San Jose State University (SJSU)
Institutional Biosafety Committee (IBC)
Charter 2024

OBJECTIVES AND SCOPE OF ACTIVITIES

The purpose of the IBC is to review and set conditions for research, teaching, diagnostic testing and other activities involving recombinant or synthetic nucleic acid molecules and other hazardous biological agents being conducted at or sponsored by SJSU, in accordance with the National Institutes of Health (NIH) Guidelines for Research Involving Recombinant DNA Molecules (*NIH Guidelines*) and the Centers for Disease Control and Prevention (CDC)/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL). It also represents the interests of the surrounding community with respect to public health and protection of the environment. The IBC reports to the Associate Vice President for Research (AVPR), who provides the 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.

STRUCTURE OF THE IBC

The IBC will be comprised of no fewer than six members, who collectively have the experience, expertise, and capability needed to assess the safety of recombinant and synthetic nucleic acid molecules projects as well as potential biological and public health risks.
At least two members will not be affiliated with SJSU except for their membership on the Committee. These two members will represent the surrounding community regarding public health and environmental protection. The Biosafety Officer (BSO) will be a member of the Committee. In addition -at least- one member from the laboratory technical staff will serve in the IBC. The Committee includes also senior or key members (non-voting members) from the College of Science, College of Engineering, College of Health & Human Sci, Health Services and College of Social Sciences that significantly contribute to the health, safety and welfare of the University workforce. Alternate members may be appointed to serve and participate on the IBC as a substitute for the primary member. When the primary member and alternate are both present, only one vote may be cast among them. The IBC may use consultants when reviewing research outside the expertise of the members. Consultants are not IBC voting members.

Procedures for Appointing Members
The Associate Vice President for Research (Institutional Officer), in consultation with the IBC chair will formally appoint the IBC members in writing. The Committee will designate the Chair and Vice-Chair which may be any IBC member. All appointed members will be required to complete training in research guidelines and regulations. Annual refresher training will be required.

Terms of Membership
All members will serve for a three-year term. The Chair and members may be reappointed for additional terms. The IBC Chair may remove a committee member, when necessary, e.g., due to resignation, excessive absence (4 or more absences in a calendar year), lack of contribution, or unavailability.

Confidentiality
IBC members will not discuss or disclose the details of meetings or submitted protocols with individuals not directly affiliated with the IBC.

Conflict of Interest Policy
No Committee member may be involved (except to provide information) in the review or approval of a project that the member expects to be engaged in or has a direct financial interest in. Each member is expected to notify the IBC Chair in these circumstances and recuse themselves when such proposals are being discussed and are up for a vote.

MEETINGS

The IBC will meet on a monthly basis to conduct its functions. Additional meetings may be called as required. Meetings are currently held via Zoom, but can also be held in person at the discretion of the IBC Chair. A proposed agenda will be developed by the BSO in collaboration with the IBC Chair. The agenda will be distributed prior to the meeting. The agenda will include a review of the previous meeting's minutes and new or old proposals for review. Any member may request to include a topic on the agenda. Meetings will be conducted in accordance with Robert's Rules of Order. Meeting minutes will be taken by the IBC Admin assistant to accurately reflect the topics of discussion. Minutes will be reviewed, approved by the members, and maintained on file for three years at the Office of Research. IBC meetings are open to the public – contact biosafety@sjsu.edu to request information about attending a meeting. IBC meeting minutes are also available to the public upon request.

Quorum Requirement
A quorum of 50 percent plus one of voting members will be required to hold a meeting, and will include the Chair and at least one community representative. The quorum is announced at the beginning of each meeting. If a quorum is not met, the meeting will be adjourned and rescheduled when feasible. For emergency and ad hoc meetings, a quorum is defined as greater than 40% of the total number of voting members, providing there is sufficient expertise in the room to ensure that appropriate discussion has taken place on the issue(s) presented. Action will be approved by majority vote and business conducted at an expedited meeting is reported to the full committee at the next scheduled meeting.
In the event that the IBC Chair is absent, the Vice-Chair will serve as Chair. Decisions such as approval of research projects, policies or other resolutions will be approved by a simple majority of voting members attending the meeting.

