting from research or teaching activities involving any of the items above. Any accident or serious breach of containment involving biological agents must be reviewed by the IBC. The IBC may recommend or require probationary approval and specific actions such as training and additional inspections to the Principal Investigator or Instructor to the AVPR. Additional sanctions may be delivered as described in the sanctions and enforcement section of this document.

Any accident or serious breach of containment involving biological agents that leads to significant personal injury must be reported to the BSO, the AVPR (richard.mocarski@sjsu.edu) and the chair of the IBC (biosafety@sjsu.edu) as soon as possible after the immediate emergency is addressed. Certain incidents, as described in the *NIH Guidelines*, must be reported to the NIH Office of Science Policy (OSP).

Reporting: The committee reports administratively to the AVPR. The committee is responsible for forwarding to the AVPR an annual written report that describes the committee's activities and deliberations during the previous year. The report should include a roster of all IBC members and their participation, description of committee accomplishments, regulatory compliance, new or modified policies, areas in need of improvement, and other items as appropriate. The AVPR will submit to NIH/OSP the annual report, which includes a roster of all IBC members clearly indicating the Chair, contact person, Biological Safety Officer, plant expert (if applicable), animal expert, human gene therapy expertise or ad hoc consultant (if applicable); and biographical sketches of all IBC members (including community members).

Meeting Minutes

Minutes will be taken at each convened meeting of the IBC. These minutes document the date and place of the meeting, whether the minutes of the previous meeting were approved, the action taken on all major motions, at the time at which the meeting was adjourned.

Any member of the public may obtain access to the minutes from IBC meetings by submitting a request to the SJSU Public Records Coordinator. Upon receipt of a request, the University will follow procedures for responding to requests made under the California Public Records Act. In keeping with the NIH Guidelines, the IBC may redact certain information from the minutes if there are concerns related to privacy or proprietary information.

Signature of approval DocuSigned by: Richard Mocarski 4F4FF6CD4A734C1... Date 5/23/2022

AVPR Richard Mocarski