UC SANTA BARBARA POLICY AND PROCEDURE

Biological Safety
Contact: **Environmental Health and Safety**
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BIOLOGICAL SAFETY

I. SCOPE

This policy governs the safe use of biological materials by all faculty, staff, students and laboratory personnel at UCSB.

II. DEFINITIONS

Biological hazard: A biological material that has the capacity to produce harmful effects on humans. Biological materials covered in UC Santa Barbara's Biological Safety Program include:

- Infectious organisms that can cause disease in humans or cause significant environmental or agricultural impact
- Human or nonhuman primate tissues, fluids, cells, or cell cultures
- Transgenic plants or animals covered by the “NIH Guidelines on Research Involving Recombinant or Synthetic DNA” (NIH Guidelines)
- Recombinant/Synthetic DNA in vitro and in vivo, except as specifically exempted in the NIH Guidelines
- Human gene transfer technology
- Recombinant/synthetic DNA intended for release to the environment
- Pathogens causing zoonotic diseases in animals hosts
- Select Agents as listed in federal regulations
- Biological toxins with a $LD_{50} \leq 100$ µg/kg body weight and those considered hazardous enough to warrant review; the latter is left to the discretion of the IBC.

Biosafety level (BSL): suite of protective measures, practices, and facilities for work with biological hazards, ranging from BSL1 (least hazardous) to BSL4 (significant hazards).

III. POLICY

Biological materials must be acquired, used, stored, and disposed in a manner that protects the health and safety of the campus community and neighboring human populations; the wild and domestic plants and animals maintained on University property and surrounding areas; and the environment.

All activities involving biological materials must be conducted in compliance with biological material laws and regulations.

A. Possession of or work with biological materials that customarily require Biosafety Level 4 (BSL4 as defined by the CDC) containment are prohibited at UCSB.

B. All teaching and research activities involving the covered biological materials must be authorized by the Institutional Biosafety Committee (IBC) before the work commences. The IBC reviews research protocols developed by a principal investigator (PI) in the context of a specific project for safety and compliance with regulations, policies and procedures. The IBC will also review biosafety level containment required, facilities, engineering controls, experimental procedures, as well as the training and expertise of personnel involved in the research. Based on this assessment, the IBC will decide whether to grant authorization to conduct the work.

C. All University research involving recombinant/synthetic DNA molecules must be conducted in compliance with the NIH Guidelines for Research Involving Recombinant/Synthetic DNA Molecules (the NIH Guidelines) regardless of the funding source. All such research must be summarized in a Biological Use Agreement (BUA) application for review and approval by the Institutional Biosafety Committee.

IV. RESPONSIBILITIES

A. Vice Chancellor of Administrative Services
   1. Ensures compliance with policies and practices that provide for safe conduct of research and instruction involving biological materials.
   2. Appoints faculty, staff and off-campus experts to the Institutional Biosafety Committee (IBC).
   3. On the advice of the IBC, terminates or restricts any project or teaching program not in compliance with this policy or procedure.

B. Institutional Biosafety Committee (IBC)
   1. Oversees research or teaching activities that involve biological materials which may pose safety, health or environmental risks.
   2. Enforces biosafety regulations and policies.
   3. Recommends modification and/or denies approval for any project that cannot be undertaken safely within University facilities.
   4. Reviews updates to compliance documents and campus biological safety-related policies.
   5. Reviews project-specific protocols for potential health surveillance issues and recommends or requires consultation with an occupational health provider as appropriate.

6. Investigates and reports to the Vice Chancellor of Administrative Services and NIH Office of Biotechnology Activities any significant problems or violations of the NIH Guidelines, any major research related accidents, and any laboratory acquired illnesses within 30 days of the incident.
7. Refers experiments that are restricted by the NIH Guidelines to the NIH Recombinant DNA Advisory Committee for review.

