

BIOSAFETY

I. POLICY

It is the policy of the University of California, San Diego (UCSD) that all research and teaching involving biohazardous materials will be conducted in a safe manner in order to protect the academic community as well as the greater community at large.

Please note that any possession of or work with biohazardous materials that customarily requires Biosafety Level 4 (BSL4) containment is prohibited at UCSD.

This section outlines the policy and procedures governing the safe use, propagation and/or release of infectious biological agents, recombinant/synthetic DNA/RNA, and recombinant/synthetic organisms, including plants, animals, and microbial agents.

Biohazard materials covered in UC San Diego's Biosafety Program include:

- Biological toxins
 - Infectious organisms that can cause disease in humans or cause significant environmental or agricultural impact
 - Human or primate tissues, fluids, cells, or cell cultures
 - Animal tissues, fluids, cells, or cell cultures
 - Recombinant/Synthetic DNA in vitro, in vivo, and in clinical trials
 - Transgenic plants or animals
 - Human gene transfer clinical trials
 - Releases of recombinant/synthetic DNA to the environment
 - Animals known to be reservoirs of zoonotic diseases
 - Select Agents
- A. All teaching and research activities involving biohazardous materials must be authorized by the Institutional Biosafety Committee (IBC) before the work commences. Persons contemplating work with any biohazardous material must submit an electronically completed "Biohazard Use Authorization" (BUA) to Environment, Health and Safety (EH&S). After assessing the risks of the proposed work the IBC will establish the practices, procedures, equipment and facilities that will be used during the course of the proposed work and will grant authorization to conduct the work.
- B. EH&S personnel will periodically conduct announced and unannounced inspections of the facilities to observe conditions and behaviors, talk to faculty and staff, and review records to ensure that the conditions required for the BUA are being met.
- C. Many people may work with or have potential for exposure to human blood, tissues (or tissue culture), or other body fluids. This exposure may be from clinical work, research, police work, first aid, life guarding, coaching, child care, etc. Since any exposure to human blood has potential to cause infection by a bloodborne pathogen (Hepatitis B virus, HIV, etc.), a series of protective measures must be implemented by the supervisor or department. These measures include a written "Bloodborne Pathogens Exposure Control Plan," a determination of "at risk" personnel, procedures for evaluation of exposure incidents, Hepatitis B vaccination acceptance / declination form, training, and recordkeeping.
- D. All University research involving recombinant/synthetic DNA molecules (r/sDNA) shall be conducted in compliance with NIH Guidelines for Research Involving Recombinant/Synthetic DNA Molecules (the NIH Guidelines) regardless of the funding source.

II. APPROVALS

- A. The following activities require approval of a Biohazard Use Authorization (BUA) by the Institutional Biosafety Committee (IBC).
1. Research activities that involve the use of recombinant/synthetic DNA technology or products (see the NIH Guidelines, Section III and Appendices).
 - a. Approval is required before initiation of work, regardless of Risk Group (biosafety level) or applicable section of the NIH Guidelines.
 - b. The NIH Guidelines provide further information on some required federal agency approval of certain types of projects that involve recombinant/synthetic DNA technology.
 2. Human gene transfer/gene transfer trials must comply with NIH Guidelines, Appendix M.
 - a. IBC Approval must be obtained after the NIH Recombinant/Synthetic DNA Advisory Committee has reviewed the project, but before any patients are enrolled.
 - b. PIs are required to contact EH&S Biosafety for consultation and feedback prior to submitting any experiments for NIH RAC review.
 3. Research and other activities involving the use of microbial agents listed as Risk Group 2 or 3 (see [CDC/NIH BMBL, fifth edition or later](#), the NIH Guidelines, or the [UC San Diego Biosafety website](#)), or agents that are customarily handled at Biosafety Level 2 or 3 regardless of Risk Group.
 - a. Use must be approved before transfer of agents to campus, medical center, or affiliated laboratories and initiation of work.
 - b. Importation of human pathogenic microbial agents also requires Centers for Disease Control approval.
 - c. Importation or interstate transfer of livestock or agricultural crop pathogenic microbial agents also requires USDA-Animal and Plant Health Inspection Service (APHIS) approval.
 - d. The activity shall be reviewed by the IBC prior to review by government agencies requiring a permit for the activity.
 4. Research activities involving the release of noxious or genetically engineered organisms, including animals, plants, and microbial agents, into the environment.
 - a. These activities also require approval by the USDA.
 - b. The activity shall be reviewed by the IBC prior to review by the USDA or any other government agency requiring a permit for the activity.
 5. Research and other activities involving the possession or use of toxins (see website for specifics) from the natural sources (including unicellular, multicellular, plant, invertebrate and vertebrate sources).
 - a. These activities require IBC review and approval before toxins can be transferred to the UC San Diego campus, medical center, or an affiliated laboratory, and before work can be initiated.
 - b. Work with toxin-producing plant and animal species that does not involve toxin extraction or isolation does not require IBC review.
 - c. Work with toxin-producing microbial agents requires IBC review and approval regardless of whether toxins are intentionally being recovered.

