CAL POLY Facilities Management & Development
Environmental Health & Safety

BIOSAFETY PROGRAM

I. PURPOSE

The Biosafety Program identifies practices, procedures and operational standards for safe handling and use of biological materials, infectious agents and recombinant DNA molecules at Cal Poly. The National Institutes of Health (NIH), Center for Disease Control and Prevention (CDC), and Cal OSHA provide regulations and guidance in the operational standards contained in this program.

II. SCOPE and APPLICATION

The program applies to all research, clinical and teaching activities conducted by Cal Poly faculty, staff, students, contract employees and other personnel working at locations where Cal Poly has management control of biohazardous materials. This program will ensure compliance with pertinent governmental and institutional guidelines, regulations and policies.

III. ROLES and RESPONSIBILITIES

Environmental, Health & Safety (EH&S) and the EH&S Biosafety Officer (BSO) are responsible for developing, communicating, implementing, providing program information and training, and conducting compliance audits and reporting results to department management for this program campus wide. See Section V.2. for details on Biosafety Officer program oversight.

Institutional Biosafety Committee (IBC), established in accordance with Federal regulations, is responsible for the review of all activities involving recombinant DNA and may evaluate other biohazardous materials that require specific expertise and awareness of containment procedures. See Section V.1. for detailed IBC program oversight duties.

Deans, Departments Chairs (or designee) are responsible for communicating, promoting and enforcing the policy and the program guidelines in areas under their control. They will work with EH&S to identify biohazardous activities under their authority that fall under the purview of this program.

Faculty, Principal Investigators (PIs), Lab Supervisors are responsible for complying with the policy and program guidelines, and for ensuring that staff and students working under their supervision are appropriately trained in the biohazards that are present in the work area and perform all work under the proper biosafety containment levels as required by this program. See Section V.3. for details. Faculty performing work in recombinant or synthetic nucleic acids on campus must comply with the NIH Guidelines for such work, regardless of funding source.

Staff, Student Assistants and Student Researchers are required to follow all training for biohazards present in areas in which they work or enter, and for working in the proper biosafety containment levels outlined in this program. They are responsible for informing others in the area of these requirements and reporting unsafe conditions to their supervisor, or EH&S.

IV. BIOSAFETY LEVEL CRITERIA

The following guidelines from the CDC publication, *Biosafety in Microbiological and Biomedical Laboratories* (BMBL), will be used by all laboratory personnel, the BSO, and the IBC to determine the proper practices, safety equipment and facilities applicable to the hazards present. See Appendix B.1 for complete Biosafety Level Summary chart.

Biosafety Level 1 practices, safety equipment and facility design and construction are appropriate for undergraduate and secondary educational training and teaching laboratories and for other laboratories in which work is done with defined and characterized strains of viable microorganisms not known to consistently cause disease in healthy adult humans.

Biosafety Level 2 practices, equipment and facility design and construction are applicable to clinical, diagnostic, teaching and other facilities in which work is done with the broad spectrum of indigenous moderate-risk agents that are present in the community and associated with human disease of varying severity.

Biosafety Level 3 practices, equipment and facility design and construction are applicable to clinical, diagnostic, teaching, research, or production facilities in which work is done with indigenous or exotic agents where the potential for respiratory transmission, and which may cause serious or potentially lethal infection.

Biosafety Level 4 practices, equipment and facility design and construction are applicable to work with dangerous and exotic agents that pose a high individual risk of life-threatening disease, which may be transmitted via the aerosol route and for which there is no available vaccine or therapy.

V. OVERSIGHT

1. **Institutional Biosafety Committee (IBC)**
   a. Review all research involving recombinant or synthetic nucleic acid molecules conducted at or sponsored by Cal Poly for conformity with the National Institute of Health (NIH) guidelines.
   b. Review and approve proposed research activities that use biohazardous materials designated as BSL-2+ or above.
   c. Oversee and review the use of potentially hazardous biological materials and Select Agents brought to the attention of the committee.
   d. The review of all of the above shall include an independent assessment of the containment required (practices, procedures, facilities and equipment used to safely

manage biohazardous materials) and an assessment of the facilities, training and expertise of personnel involved in the research.

e. Report any significant violations of the *NIH Guidelines,* or significant research-related accidents/ illnesses to the chair of the IBC immediately for dissemination to appropriate campus administrator and NIH Office of Science Policy (OSP). Any significant research related accidents or illnesses must be reported to NIH OSP within 30 days or immediately depending on the nature of the incident.

f. Meet as necessary.

2. Biosafety Officer/Environmental Health and Safety (EH&S)

a. Responsible for the development and implementation of the campus biosafety program.

b. Understand all applicable laws and regulations. Develop guidelines pertaining to biosafety/biohazards.

c. Review proposed research or instructional activities involving the use of biohazardous materials. Prepare recommendations to the IBC.

d. Develop emergency plans for handling accidental spills and personnel contamination.

e. Investigate laboratory accidents involving biohazardous materials.

f. Develop and conduct training on biosafety issues, practices, and procedures.

g. Report to the IBC any significant problems, violations of biosafety policy, practices or procedures and any significant research-related accidents or illnesses.

h. Conduct periodic hazard assessments and inspections to ensure that required laboratory practices and procedures are followed in all BSL-2 or higher labs and report results to department management. Refer to Appendix B.7 for inspection criteria.

i. Review biosafety facility construction/renovation plans and provide recommendations as necessary.

j. Dispose of biohazardous, medical and animal waste.

k. Serve as a member of the IBC.

l. Report any significant violations of the *NIH Guidelines,* or significant research-related accidents/ illnesses to the IBC for appropriate reporting to campus official and NIH OSP.

3. Principal Investigator (PI): As the faculty member in whose assigned space a research activity is conducted, the PI performs and/or oversees activities that utilize or produce biohazardous materials. Responsibilities include:

a. Before any laboratory work can begin, the P.I. must identify agent hazards and perform an initial assessment of risks for experimental procedure(s). Using the Biological Risk Assessment Worksheet (Biological Risk Assessment) and consultation with the Biosafety Officer, develop specific protocols based on hazard assessment to ensure the safe use of biohazardous materials and ensuring that all laboratory personnel comply with the specific safety protocols.

b. Based on the National Institutes of Health (NIH) Risk Groups (see Appendix B:3) the required levels of physical and biological containment (biosafety levels), as well as appropriate microbiological practices and laboratory techniques.

c. All work involving recombinant and synthetic nucleic acid molecules and Select Agents and Toxins must be reviewed by the IBC before any work can begin. See Section VI.

d. If the Biological Risk Assessment Worksheet determines a level above BSL-2, no work

can be done until the project goes through the IBC review process listed below in Section VI.

e. Ensure that the containment equipment and facility requirements for activities performed under his/her direction meet the criteria for the appropriate BSL and certification standard.
f. The PI is responsible for restricting access as required by the assigned biosafety containment level.
g. All biosafety cabinets must be certified at least annually to the NSF/ANSI Standard 49 and the manufacturer's specifications. Certification documentation shall be kept with the biosafety cabinets for the last three years and copies sent to the Biosafety Officer at EH&S.
h. Ensure autoclaves used for disinfection of contaminated material are functioning properly and maintenance and verification is performed as per manufacturers' suggested procedures.
i. Ensure that all maintenance in, on or around contaminated equipment is conducted only after that equipment is thoroughly decontaminated by the laboratory staff.
j. Develop specific protocols that outline proper emergency procedures for response to an accidental exposure of personnel or the environment to the biological agents and ensuring that all laboratory staff complies with the emergency procedures.
k. Obtain approvals, as appropriate, from the different committees relevant to the project -- Institutional Animal Care and Use Committee (IACUC) when animals are used, Institutional Review Board (IRB) if human subject are involved, or Radiation Safety Committee (RSC) if the project involves radioisotopes.
l. Comply with the specific federal, state and local safety protocols and practices, as applicable.
m. Ensure that all laboratory staff under his/her supervision are appropriately trained on the safe use of biohazardous materials and enrolled in medical surveillance, if appropriate before work begins. Training and medical surveillance include animal care personnel not directly supervised by the PI who provide care for infected animals.
n. Comply with medical waste laws in the handling of medical waste in the laboratory and have access to an autoclave or an approved medical waste accumulation area.
o. Ensure that all laboratory staff, maintenance personnel and visitors who may be exposed to any biohazard are informed in advance of their potential risk and of the actions required to minimize that risk.
p. Report any significant problems, violations of the policies, practices and procedures set forth in this program, or any significant research- related accidents and/or laboratory-acquired infection to the Biosafety Officer in Environmental Health and Safety within 24 hours.
q. In conjunction with the BSO or EHS staff, conduct inspections of the laboratory area at least annually using the inspection criteria Appendix B.7.
r. Comply with shipping requirements for biohazardous materials.

