

BIOSAFETY

I. REFERENCES

- A. NIH "Guidelines for Research Involving Recombinant DNA Molecules"
- B. CDC-NIH "Biosafety in Microbiological and Biomedical Laboratories"
- C. National Sanitation Foundation International Standard 49, "Class II Biohazard Cabinetry"
- D. National Research Council "Guide for the Care and Use of Laboratory Animals"
- E. California Code of Regulations Title 8, Chapter 4, Section 5193 "Bloodborne Pathogens"
- F. California Health and Safety Code Chapter 6.1 "Medical Waste Management Act"
- G. San Diego County Code of Regulatory Ordinances Title 6 Section 68.1201 "Medical Wastes"
- H. U.S. Department of Agriculture, Animal and Plant Inspection Service, National Center for Import and Export
- I. Centers for Disease Control and Prevention - Additional Requirements for Transferring or Receiving Select Agents
- J. Department of Transportation - Code of Federal Regulations Title 49 Parts 171-180 Shipping Infectious Substances
- K. *UCSD Biosafety Handbook*, 1996 (<http://www-ehs.ucsd.edu/bio.htm>)

II. POLICY

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

Further, it is University policy that no risk Group 4 agents may be used or stored at UCSD.

"Biohazardous Materials" shall be defined as: *All infectious organisms (bacteria, fungi, parasites, prions, rickettsias, viruses, yeasts, etc.) which can cause disease in humans, or cause significant environmental or agricultural impact. This shall include work with human or primate tissues, fluids, cells, or cell culture; recombinant DNA; transgenic plants or animals; human gene therapy; releases of recombinant DNA to the environment; and work with animals known to be vectors of zoonotic diseases.*

III. PROCEDURES

- 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 a fully completed "Application for Biohazardous Materials Use Authorization" 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 Biohazardous Materials Use Authorization 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 "Exposure Control Plan," a determination of "at risk" personnel, procedures for evaluation of exposure incidents, Hepatitis B vaccinations, training, and recordkeeping.

IV. 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. Establish and implement policies that provide for the safe conduct of research and teaching involving biohazardous materials.
2. Appoint and maintain an active Institutional Biosafety Committee.
3. Appoint a Biosafety Officer.
4. Assist and ensure compliance with the regulations and guidelines by Principal Investigators conducting research at UCSD.
5. 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.

B. Institutional Biosafety Committee (IBC)

The Institutional Biosafety Committee is advisory to the Chancellor on all matters relating to the safe use of biohazardous materials and organisms. It is the Committee's responsibility to establish, monitor, and enforce policies and procedures which meet or exceed applicable norms or regulations for biohazardous materials. Any use of biohazardous materials must be reviewed and approved by the Committee (or the Biosafety Officer operating within the guidelines established by the Committee). The Committee 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 Committee 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.

1. Committee Membership and Procedures
 - (a) The IBC is comprised of 10 voting members and three or more non-voting members. Voting members include two representatives from the community

with no other UCSD affiliation. Also included are faculty representatives from School of Medicine, Scripps Institution of Oceanography, the general campus, an infectious disease specialist, a recombinant DNA specialist, campus veterinarian, a staff representative, and the UCSD Biosafety Officer. Non-voting members include: School of Medicine Safety Officer, Chair of the Veterans Affairs Biosafety Committee, and Associate UCSD Biosafety Officer.

IBC members are selected so that they have collective experience and expertise to fully evaluate the biohazard risks associated with the wide variety of research proposals which come under its scrutiny. Non-committee faculty or staff with a particular expertise will be asked to advise the Committee when the need arises.

- (b) No member of the IBC may be involved (except to provide information requested by the IBC) in the review or approval of a project in which he/she has been or expects to be engaged or has a direct financial interest.
- (c) The IBC Chair is responsible for ensuring that IBC members are appropriately trained.
- (d) IBC meetings are normally held monthly. The IBC will meet no less than six times per year.

2. Functions of the IBC

- (a) 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.
- (b) Review biohazardous materials work conducted at or sponsored by UCSD for compliance with adopted policies, regulations and guidelines. This review shall include an independent assessment of the containment¹ 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.
- (c) Set required containment for research projects. The IBC will use the biosafety levels (BSL) recommended by the Centers for Disease Control and Prevention (CDCP) and National Institutes of Health (NIH) as the usual standards of containment to be set for work with a given biohazardous material. The IBC may, at its discretion, increase or reduce the BSL depending on the circumstances presented by a specific project.
- (d) Periodically review procedures and the effectiveness of the UCSD Biosafety Program.
- (e) Develop and implement emergency plans to cover accidental biohazardous materials spills and personnel contamination. The IBC will coordinate with institutional officials and will cooperate with state and local public health

1 "Containment" is the term used to describe methods, practices, procedures, facilities, and equipment used to safely manage biohazardous materials in the laboratory. The purpose of containment is to reduce or eliminate exposure of people or the environment to potentially hazardous agents.

departments. The IBC will report any significant research-related illness or accident that may be hazardous to the public health.

- (f) 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.
- (g) 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.
- (h) Develop design specifications and criteria for biohazardous materials containment facilities.
- (i) Perform such other functions as may be delegated to the IBC by the Chancellor.

