

Activities Covered by the SJSU IBC

Unless your research specifically falls under the Exempt category ([BUA Exemption Request Form](#)), all research and teaching activities undertaken at the San Jose State University require review by, and the approval of, the Institutional Biosafety Committee (IBC). The IBC is charged under NIH Guidelines to review, approve, and oversee projects involving recombinant or synthetic nucleic acid (r/s NA) molecules. The NIH Guidelines not only establish the requirement for an IBC but also allow the extension of IBC's responsibilities to include biological research that does not involve r/s NA. The SJSU IBC oversight includes applications involving:

- Recombinant/synthetic nucleic acid molecules (r/s NA), 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 Biosafety in Microbiological and Biomedical Laboratories (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 NIH Guidelines
- Dual Use Research of Concern activities
- Other biological materials, as determined necessary by the BSO or IBC Vice Chair

If research and/or teaching activities involve any of the above, you are required to submit a Biological Use Application (BUA) for IBC review

Possession of and work involving unapproved materials by the PI and/or their staff constitutes a violation of the SJSU Charter, funding agency/sponsor requirements, and State and Federal laws.

IBC Process for Reviewing BUA Applications

1. Submission of the BUA

The BUA application is available from the SJSU IBC website. If your work is exempt, you must complete the BUA Exemption Request Form ([BUA Exemption Request Form](#)). If your work is non-exempt, you must complete all applicable BUA forms ([Biological Use Authorization](#)). You may use the following resource when preparing your BUA ([BUA Pre Review Completion](#)).

2. Pre-screening of the BUA Applications

Initial review of applications will be conducted by the Biosafety Officer (BSO), or designee for completeness and clarity. The initial review will determine what level of review (full committee, expedited or administrative) is necessary for the application based on the activities and whether the NIH Guidelines apply. The Chair will assign the primary/secondary reviewer(s). The PI will be contacted by the BSO to clarify any questions from the initial review.

3. Procedure for Full Committee Review

BSO confirms a meeting date when a quorum can be present, prepares the meeting agenda, and distributes the materials to the IBC two weeks prior to the meeting. The primary reviewer will present their findings to the committee. Overall, the presentation should be concise, organized and visually presented to facilitate comprehension. It will include research goals, specific biological materials the PI plans to use, experimental procedures with emphasis on the safety measures, biosafety required and NIH guidelines proposed by the PI.

IBC members who have a conflict of interest with the presented application will recuse themselves from the meeting.

Members may be physically present or use video conference in real time.

If a quorum is lost during an IBC meeting, the matter being discussed (e.g., new policies, BUA) will be reviewed again at the next scheduled IBC meeting.

Minutes of meetings are recorded and will include any dissenting views and resolution through vote. The minutes are shared with the committee following the meeting.

The BSO or Chair may request an expedited review process if a BUA application cannot wait for review to the next scheduled IBC meeting (e.g., need to collect seasonal samples, a funding deadline approaching, etc.). For expedited review, the IBC Chair will convene an expedited review meeting. All members are invited and a minimum of four voting members are required to approve the protocol under review. Action from an expedited meeting is reported to the full committee to approve the expedited action.

4. Administrative Review

This review may be used to verify minor points or clarifications requested when determined, through vote by the full IBC, to be administrative in nature with no impact on biosafety (approved pending minor issues). This review can be conducted by the BSO or IBC Chair. Examples of minor points/clarification include but are not limited to: typographical or grammatical errors, funding source information, linking IRB or IACUC protocols, contact information, and verification of training, or verification of biosafety cabinet certification, etc.). All applications administratively approved by the BSO or Chair will be reported to the full committee to approve the administrative approval.

IBC Actions

Review by the IBC will result in one of the following:

- Approved: The PI is authorized to perform activities as stated in the BUA
- Approved pending minor modifications: Conditionally approval pending minor changes
- Tabled: The IBC Chair works with PI to address significant issues identified
- Not approved

The PI will be notified in writing by the BSO of the determination made by the IBC.

If a BUA application is not approved, the IBC must provide the rationale in writing and give the PI an opportunity to respond or appeal the findings. The PI has the right to appeal the decision, within two weeks of notification from IBC that approval has been withheld. The appeal should be initiated by submitting a letter to the IBC Chair (biosafety@sjsu.edu) addressing relevant issues. The appeal will be discussed by the full committee. Any decision to reverse a non-approved protocol requires a vote by the full committee.

