

## UC Davis Policy and Procedure Manual

### Chapter 290, Health and Safety Services

#### Section 55, Biological Safety

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Responsible Department: Environmental Health and Safety (EH&S)

Source Documents: National Institutes of Health (NIH) Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules; Select Agent Regulations 42 CFR § 73, 9 CFR § 121, 7 CFR § 331.

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#### I. Purpose

This section establishes the authority of the Institutional Biosafety Committee (IBC), outlines the policies governing the acquisition and use of biological hazards, select agents, and details IBC approval requirements for human gene transfer research.

#### II. Definitions

- A. Biological hazard—contaminants (human, animal, or plant), potentially infectious materials (e.g., human tissues, cell lines, blood), recombinant and synthetic nucleic acids, toxins.
- B. Biosafety level (BSL)—suite of protective measures, practices, and facilities for work with biological hazards, ranging from BSL1 (least hazardous) to BSL3 (significant hazards).
- C. Select agents—Pathogenic microbial agents and toxins whose possession, transfer, and use is regulated by the federal government under 42 CFR § 73, 9, CFR § 121, or 7 CFR § 331.

#### III. Policy

- A. Biological hazards 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.
- B. All activities involving recombinant and synthetic nucleic acid molecules must be conducted in compliance with the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules regardless of the funding sources.
- C. Activities that require IBC approval and also require regulatory agency permits may be initiated only after receiving IBC approval and agency permits authorizing the activities.
- D. Research with biological hazards, (human, animal, plant, or recombinant), release of genetically modified organisms to the environment, or long-term storage of biological hazards for which no use is planned requires an IBC-approved Biological Use Authorization (BUA) before biological hazards may be transferred, or work with biological hazards may be initiated.
- E. Projects involving recombinant nucleic acid transfer to human research subjects require an approved BUA for Human Gene Transfer.
  - 1. No patients may be enrolled in the project until IBC and all other required approvals have been received.
  - 2. Other documents required for IBC review of human gene transfer projects specified in the Human Gene Transfer BUA application should be submitted with the application to ensure timely IBC review.
- F. The IBC reviews and approves Standard Operating Procedures for UC Davis academic courses that produce recombinant or synthetic nucleic acid constructs or use other biological hazards, and

core facilities that perform services involving use, processing, or production of recombinant or synthetic nucleic acid constructs or other biological hazards for campus and off-campus clients.

- G. All activities involving select agents must be conducted in compliance with the select agent laws and regulations.
- H. Possession, transfer, or use of select agents requires the prior authorization of the select agent Responsible Official (RO), in addition to a current approved BUA.

#### **IV. Procedures**

1. All forms and online registration systems are available on the Safety Services website, [Biological Safety](#) section.
2. The Principal Investigator (PI) submits the BUA or SOP application as instructed in the Biological Safety section of the Safety Services Website.
3. The IBC reviews the application and sets the BSL(s) for the project.
  - a. If the BUA is approved, the Biological Safety Office notifies the PI of the approval, the BSL, and the BUA expiration date.
  - b. If a BUA application is conditionally approved or tabled, the Biological Safety Office advises the PI of the information needed for full approval. The PI must respond with the required BUA application modifications within the time period specified.
4. The PI must apply for a renewal of the BUA prior to the expiration date (three years from the date of approval) or cease all work covered by the BUA until a renewal is approved.

#### **V. Responsibilities**

- A. Vice Chancellor—Administrative and Resource Management
  1. Appoints IBC members proposed by the IBC chair, in compliance with the NIH Guidelines.
  2. Receives the annual report on IBC activities.
  3. Appoints the select agent program Responsible Official (RO).

- B. IBC

The IBC duties include but are not limited to:

1. Acts as the NIH-mandated Institutional Biosafety Committee.
2. Sets biological safety policy for all UC Davis activities that use biological hazards or that involve human gene transfer.
3. Reviews and approves all UC Davis activities involving biological hazards or human gene transfer; denies approval for projects that cannot be conducted safely at University facilities.
4. Determines the appropriate BSL for projects.
5. Modifies, suspends, or terminates activities that involve biological hazards when in the best interest of the University or the community.
6. Approves the initial and annual operation of all BSL3 facilities.
7. Approves standardized campus biological safety-related practices (e.g., spill handling, laboratory hygiene and conduct, emergency response procedures).

