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 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 [https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.html#_Toc3457056].

Membership

Committee members are recommended to the Associate Vice President for Research (AVPR) by the IBC chair and approved for a term of three years. The IBC shall be comprised of no fewer than six (6) individuals including two non-affiliated community members. The remaining members shall have titles and expertise in the following areas:

Biosafety Officer (BSO)

The Biosafety Officer (BSO) shall be a University member appointed position to the IBC and will serve as the committee chair. The BSO will be responsible for the following tasks:

1) Convene an annual meeting
2) Call for full proposal reviews as needed
3) Assist in overseeing and review of lab safety inspections
4) Report to the IBC and the Institution any NIH Guidelines violations within 30 days
5) Investigate Research related accidents involving rDNA research and/or incidents involving hazardous biological agents
6) Submit an annual report to the AVPR for submission to the NIH/OBA consisting of:
    a. A current member roster
    b. Biographical Sketches

Chemical Hygiene Officer (CHO)

The University shall appoint a staff member to be the Institution's Chemical Hygiene Officer (CHO) to serve as both a point of contact with the University's Environmental Health and Safety (EHS) department, and provide additional expertise in the area of laboratory safety, OSHA, EPA, and other applicable regulations. Working with the BSO, the CHO 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 research safety procedures
3) Provide training for PI, faculty, staff, and students where needed

Biohazardous Waste Technician

The University shall appoint a staff member who has expertise and is responsible for the handling, processing, and tracking of biohazardous waste for shipment, treatment and disposal. The position requires knowledge of county, state, and federal regulations pertaining to biohazardous waste.

Molecular Biology Expert(s)

The University shall appoint at least one expert (faculty or staff member) in this area to professionally address the research that requires IBC approval in accordance with NIH Guidelines.

Community Members (Non-Affiliated Members)
The University shall appoint two volunteers from the community who are unaffiliated with the University. These members will represent the community with respect to health and protection of the environment

Responsibilities
Reporting to the AVPR, the SJSU IBC primary responsibilities lie in reviewing two areas of research: 1) programs involving recombinant or synthetic nucleic acid molecules and 2) programs that pose potential risk to the environment and public health. Within these areas, the committee also provides oversight on institutional and investigator compliance, and research plans to ensure conformity with NIH Guidelines, which includes assigning proper containment levels, adequacy of facilities, PI and personnel training, and standing 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 conducted by faculty, staff, students and/or visiting scientists and ensuring that they are aware of the responsibility to register the use of biological agents or activities as described below:

a) Microorganisms;
b) Activities subject to the NIH Guidelines for Research Involving Recombinant DNA or Synthetic Nucleic Acid Molecules (*NIH Guidelines*);
c) Materials derived from human and nonhuman primates;
d) Biological Toxins with an LD_{50} of less than 100 micrograms per kilogram of body weight in vertebrates;
e) Select agents or toxins subject to 42 CFR Part 73, 9 CFR Part 121, or 7 CFR Part 331 [https://www.selectagents.gov/Regulations.html];
f) Proposed research 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 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 recombinant DNA research (*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 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 month 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.

The BSO will serve as a functional arm of the IBC and manage day-to-day operations in conjunction with IBC administrative staff and EHS staff. Services include providing technical expertise, periodic inspections to ensure that laboratory standards are rigorously followed, reporting of incidents or violations to the committee, development of emergency plans for spills or contamination, advice on laboratory biosecurity, recommendations for improvement, regulatory updates, and other support as needed.

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: 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. In matters that are deemed immediately dangerous to life and health, the IBC will immediately suspend research involving biological agents. In such extreme cases, and after consultation with the AVPR, the IBC may also authorize access restriction, or removal of personnel.

Accidents or Breach of Containment:
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 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 AVPR. 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).

Approved:

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Mohamed Abousalem
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Mohamed Abousalem,
Vice President
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Date