VI. REVIEW PROCESS

An initial Biological Risk Assessment (BRA) form will be submitted by the principal investigator to the BSO. The BSO will review the assessment form and will determine the process necessary for review, including whether or not further review by the IBC is warranted. If necessary, the PI will be directed to complete an Application for Biological Use Authorization (BUA). These forms, along with other related documents must be submitted to the IBC via the BSO for all research above a BSL-2, research involving recombinant or synthetic nucleic acid molecules, and select agents or toxins (see Review process, Appendix B-6). Review includes evaluation for compliance and conformance with the relevant regulations, laws and policies; assessment of the containment levels required by the guidelines; assessment of facilities, procedures and practices; and consideration of the training and expertise of personnel involved with the research.

Research plans, protocols and provisions for containment for work with biohazardous materials under field conditions (outside a lab, greenhouse, growth chamber, containment or cage) require additional information and program review. Environmental safety and risk must be considered for potentially self-replicating biological material. Researchers should anticipate potential testing, evaluation, or release of recombinant DNA products (at least one-year lead time) in the preparation and review of approval documents.

Program review and approval of BUA applications will take several weeks, or longer, depending upon workload and project complexity, among other factors. Investigators are advised to allow plenty of time for the review process.

BUAs for Teaching and Laboratory Coursework

In some instances, multiple teaching activities or courses can be included on one application. However, teaching activities and laboratory coursework must have a distinct BUA, separate from any research BUA.

Information on the BUA Application- The Application for Biological Use Authorization (BUA) will require project lead personnel (e.g., principal investigators or classroom laboratory directors) to provide the following information: title of the project, personnel details, funding information (if any), location(s) at which work will be performed, biological system information (host-vector system and target system), a project description, a risk assessment, plans for biological containment, and plans for personnel safety.

Personnel Details: The BUA application should include names and positions of personnel involved in the work, including dates for any completed training (required for research personnel conducting work at biosafety level 2).

Funding Information: A list of any external funding supporting the project should be included on the BUA application.

Facilities and Locations: The BUA application should indicate the physical location, functions to be performed in the space (lab work, field work, storage, microscopy, etc.), and whether or not the space will be shared.

Biological System Information: The BUA application should indicate -- for recombinant DNA work -- the host, cells, vectors, DNA sources, and/or genes of the host-vector and the organisms; and the cell lines, phage, and/or viruses of the target system. The BUA application should indicate – for other types of biohazards – a description of the biological materials.

Project Description: The BUA application will indicate the project objectives and a summary of the experimental procedures, in language that can be understood by non-specialists (except where necessary to convey important technical details). The description should include, as applicable, the original sources of DNA, including species name, common name and other relevant information (e.g., vertebrate or plant pathogen, food organism or common saprophyte, synthetic polypeptide, virus name, and strain); the nature and function (including expression products) of the inserted rDNA sequence; and the identity of vectors and microbial, animal, or plant hosts of the rDNA including species name, common name and other relevant information (e.g., disarmed agrobacterium promoters).

Risk Assessment: The BUA application will indicate a description of the hazards (human, animal, environmental) associated with the proposed work, potential consequences of accidental release or exposure, and how they will be minimized.

Biological Containment: The BUA application will include plans for containment, developed in accordance with governmental and institutional guidelines (using the appropriate source). These plans should include post-exposure procedures.

Personnel Safety: The BUA application should indicate a) if the work involves any human health hazardous material; b) if and how personnel are informed of health hazards and appropriately trained; and c) if employee health surveillance will be needed.

Review Types

BUA applications, after acceptance and initial review by the BSO, will be sent to the Chair of the IBC for initial review. The initial review by the chair determines whether the project is "Exempt/No Significant Risk" or "Not Exempt". BUAs determined to be "Exempt/No Significant Risk" will not require approval from the IBC and the PI notified the work can begin by the IBC chair. "Not Exempt" projects will go through the following review process.

IBC Review. This type of review is for new and renewal BUA applications that involve the use of biohazardous materials which include, but are not limited to recombinant DNA, and are determined to be BSL-2+ or higher. The procedures for IBC review are detailed in the *Procedures and Guidelines for the Institutional Biosafety Committee.*

VII. REVIEW DECISIONS

Following the review of the BUA application, the IBC will provide a decision; outcomes may include approved, conditionally approved, clarifications or changes required, or approval denied. Work cannot commence until unconditional approval has been obtained.

Approved. The activity is approved as submitted and the submitter will be notified.

Approved with Conditions. A conditional approval is awarded if there are correctable concerns. Correspondence will be sent to the submitter indicating the conditions, and once all the conditions have been satisfied, the submitter will be notified. The BSO and/or IBC Chair will conduct an administrative review of the revised procedures and/or documents to determine if the conditions have been satisfied.

Clarifications or Changes Required or Insufficient Information. The activity has substantive issues, or missing information, that will require correction or completion before the BSO or IBC can determine if approval will be provided. Correspondence will be sent to the submitter indicating the questions or concerns, and the submitter will be required to respond before a decision will be made regarding approval. If the activity is undergoing full IBC review, the committee will be convened to review the revised procedures and/or documents to determine if the conditions have been satisfied.

Approval Denied. The activity has significant issues which make approval unwarranted. The activity cannot be conducted, and the IBC will provide the rationale for the decision. If the activity's approval is denied, the submitter may resubmit the project for additional review if the reasons given for disapproval can be corrected and addressed. In order to appeal a decision, the investigator should submit a revised form and related documents to the BSO and/or Compliance Officer.

With any type of review or decision, an investigator is welcome to submit additional information to clarify the planned practices at any point during the review process and may request to meet with the BSO, the Compliance Officer, the IBC Chair, the Dean of Research, or the IBC to discuss the decision on the application.

All decisions are provided in writing, by either the BSO or the IBC Chair, to the submitter(s). Reports of the actions of the fully convened IBC are provided in the form of minutes, which are maintained by the Compliance Officer in the Office of Research and Economic Development.

VIII. APPROVED PROTOCOL COMPLIANCE

Approval Period

At the time of initial and continuing review, the IBC will determine the length and terms of approval, usually three years. The approval period may be less if the BSO or IBC determines that a more frequent interval of review is required.

Commencement of Research

Work cannot commence until unconditional approval has been obtained. Submitters of BUA applications will receive documented approval from the BSO and/or IBC and will not begin work until notice has been provided.

Modifications or Problems

Investigators must promptly report to the BSO any significant alterations in their personnel, funding, materials or procedures not addressed in their initial submission material, as well as any accidents or unplanned exposure.

Termination of Approval

The BSO and/or IBC reserves the option of withdrawing approval of a project if circumstances warrant. For example, approval may be withdrawn if the procedures are found to produce greater chance of exposure or accidental release than previously anticipated; if it is found that the activity is not being conducted in adherence with the approved application; or if any modifications or accidents are determined to have increased the potential for accidental release or exposure.

IX. CONTINUING REVIEW OF ACTIVE PROJECTS (Extensions/Renewals)

Approved activities are subject to continuing review at least every three years (or more frequently if specified by the approval decision). Generally, renewal requests should be submitted 30-60 days prior to the expiration date, but more time may be needed if the project renewal request will require review IBC review, or if there are modifications or problems to report. The review must take place before the expiration date.

Continuing Review Process

Projects needing renewal can be submitted to the Chair of the IBC directly, via either hard copy or email. A BUA is not required, unless there are substantial changes to report. The request for extension/renewal should include the title of the project, the expiration date, and a statement on whether or not there are any significant modifications or problems to report; it can be submitted via hard copy or email. If any report needs to be made, details and modified documents (modified from the approved application) should be provided. An administrative review will be conducted and the project will be renewed, or it will be referred for IBC (full committee) review, depending upon the reported modifications, problems, and level of initial review. Investigators should allow one to three weeks for extension/renewal approvals, but possibly longer for renewals requiring approval by the full IBC.

X. REVIEW OF CHANGES TO ACTIVE PROJECTS (Modifications)

Lead personnel working on approved projects must promptly report any significant modifications to the personnel, funding, materials, or procedures that were not approved in the initial submission materials. Modified procedures cannot be instituted until they have been reviewed and approved. If the proposed change is to eliminate an immediate hazard, advance approval is not required but the IBC must be notified *immediately,* so that the change can be reviewed to determine that it is consistent with ensuring the safe handling of the materials.