- B. The following activities are regulated under OSHA Bloodborne Pathogen and Medical Waste Management statutes, and require approval of a BUA by the IBC only as noted below.
1. Activities involving the use of human body fluids, human primary cell cultures, established human cell lines, and unfixed human tissues.
 - a. These activities require the completion of a Bloodborne Pathogen Exposure Control Plan as part of the Injury Illness Prevention Plan (IIPP).
 - b. These materials are always handled at Biosafety Level 2 or greater. Note that any work requiring Biosafety Level 4 containment is prohibited here at UCSD.
 - c. Initial training and annual refresher training in biological safety and bloodborne pathogen exposure control are required.
 - d. Activities involving tissues or cells require approval of a BUA by the IBC.
 2. Activities involving the use of nonhuman primate body fluids, nonhuman primate primary cell cultures, established nonhuman primate cell lines, and unfixed nonhuman primate tissues.
 - a. Initial training in biological safety and documentation is required as part of the IIPP.
 - b. These materials are always handled at Biosafety Level 2 or greater. Note that any work requiring Biosafety Level 4 Containment is prohibited here at UCSD.
 - c. Activities involving tissues or cells require approval of a BUA by the IBC.
 3. Activities that generate medical waste (i.e., human tissues, materials contaminated with human tissues including body fluids, potential or known human infectious agents, human pathogenic agents, or toxin-producing agents including zoonotic agents).
 - a. Training on medical waste disposal is required as part of the Laboratory Safety Principles IIPP.

III. RESPONSIBILITY

A. Chancellor

The Chancellor is responsible for ensuring that research is conducted in full conformity with the provisions of the above references. In order to fulfill this responsibility, the Chancellor shall:

1. Appoint and maintain an active Institutional Biosafety Committee (IBC).
2. Appoint a Biosafety Officer.
3. On the advice of the IBC, terminate, restrict, or deny any project or teaching program not in compliance with this policy.

B. Institutional Biosafety Committee (IBC)

The IBC is advisory to the Chancellor through the Vice Chancellor – Resource Management and Planning on all matters relating to the safe use of biohazardous materials and organisms. It is the IBC's responsibility to establish, monitor, and enforce policies and procedures which meet or exceed applicable norms or regulations for biohazardous materials and/or recombinant/synthetic DNA, including gene transfer clinical trials. Any use of biohazardous materials or recombinant/synthetic DNA must be reviewed and approved by the IBC (or the Biological Safety Officer operating within guidelines established by the IBC).

The IBC has the authority to impose disciplinary measures in cases where there is willful or negligent violation of UCSD's established biosafety practices and procedures. The sanctions are subject to review and/or modification by the Chancellor. The IBC shall maintain diverse membership representing the community and a variety of University interests. Non-committee faculty or staff with a particular expertise will be asked to advise the committee when the need arises.