8. Monitors the enrollment of all users of biological hazards in the campus's Occupational Health Surveillance System.
  9. Reports adverse events involving recombinant or synthetic nucleic acid experiments, and violations of the NIH Guidelines, to the NIH Office of Biotechnology Activities.
- C. Biological Safety Officer (or designated Associate Biological Safety Officer)
1. Administers and manages the biological safety program.
  2. Communicates IBC decisions to PIs.
  3. Provides guidance in the design, development, operations, and management of BSL3 laboratories.
  4. Verifies the safety features of BSL3 laboratories before they become operational and annually thereafter.
  5. Conducts annual inspections of research laboratories, teaching laboratories, and core facilities that handle biological hazards to monitor compliance with BUA terms and conditions and with regulatory requirements.
  6. Develops biological safety policy and procedures for IBC approval.
  7. Develops plans for handling biological hazard-related emergencies and for investigating laboratory accidents.
  8. Develops and provides training on biological safety and security.
  9. Manages the IBC business and serves as an *ex officio* member of the IBC.
  10. Serves as an *ex officio* member of the Institutional Animal Care and Use Committee (IACUC)
  11. Reviews research grant proposals and Animal Care and Use Protocols (ACUP) when the proposed work involves biological hazards, to determine whether the project requires a BUA.
  12. Manages the medical/biohazardous waste program.
- D. Select Agent RO
1. Is responsible for all administrative aspects of the UC Davis select agent program.
  2. Acts as the liaison between the University and the Centers for Disease Control and USDA-APHIS Divisions of Select Agents and Toxins.
  3. Provides compliance guidance and assistance to PIs who work with select agents.
  4. Ensures institutional compliance with all parts of the select agent laws and regulations.
  5. Manages the Security Risk Assessment (SRA) approval process (42 CFR § 73.10) for individuals seeking approval for access to select agents.
    - a. Receives the names of individuals proposed for access to select agents from select agent PI's.
    - b. Conducts an initial suitability assessment and provides initial training in security and biological safety expectations for individuals who have requested authorization for access to select agents. Complete training in security, biological safety, and incident response is the responsibility of the PI.

- c. Submits the names of individuals who receive initial approval to the Centers for Disease Control Division of Select Agents and Toxins (CDC-DSAT), and coordinates fingerprinting at UC Davis Police and submission of the fingerprints to the FBI Criminal Justice Information System (CJIS) for background investigation (no one may have access to select agents until cleared by CJIS and approved by CDC-DSAT and the RO).
  - d. Communicates SRA approval status to the select agent PI, and provides institutional authorization for access to select agents. This authorization is revocable at any time.
6. Conducts annual inspections of all select agent laboratories and programs.
  7. Accompanies agency inspectors during compliance inspections.
  8. Responds to select agent-related agency inspection reports and inquiries.
  9. Reviews BUAs for select agent work for approval prior to review by the IBC. RO approval of all BUA applications and amendments for select agent possession, transfer, or use is a prerequisite for IBC review.
  10. Designates Alternate Responsible Officials (ARO) to act for the RO in the RO's absence.
- E. Department Head
1. Reviews and provides department level approval of BUA applications before submission to the IBC.
  2. Ensures the availability of resources necessary to control biological hazards following PI departure from UC Davis.
- F. PIs, core facility directors and teaching laboratory instructors
1. Conduct work in accordance with applicable laws and regulations, NIH Guidelines, University policies and procedures, and within IBC-specified restrictions and requirements.
  2. Ensure the safe operation of the laboratory or facility.
  3. Obtain IBC approval of a BUA or other required documents.
  4. Obtain required government agency permits for activities involving biological hazards.
  5. Submit amendment applications for existing BUAs to the IBC when changes of procedures, personnel, or locations are proposed, or when biological hazards are to be changed or modified.
  6. Provide initial and annual documented training in procedures for all laboratory personnel for existing projects and before initiation of new projects.
  7. Ensure that all laboratory personnel receive initial and annual safety training before beginning work.
  8. Report adverse events or research accidents involving biological hazards to the Biological Safety Officer or to the IBC (see [NIH Guidelines, Appendix M-I-C-4 for human gene transfer research reporting requirements](#)).
  9. Enroll in the Occupational Health Surveillance System and ensure compliance with the Occupational Health Physician's health surveillance recommendations associated with activities authorized by the IBC.
  10. Ensure that all biological safety cabinets are certified under National Sanitation Foundation/American National Standards Institute Standard 49 at the time of installation,

annually, after repairs, or when a cabinet has been moved (See [Biological Safety Cabinet use](#)).

11. Verify that laboratory HVAC HEPA filters are certified by the vendor before working in a laboratory, when a filter is replaced or repaired, and on an annual basis.