RESPONSIBILITIES OF THE IBC

The responsibilities of the IBC include:

- ✔ Review and approves protocols for research and teaching laboratories involving the following materials
  - Recombinant/synthetic nuclei acid molecules (r/s DNA), as covered by the *NIH Guidelines*
  - Biological agents (including bacteria, viruses, parasites, fungi, prions) that can cause disease in healthy humans and/or have a significant environmental impact, or otherwise require BSL-2 containment and practices, as covered by the BMBL
  - Human and nonhuman primate blood, serum, plasma, tissues, secretions, excretions or cell lines, unless documented to be free of bloodborne pathogens, as covered by the Cal/OSHA Bloodborne Pathogen Standard
  - Biological toxins (e.g., cholera toxin, snake venom toxin, tetrodotoxin, etc.)
  - Poisonous plants posing a risk to humans via dermatological contact, inhalation or another route of exposure
  - Diagnostic specimens or environmental samples likely to contain any of the above and posing a significant risk to humans or livestock
  - Genetically-modified animals, as covered by the *NIH Guidelines*
  - Dual Use Research of Concern activities
  - Other biological materials, as determined necessary by the BSO or IBC Chair

- ✔ Determine the appropriate biosafety containment level for each research protocol
- ✔ Periodically review r/s DNA research conducted at SJSU to ensure compliance with *NIH Guidelines*
- ✔ Notify the PIs of the results of the IBC's review and approval
- ✔ Adopt emergency plans covering accidental spills and personnel contamination resulting from r/s DNA research
- ✔ Investigate any research-related accidents or illnesses involving potential biological hazards and file reports, as required, with the NIH Office of Biotechnology Activities (OBA). Laboratory incidents will first be reported to the PI in the lab in which the incident occurred. The PI will immediately notify the BSO, who will report the incident to the IBC. The IBC will decide, based on the requirements of the *NIH Guidelines*, whether the incident requires reporting to OBA (within 30 days). Prior to sending to OBA, the incident report will be provided to the PI in whose lab the incident occurred for his/her comments
- ✔ Investigate allegations of noncompliance with *NIH Guidelines* or other unsafe practices
- ✔ Provide a forum for development and modification of university biosafety policies
- ✔ Additionally, the IBC may withhold approval for all or any portion of a protocol and require modifications

PRINCIPAL INVESTIGATOR RESPONSIBILITIES

PIs will comply with the *NIH Guidelines* and:

- ✔ Submit new and modified (renewal or amendment) Biological Use Authorization (BUA) applications to the Committee as required

- ✔ Not conduct research on new or modified protocols prior to the receipt of written approval from the Committee for protocols falling under Sections III-A, III-B, III-C, or III-D of the *NIH Guidelines*
- ✔ Participate in the annual review of each of their research protocols involving the use of r/s nucleic acid molecules
- ✔ Ensure they and all laboratory staff are appropriately trained including, at a minimum: containment methods, disinfectant and disposal practices, utilization of personal protective equipment, and required actions in the event of a spill
- ✔ Ensure required safety practices and techniques are employed
- ✔ Comply with all other requirements of the IBC approval, inspections and Biosafety program

BIOSAFETY OFFICER RESPONSIBILITIES

The BSO's responsibilities include:

- ✔ Follow the directives of the IBC
- ✔ Conduct periodic inspection of labs
- ✔ Report to the IBC and EHS any problems, violations, research-related accidents or illnesses
- ✔ Develop emergency plans for handling accidental spills and individual contamination
- ✔ Advise on lab security
- ✔ Provide technical advice to PIs and the IBC on research safety procedures
- ✔ Ensure compliance with specified IBC-related training requirements for PIs and IBC members

IBC MEMBERS RESPONSIBILITIES

The IBC Members' responsibilities include:

- ✔ Understand all functions, policies, and procedures of the IBC and the EHS biosafety program
- ✔ Attend scheduled meetings of the IBC
- ✔ Notify the BSO when unable to attend IBC meetings
- ✔ Complete required biosafety trainings
- ✔ Review protocols as requested and provide feedback to the IBC Chair, and/or the BSO
- ✔ Assist with periodic reviews of IBC policies and procedures

The Chair's responsibilities include:

- ✔ Serve as a member of the IBC and understand all functions, policies, and procedures of the IBC and the EHS biosafety program
- ✔ Attend scheduled meetings of the IBC
- ✔ Direct the proceedings of convened meetings of the IBC
- ✔ Review research protocols, including protocols slated for review via an expedited review process and at convened meetings of the IBC
- ✔ Assist in setting meeting agendas

- ✔ Assist the BSO in drafting letters from the IBC regarding IBC decisions and actions
- ✔ Sign IBC letters, as needed
- ✔ Make decisions about researcher responses to IBC conditions for protocol approval, in collaboration with the BSO
- ✔ In concert with the BSO and other members of the IBC, conduct post-approval monitoring of protocols
- ✔ Assist in the development and implementation of new standard operating procedures (SOPs)
- ✔ Assist with periodic reviews of IBC policies and procedures
- ✔ Participate in periodic review of the IBC Charter and update as necessary
- ✔ Complete required biosafety trainings