The IBC shall maintain a record of committee membership and procedures.

1. Functions of the IBC

- a. Establish and implement policies that provide for the safe conduct of research and teaching involving biohazardous materials.
- b. Ensure appropriate training for the IBC Chair and members, Biosafety Officer, Principal Investigators, and laboratory staff regarding laboratory safety and implementation of the regulations and guidelines. The institution is responsible for ensuring that the Principal Investigator has sufficient training; however, this responsibility may be delegated to the Institutional Biosafety Committee.
- c. Establish, monitor, and enforce policy, practices, and procedures for all work involving biohazardous materials at UCSD. The IBC shall ensure adopted policies, practices, and procedures meet applicable regulatory standards and guidelines.
- d. Review and approve research proposals and other activities that involve biohazardous materials.
- e. Review with biohazardous materials conducted at or sponsored by UCSD for compliance with adopted policies, regulations and guidelines involving any of the following: (a) Recombinant/Synthetic DNA technology, (b) Human gene transfer/gene therapy, (c) biohazardous agents. This review shall include an independent assessment of the containment required, an assessment of the facilities and operational procedures, as well as training and expertise of personnel involved in the research. The IBC shall ensure that the Principal Investigator is provided the results of the review and determination of approval in a timely manner.
- f. Determine the appropriate containment and handling (Biosafety) level (BSL) for all projects reviewed in the BUA process.
- g. Recommend modification, suspension, or termination of projects when it is in the best interest of the health and safety of the campus and surrounding community. Deny approval for any project that cannot be undertaken safely at UC San Diego facilities. Refer prohibited experiments (see the NIH Guidelines III.A) to the NIH Recombinant/Synthetic DNA Advisory Committee for review.
- h. Develop and implement emergency plans to cover accidental biohazardous materials spills, including r/sDNA, and personnel contamination. The IBC will coordinate with institutional officials and will cooperate with state and local public health departments.
- i. Approve campus biological safety-related practices (e.g., spill handling, laboratory hygiene and conduct, standard practices, emergency response procedures).
- j. The IBC will report to any appropriate regulatory agency any significant research-related exposure, illness or release that may be hazardous to the public health.

- k. Investigate any significant violation of policies, practices, and procedures. The IBC will also investigate any significant research-related accidents, exposures, or illnesses. The IBC will determine and impose appropriate disciplinary action should a thorough investigation reveal significant violations of policy, practices, or procedure. The IBC will report its findings and actions to appropriate UCSD institutional officials and to the granting agencies as required.
- l. Review and recommend policies and procedures for health surveillance of individuals involved in programs using biohazardous materials. Determine when employees who work with biohazardous materials should be offered health surveillance. Determine the specific medical surveillance tests which are appropriate for a given biohazardous materials risk. The institution shall establish and maintain a health surveillance program for at-risk personnel.
- m. Review criteria for biohazardous materials containment facilities.
- n. Report adverse events and violations of the NIH Guidelines to the NIH Office of Biotechnology Activities unless it determines that the principal investigator involved has already made such a report (e.g., adverse events in gene therapy trials).

C. Research Safety Manager -EH&S

- 1. Acts as Alternate Responsible Official or Responsible Official for the Select Agent program as described in 42 CFR Section 73.