Modification Review Process

Modification requests can be submitted, via either hard copy or email, to the Chair of the IBC. A BUA application is not required unless the changes are significant enough to warrant revisions to the original application. The modification request should provide clear details on the modifications requested. For projects originally reviewed via IBC review, the review of the modifications will be referred to the IBC (in whole or part). For projects originally approved via an administrative review, the BSO will either approve the modifications or refer the decision to

the IBC (in whole or part). Modification request approvals may take one to three weeks but may take substantially longer if IBC (full committee) review is required.

XI. HANDLING, CONTAINMENT, AND EMERGENCY PROCEDURES

The handling of all biological materials will employ the Principles for Good Microbiological Practice, as indicated in Appendix B.4, as the base for all biosafety levels. In addition, the following requirements will also be employed:

1. Biosafety Lever 1 or higher:

a. The guidelines of this Biosafety Program must be enforced by the PI or lab supervisor for his or her lab spaces and personnel (staff and students).
b. To prevent contamination while working with potentially hazardous biological material; personnel must wear appropriate personal protective equipment (PPE); gloves, closed toe shoes, and safety glasses, and remove them when leaving the work area.
c. Universal Precautions must be followed. These precautions were designed for working with bloodborne pathogens and are required for work with any Biosafety Level 2 and higher infectious agents. In addition, it is an excellent system to employ while working with any biological material.
d. When work is being conducted all work surfaces must be decontaminated with approved sanitizers once per day after work is complete and after any spill of viable material.
e. Eating, drinking and applying cosmetics are not permitted in labs. Food must be stored in cabinets or refrigerators designated for this purpose and must be located outside the work area.
f. Hand washing should occur after handling viable materials and animals and before leaving the lab.
g. Biological materials must be transported in labeled, leak-proof containers. In addition, infectious material must be placed in a red biohazard bag.

2. Biosafety Level 2 or higher- *includes all of BSL-1 requirements above plus*:

a. Access must be limited to authorized individuals in areas where experiments with infectious agents are in progress.
b. A sign incorporating the universal biohazard symbol must be posted at the entrance to the laboratory when infectious agents are present (see Appendix B-5). Posted information must include: the laboratory's biosafety level, the supervisor's name (or other responsible personnel), telephone number, and required procedures for entering and exiting the laboratory.
c. Clearly label areas in which infectious agents are used or stored and, using the biohazard symbol, designate specific areas or equipment where those materials are routinely used or stored.
d. Individuals working with known infectious agents must be provided with medical surveillance and offered appropriate immunizations when applicable.
e. Laboratory supervisors must ensure that laboratory personnel demonstrate proficiency in standard and special microbiological practices before working with BSL-2 agents.
f. Incidents involving potential exposure must be reported immediately to the PI and

Biosafety Officer/EH&S.

g. All procedures involving the manipulation of infectious materials that may generate an infectious aerosol or splashes should be conducted within a certified biological safety cabinet (BSC) or other physical containment devices. These may include pipetting, centrifuging, grinding, blending, mixing, sonicating, opening containers of infectious materials, inoculating animals intranasally, and harvesting tissue from animals or eggs.
h. Personal protective equipment (PPE) must be worn at the level determined by the Laboratory Hazard Assessment Tool (LHAT) in the Personal Protective Equipment Program for Laboratory and Technical Areas.

NOTE: Current campus facilities do not support work at any level higher than BSL-2. Any projected work at a higher level must be approved by the IBC and Biosafety Officer.

3. Animal Biosafety

Laboratory animal facilities are a special type of laboratory. As a general principle, the biosafety level (facilities, practices, and operational requirements) recommended for working with infectious agents *in vivo* and *in vitro* are comparable. In the animal room (vivarium), the activities of the animals themselves can present unique hazards not found in standard microbiological laboratories. Animals may generate aerosols, may bite and scratch, and they may be infected with a zoonotic agent.

Allergens are associated with lab animal materials, including fur, skin, dander, saliva, urine, and feces. The concentration of allergens can vary significantly by species, sex, and age of the animal (for example, males, older males, and the C57BL/6J strain all produce greater amounts of mouse urinary proteins). Workers can be exposed through inhalation of airborne particles, skin contact, and contact with facial mucous membranes. Basic allergen containment should be employed where applicable.

A summary of Animal Biosafety Levels 1 and 2 can be found in Appendix B:2. At this time, only work at ABSL-1 and ABSL-2 on the campus is permitted.

4. Bloodborne Pathogens (BBP)

Bloodborne pathogens are pathogenic microorganisms that are transmitted via human blood and cause disease in humans. They include, but are not limited to, hepatitis B virus (HBV) and human immunodeficiency virus (HIV). All work with human-derived blood, body fluids, tissues or primary human cell lines where the presence of an infectious agent may be unknown will be performed using BSL-2 containment procedures.

5. Hazard Communication

a. Signs shall be posted at the entrance to all BSL-2 or higher work areas which shall bear:

- Name of the infectious agent(s).
- International symbol for biohazard in fluorescent orange-red. See Appendix B-4 for sign form.

- Special requirements for entering the area.
- Name and telephone number of the laboratory PI or other responsible person.

b. Warning labels shall be affixed to: containers of infectious waste; refrigerators and freezers containing blood and other potentially infectious materials; and other containers used to store or transport blood or other potentially infectious materials. Labels shall have the international biohazard symbol. The labels shall be fluorescent orange or orange-red with lettering or symbols in a contrasting color. The labels shall either be an integral part of the container or shall be tightly affixed to the container by adhesive to prevent their loss or removal.

6. Training

Individual supervisors and PIs, in consultation with EH&S, shall ensure that all students and employees with potential for occupational exposure are trained in:

a. The proper techniques for handling and disposal of biohazardous materials.
b. PIs and supervisors must ensure that students and employees are trained in and demonstrate proficiency in standard microbiological practices and in operations specific to the laboratory in question before being allowed to work with biohazards.
c. Specific training on the warning signs and symptoms of infection with the biohazard being used shall be included.
d. If applicable, training should also include aspects of the Bloodborne Pathogen program that would directly affect their specific laboratory work.
e. Emergency procedures for spills and personnel contamination as outlined in this program.
f. Emergency procedures for injuries or accidents involving laboratory personnel.

7. Disposal of Biological Waste

a. **Laboratory cultures** include the biological agents that contains or has been in contact with infectious agents, potentially infectious materials or recombinant or synthetic nucleic acids, (cells cultures, plants, algae, or other living entity) from research laboratories, wastes from their production, and culture dishes and devices used to culture, transfer, inoculate, and mix cultures.
    1) All biologically active materials must be inactivated by autoclaving, ultraviolet (UV) light, germicidal agent, or any other proven effective method before disposal into the regular trash*. All waste must be rendered "environmentally neutral" before placing in the regular trash.*
    2) All inactivated biological waste that is contained in bags that have a biohazard symbol MUST be placed in an opaque bag (no biohazard symbol or red bag should be visible) before disposal into the regular trash.
    3) Unless otherwise established, inactivated waste will be taken directly to the regular trash bins by the user.

b. **Animal Waste**
    1) Vertebrates or fish must be placed in clear plastic bags and frozen, when possible, and EH&S called to arrange disposal as pathological waste.
    2) Invertebrates must be placed in tightly closed plastic bags and taken directly to dumpsters outside the building. Disposal should be avoided on Fridays because trash

will not be picked up until the following week.