G. Employees, students, postdoctoral fellows, and volunteers

- a. Become familiar with the project and its associated potential hazards as directed by the PI.
- b. Follow the safety procedures outlined in the BUA and in training provided by the PI or laboratory instructor.
- c. Use provided safety equipment.
- d. Report unsafe or hazardous situations immediately to the supervisor, PI, or Environmental Health and Safety (EH&S).
- e. Enroll in the Occupational Health Surveillance System and follow the recommendations of the Occupational or Student Health Physician.
- f. Participate in required safety training.
- g. Follow campus [medical waste](#) and [hazardous waste](#) disposal procedures.

H. Occupational Health Physician

1. Serves as an *ex officio* member of the IBC.
2. Provides the appropriate level of health surveillance to employees associated with projects involving biological hazards.
3. Consults with the Student Health Physician regarding appropriate medical surveillance of students involved in work with biological hazards.

I. Student Health Physician

1. Consults with the Occupational Health Physician regarding appropriate medical surveillance of students involved in work with biological hazards.
2. Provides health surveillance of students associated with projects involving biological hazards.

J. Attending Veterinarian

1. Serves as an *ex officio* member of the IBC
2. Works with the IBC and the Biological Safety Officer to ensure that animal facilities and containment practices meet standards set in BMBL, NIH Guidelines, and other biological safety standards.

K. IACUC

1. Collaborates with the IBC to ensure that animal care staff and other personnel receive the information necessary to work safely with animals used in research or other activities involving biological hazards.
2. Refers ACUPs that involve biological hazards to the Biological Safety Office for review and confirmation that the PI has complied with BUA requirements.

- a. IACUC approval of any ACUP involving biological hazards is contingent on IBC approval of the corresponding BUA.
- L. Institutional Review Board (IRB)
1. Forwards human subjects research protocols that involve human gene transfer or recombinant vaccine trials to the IBC for approval of a corresponding BUA prior to approval by the IRB.
  2. Refers any human subjects research protocol that involves the use of or exposure to biological hazards on the part of the human subjects or the research or clinical staff to the IBC for evaluation and potential approval of a corresponding BUA application prior to approval by the IRB.
- M. Office of Research, Sponsored Programs (SP)
- Refers research proposals that involve biological hazards to the Biological Safety Office for review and confirmation that the PI has complied with BUA requirements before release of the related research awards or funds.
- N. Design and Construction Management
1. Consults with the Biological Safety Officer for concurrence regarding the development of campus design standards for facilities where biological hazards will be used.
  2. Consults with the Biological Safety Officer whenever a new BSL3 laboratory is proposed for development or an existing BSL3 laboratory is proposed for upgrade or remodel.
  3. Obtains Biological Safety Officer approval for specific BSL3 laboratory project design and construction specifications.
  4. Retains third party containment laboratory commissioning services for the design and construction of all BSL3 and related high containment laboratories.
- O. Facilities Management
1. Ensures that all HVAC HEPA filters are tested and certified at the time of installation, annually, and when the filters are replaced or repaired.
  2. Works with the Biological Safety Officer on maintenance and annual shutdown and reverification of BSL3 laboratory facilities.

## VI. Further Information

BUA forms and additional information on biological safety standards and IBC procedures are available on the Safety Services website, [Biological Safety section](#).

## VII. References and Related Policies

- A. UC Office of the President:
1. [Contract and Grant Manual Section 3-400](#), University Policy on Biohazards and Recombinant DNA.
  2. [University Policy on Management of Health, Safety, and the Environment](#).
- B. Federal Guidelines and Regulations:
1. [National Institutes of Health Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules](#), 2013 or later revision.

2. [CDC/NIH Biosafety in Microbiological and Biomedical Laboratories \(BMBL\), 5<sup>th</sup>](#) or later edition (2007).
  3. Select agent regulations [42 CFR §73](#), [7 CFR §331](#), and [9 CFR §121](#).
  4. [USDA Biotechnology Guidelines](#), and [7 CFR §340.0 – 340.8](#) [7 CFR §330.200-300](#)).
- C. California State Regulations
1. Cal-OSHA Standards [5193](#) (Bloodborne Pathogens), [5199](#) (Aerosol Transmissible Diseases), and [5199.1](#) (Zoonotic Aerosol Transmissible Diseases).
  2. [California Medical Waste Management Act](#) (California Department of Public Health).
- D. UC Davis Policy and Procedure Manual:
1. [Section 220-03](#), Anatomical Specimens.
  2. [Section 290-15](#), Safety Management Program.
  3. [Section 290-25](#), Health Services for Individuals Having Animal Contact.
  4. [Section 290-27](#), Hazardous Substances Communication Program.
  5. [Section 290-30](#), Use and Care of Animals in Research and Teaching.
  6. [Section 290-35](#), Environmental Protection.
  7. [Section 290-50](#), Protective Clothing and Equipment.
  8. [Section 290-60](#), Occupational and Preventive Medicine.