D. UCSD Biosafety Officer

The UCSD Biosafety Officer is appointed by the University, is a member of the Environment, Health and Safety staff, and serves as a member of the Institutional Biosafety Committee (IBC). The Biosafety Officer's duties include, but are not limited to:

- 1. Administers the campus biological safety program (see also the NIH Guidelines, Section IV.B.3.c).
- 2. Provides services to Faculty and Staff
 - a. Review proposed biohazard research projects and recommends the biosafety levels (BSL) for research projects to the IBC based on the Biosafety in Microbiological and Biomedical Laboratories (BMBL) and NIH r/sDNA Guidelines.
 - b. Provide technical advice to Principal Investigator s and to the IBC regarding research safety procedures. This includes developing exposure control plans for the safe handling, storage, and use of biohazardous materials.
 - c. Advise on the selection, installation, maintenance, and use of laboratory equipment which provides or aids in containment of biohazardous materials.
 - d. In consultation with faculty, staff, and the IBC, develop and implement policies, procedures, and practices to reduce the risks of work with biohazardous materials.
 - e. Investigate laboratory accidents, exposures, or releases involving biohazardous materials research.
 - f. Performs periodic inspections to ensure that laboratory standards are rigorously followed.

- g. Review government agency permit applications that involve biohazardous materials
 - h. Provide guidance in the development, operations, and management of Biosafety Level 3 laboratories. Verifies the safety of these laboratories before they become operational and annually thereafter.
 - i. Recommends appropriate modifications of the Animal Care and Use Protocol to reduce biohazard risk.
 - j. Ensures continual accuracy of campus policies on the Biosafety website.
3. Provides Training Services
- a. Plan, develop, and conduct training on biosafety issues, practices, and procedures. Provides training for safe handling practices involving biohazardous materials.
 - b. Review and approve laboratory-specific training plans for high-hazard biohazardous materials research laboratories.
4. Provides IBC support
- a. Report any significant problems, adverse events, violations of the NIH Guidelines and/or UCSD BioSafety policy violations, or any significant research-related accidents or illness to the IBC (unless a report has already been filed by the Principal Investigator).
 - b. Implement the decisions of the IBC.
 - c. Review BUA applications and prepares them for submission to the IBC.
5. Provides services to Facilities, Design and Construction, and Facilities Maintenance
- a. Review biosafety facility construction/remodeling plans and specifications. Inspect construction/remodeling and authorize initiation of biohazardous materials work following completion of construction.
 - b. Provide advice on biosafety facility design, ventilation needs, laboratory security and other supporting services.
6. Manages the select agent program when needed and serves as the Alternate Responsible Official as defined in 42 CFR Section 73.

E. Campus Veterinarian and or Vivarium Safety Officer

1. At the request of the IBC, the Campus Veterinarian shall assist in:
- a. Review proposed biohazardous work in animals as part of the BUA process.
 - b. Periodically inspecting areas where infectious agents are used in animal experiments.
 - c. Training and instructing animal caretakers in recognizing the potential risks and utilizing special precautions when animals are exposed to biohazard materials.
 - d. Clearly posting and labeling all such animal rooms.
 - e. Overseeing contamination control with regard to excreta, animal carcasses and tissues, contaminated cages, cage bedding, and any other equipment or object which has come in contact with animals or their products.

F. Principal Investigator

The Principal Investigator (PI) is responsible for full compliance with the policies, practices, and procedures set forth in the policies on the UCSD Biosafety websites. . This responsibility extends to all aspects of biosafety involving all individuals who enter or work in his/her laboratory or other approved locations to carry out his/her research. Although the PI may choose to delegate aspects of the biosafety program in his/her laboratory to other laboratory personnel or faculty, this does not absolve the PI from the ultimate responsibility. The PI remains accountable for all activities occurring in his/her lab.

1. General Responsibilities

As part of the general responsibilities, the PI shall:

