INSTITUTIONAL BIOSAFETY COMMITTEE
SAN JOSÉ STATE UNIVERSITY
BUA PRE-REVIEW COMPLETION CHECKLIST

This document provides a list of the most common errors and miscommunications that lead to BUA approval delays. Please carefully review your BUA submission to confirm that you have addressed these common errors. Reach out to biosafety@sjsu.edu if you have any questions.

Contacts and Room Numbers

- Make sure all **contacts and room numbers** are up to date throughout the document. Carefully review the "Laboratory Locations" table, the "Laboratory Personnel" table, and the signature page.
- Make sure to cross-check this information with SOPs and any shared space letters. The lab locations listed on SOPs should be specific to the work described– for example only list the BSL-2 lab locations on the BSL-2 SOP. Noting the lab locations based on the equipment required to complete the SOP can help make sure all required rooms are included.

Shared Space Authorization Letter

The IBC now requires a letter from the managers of shared spaces authorizing the PI to use the space and clarifying the hazard communication to other shared space users.

- Carefully make sure that this letter lines up with the Laboratory Locations table of your Main Form.
- You can reach out to your shared space manager (usually dept chairs) to get a pre-filled document. The IBC also accepts a list of all shared equipment from the space manager if it notes the BSL allowed for the equipment, any specific restrictions on materials, and the hazard communication requirements.
- If your department does not already have a template, you can find a template here. IBC BUA shared space dept chair approval template.docx

Main BUA Form

Associated Institutional/Agency Approvals

The **"Associated Institutional/Agency Approvals"** table is for classes that use samples from students (finger pricks, saliva, etc.) for **exclusively teaching purposes** (NOT research):

- Respond YES to "Does this work involve human subjects or unfixed tissues?"
- The IRB information should state "IRB oversight is not required for exclusively teaching purposes."

Containment Methods

The **"Containment Methods"** table reviewed by the IBC is primarily focused on **preventing liquid leaks and aerosol generation**. Carefully cross-check this with your SOPs to include all steps that can potentially generate aerosols.

- Aerosol generating processes include– centrifuging, grinding, blending, vigorous shaking or mixing, sonic disruption, opening containers with high internal pressures (i.e., cryovials that leaked to contain liquid nitrogen), Inoculating animals intranasally, harvesting tissues from animals or embryonated eggs, and dumping small hazardous waste containers into larger containers when waste could be contaminated with biohazardous liquid.
- You may find this table helpful as you consider minimum required containment– https://blink.ucsd.edu/safety/research-lab/biosafety/containment/chart.html – *this table is based on*

Biosafety in Microbiological and Biomedical Laboratories—6th Edition used by IBC reviewers to evaluate your BUA

Biohazardous Materials and Waste Disinfection/Decontamination and Disposal

The **"Biohazardous Materials and Waste Disinfection/Decontamination and Disposal"** table should only include **autoclaves** for decontamination if your waste is processed by the Microbiology Service Center. No other autoclaves on campus are certified for waste decontamination– all other autoclaves can only be used for sterilization but NOT for decontamination of waste or contaminated materials. Please also double check your SOPs to make sure autoclave decontamination is only mentioned if you have access to the Microbiology Service Center.

- MAKE SURE THIS TABLE MATCHES YOUR SOP!

Work Surfaces, Instruments, Equipment

The **"Work Surfaces, Instruments, Equipment"** table is focused on the decontamination of items that will be re-used in your BUA. Disposable items and biological wastes are already addressed in the "Biohazardous Materials and Waste Disinfection/ Decontamination and Disposal" table.

- **Autoclave decontamination is ONLY an option for those using the Microbiology Service Center.** You must have another decontamination method if you are using autoclaves for sterilization– for example bleach your glassware that could be contaminated with biohazards to decontaminate it, then autoclave to sterilize when you make more cell culture media.
- **Minimum contact times** recommended by EHS can be found at the link below. If you have a special situation for decontamination, please reach out to biosafety@sjsu.edu for a risk assessment consultation OR make use of the "other" row in this table: SJSU biohazard decontamination & waste guidance
- The **Agent(s)/ Material(s)** column should note the biohazardous material you need to decontaminate. You may generalize if you have multiple biohazards (i.e., "all BSL-2 agents listed in Attachment C" or "bacterial cells"). Please note that this should only cover agent(s)/material(s) in contact with re-usable surfaces/items– NOT wastes.
- Each remaining column (benchtop… instrument… etc.) should have a selection for "after spill" and for either "after use" or "daily". Most BUAs on this campus select for "after spill" and "after use".
- MAKE SURE THIS TABLE MATCHES YOUR SOP!

Laboratory Locations

The **"Laboratory Locations"** table should list all major equipment. This is especially critical for BSL-2 work since this list will be used to check for proper hazard communication. If you have a mixture of BSL-1 and BSL-2 work in your protocol, you should **note the BSL for each equipment** in parenthesis next to the equipment.