3) Preserved animals and animal parts must be placed in plastic bags and EH&S consulted for disposal. Any animal carcass or animal parts which have been preserved in formaldehyde or any other preservative must have as much of the preservatives decanted from the carcass as possible and be drained completely of any fluids before they can be placed in any container for disposal. Please note: the decanted preservative is hazardous waste and will be placed in a labeled waste container. *Notify EH&S for pickup of the pathological and hazardous waste collected from the preserved specimens*.

c. **Medical Waste** must be placed in red (labeled) "biohazard" bags and placed in biohazardous accumulation shed for pickup.

d. **Sharps needle waste** must be placed in red (labeled) "biohazard" plastic sharps container. When the container is ¾ full, place in gray tub in biohazardous accumulation shed for pick up.

e. **Mixed waste** is waste that has different categories of waste, such as biological waste mixed with chemicals or radioactive material. Use the following hierarchy to categorize the waste.
   1) If biohazardous and radioactive:
   2) Inactivate the biohazard, if possible (use procedures approved by the Radiation Safety Officer which restrict further contamination). Classify as radioactive and treated accordingly.
      - See campus Radiation Safety manual for treatment of radioactive materials.
   3) If chemically hazardous and biohazardous:
      - Classify as chemically hazardous and treat accordingly.
      - Call Chemical Hygiene Officer/EH&S for specific instructions.
   4) If biohazardous, chemically hazardous and radioactive:
      - Classify as radioactive and treat accordingly.
   5) If chemically hazardous and radioactive (no biohazards present):
      - Contact Radiation Safety Officer/EH&S for specific treatment or pickup for those radioactive materials and chemicals.

f. **Miscellaneous Biological Waste**
   1) Animal blood and body fluids -- fresh, uninfected, untreated body fluids (USDA Grade, for example) must be disposed of in the laboratory drain (sanitary sewer), with copious amounts of water.
   2) Human or animal urine – dispose of in the toilet or the laboratory drain with copious amounts of water; rinse the sink thoroughly with a 0.1% bleach solution.
   3) Human cheek cells collected on swabs – dispose of in normal trash.

g. **Medical Waste Disposal Deadlines**
   1) Medical waste, when full or deemed ready for disposal, is to be shipped off campus either:

- Within seven days, if stored at room temperature, or
- Within 90 days, if stored at or below 0° C.

2) EXCEPTION: Sealed sharps containers must be collected, placed in the biohazard waste accumulation shed, and shipped off campus within seven days after deemed full, regardless of storage temperature.

Autoclave Use for Biological Waste

An autoclave uses high pressure saturated steam to sterilize equipment and supplies and is highly effective for inactivating biohazardous materials. Use the following guidelines to safely sterilize biological waste. Inactivation of biological waste must follow the standard operating procedures for autoclave sterilization and calibration listed in the Medical Waste Management Plan. Autoclaves must be maintained as per manufacturers' suggested procedures by qualified personnel.

a. **Solid Waste**
   1) Waste must be in an autoclave bag, with at least 200 ml of liquid.
   2) Bag must be vented to allow proper steam penetration.
   3) Bag should have a temperature indicator (e.g., autoclave tape).
   4) Bag must be placed in a metal pan to catch any leakage.
   5) Waste must be autoclaved for at least 45 minutes on LIQUID setting.
   6) Temperature must reach and be maintained at 250°F (121°C) and pressure must be maintained at 15 lbs. for the entire autoclave time.
   7) Place autoclaved waste into regular trash bags and, after the waste has cooled, take directly to outside dumpsters.

b. **Liquid Waste**
   1) Place containers of liquid waste in trays to collect any spilled material.
   2) Autoclave for 45 minutes on LIQUID setting.
   3) Dispose of liquid in lab sinks.
   4) Strain out any solid material, place in plastic bags and take directly to the dumpsters.

Emergency Procedures

Appropriate emergency procedural documents must be available in all areas where biohazardous work occurs. In the event of any spill or contamination, immediately notify the PI or instructor and the Biosafety Officer as soon as possible for follow-up.

a. **BSL-1 Spills**

   Usually a "just clean it up" approach is most appropriate. Administrative follow-up is not required unless the spill involves personal injury, or a spill of recombinant DNA in a publicly accessible area such as a corridor.
   1) Cover spill with paper towels.
   2) Carefully pour disinfectant onto the paper towels, starting at the periphery and working inward toward the center. Allow sufficient contact time for disinfectant.
   3) If sharps are involved do not use hands to pick up; rather, use forceps or a brush and dustpan.
   4) Transfer to appropriate waste container.
   5) If spill involves personal injury, report to supervisor immediately.

6) If spill is a recombinant DNA spill of more than 500 mL or the spill is in a publicly accessible area such as a corridor, notify the BSO immediately.

b. **BSL-2 Spills**

The spill response depends upon location and volume.

- Spills inside the biosafety cabinet (BSC) are considered "contained".
- Spills outside the BSC are of much greater concern since there is a risk of exposure to an infectious agent via aerosols or possible skin exposure via a splash.
- Categories of spills also are subdivided into "minor" and "major."
- "Minor spills" are somewhat arbitrarily defined as spills of 10 ml or less, where there is little chance that a splash could get out of control before it could be contained with absorbent material.
- "Major spills" are anything over 10 ml, where there is a risk that the liquid is not easily contained.
- Special considerations are required for centrifuge accidents, biohazard spills involving radioactivity (decontaminate first, then clean up as for radioactive spills), and biohazards with toxic chemicals.
- Labs working with biological toxins must have standard operating procedures (SOPs) for decontamination of those agents.

Appendix C.1 contains general SOPs for clean-ups of various types of spills. Copies must be available in laboratories where work with BSL-2 materials are used.

c. **Spills containing recombinant or synthetic nucleic acid molecules**

Spills and accidents which result in overt exposures to organisms containing recombinant or synthetic nucleic acid molecules are immediately reported to the:

- Institutional Biosafety Committee or Biosafety Officer (BSO) and;
- NIH OSP- reports to NIH OSP shall be sent to the Office of Science Policy, National Institutes of Health, preferably by e-mail to: NIHGuidelines@od.nih.gov; (301) 496-9838. Additional contact information is also available on the OSP website;
- Medical evaluation, surveillance, and treatment are provided as appropriate and written records are maintained.

d. **Composition of a Basic Spill Kit**

Microbiological and biomedical research laboratories should prepare and maintain a biological spill kit. A spill kit is an essential safety item for labs working with microbiological agents classified at BSL-2 or higher and for groups working with large volumes (more than 1 liter) of BSL-1 material. A basic spill kit should include:

- Concentrated household bleach
- A spray bottle for making 10 percent bleach solutions
- Forceps, autoclavable broom and dust pan, or other mechanical device for handling sharps
- Paper towels or other suitable absorbent
- Biohazard autoclave bags for the collection of contaminated spill clean-up items

- Utility gloves and medical examination gloves
- Face protection (eye wear and mask, or full-face shield)

e. **Personnel Contamination**

i. Remove contaminated clothing
ii. Wash the exposed area with soap and rinse with water for 15 minutes. Use a safety shower or eyewash as necessary.
iii. Obtain medical evaluation and treatment if appropriate.
iv. Any sharps or puncture wound, animal bite, or contamination by BSL-2 or higher must by subject to medical evaluation followed by notification to the Biosafety Officer and PI or supervisor.

f. **Research Related Illness**

A research related illness may be suspected if an illness develops with symptoms of those for the biological agent being studied.

i. Steps:

1. For treatment/counseling go to Health Center (student or student assistant), MedStop, or Sierra Vista Emergency Room
2. Notify supervisor.
3. Supervisor notifies Biosafety Officer or EH&S within 48 hours for follow-up and reporting to appropriate entities.

XII. REPORTING PROBLEMS

Researchers are required to report to the BSO any significant problems pertaining to the execution and implementation of biohazard-containment practices and procedures, violations of the NIH Guidelines, and all significant research-related accidents and illnesses. Serious problems or events – such as those resulting in serious injury or death – must be reported to the BSO immediately whenever possible or at least within 48 hours from the onset of the incident. Other, non-serious incidents must be reported within five business days.

Reporting Process

All reports should be submitted to the BSO. After initial review, the BSO, in consultation with the IBC Chair or the Dean of Research (for research-related activities), will possibly contact the submitter for additional information or discussion, including whether or not measures have been put in place to remedy the problem. After determining the nature or seriousness of the problem, 1) the report will be routed to the IBC Chair or Dean of Research for immediate response; or 2) the report will be filed and/or provided to the IBC, if applicable, at the next meeting. The response from the BSO, Dean, Chair, or IBC could include – depending upon the seriousness of the problem – revisions to the research practices or processes, or termination of approval. Federal guidelines also may require that the incident be reported to the NIH or other Federal regulatory agency.

XIII. DEFINITIONS

Animal Waste is carcasses and body parts of preserved and unpreserved animals.

Biohazard bags are red bags meeting ASTM standards for strength.