- a. Every PI who is new to the UCSD research community, and/or plans to begin work with biological is required to attend a New PI Orientation. There are no fixed schedules for these classes. They are arranged as needed. Call extension 45366 for more information.
- b. Develop and implement written laboratory-specific biosafety procedures (e.g. Exposure Control Plans and Standard Operating Procedures) consistent with the nature of current and planned research activities and available laboratory facilities. The PI shall ensure that all laboratory personnel, including other faculty members, understand and comply with these lab-specific biosafety procedures.
- c. Delay commencement or modification of biohazardous materials work which requires IBC approval prior to initiation (e.g. all Risk Group 2 or greater agents until that work or the proposed modification has been approved by the IBC and meets all other requirements of the policies on the UCSD Biosafety website.
- d. Should any research project be required by the NIH Guidelines (see the policies on the UCSD website appendices) or by another agency to have prior agency approval before initiation, these projects must be reviewed and approved by the IBC before they are submitted to the agency.
- e. Ensure that all laboratory personnel, maintenance personnel, and visitors who may be exposed to any biohazard are informed in advance of their potential risk and of the behavior required to minimize that risk. It is essential that everyone who may have any potential exposure to biohazardous materials enter and/or work in the laboratory under the principle of Informed Consent. Refer to PPM 516-5.2, Hazard Communication Program.
- f. If any element of the UCSD biosafety policy covered in your BUA is considered to be unachievable, the UCSD Biosafety Officer should be notified immediately. Written notification must be sent to the Biosafety Officer within five working days of the determination.
- g. Ensure that all maintenance work in, on, or around contaminated equipment is conducted only after that equipment is thoroughly decontaminated by the laboratory staff.
- h. Report any significant problems, violations of the policies, practices, and procedures set forth in the policies on the UCSD Biosafety website or any significant research-related accidents and illnesses to the UCSD Biosafety Officer within 24 hours.
- i. Notify the UCSD Biosafety Officer immediately if a laboratory-acquired infection is known or suspected.
- j. Be adequately trained in good microbiological techniques.

- k. Ensure that all research personnel are appropriately trained in biosafety and receive appropriate medical surveillance.
 - l. Develop emergency plans for handling accidental spills and personnel contamination.
 - m. Create and foster a culture of safety in the laboratory which encourages open discussion of biosafety issues, problems, and violations of procedure. The PI will not discipline or take any adverse action against any person for reporting problems or violations to the Biosafety Officer or IBC.
 - n. Comply with all applicable shipping and import/export requirements for biohazardous materials.
2. Submissions of Proposed Work to the IBC
The PI shall:
 - a. Understand and recognize the required levels of physical and biological containment in accordance with the requirements set forth in the policies on the UCSD Biosafety website and the NIH r/sDNA guidelines.
 - b. Select appropriate microbiological practices and laboratory techniques to be used for the research.
 - c. Submit an amendment to the BUA for all changes other than personnel to the IBC for review and approval.
3. Prior to Initiating Research
The PI shall:
 - a. Submit an amendment to the BUA for all changes other than personnel to the IBC for review and approval.
 - b. Make available to all laboratory staff the protocols that describe the potential biohazards and the precautions to be taken.
 - c. Instruct and train all research personnel in: (i) the practices and techniques required to ensure safety, (ii) the procedures for dealing with accidents; and (iii) biohazard risk assessment (iv) ensure lab personnel receive any required EH&S training prior to commencing work.
 - d. Inform the laboratory staff of the required precautionary medical practices.
 - e. Ensure that collaborators are made aware in advance of any biohazardous material sent to them and the biosafety precautions to be followed.
4. During the Conduct of the Research
The PI shall:
 - a. Supervise the safety performance of the laboratory staff to ensure that the required safety practices and techniques are employed.
 - b. Investigate and report any significant problems pertaining to the operation and implementation of containment practices and procedures in writing to the UCSD Biosafety Officer.