- For example: biosafety cabinets (BSL-1 & BSL-2), incubators (BSL-1 & BSL-2), centrifuges (BSL-1 & BSL-2), vortexes (BSL-1), PCR cabinets (BSL-1), water baths (BSL-1 & BSL-2), flow cytometer (BSL-1), liquid nitrogen Dewar (BSL-2), fridge/freezer (BSL-1 & BSL-2)
- The reviewers focus is on MAJOR equipment that may contain biohazards– NOT sealed tubes or filters that are already listed in the "Containment table".

Health Status, Health Surveillance, and/or Immunization Program: Potentially Infectious BSL-2 Pathogens

The IBC requires specific exposure response plans for any BSL-2 pathogens that can infect humans and that aren't already covered by the SJSU Bloodborne Pathogen Program. This information should be included in the "Health Status, Health Surveillance, and/or Immunization Program" Table of the main page and in first-aid sections of the SOP.

- Insert an exposure response plan in the "Are special post-exposure prophylaxis or medical management services needed in case of accidental exposure? If so, please describe them." section of the "6) Post Exposure Evaluation and Follow-Up" table.

- SJSU Bloodborne Pathogen Program for an example of the depth we are expecting. SJSU Bloodborne Pathogens Program_2023-0515.pdf
- Please find pathogen-specific examples here. Make sure to adapt these to standard SJSU accident response protocols if you choose to use them.
    - https://viceprovost.tufts.edu/biological-exposure-response-plans-laboratory-handling.
    - https://www.bu.edu/research/ethics-compliance/safety/rohp/agent-information-sheets/
- Cross check with the appropriate SOPs to make sure this information is easily accessible to personnel– the best place to note these requirements is where most SOPs advise that exposed areas of the body should be washed for 15 mins.
- Please note that the SJSU Wellness Center will be assisting with IBC review of these new exposure response plans. I want to assure you that a medical professional will be double checking your work-- we don't expect you to reach that level of expertise for this section.

Material Transport

The **"Material Transport"** table should note any transport required for your biohazardous materials of any BSL designation including plasmids, cells, tissues, invertebrates, and vertebrates.

- Transportation within campus falls under county regulatory agencies and by road/air falls under national and international regulations. You can email biosafety@sjsu.edu to set up an EHS consultation to help create compliant transportation protocols. EHS can also advise you about the training requirements for those that frequently ship hazardous materials.
- If your lab is transporting biohazardous materials **on campus**, confirm that this activity is appropriately described in your SOP. Specifically note requirements for leak-proof secondary containers and biohazard sticker labeling of secondary containment when transporting biohazardous materials in public university spaces (i.e., hallways, sidewalks, and elevators). The use of a cart for transport is strongly recommended. Your BUA does not have to cover the roles of Distribution Services, College, or Department in the delivery of shipments to your lab space.
- If you are **shipping biohazardous materials from SJSU to someone else** (i.e., a contract lab for analysis or to collaborators) you must include this in your SOP. DOT and IATA shipping regulations should be reviewed by David Griffith in EHS on a case-by-case basis. This EHS consultation is also required for any shipments of hazardous chemicals from SJSU including corrosives, ethanol, dry ice, preservatives, or cryogenic liquids. EHS can provide this training proactively and provide you with specific instructions so you will be prepared when the time to ship arrives.
    - Existing main page instructions that should be covered in relevant SOPs– note that a CITI training is required to ship and transport biological material: *"Shipping and Transporting Biological Material" training through CITI is required prior to shipment. Shipping of biological materials and other dangerous goods (e.g., dry ice, liquid nitrogen, ethanol) requires packaging by or review of packaging by an individual trained to ship such materials. The transport (shipping and receiving) of biological material may require a permit from a variety of agencies, including USDA/APHIS, CDC, and DOC. Approved permits must be on file with the IBC."*
- If your lab is transporting potentially biohazardous materials in **personal or university vehicles**, you must include instructions in your SOP. DOT and IATA shipping regulations should be reviewed by David Griffith in EHS on a case-by-case basis. EHS can provide training proactively and provide you with specific instructions so you will be prepared when the time to ship arrives. Please see these UCD guidance documents for an example:
    - https://safetyservices.ucdavis.edu/units/ehs/biological-safety/guides-forms-policies/transporting-clinical-human-samples
    - https://safetyservices.ucdavis.edu/units/ehs/biological-safety/pest-permits#samples
    - Existing main page instructions that should be covered in relevant SOPs– note that a CITI training is required to ship and transport biological material: *"Shipping and Transporting Biological Material" training through CITI is required prior to shipment. Shipping of biological materials and other dangerous goods (e.g., dry ice, liquid nitrogen, ethanol) requires packaging by or review of packaging*

by an individual trained to ship such materials. The transport (shipping and receiving) of biological material may require a permit from a variety of agencies, including USDA/APHIS, CDC, and DOC. Approved permits must be on file with the IBC."