The IBC Vice-Chair responsibilities include:

- ✔ Serve as a member of the IBC and understand all functions, policies, and procedures of the IBC and the EHS biosafety program
- ✔ Attend scheduled meetings of the IBC
- ✔ Perform duties of the Chair in the Chair's absence or in instances where the Chair has a conflict of interest
- ✔ Participate in periodic review of the IBC Charter and update as necessary
- ✔ Assist with periodic reviews of IBC policies and procedures
- ✔ Complete required biosafety trainings

ADMINISTRATIVE AND PROFESSIONAL SUPPORT TO THE IBC

Institutional Official (IO)

The IO's responsibilities include:

- ✔ Appoints IBC members
- ✔ Supports the successful execution of IBC responsibilities and authorities
- ✔ Provides administrative support for the functioning of the IBC
- ✔ Serves as a contact for the NIH Office of Science Policy (OSP) to provide news, updates, and approvals
- ✔ Maintain official files of the IBC, including minutes, agendas, correspondence with PIs or IBC Chair, disciplinary recommendations, etc.
- ✔ Make available to the public, upon request, all minutes of IBC meetings and any documents submitted to or received from funding agencies which the latter are required to make available to the public
- ✔ Submits the annual update of the IBC roster to the NIH OSP
- ✔ Serve as liaison between research personnel, the IBC, federal and regulatory agencies
- ✔ With the IBC Chair and BSO, generate and send the annual report to NIH

IBC Admin Assistant

The IBC Admin assistant's responsibilities include:

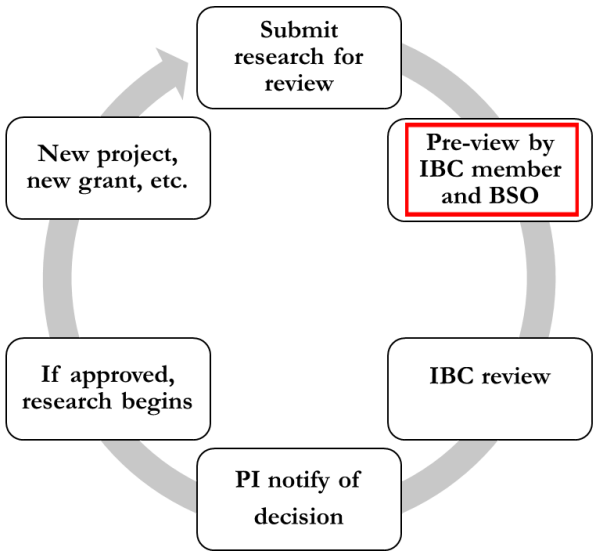
- ✔ With the IBC Chair prepares and distributes meeting agenda
- ✔ Schedules IBC meetings, and invites members

- ✔ Inform public regarding meetings' time to allow attendance
- ✔ Communicate to the IBC Chair if a scheduled meeting will not meet quorum requirements
- ✔ With the IBC Chair, finalize meeting minutes and distribute to members
- ✔ Review and revise the IBC Charter at least annually, in consultation with the IBC Chair and the BSO
- ✔ Receives and reviews biological applications for completeness in advance of the meeting

PROCEDURES

- ✔ The PI submit the proposed research to the IBC using a Biological Use Authorization (BUA) application form that was specifically designed to identify information needed for assessment.
- ✔ An IBC member and the BSO will review, request modifications and approve the IBC applications for research that is exempt from the *NIH Guidelines* and/or the *SJSU Charter*.
- ✔ All research that is not exempt from the *NIH Guidelines* or the *SJSU Charter* will be reviewed and approved by the IBC prior to initiation of the research.
- ✔ BUA applications for all research involving BSL-2 pathogens or rDNA will be assigned to two committee members for review (primary and secondary reviewer). Prior to the IBC meeting, members will review the BUAs requested and provide feedback to the committee.
- ✔ During the IBC meeting, the primary reviewer will lead the discussion of the BUA including comments made by other members of the IBC. At the conclusion of the discussion, the voting members will vote on whether to approve the application, or tabled it pending clarification or more information prior approval. Members of the applicant BUA that sit on the committee should be recused from voting (conflict of interest).
- ✔ Proposals are approved for 3 years. PIs must complete an IBC continuing review report form each year to continue work for up to three years after the initial approval. After three years, the proposal must be updated by the PI, and submitted to the IBC for a complete review.