Protocols will be approved for a maximum period of 3 years. The PI will be informed in writing of the IBC's review decision. The Department Chair, Co-PIs and IBC will be included in the correspondence using DocuSign. The PIs will submit an [Annual Continue Review Report Form](#) to assess any changes that may have occurred during the previous

year. If a change to the initial BUA application has occurred, a BUA Amendment Form must accompany the continuing report. Annual Continuous Review Forms should be sent to biosafety@sjsu.edu.

The approval date is the date the full committee approves the BUA application. If the IBC uses administrative review subsequent to full committee review, the approval date is the date that the full committee approved the study pending the minor modifications.

Exempt activities will be reviewed by the IBC every 3 years

Any member of the IBC may, at any time, request to see the revised protocol and/or call for full committee review.

Modifications to an Approved IBC Protocol

Modifications to an existing BUA must be submitted to the IBC using the [BUA Amendment Form](#). Depending on the type of modification requested (minor or major), the amendment may be reviewed through administrative, expedited or full IBC review.

- Modifications allowable under administrative review must have no impact on the biosafety level/risk group/NIH classification. Administrative changes may include typographical or grammatical errors, funding source information, linking IRB or IACUC protocols, contact information, or verification of biosafety cabinet certification, and other minor changes. There are no deadlines for submitting minor amendments.
- Major modifications to protocols that may result in a higher risk than previously approved standard operating procedures must be reviewed by the full committee. E.g., change in the scope of research, change in Risk Assessment, adding/changing infectious agents, change in the containment level, change in sections of the NIH Guidelines, additional research procedures, change in Principal Investigator, and other major changes.

If the PI changes in a research BUA (not teaching BUAs), a Change in Principal Investigator Form must be completed and submitted to biosafety@sjsu.edu for review and approval.

All major changes to a previously approved BUA should be made by incorporating the changes into the bodies of the BUA forms using track changes. Amendments submitted without track changes will be returned to the PI as an incomplete submission. The "Amendment" box should be selected on the Main BUA Form (page 1). Submissions must be received at least two weeks prior to an IBC meeting to be considered for review at that meeting. All meeting dates are posted on the SJSU IBC website.

The PI will be notified in writing by the IBC Chair of the determination made by the IBC. Changes may not be implemented until the amendment has been approved by the IBC.

BUA Protocol Renewal Process

Principal Investigators will be notified approximately 60 and 30 days prior to their protocol expiration date. At this time, the PI must decide whether they wish to request a BUA renewal or to close the BUA. Principal Investigators who plan to renew their project must review and update their protocol and re-submit a BUA application selecting the "Renewal" box (approved for a 3-year period) on the application prior to the protocol expiration date. The IBC will conduct a *de novo* review of the renewal BUA application. The PI will be notified in writing of the determination made by the IBC.

To prepare a resubmission (renewal), ensure you're using the latest [BUA forms](#). If not, download the latest templates to your Google Drive or as Word documents, and then copy the information from your previous submission into the

new template. Make changes using the "suggesting mode" in Google Docs (or a similar feature in Word). To facilitate faster review, use a separate "changes" document to clearly present the modifications made to the forms.

Failure to renew a BUA in advance of the expiration date will put the BUA into a lapse state for 60 days after the expiration date, and all research activities involving recombinant or synthetic nucleic acid molecules, infectious agents, or biological toxins will stop during that time. Lapsed protocols that are not renewed will be closed automatically after 60 days.

BUA Closures

If a PI wishes to close their BUA, they may submit a BUA Closure Request Form to biosafety@sjsu.edu.

A copy of the BUA closure letter will be forwarded to the PI and the Chair/Dean of the department.

Closure of the BUA protocol may require closure of any related IACUC or IRB protocols.

If a PI leaves SJSU but does not close the BUA, the BSO will investigate the status of listed biological materials and will have the authority to dispose of the remaining materials. Following BSO investigation and disposal, if applicable, the BUA may be closed administratively.

Procedures for Managing Allegations of Potential Noncompliance

TBD