C. 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. The Biosafety Officer's duties include, but are not limited to:

1. Services to the Laboratories
 - (a) Conduct periodic inspections to ensure that laboratory practices and procedures are rigorously followed;
 - (b) Assists Principal Investigators and research staff in developing exposure control plans and provides technical advice to facilitate safe handling, storage, and use of biohazardous materials.
 - (c) In consultation with faculty, staff, and the IBC, develop and implement policies, procedures, and practices to reduce the risks of work with biohazardous materials with consideration given to having minimal interference with the conduct of research and teaching.
 - (d) Develop emergency plans for handling accidental spills and personnel contamination. Investigate laboratory accidents involving biohazardous materials research.
 - (e) Review proposed biohazardous materials work. Acting within guidelines established by the IBC, approve low risk activities; forward to the IBC all other proposals.
2. Training Services
 - (a) Plan, develop, and conduct training on biosafety issues, practices, and procedures.

- (b) Review and approve laboratory-specific training plans for high-hazard biohazardous materials research laboratories.
- 3. Institutional Biosafety Committee support
 - (a) Report to the IBC any significant problems, violations of UCSD biosafety policy, practices or procedures, and any significant research-related accidents or illnesses of which the Biosafety Officer becomes aware.
 - (b) Implement the decisions of the IBC.
 - (c) Serve as executive secretary for the IBC. Maintain records of all biosafety program activity, schedule meetings, prepare letters, prepare minutes, etc.
- 4. Services on Behalf of the Laboratories
 - (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, and other supporting services.
 - (c) Advise on the selection, installation, maintenance, and use of laboratory equipment which provides or aids in containment of biohazardous materials.

D. Campus Veterinarian

- 1. At the request of the IBC, the Campus Veterinarian shall assist in:
 - (a) Periodically inspecting areas where infectious agents are used in animal experiments.
 - (b) Training and instructing animal caretakers in recognizing the potential risks and utilizing special precautions when animals are infected with pathogenic organisms.
 - (c) Clearly posting and labeling all such animal rooms.
 - (d) 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.

E. Principal Investigator (PI)

The Principal Investigator is responsible for full compliance with the policies, practices, and procedures set forth in the *UCSD Biosafety Handbook*. This responsibility extends to all aspects of biosafety involving all individuals who enter or work in his/her laboratory or collaborate in carrying 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. Documentation of training and compliance with appropriate biosafety practices and procedures is essential.

- 1. General Responsibilities

As part of the general responsibilities, the Principal Investigator shall:

- (a) Every Principal Investigator who is new to the UCSD research community, and/or plans to begin work with biological and chemical agents (for the first time) 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 (Exposure Control Plan) 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 of (or modification of) biohazardous materials work which requires IBC approval prior to initiation (e.g., Biosafety Level 2 or greater containment required), until that work (or the proposed modification) has been approved by the IBC and meets all other requirements of the *UCSD Biosafety Handbook*.
- (d) Should any research project be required by the NIH Guidelines (see the *UCSD Biosafety Handbook* 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) Where biohazardous materials work requires Biosafety Level 1 containment, the IBC must be notified upon initiation of this work.
- (f) 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 516-13, Hazard Communication Program.
- (g) If any element of biosafety is considered to be unachievable, the UCSD Biosafety Officer should be notified immediately. A written report must be sent to the Biosafety Officer within five working days of the determination.
- (h) Ensure that all maintenance work in, on, or around contaminated equipment is conducted only after that equipment is thoroughly decontaminated by the laboratory staff.
- (i) Report any significant problems, violations of the policies, practices, and procedures set forth in the *UCSD Biosafety Handbook* or any significant research-related accidents and illnesses to the UCSD Biosafety Officer within 24 hours.
- (j) Notify the UCSD Biosafety Officer immediately if a laboratory-acquired infection is known or suspected.
- (k) Be adequately trained in good microbiological techniques.
- (l) Ensure that all research personnel are appropriately trained in biosafety and receive appropriate medical surveillance when needed.

- (m) Develop (with the assistance of the Biosafety Officer) emergency plans for handling accidental spills and personnel contamination.
- (n) Create and foster an environment 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.
- (o) Comply with shipping requirements for biohazardous materials.

2. Submissions of Proposed Work to the Institutional Biosafety Committee

The Principal Investigator shall:

- (a) Make an initial determination of the required levels of physical and biological containment in accordance with the requirements set forth in the *UCSD Biosafety Handbook*.
- (b) Select appropriate microbiological practices and laboratory techniques to be used for the research.
- (c) Submit any significant changes to the IBC for review and approval. [Examples could include: i) work with mouse cells is changed to work with human or primate cells; ii) work begins with a new cell line that carries a potentially infectious organism; iii) work with a small part of an agent's genome is modified to working with > 2/3 of that genome; iv) change in animal species; v) change in host-vector system; etc.]

3. Prior to Initiating Research

The Principal Investigator shall:

- (a) Make available to all laboratory staff the protocols that describe the potential biohazards and the precautions to be taken.
- (b) 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.
- (c) Inform the laboratory staff of the reasons and provisions for any precautionary medical practices advised or requested (e.g., vaccinations or serum collection).
- (d) Ensure that collaborators are made aware in advance of any biohazardous material sent to them and the biosafety precautions to be followed. PI's are advised to maintain a log of all biologic material received and sent out.

4. During the Conduct of the Research

The Principal Investigator 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.
- (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.

F. 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.

1. 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:
2. Conscientiously follow lab-specific biosafety practices and procedures.
3. Report to the Principal Investigator or the supervisor all problems, violations in procedure, or spills as soon as they are identified.
4. 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.
5. 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.