A



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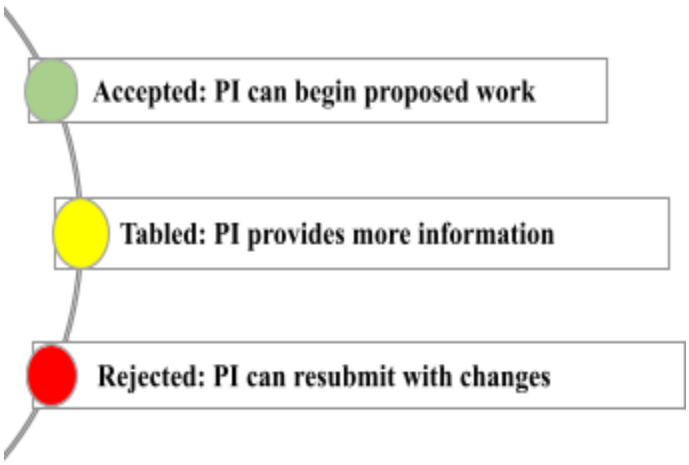

Figure 1. (A) Institutional Biosafety Committee review process. (B) IBC review outcomes

REFERENCES

NIH Guidelines for Research Involving Recombinant DNA Molecules. Dept. of Health and Human Services, NIH (April 2019).
https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf

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So You Want to Start an Institutional Biosafety Committee. Maren Schniederberend, Benjamin Fontes, and Rachel Jeffrey. Applied Biosafety: Journal of ABSA International 2019, Vol. 24(3) 161-169

INSTITUTIONAL ENDORSEMENT

DocuSigned by:
Jessica Trask
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12/3/2024

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San Jose State University (SJSU)

Institutional Biosafety Committee (IBC) Member Agreement

Please read, sign, and return this document to the Institutional Officer Jessica Trask

As a regular, appointed, member of the IBC, I agree to meet the following expectations:

- **Meeting attendance:** Regular meeting attendance by IBC members is necessary to achieve and maintain the quorum required to conduct official business. **IBC members are expected to attend at least 75% of all scheduled full committee meetings**.

- **Protocol Review:** IBC members will review protocols and amendments within approximately 7 days of assignment and inform the IBC Biosafety Officer if unavailable to serve as a reviewer during a certain period of time (e.g., vacations, sabbaticals, other extended absences).

- **Confidentiality Requirements:** IBC members are required to maintain strict confidentiality as it relates to information disclosed in IBC documentation, information discussed during meetings of the IBC, meeting activities, including but not limited to information learned through facility inspections, the contents of Biosafety Use Authorization applications (i.e., IBC protocols) and/or SJSU intellectual property. IBC members will neither use nor disclose Confidential Information for any purpose other than participation in the IBC.

- **Conflicts of interest:** The NIH Guidelines (IV-B-2-a-(4)) states "*no member of an IBC may be involved in the review or approval of a project in which he or she has been or expects to be engaged or has a direct financial interest*". IBC members are required to disclose the existence of any conflict of interest they may have related to the activities. If an applicant submitting a protocol believes that an IBC member has a potential conflict, the applicant may request that the member be excluded from the review of the protocol. When a member has a conflict of interest, the member should notify the IBC Chair and may not participate in the IBC review or approval except to provide information if the committee requests such. Other examples of conflicts of interest include the following:

    - A member is involved in a potentially competing research program.
    - Accesses to funding or information may provide an unfair competitive advantage.
    - A member's personal biases may interfere with his or her impartial judgment.

- **Facility Inspections:** IBC members will participate in any facility inspections as

requested by the Biosafety Officer or any IBC member.

- **Regulatory oversight:** IBC members are expected to become knowledgeable regarding Federal, State, and institutional regulations and policies.

- **Training:** IBC members are expected to maintain current IBC training, renewing/refreshing as necessary, and to participate in educational opportunities that are relevant to the IBC, whether offered by the institution, professional societies, or other sources, throughout their terms of service.

- **IBC Performance:** IBC members will participate in regular assessments of the IBC's performance and compliance with the National Institute of Health ("NIH") Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules ("NIH Guidelines") and other applicable expectations.

- **Expense Reimbursement.** IBC members who are SJSU employees will participate in the IBC on a volunteer basis and will not be compensated for their time. Non-employee members may be eligible for reimbursement of reasonable pre-approved expenses related to attendance at meetings of the IBC, in the sole discretion of the University. Any such reimbursement may be subject to federal or state transparency laws and reporting by SJSU. In that event, IBC members will provide any documentation and assistance reasonably requested by SJSU in connection with the University's compliance with such laws.

I, _____ (*print name*), as a member of the Institutional Biosafety Committee, agree to abide by the expectations set forth above.

_____ _____

Signature Date