Biohazardous waste is technically a subset of medical waste as defined in the Medical Waste Management Act (California Health and Safety Code; see sections 117690 & 117700 for more precise definitions). For Cal Poly's purposes, biohazardous waste is any of the following:

1. Waste generated or produced as a result of:
    a. Diagnosis, treatment, or immunization of human beings or animals
    b. Research pertaining to activities in above
    c. Regulated waste from trauma scenes
2. Laboratory waste including the following:
    a. Human or animal specimen cultures from medical and pathology laboratories
    b. Culture and stocks of infections agents (human or animal pathogens) from research and industrial laboratories
    c. Wastes from the production of bacteria, viruses, or the use of spores, discarded live and attenuated vaccines used in human health care or research, discarded animal vaccines, including only Brucellosis, Contagious Ecthyma, and other animal vaccines, as identified by the department, and culture dishes and devices used to transfer, inoculate, and mix cultures.
    d. Waste containing any microbiologic specimens.
3. Human surgery specimens or tissues suspected of being contaminated with infections agents
4. Animal parts, tissues, fluids, or carcasses suspected by the attending veterinarian of being contaminated with infectious agents known to be contagious to humans
5. Waste containing recognizable fluid blood, fluid blood products, containers of fluid blood, or equipment containing blood that is fluid or blood from animals known to be infected with diseases which are highly communicable to humans
6. Waste contaminated with excretion, exudate, or secretions from humans or animals under isolation to prevent infection
7. Waste from human surgery or tissues fixed in formaldehyde or contaminated with chemotherapeutic agents
8. Pharmaceutical waste
9. Biohazardous sharps waste to include home-generated sharps, but also includes sharps generated from above activities including anything that can produce a sharp protuberances or acute rigid corners (e.g. Glass/plastic pipettes, needles from syringes, scalpels, broken glass, glass vials, microscope slides, etc.)

Biohazardous waste is NOT:

- Waste generated in food processing or biotechnology that does not contain an infectious agent, or an agent capable of causing an infection that is highly communicable.

- Waste generated in biotechnology that does not contain human blood or blood products or animal blood or blood products suspected of being contaminated with infectious agents known to be communicable to humans or a highly communicable disease.
- Urine, feces, saliva, sputum, nasal secretions, sweat, tears, or vomitus, unless it contains visible or recognizable fluid blood.
- Waste which is not biohazardous, such as paper towels, paper products, articles containing non-fluid blood, and other medical solid waste products commonly found in the facilities of medical waste generators.
- Hazardous waste, radioactive waste, or household waste.
- Waste generated from normal and legal veterinarian, agricultural, and animal livestock management practices on a farm or ranch unless otherwise specified in law.

Biosafety levels are the levels of safety from exposure to infectious agents. They are a combination of practices, techniques, safety equipment and laboratory facilities required to isolate dangerous biological agents in an enclosed facility. The four levels of biosafety are summarized in Appendix B.1.

Biosafety Officer (BSO) is responsible for planning and implementation of the campus Biosafety Program with the purpose to ensure the health and safety of all personnel working with biohazardous agents.

Bloodborne Pathogens are pathogenic microorganisms that are present in human blood and can cause disease in humans. These pathogens include, but are not limited to, hepatitis B virus (HBP), hepatitis C virus (HVC) and human immunodeficiency virus (HIV). For information on the campus Bloodborne Pathogen program, please go the EHS website:
https://afd.calpoly.edu/ehs/docs/pathogens.pdf

Containment is a method of managing infectious agents in the laboratory environment where they are being handled or maintained. The purpose of containment is to reduce or eliminate exposure of laboratory personnel, other persons and the outside environment to potentially hazardous agents.

- ***Primary containment*** involves the protection of personnel in the immediate laboratory environment from exposure to infectious agents, and is provided by good microbiological technique, the use of proper safety equipment and appropriate vaccines.
- ***Secondary containment*** refers to the protection of the environment external to the laboratory from exposure to infectious materials and is provided by a combination of facility design and operational practices.

Infectious agent is a type of microorganism, bacteria, mold, parasite or virus, including, but not limited to, organisms managed as Biosafety Level II-IV by the CDC that normally causes, or significantly contributes to the cause of, increased morbidity or mortality of human beings.

Institutional Biosafety Committee (IBC) is charged with the review of all campus research involving recombinant or synthetic nuclei acid molecules for conformity with National Institute of Health (NIH) Guidelines. Cal Poly's IBC will also review all work with select agents and toxins. Committee membership will be determined by the Dean of Research. The Biosafety Officer from Environmental Health and Safety will be a standing member.

Medical Waste is any biohazardous, pathology, pharmaceutical, or trace chemotherapy waste not regulated by the federal Resource Conservation and Recovery Act of 1976 (Public Law 94-580), as amended;

1. Sharps and trace chemotherapy wastes generated in a health care setting in the diagnosis, treatment, immunization, or care of humans or animals
2. Waste generated in autopsy or necropsy; waste generated in research pertaining to the production or testing of microbiologicals
3. Waste generated in research using human or animal pathogens
4. Sharps and laboratory waste that poses a potential risk of infection to humans generated in the inoculation of animals in commercial farming operations
5. Waste generated from the consolidation of home-generated sharps including personally generated waste such as syringe waste generated by persons who self-administer insulin for diabetic
6. Waste generated in the cleanup of trauma scenes.

Select Agents are pathogens and biological toxins which have been declared by the U.S. Department of Health and Human Services or by the U.S. Department of Agriculture to have the "potential to pose a severe threat to public health and safety." The Centers for Disease Control administers the Select Agent Program, which regulates the laboratories which may possess, use, or transfer select agents within the United States. A list of these materials can be found at http://www.selectagents.gov/select%20agents%20and%20Toxins%20list.html

Sharps means any device having acute rigid corners, edges, or protuberances capable of cutting or piercing, including, but not limited to, all of the following: any object used with infectious material that can be reasonably anticipated to penetrate the skin or any other part of the body, and to result in an exposure incident, including, but not limited to, needles, scalpels, lancets, broken glass, and broken capillary tubes.
Sharps waste includes:

- Hypodermic needles with or without syringes
- Syringes contaminated with biohazardous waste
- Broken glass, such as Pasteur pipettes and
- Blood vials contaminated with biohazardous waste
- Any contaminated trauma scene waste capable of cutting or piercing

Universal Precautions is a method of infection control by treating all human blood and certain human body fluids as infectious for HIV, HBV, HCV, and other bloodborne pathogens.

APPENDIX A: REFERENCES

- Bloodborne Pathogens, Title 8 California Code of Regulations, Section 5193
- Biosafety in Microbiological and Biomedical Laboratories Fifth Edition, 2009, U. S. Dept. of Health and Human Services, Centers for Disease Control and Prevention (CDC) and National Institutes of Health (NIH).
- The NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, NIH Guidelines
- The Association of Biosafety and Biosecurity, ABSA International
- Medical Waste Management Act, California Health and Safety Code Sections 117600-118360.
- Select Agents Program National Select Agents Registry

APPENDIX B: SUPPORTING DOCUMENTS/ FORMS

See pages below.

Appendix B.1: Biosafety Level Summary

BSL	Agents	Practices and Techniques	Safety Equipment	Facilities
1	Not known to consistently cause disease in healthy adults	Standard microbiological practices. See Appendix B:3	None: primary containment provided by adherence to standard laboratory practices during open bench operations.	Open bench top and sink
2	Agents associated with • Human disease. • Hazards include skin absorption, ingestion, mucous membrane exposure	BSL 1 practice plus: • Limited access • Biohazard warning signs • Sharps precautions • Waste decontamination • Medical surveillance	• Primary containment = Class II BSCs or other physical containment devices used for all manipulations of agents that cause splashes or aerosols of infectious materials • PPE: laboratory coats; gloves; face protection, as needed	Basic BSL 1 plus: Autoclave available
3 *	Indigenous or exotic agents with • Potential for aerosol transmission • Disease may have serious or lethal consequences	BSL 2 practice plus: • Controlled access • Decontamination of all waste • Decontamination of lab clothing before laundering • Baseline serum	• Primary containment = Class II or III BSCs or other physical containment devices used for all open manipulations of agents. • PPE: protective lab clothing; gloves; respiratory protection as needed.	BSL 2 plus: • Physical separation from access corridors • Self-closing, double- door access • Exhausted air not recirculated • Negative airflow into laboratory
4*	• Dangerous/exotic agents which post high individual risk of aerosol-transmitted laboratory infections that are frequently fatal, for which there are no vaccines or treatments • Agents with a close or identical antigenic relationship to an agent requiring BSL-4 until data are available to redesignate the level • Related agents with un-known risk of transmission	BSL-3 practices plus: • Clothing change before entering • Shower on exit • All material decontaminated on exit from facility	Primary barriers: • All procedures conducted in Class III BSCs or Class I or II BSCs in combination with full-body, air-supplied, positive pressure suit	BSL-3 plus: • Separate building or isolated zone • Dedicated supply and exhaust, vacuum, and decontamination systems • Other requirements outlined in the text

***All work using BSL-3 and BSL-4 materials is currently not permitted in Cal Poly campus facilities.**

Appendix B.2: Animal Biosafety Level Summary

BSL	Agents	Practices and Techniques	Safety Equipment	Facilities
1	Not known to consistently cause disease in healthy adults	Standard animal care and management practices, including appropriate medical surveillance programs.	As required for normal care of each species.	Standard animal facility. • No recirculation of exhaust air • Directional airflow recommended.
2	Associated with human disease, hazard = percutaneous injury, ingestion, mucous membrane exposure.	ABSL 1 practice plus: • Limited access • Biohazard warning signs • Sharps precautions • Decontamination of all infectious wastes and animal cages prior to washing	• Primary containment = equipment appropriate for animal species • PPE: laboratory coats; gloves; face protection, as needed	Basic ABSL 1 plus: • Autoclave available • Handwashing sink available in the animal room.