- c. Immediately notify the UCSD Biosafety Officer of any laboratory spills, accidents, containment failure, or violations of biosafety practice which result in the release of biohazardous material and/or the exposure of laboratory personnel (or the public) to infectious agents and r/sDNA.
- d. Correct work errors and conditions that may result in the release of biohazardous materials.
- e. Ensure the integrity of all containment systems used in the project.
- f. Restrict access as required by the laboratory-specific biosafety practices procedures and by the biosafety containment level approved by the IBC.
- g. Conduct work in compliance with all Federal, State, and University requirements.
- h. Prepare, submit, and obtain approval of a BUA and government agency permits as required (see II, above).
- i. Provides initial and annual documented training of laboratory personnel and students for existing projects and prior to initiation of new projects.
- j. Ensure compliance with the Center for Occupational and Environmental Medicine recommendations associated with projects.
- k. Ensures certification of all Class II and III biological safety cabinets at the time of installation, annually, after the filter or motor is replaced or repaired, or when a cabinet is moved.
- l. Ensures certification of all in-place building HEPA filters serving BSL-3 laboratories at the time of installation, annually, or when a filter is replaced or repaired.

G. Individual Employees

Whoever works in the laboratory in a technical (rather than purely administrative) capacity is defined as a lab worker, even if the person is a faculty member, a student, an intern, a visiting scholar, or a volunteer.

The laboratory staff members are the most critical element in maintaining a safe working environment. Each person must look out for their own safety and that of their co-workers. If individuals do not follow the University's and the laboratory-specific biosafety practices and procedures in the conduct of their laboratory duties, we cannot have a safe working environment.

The laboratory staff's responsibilities include:

1. Conscientiously follow lab-specific biosafety practices and procedures.
2. Report to the Principal Investigator (PI) or the supervisor all problems, violations in procedure, or spills as soon as they are identified. Report to the UCSD Biosafety Officer any significant violations in biosafety policy, practices, or procedures which are not resolved by the PI within a reasonable amount of time.
3. Refuse to take any adverse action against any person for reporting problems or violations of procedures to supervisors, the PI, the Biosafety Officer, or the IBC.
4. Become familiar with the project and its associated potential hazards.
5. Use provided safety equipment.
6. Participate in mandated medical surveillance programs.

7. Participate in required safety training and ensure understanding of all elements of the training and instruction.
8. Follow campus medical waste and hazardous waste disposal procedures

IV. PROCEDURES

- A. UCSD Biosafety Website:
<http://blink.ucsd.edu/safety/research-lab/biosafety/index.html>

V. REFERENCES

- B. Federal Regulations
1. U.S. Department of Agriculture (USDA), Animal and Plant Inspection Service, National Center for Import and Export
 2. Centers for Disease Control and Prevention (CDC) - Additional Requirements for Transferring or Receiving Select Agents
 3. Department of Transportation (DOT) - Code of Federal Regulations Title 49 Parts 100-185 Shipping Infectious Substances
 4. Code of Federal Regulations Title 42, Public Health, Sections 72 and 73.
- C. California Regulations
1. California Code of Regulations, Title 8, Chapter 4, Section 5193 "Bloodborne Pathogens"
 2. California Code of Regulations, Title 8, Section 5199, "Aerosol Transmissible Diseases"
 3. California Health and Safety Code (HSC) Section 117600-118360; "Medical Waste Management Act"
 4. San Diego County Code of Regulatory Ordinances Title 6 Section 68.1201 "Medical Wastes" (only as referenced by state regulations)
- D. Federal Guidelines
1. National Institutes of Health (NIH) "Guidelines for Research Involving Recombinant/Synthetic DNA Molecules"
 2. CDC/NIH "Biosafety in Microbiological and Biomedical Laboratories" (BMBL)
 3. National Research Council Guide for the Care and Use of Laboratory Animals"
 4. USDA Biotechnology Guidelines.
- E. Professional Organization Guidelines
1. National Sanitation Foundation International Standard 49, "Class II Biohazard Cabinetry"
- F. University of California Policies and Procedures
1. Contract and Grant Manual Section 3-400, University Policy on Biohazards and Recombinant/Synthetic DNA.
 2. University Policy on Management of Health, Safety, and the Environment.
 3. UC San Diego Policy Procedures Manual 516-5.1
 4. UC San Diego Policy Procedures Manual 516-5.2
 5. UC San Diego Policy Procedures Manual 516-26