C. Biosafety Officer (BSO)
   1. Administers the campus biological safety policies and program.
   2. In consultation with faculty, staff, and the IBC, develops and implements policies, procedures, and practices to reduce the risks of work with biological materials with consideration given to maximizing the effectiveness of research and teaching.
   3. Reviews research proposals from the Office of Research, Sponsored Programs, when the work involves biological materials or recombinant DNA techniques and determines whether the project requires approval of a BUA.
   4. Informs the Principal Investigators of the requirement to have approved, project-specific BUA in place prior to the start of research.
   5. Assists Principal Investigators and research staff in developing exposure control plans and reviews exposure control plans to document compliance with state and federal regulations.
   6. Provides technical advice to Principal Investigators and the IBC regarding safe handling, storage, and use of biological materials. Plans, conducts and documents training on biosafety issues and safe handling practices involving biological materials for laboratory personnel on existing projects and prior to initiation of new projects.
   7. Performs inspections of project facilities prior to IBC approval of research with biological materials and annually thereafter to ensure that appropriate laboratory practices are followed.
   8. Reports to the IBC any suspected laboratory-acquired infections, laboratory spills, accidents, containment failures, or violations of biosafety practice which result in the release of biological material and/or the exposure of laboratory personnel to infectious agents.
   9. Reviews Animal Use and Care Protocols.
      i. Determines whether project requires approval of a BUA.
      ii. Reports the PI and project BUA status to the Institutional Animal Care and Use Committee.
      iii. Recommends appropriate modifications of the Animal Care and Use Protocol to reduce biological risk or release of recombinant DNA.

D. Department Chairs, ORU Directors, Directors of Centers for Excellence, Directors of the Institute for Collaborative Biotechnology, or Heads of other dedicated research units
    1. Reviews and provides department level approval of BUA and government agency permit applications in advance of submission to IBC.
    2. Ensures resources necessary to control potential hazards and enforces biological safety policies and procedures.

E. Principal Investigator (PI)
    1. Ensures work conducted in his/her group is in compliance with all Federal, State, and University requirements.
    2. Responsible for writing BUA applications as well as obtaining, updating and amending BUA(s) and government agency permits as required.
    3. Makes an initial determination of the required levels of physical and biological containment in accordance with the requirements set forth in the NIH Guidelines and selects appropriate microbiological practices and laboratory techniques to be used for the research.
    4. Develops, implements and communicates written laboratory-specific biosafety procedures and emergency plans that are consistent with the nature of current and planned research activities and available laboratory facilities.
    5. Ensures that all laboratory personnel understand the potential biological hazards, the necessary precautions, and the lab-specific biosafety procedures. Ensures that all involved lab personnel have read, understood, and signed off on the BUA after its approval.
    6. Ensures that all research personnel are appropriately trained in biosafety and supervises the safety performance of the laboratory personnel to ensure that the required practices and techniques are employed.
    7. Maintains documentation of all initial and refresher training given to laboratory personnel.
    8. Ensures that research personnel receive appropriate occupational medical attention and surveillance as needed. Medical surveillance includes the Hepatitis B vaccine, serologic testing if indicated, or documented vaccine declination, for employees at risk of exposure to human blood or tissues.
    9. Reports any significant problems, violations of the NIH Guidelines, or any significant research-related incidents to the department of Environmental Health and Safety within 24 hours.
    10. Ensures the integrity of all containment systems used in the project, including the annual certification of biosafety cabinets used for potentially infectious biological materials.
    11. Complies with shipping requirements for biological materials.

F. Employees, students, postdoctoral fellows, volunteers, and all other laboratory personnel

1. Become familiar with the project and its associated potential hazards.
2. Read, understand, and sign off on the BUA to acknowledge responsibility to follow the safety procedures outlined therein and in the training provided by the PI.
3. Use provided safety equipment.
4. Report unsafe or hazardous situations immediately to the laboratory supervisor, instructor, or PI.
5. Participate in medical surveillance programs as appropriate.
6. Participate in required safety training and ensure understanding of all elements of the training and instruction.
7. Follow campus medical and biological waste disposal procedures.

G. Environmental Health and Safety (EH&S)

1. Conducts announced and unannounced annual inspections of campus laboratory facilities to observe conditions and behaviors, talk to faculty and staff, and review records to ensure that the conditions required for safe research are being met.
2. Reviews facility construction/remodeling plans and specifications and provides advice on facility design, ventilation needs, and other supporting services.
3. Inspects construction/remodeling and authorizes initiation of biological materials work following completion of construction.
4. Provides consultation as requested.
5. Manages the Select Agent program and provides an employee to serve as the Responsible Official or Alternate Responsible Official as defined in Select Agents Regulations.
6. Reviews government agency permit applications that involve biological materials and prepares them for submission to the IBC.

H. Office of Research

1. Informs the Biosafety Officer of receipt of research proposals that indicate use of biological materials for review and determination that the PI has complied with BUA requirements.
2. Postpones acceptance of research funds or approvals from other institutional committees until receipt of verification that BUA requirements are met.