***Work above ABSL-2 is currently not permitted in Cal Poly campus facilities.**

Appendix B-3: Classification by Risk Group

Risk Group Classification*:	**Characteristics of Agent:**
Risk Group 1 (RG1)	Agents that are not associated with disease in healthy adult humans. This group includes a list of animal viral etiologic agents in common use. These agents represent no or little risk to an individual and no or little risk to the community.
Risk Group 2 (RG2)	Agents that are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are often available. These agents represent a moderate risk to an individual but a low risk to the community.
Risk Group 3 (RG3)	Agents that are associated with serious or lethal human disease for which preventive or therapeutic interventions may be available. These agents represent a high risk to an individual but a low risk to the community.
Risk Group 4 (RG4)	Agents that are associated with serious or lethal human disease for which preventive or therapeutic interventions may be available. These agents represent a high risk to an individual but a low risk to the community.

***National Institutes of Health (NIH) Guidelines**

Appendix B.4: Principles of Good Microbiological Practice

1. Never mouth pipette. Avoid hand-to-mouth or hand-to-eye contact in the laboratory. Never eat, drink, apply cosmetics or lip balm, handle contact lenses or take medication in the laboratory.
2. Use aseptic techniques. Hand washing is essential after removing gloves and other personnel protective equipment, after handling potentially infectious agents or materials and prior to exiting the laboratory.
3. CDC/NIH *Biosafety in Microbiological and Biomedical Laboratories* (BMBL) recommends that laboratory workers protect their street clothing from contamination by wearing appropriate garments (e.g., gloves and shoe covers or lab shoes) when working in Biosafety Level-2 (BSL-2) laboratories. In BSL-3 laboratories, the use of street clothing and street shoes is discouraged; a change of clothes and shoe covers or shoes dedicated for use in the lab is preferred. BSL-4 requires changing from street clothes/shoes to approved laboratory garments and footwear.
4. When utilizing sharps in the laboratory, workers must follow OSHA'S Bloodborne Pathogens standard requirements. Needles and syringes or other sharp instruments should be restricted in laboratories where infectious agents are handled. If you must utilize sharps, consider using safety sharp devices or plastic rather than glassware. Never recap a used needle. Dispose of syringe-needle assemblies in properly labeled, puncture resistant, autoclavable sharps containers.
5. Handle infectious materials as determined by a risk assessment. Airborne transmissible infectious agents should be handled in a certified Biosafety Cabinet (BSC) appropriate to the biosafety level and risks for that specific agent.
6. Ensure engineering controls (e.g., BSC's, eyewash units, sinks, and safety showers) are functional and properly maintained and inspected.
7. Never leave materials or contaminated labware open to the environment outside the BSC. Store all biohazardous materials securely in clearly labeled, sealed containers. Storage units, incubators, freezers or refrigerators should be labeled with the Universal Biohazard sign when they house infectious material.
8. Doors of all laboratories handling infectious agents and materials must be posted with the Universal Biohazard symbol, a list of the infectious agent(s) in use, entry requirements (e.g., PPE) and emergency contact information.
9. Avoid the use of aerosol-generating procedures when working with infectious materials. Needle clipping, pipetting mixing, sonication, and centrifugation can produce substantial aerosols. If you must perform an aerosol generating procedure, utilize proper containment devices and good work practice controls to mitigate potential exposures; tightly cap tubes prior to centrifuging or vortexing; allow aerosols to settle prior to opening tubes, equipment; open tubes or equipment inside a containment device whenever feasible; shield instruments or activities that can emit splash or splatter.
10. Use disinfectant traps and in-line filters on vacuum lines to protect vacuum lines from potential contamination.
11. Follow the laboratory biosafety plan for the infectious materials you are working with and use the most suitable decontamination methods for decontaminating the infectious agents you use. Know the laboratory plan for managing an accidental spill of pathogenic materials. Always keep an appropriate spill kit available in the lab.
12. Clean laboratory work surfaces with an approved disinfectant after working with infectious materials. The containment laboratory must not be cluttered in order to permit proper floor and work area disinfection.
13. Never allow contaminated, infectious waste materials to leave the laboratory or to be put in the sanitary sewer without being decontaminated or sterilized. When autoclaving use adequate

temperature (121 C), pressure (15 psi), and time, based on the size of the load. Also use a sterile indicator strip to verify sterilization. Arrange all materials being sterilized, so as not to restrict steam penetration.

14. When shipping or moving infectious materials to another laboratory, always use U.S. Postal or Department of Transportation (DOT) approved, leak-proof sealed and properly packed containers (primary and secondary containers). Avoid contaminating the outside of the container and be sure the lid is on tight. Decontaminate the outside of the container before transporting. Ship infectious materials in accordance with Federal and local requirements.
15. Report all accidents, occurrences and unexplained illnesses to your work or lab supervisor and the seek medical treatment. Understand the pathogenesis of the infectious agents you work with.
16. Think safety at all times during laboratory operations. Remember, if you do not understand the proper handling and safety procedures or how to use safety equipment properly, do not work with the infectious agents or materials until you get instruction. Seek the advice of the appropriate individuals.

This Fact Sheet was developed as a product of the OSHA and American Biological Safety Association Alliance for informational purposes only. It does not necessarily reflect the official views of OSHA or the U.S. Department of Labor.

Appendix B.5: Biosafety Level 2 Signage

BIOSAFETY LEVEL 2

AUTHORIZED PERSONNEL ONLY!!

Hazard:

Location:

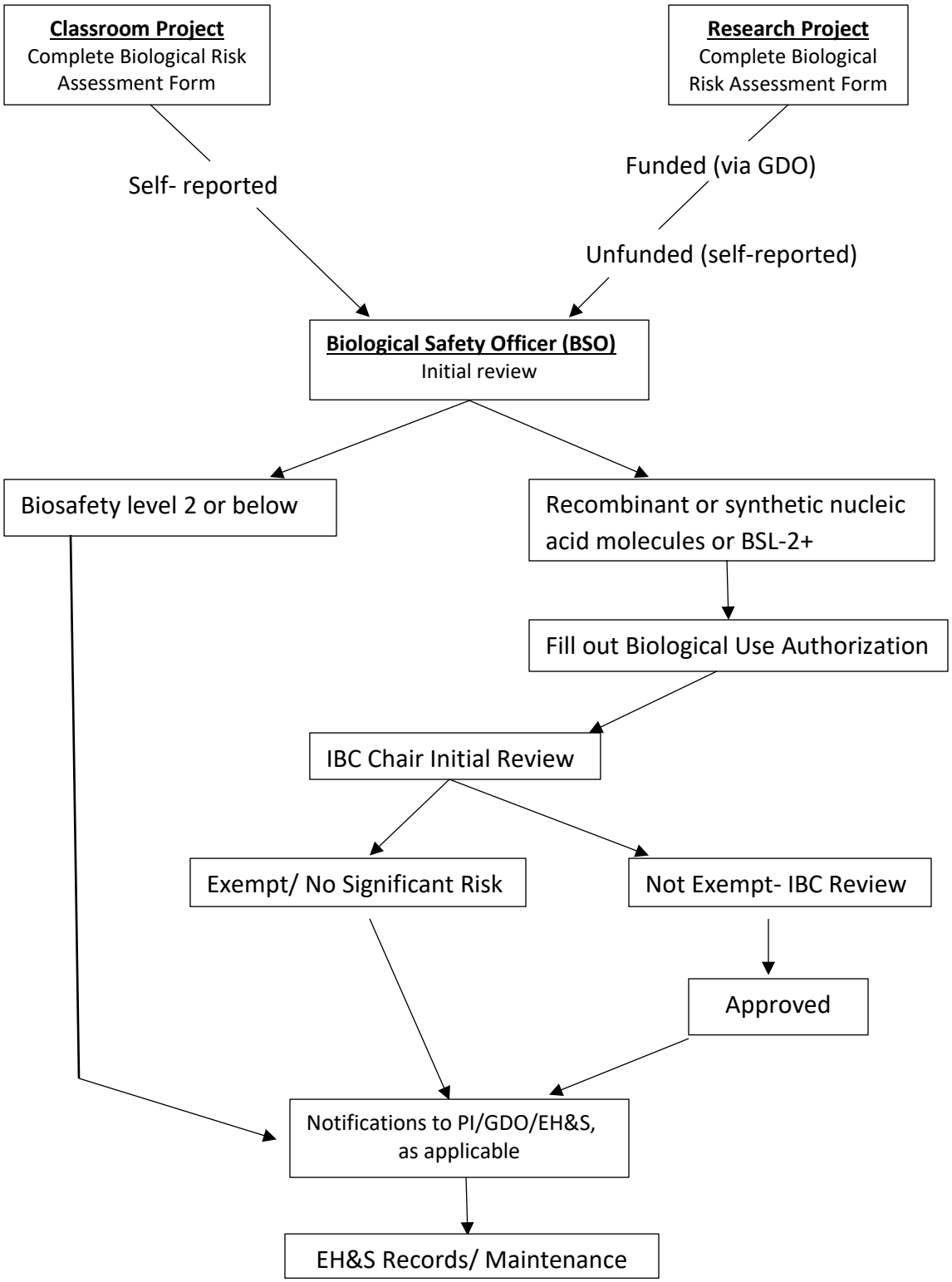
Instructions: PPE-lab coat, gloves, eye protection required.