Guidelines for Creation, Importation and/or Breeding of Transgenic Organisms

The **"Guidelines for Creation, Importation and/or Breeding of Transgenic Organisms"** needs to be reviewed and the box in the acknowledgement section needs to be checked for many folks with Attachment A. This one page document applies to transgenic organisms generated in your laboratory, purchased from vendors, or obtained from other laboratories. Genetically modified organisms include all organisms that have nucleotide sequences that are introduced by researchers. **"Organisms" include single cells** like bacteria and yeast for this checkbox and document.

Attachment A

- Make sure to click appropriate boxes in the first table– these correspond to the "5. Section III of NIH Guidelines" in the last table so be sure to cross-check.
- In the **"Hosts" table**, clearly indicate whether you are using K12 or K12-derived *E. coli* (*Saccharomyces cerevisiae, S. uvarum, Bacillus subtilis or B. licheniformis.)*. This impacts the "5. Section III of NIH Guidelines" table. A resource is linked in attachment A and many manufacturers provide this information: https://blink.ucsd.edu/safety/research-lab/biosafety/nih/e-coli.html.

Attachment C

The **SJSU Bloodborne Pathogen Program was updated** in May 2023. Most importantly, the **Hepatitis B vaccination form was transitioned to DocuSign**. You can now find the form at https://app.docusign.com/templates by searching for "EH&S HEPATITIS B VACCINE FORM". SJSU Bloodborne Pathogens Program_2023-0515.pdf. Follow college/department policies on the implementation of the Bloodborne Pathogen Program. Here are some general clarifications at the campus level:

- **Employees** are any person that is given a paycheck for work at SJSU. This includes student researchers, TAs, and other part-time employees. This includes those paid by the campus affiliates (like the Research Foundation or Tower Foundation). Their employers must provide them with Hep B vaccination for free during their working hours.
- This form will also be used to document hazard communication to **students & volunteers.** Individual research labs or teaching labs may implement this form themselves – this option is usually best for departments with few Attachment C research labs and no specific graduation requirements covered in Attachment C. Departments that include graduation requirements that fall under Attachment C (like core lab classes required of all students) are encouraged to provide this form to students as soon as possible when they join that academic program/pathway– this gives the student the maximum amount of time for the vaccination to reach effectiveness before coming in contact with potentially infectious materials.
- **Appropriate administrators** for this form could be direct supervisors (PIs, managers, etc.) OR a personnel management staff member for your department/college. The appropriate administrator needs to be able to arrange for employees to receive a vaccination at no cost to themselves.
- **Funding:** You can use grant money to pay for vaccinations for your employees. Departments and colleges may provide other funding to help assist with these costs. The university does not currently have a funding stream to provide students/volunteers with vaccinations.

SOPs

SOPs can be customized to fit your lab's needs: The attachments provide instructions about which elements of your BUA require an SOP. The minimum requirements are:

- HAZARD OVERVIEW noting particular biohazards, chemical hazards, or other hazards of concern.
- BIOLOGICAL MATERIALS detailing at minimum which biological materials will be handled with BSL 1 or BSL 2 conditions.
- ENGINEERING/VENTILATION CONTROLS– information relevant to the "containment" table of the main form.
- ADMINISTRATIVE CONTROLS– examples follow:
    - Special training requirements or certifications (like phlebotomy)
    - Rules about transportation on or off campus (including shipping)
    - Rules about handwashing and banning food/cosmetics/vaping/mouth pipetting.
    - Rules about working alone
- PERSONAL PROTECTIVE EQUIPMENT
- SPILL AND EMERGENCY PROCEDURES
- WASTE MANAGEMENT AND DECONTAMINATION

Citations

Citations are not required, but if you use them, you should make sure all the links are live or that you have copies available to lab personnel.

Potentially Infectious BSL-2 Pathogens Through Mucous Membrane Contact with Aerosols

EHS requires the following practices for solid waste that contains BSL-2 pathogens that are infectious through aerosols. This requirement must be clearly communicated to lab members, especially in shared spaces where technical staff may be the ones emptying the small biohazard containers. This special consideration is NOT required for BSL-1 materials. This is NOT required for BSL-2 materials that are unlikely to be infectious through aerosols (i.e., opportunistic pathogens or immortalized cell lines). Reach out to biosafety@sjsu.edu for a risk assessment if you are unsure about the routes of exposure for your BSL-2 materials.

- BSL-2 solid waste in small containers (i.e., containers in a biosafety cabinet) must be transferred into the larger biohazard waste containers in a way that prevents aerosol generation.
    - Potentially contaminated disposable items can be sterilized in the hood (dip in disinfectant) before placing them in the small container, then the small container can be dumped into the large container.
    - The small container could be closed when exiting the hood (flasks, tubes, etc.) so that aerosols cannot be released.
    - The potentially contaminated waste could be collected into a container lined with a small biohazard waste bag that can be sealed and gently placed into the larger waste container.

Emergency Spill and Injury Information

Emergency spill and injury information should be copied out of these templates and carefully modified with your lab-specific information like post-exposure SOPs and field site specific information. SJSU biosafety emergency response