I. Director of Animal Facility

1. Periodically inspects areas where live vertebrate animals are exposed to or treated with infectious or infecting agents.
2. Oversees the training and instruction of animal caretakers in recognizing the potential risks and utilizing special precautions when handling and caring for live vertebrate animals that have been exposed to or treated with infectious or infecting agents.
3. Ensures that appropriate warnings and notices are posted on the door(s) of the animal room(s) containing animals exposed to or treated with infectious agents.

4. Oversees aspects of the animal care and use program, including contamination control with regard to animal husbandry and housing, and animal carcasses disposal.
5. Ensures resources necessary to control potential hazards and enforces biological safety policies and procedures in the vivaria.

IV. PROCEDURES

A. Principal investigators contemplating work with the covered biological materials must complete and submit a Biological Use Authorization (BUA) application to the Campus Biosafety Officer at Environmental Health and Safety (EH&S).
B. The Institutional Biosafety Committee must approve the Biological Use Authorization before initiation of work or transfer of agents to campus.
C. Investigators with laboratory work that has the potential for exposure to human blood, tissues (including tissue culture) or other body fluids, including Principal Investigators who are new to work with these materials, must attend training on the bloodborne pathogens standards.
D. For laboratory work that has the potential to expose employees to human blood, tissues (including tissue culture) or other body fluids, the responsible employer/Principal Investigator must implement the following measures:
    - Write a site-specific "Bloodborne Pathogens Exposure Control Plan" to be filed at EH&S and reviewed by the Campus Biosafety Officer,
    - Determine the at risk personnel,
    - Ensure that at risk personnel have read, understood and signed off on the plan,
    - Offer the Hepatitis B vaccination series at the expense of the employer,
    - Document acceptance or declination of vaccination, annual training, and recordkeeping.
    - Potential exposures may be from clinical work, research, police work, first aid, life guarding, coaching, child care, etc.
E. EH&S personnel will periodically conduct announced and unannounced inspections of the facilities to observe conditions and behaviors, talk to faculty and laboratory personnel, and review records to ensure that the conditions required for the BUA are being met.
F. All parties named in this policy may refer to the general precautions and containment strategies for biological materials as recommended in BMBL, current edition.

V. REFERENCES

A. UC Office of the President Policies

1. Management of Health, Safety, and the Environment
2. Laboratory Safety Training
3. Minors in Laboratories and Shops

4. Personal Protective Equipment

B. UCSB Policies

1. Environmental Health and Safety

C. Federal Guidelines and Regulations

1. Chosewood, L.C. and D.E. Wilson (Eds., 2009) *Biosafety in Microbiological and Biomedical Laboratories* (BMBL), current edition. U.S. Department of Health & Human Services, Centers for Disease Control and Prevention and National Institutes of Health. http://www.cdc.gov/od/ohs/biosfty/bmbl5/bmbl5toc.htm
2. "Hepatitis B FAQs for Health Professionals," U.S. Department of Health & Human Services, Centers for Disease Control and Prevention, Division of Viral Hepatitis and National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention http://www.cdc.gov/hepatitis/hbv/hbvfaq.htm
3. *NIH Guidelines for Research Involving Recombinant and Synthetic DNA Molecules*. (March 2013). Washington, DC: U.S. Government Printing Office. http://oba.od.nih.gov/oba/rac/Guidelines/NIH_Guidelines.htm
4. Select Agents and Toxins List: http://www.selectagents.gov/select agents and toxins list.html
5. Title 42 Code of Federal Regulations Part 72 & 73 (42 CFR 72, 73) *Possession, Use, and Transfer of Select Agents and Toxins; Final Rule* (March 2005). United States Department of Health and Human Services. http://www.selectagents.gov/resources/aphisFinalRule.pdf
6. Title 7 Code of Federal Regulations Part 331 (7 CFR 331) and Title 9 Code of Federal Regulations Part 121 (9 CFR 121) *Agricultural Bioterrorism Protection Act of 2002; Possession, Use, and Transfer of Biological Agents and Toxins; Final Rule* (March 2005). U.S. Department of Agriculture. http://www.selectagents.gov/resources/42_cfr_73_final_rule.pdf
7. Ventilation Requirements for Laboratory-Type Hood Operations, CCR Title 8 Section 5154.1, California Department of Industrial Relations.

D. California Guidelines and Regulations

1. Medical Waste Management Act, California Health and Safety Code, Sections 117600 – 118360.
2. Bloodborne Pathogens Standard, California Code of Regulations (CCR) Title 8 Section 5193, California Department of Industrial Relations.