Contact Cal Poly Biosafety Officer for exposures at 756-6628

	Name:	Phone:
Principal Investigator		
Alternate		

Appendix B.6: Review Process for Use of Biohazardous Material

Biosafety Program and Institutional Biosafety Committee



Appendix B.7: NIH Compliant Inspection Checklist

Cal Poly Biosafety Inspection List

This checklist complies with NIH Guidelines (2019) for work with recombinant or synthetic nucleic acid on campus. **ALL work with recombinant or synthetic nucleic acids, regardless of funding is subject to this checklist for annual inspection** by the Biosafety Officer, Institutional Biosafety Committee (IBC) or Environmental Health and Safety Office.

Principal Investigator:
Additional lab contact (if applicable):
Inspection date:
Inspector:
Building/Room number:
Study Agent:

1. **NIH: G-11-B-1-a** Access to the laboratory is limited or restricted by the Principal Investigator when work with organisms containing recombinant or synthetic nucleic acid molecules is in progress.

   ☐ Yes ☐ No ☐ NA ☐ Other
   Comments:

2. **NIH: G-11-B-1-b** Work surfaces are decontaminated at least once a day and after any spill of viable material.

   ☐ Yes ☐ No ☐ NA ☐ Other
   Comments:

3. **NIH: G-11-B-1-c** All contaminated liquid or solid wastes are decontaminated before disposal.

   ☐ Yes ☐ No ☐ NA ☐ Other
   Comments:

4. **NIH: G-11-B-1-d** Mechanical pipetting devices are used; mouth pipetting is prohibited.

   ☐ Yes ☐ No ☐ NA ☐ Other

Comments:

5. **NIH: G-11-B-1-e** Eating, drinking, smoking, and applying cosmetics are not permitted in the work area.

   ☐ Yes ☐ No ☐ NA ☐ Other
   Comments:

6. **NIH: G-11-B-1-e** Food may be stored in cabinets or refrigerators designated and used for this purpose only.

   ☐ Yes ☐ No ☐ NA ☐ Other
   Comments:

7. **NIH: G-11-B-1-f** Persons wash their hands: (i) after handling materials involving organisms containing recombinant or synthetic nucleic acid molecules and animals, and (ii) when exiting the laboratory.

   ☐ Yes ☐ No ☐ NA ☐ Other
   Comments:

8. **NIH: G-11-B-1-g** All procedures are performed carefully to minimize the creation of aerosols.

   ☐ Yes ☐ No ☐ NA ☐ Other
   Comments:

9. **NIH: G-11-B-1-h** Experiments of lesser biohazard potential can be conducted concurrently in carefully demarcated areas of the same laboratory.

   ☐ Yes ☐ No ☐ NA ☐ Other
   Comments:

10. **NIH: G-11-B-2-a** Contaminated materials that are to be decontaminated at a site away from the laboratory are placed in a durable leakproof container which is closed before being removed from the laboratory.

    ☐ Yes ☐ No ☐ NA ☐ Other
    Comments:

11. **NIH: G-11-B-2-b** The Principal Investigator limits access to the laboratory. The Principal Investigator has the final responsibility for assessing each circumstance and determining who may enter or work in the laboratory.

    ☐ Yes ☐ No ☐ NA ☐ Other
    Comments:

12. **NIH: G-11-B-2-c** The Principal Investigator establishes policies and procedures whereby only persons who have been advised of the potential hazard and meet any specific entry requirements (e.g., immunization) may enter the laboratory or animal rooms.

    ☐ Yes ☐ No ☐ NA ☐ Other
    Comments:

13. **NIH: G-11-B-2-d** When the organisms containing recombinant or synthetic nucleic acid molecules in use in the laboratory require special provisions for entry (e.g., vaccination), a hazard warning sign incorporating the universal biosafety symbol is posted on the access door to the laboratory work area.

    ☐ Yes ☐ No ☐ NA ☐ Other
    Comments:

14. **NIH: G-11-B-2-d** The hazard warning sign identifies the agent, lists the name and telephone number of the Principal Investigator or other responsible person(s), and indicates the special requirement(s) for entering the laboratory.

    ☐ Yes ☐ No ☐ NA ☐ Other
    Comments:

15. **NIH: G-11-B-2-e** An insect and rodent control program is in effect.

    ☐ Yes ☐ No ☐ NA ☐ Other
    Comments:

16. **NIH: G-11-B-2-f** Laboratory coats, gowns, smocks, or uniforms are worn while in the laboratory.

    ☐ Yes ☐ No ☐ NA ☐ Other

Comments:

17. **NIH: G-11-B-2-f** Before exiting the laboratory for non-laboratory areas (e.g., cafeteria, library, administrative offices), this protective clothing is removed and left in the laboratory or covered with a clean coat not used in the laboratory.

    ☐ Yes ☐ No ☐ NA ☐ Other
    Comments:

18. **NIH: G-11-B-2-g** Animals not involved in the work being performed are not permitted in the laboratory.

    ☐ Yes ☐ No ☐ NA ☐ Other
    Comments:

19. **NIH: G-11-B-2-h** Special care is taken to avoid skin contamination with organisms containing recombinant or synthetic nucleic acid molecules. Lab coats and gloves are required PPE, work is done in BSCs.

    ☐ Yes ☐ No ☐ NA ☐ Other
    Comments:

20. **NIH: G-11-B-2-h** Special care is taken to avoid skin contamination with organisms containing recombinant or synthetic nucleic acid molecules; gloves should be worn when handling experimental animals and when skin contact with the agent is unavoidable.

    ☐ Yes ☐ No ☐ NA ☐ Other
    Comments:

21. **NIH: G-11-8-2-i** All wastes from laboratories and animal rooms are appropriately decontaminated before disposal.

    ☐ Yes ☐ No ☐ NA ☐ Other
    Comments:

22. **NIH: G-11-B-2-j** Hypodermic needles and syringes are used only for parenteral injection and aspiration of fluids from laboratory animals and diaphragm bottles.

    ☐ Yes ☐ No ☐ NA ☐ Other
    Comments:

23. **NIH: G-11-B-2-j** Only needle-locking syringes or disposable syringe-needle units (i.e., needle is integral to the syringe) are used for the injection or aspiration of fluids containing organisms that contain recombinant or synthetic nucleic acid molecules.

    ☐ Yes ☐ No ☐ NA ☐ Other
    Comments:

24. **NIH: G-11-B-2-j** Extreme caution should be used when handling needles and syringes to avoid autoinoculation and the generation of aerosols during use and disposal.

    ☐ Yes ☐ No ☐ NA ☐ Other
    Comments:

25. **NIH: G-11-B-2-j** Needles should not be bent, sheared, replaced in the needle sheath or guard, or removed from the syringe following use.

    ☐ Yes ☐ No ☐ NA ☐ Other
    Comments:

26. **NIH: G-11-B-2-j** The needle and syringe should be promptly placed in a puncture resistant container and decontaminated, preferably autoclaved, before discard or reuse.

    ☐ Yes ☐ No ☐ NA ☐ Other
    Comments:

27. **NIH: G-11-B-2-k** Spills and accidents which result in overt exposures to organisms containing recombinant or synthetic nucleic acid molecules are immediately reported to the Institutional Biosafety Committee and NIH / OBA. Reports to NIH / OBA shall be sent to the Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, MD 208927985 (20817 for non- USPS mail), 301-496-9838, 301-496-9839 (fax).

    ☐ Yes ☐ No ☐ NA ☐ Other
    Comments:

28. **NIH: G-11-B-2-k** Medical evaluation, surveillance, and treatment are provided as appropriate and written records are maintained.

    ☐ Yes ☐ No ☐ NA ☐ Other
    Comments:

29. **NIH: G-11-B-2-I** When appropriate, considering the agent(s) handled, baseline serum samples for laboratory and other at-risk personnel are collected and stored.

    ☐ Yes ☐ No ☐ NA ☐ Other
    Comments:

30. **NIH: G-11-B-2-I** Additional serum specimens may be collected periodically, depending on the agents handled or the function of the facility.

    ☐ Yes ☐ No ☐ NA ☐ Other
    Comments:

31. **NIH: G-11-B-2-m** A biosafety manual is prepared or adopted (use of Cal Poly Biosafety Program).

    ☐ Yes ☐ No ☐ NA ☐ Other
    Comments:

32. **NIH: G-11-B-2-m** Personnel are advised of special hazards and are required to read and follow instructions on practices and procedures.

    ☐ Yes ☐ No ☐ NA ☐ Other
    Comments:

NIH: G-11-B-3-a Biological safety cabinets (Class I or 11) or other appropriate personal protective or physical containment devices are used whenever:

33. **NIH: G-11.;.B-3-a-(1)** Procedures with a high potential for creating aerosols are conducted. These may include centrifuging, grinding, blending, vigorous shaking or mixing, sonic disruption, opening containers of materials whose internal pressures may be different from ambient pressures, intranasal inoculation of animals, and harvesting infected tissues from animals or eggs.

    ☐ Yes ☐ No ☐ NA ☐ Other
    Comments:

34. **NIH: G-11-B-3-a-(2)** High concentrations or large volumes of organisms containing recombinant or synthetic nucleic acid molecules are used. Such materials may be centrifuged in the open laboratory if sealed beads or centrifuge safety cups are used and if they are opened only in a biological safety cabinet.

☐ Yes ☐ No ☐ NA ☐ Other
Comments:

35. **NIH: G-11-B-4-a** The laboratory is designed so that it can be easily cleaned.

☐ Yes ☐ No ☐ NA ☐ Other
Comments:

36. **NIH: G-11-B-4-b** Bench tops are impervious to water and resistant to acids, alkalis, organic solvents, and moderate heat.

☐ Yes ☐ No ☐ NA ☐ Other
Comments:

37. **NIH: G-11-B-4-c** Laboratory furniture is sturdy and spaces between benches, cabinets, and equipment are accessible for cleaning.

☐ Yes ☐ No ☐ NA ☐ Other
Comments:

38. **NIH: G-11-B-4-d** Each laboratory contains a sink for handwashing.

☐ Yes ☐ No ☐ NA ☐ Other
Comments:

39. **NIH: G-11-B-4-e** If the laboratory has windows that open, they are fitted with fly screens.

☐ Yes ☐ No ☐ NA ☐ Other
Comments:

40. **NIH: G-11-B-4-f** An autoclave for decontaminating laboratory wastes is available.

☐ Yes ☐ No ☐ NA ☐ Other
Comments:

41. **BMBL, 5th Ed.** An eyewash station must be readily available in the laboratory.

☐ Yes ☐ No ☐ NA ☐ Other
Comments: Flushed weekly □ cleaned monthly □ Records kept □

APPENDIX C: STANDARD OPERATING PROCEDURES (SOPs)

Appendix C.1: Biohazard Spill Procedures (BSL-2 or higher)

SPILLS INSIDE THE BIOSAFETY CABINET

1. Make sure the cabinet continues to operate. Wait five minutes to allow aerosols to be pulled through the HEPA filter.
2. Decontaminate the surfaces within the cabinet wearing appropriate protective equipment. Gently cover the spill with absorbent paper towels and apply the appropriate disinfectant starting at the perimeter and working towards the center. * Note: Examine drain pan for contents of the spill. Disinfect if needed.
3. Discard soaked paper towels in a biohazard bag. Wipe up residual fluids. Wipe down surfaces with 70 percent ethanol, discarding towels in a biohazard bag.

SPILLS OUTSIDE THE BIOSAFETY CABINET- Small spill <10 ML, localized to small area

1. Alert personnel in the vicinity.
2. Check for contaminated clothing, including shoes. Decontaminate if necessary.
3. Evacuate the room. Close door. Discard potentially contaminated PPE, remove and decontaminate any contaminated clothing. Wash hands.
4. Notify PI. Wait for 20 minutes to allow for room air exchanges to clear aerosols through room exhaust. Keep all personnel out of lab while clearing aerosols.
5. Don fresh PPE: lab coat or gown, gloves, mask, eye protection.
6. Cover spill with paper towels.
7. Soak paper towels with the appropriate disinfectant, from perimeter toward the center.
8. Allow 20 minutes of contact time. Work can continue during contact time.
9. Pick up sharps with tongs and place in sharps container. Discarded towels go in biohazard bags.
10. Wipe down spill area one final time with appropriate disinfectant.

SPILLS OUTSIDE THE BIOSAFETY CABINET- Major Spill, > 10 ML, localized to small area

1. Alert personnel in the vicinity.
2. Check for contaminated clothing, including shoes. Decontaminate if necessary.
3. Evacuate the room. Close door. Discard potentially contaminated PPE and remove any contaminated clothing. Wash hands thoroughly.
4. Post warning sign: “DO NOT ENTER: Biological spill!”
5. Wait 20 minutes. Meanwhile, notify PI and a Biosafety Officer/Specialist (6-6628).
6. If assistance is needed, discuss with Biosafety Officer.
7. Don fresh PPE: lab coat or gown, gloves, mask, eye protection.
8. Re-enter the room, cover spill with paper towels.
9. Soak paper towels with appropriate disinfectant, from perimeter toward the center.

10. Allow 20 minutes of contact time. Work can continue during contact time.
11. Pick up sharps with tongs and place in sharps container. Discarded towels go in biohazard bags.
12. Wipe down spill area one final time with appropriate disinfectant.
13. With PI, write up a report and submit to the Biosafety Officer.

SPILLS INSIDE AN INCUBATOR

1. Decontaminate water pan via autoclave.
2. Alert personnel in the vicinity.
3. Evacuate the room. Close door. Discard potentially contaminated PPE and remove any contaminated clothing. Wash hands thoroughly.
4. Notify PI.
5. Don fresh PPE: lab coat or gown, gloves, mask, eye protection.
6. Cover spill with paper towels.
7. Soak paper towels with appropriate disinfectant, from perimeter toward the center.
8. Allow 20 minutes of contact time.
9. Pick up sharps with tongs and place in sharps container. Discarded towels go in biohazard bags.
10. Wipe down spill area one final time with appropriate disinfectant.

SPILLS INSIDE A CENTRIFUGE

1. Open lid of centrifuge slowly.
2. If there has been no breach of containment, spray rotor with 70 percent ethyl alcohol.
3. If inside of rotor is contaminated, decontaminate in the biosafety cabinet (BSC). As a precautionary measure, decontaminate the centrifuge chamber.
4. If rotor buckets are damaged, close centrifuge lid.
5. Alert personnel in the vicinity. Evacuate room.
6. Wait 30 minutes. Meanwhile, notify PI and a Biosafety Officer/Specialist (6-6628).
7. If assistance is needed, discuss with Biosafety Officer.
8. Open lid slowly and add paper towels.
9. Spray walls of chamber and rotor with 70 percent ethyl alcohol.
10. Close centrifuge lid for 20 minutes contact time.
11. Finish centrifuge clean-up as for major spill outside the BSC. Transport rotor to BSC.
12. Open and decontaminate rotor/buckets in the BSC.
13. With PI, write up a report and submit to Biosafety Officer.