High-Containment Research Policy

Responsible Officer:	Chief Risk Officer
Responsible Office:	RK - Risk / EH&S
Issuance Date:	
Effective Date:	
Last Review Date:	
Scope:	All High-Containment Laboratories and Research activities at all University-owned, -operated and/or leased locations.

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I. POLICY SUMMARY

This Policy outlines the University of California's (UC) requirements for overseeing and operating High-Containment Laboratories. It sets the minimum standards for the design,

construction, operation, maintenance, training, and oversight of these laboratories. The Policy specifies biosafety and Laboratory Biosecurity practices necessary for the effective management of High-Containment Laboratories.

The Policy provides guidance for all High-Containment Research activities, including how to work safely and protect public health and the environment while fulfilling all relevant regulations and guidelines.

II. DEFINITIONS

Biosafety: The use of specific practices, procedures, safety equipment, specialized facilities to help protect workers, the community and the environment from accidental exposure or unintentional release of infectious agents, toxins or other biological hazards.

Biosafety Level 3 (BSL-3): see High-Containment Laboratory.

Biosafety Officer: A designated employee at each UC Location that serves as an administrative official and oversees the use of recombinant or synthetic nucleic acid molecule research in High-Containment Laboratories as described by the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*. This individual reviews proposed use of biological materials in High-Containment Laboratories.

Export Control Officer: The position at each UC Location designated to be responsible for export control oversight.

High-Containment Laboratory Oversight Group (HCLOG): The committee at each UC Location that operates High-Containment Laboratories and is responsible for providing High-Containment Laboratory oversight and guidance at that location.

High-Containment Laboratory: A specialized laboratory designed and operated to safely conduct research with Risk Group 3 infectious materials and other biological materials that require High-Containment. These facilities achieve a designated level of containment through a combination of administrative controls, work practices and procedures, safety equipment, and facility features. High-Containment Laboratories include facilities with the following containment designation: General Biosafety Level 3 (BSL-3), Animal Biosafety Level 3 (ABSL-3), Large Animal Biosafety Level 3 (ABSL-3Ag), Plant Biosafety Level 3 (BSL-3P), and Arthropod Containment Level 3 (ACL-3). Collectively, these are referred to as High-Containment Laboratories, BSL-3 laboratories, or BSL-3 facilities.

High-Containment Laboratory Director (HCLD): A designated employee at each UC Location that serves as the UC Location administrative official and oversees the High-Containment Laboratories, which includes all operations, maintenance and provision of training. The title may vary at UC Locations, but the responsibilities remain the same.

High-Containment Laboratory Management Plan (HCL Plan): The plan developed at each UC Location that details the High-Containment Laboratory management and operations (outlined below in the Procedures section).

High-Containment Laboratory Oversight Program (HCL Program): The collection of

activities at a UC Location used to manage High-Containment Laboratories. The HCL Program includes the HCLOG, HCLD and HCL Plan.

High-Containment Research: Research with biological materials that are designated to be conducted in a High-Containment Laboratory.

Institutional Animal Care and Use Committee (IACUC): The oversight committee at each UC Location which is responsible for the proper care, use and treatment of laboratory animals used in research, including High-Containment Research.

Institutional Biosafety Committee (IBC): The committee at each UC Location which is responsible for reviewing and approving work with infectious agents and recombinant materials, including proposed work to be conducted in High-Containment Laboratories.

Institutional Review Entity (IRE): A committee at each UC Location that provides oversight as described in the United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential.

Laboratory Biosecurity: The protection, control, and accountability of biological agents, toxins, and research related information within laboratories to prevent unauthorized possession, loss, theft, misuse, diversion, or intentional release of these materials. This program encompasses measures for personnel suitability, information security, and physical security to ensure that biological materials and information are handled safely and responsibly.

Principal Investigator: An individual who is designated by the UC Location to direct a project or program and who is responsible to the funding agency and/or UC for the scientific and technical direction of that project or program.

Responsible Official for Select Agents and Toxins (RO): The individual designated to ensure compliance with the Select Agent regulations (42 CFR Part 73, 9 CFR Part 121, and 7 CFR Part 331). The RO has the authority and responsibility to act on behalf of the entity, overseeing all activities involving Select Agents and/or Toxins.

Risk Group 3 Infectious Material (RG3): Pathogens associated with serious or lethal disease often transmitted through the respiratory route for which preventive or therapeutic interventions may be available.

Select Agents and/or Toxins: Biological agents and/or toxins that have the potential to pose a severe threat to public health, animal health, plant health, or animal and plant products. These agents and toxins are regulated by the U.S. Government (42 CFR Part 73, 9 CFR Part 121, and 7 CFR Part 331) to ensure safe handling and to prevent misuse.

UC High-Containment Laboratory Oversight Committee (UC HCLOC): The systemwide committee that provides overall coordination and oversight of High-Containment Laboratory management practices.

University of California Location (UC Location): All UC campuses, health locations, Lawrence Berkeley National Laboratory (LBNL), Agriculture and Natural Resources (ANR),

Natural Reserve System (NRS), and any other UC-owned or -operated laboratories, including arrangements in which UC is either the lessor or lessee.

III. POLICY TEXT

A. Each UC Location must implement a HCL Program that facilitates the long-term management of High-Containment Laboratories. The use of these laboratories is essential to the UC's teaching, research, and healthcare mission for research on a wide array of human, animal, and plant pathogens and toxins. This research facilitates a fundamental understanding of pathogens and the diseases they cause, which is essential for evaluating and developing countermeasures against emerging infectious diseases that threaten public health and agriculture. This Policy requires all High-Containment Research is conducted safely and adheres to all relevant regulations and guidelines.

B. UC Locations that operate, build, maintain or conduct research in High-Containment Laboratories must abide by all UC BSL-3 standards approved by the UC HCLOC and all UC requirements, standards and policies.

C. The HCL Program must be designed to conform with the specific elements outlined in VI. Procedures, below, which includes the following:

   a. Establishment of a HCLOG;

   b. Designation of a HCLD; and

   c. Development of a HCL Plan.

D. Non-UC personnel that work or visit UC High-Containment Laboratories must comply with all UC policies and standards.

IV. COMPLIANCE/RESPONSIBILITIES

A. The Office of the President, Office of Risk Services is responsible for sponsoring and providing administrative support to the systemwide UC High-Containment Laboratory Oversight Committee (UC HCLOC).

B. The UC High-Containment Laboratory Oversight Committee (UC HCLOC) is responsible for:

   a. maintaining and updating this Policy;

   b. providing oversight of UC's High-Containment Laboratory management practices;

   c. establishing and reviewing High-Containment Laboratory Biosafety and Laboratory Biosecurity best practices to guide UC High-Containment Laboratory policies and standards;

   d. providing oversight of the interpretation and assessing effective implementation of this Policy at UC Locations;

   e. ensuring that UC Locations that operate High-Containment Laboratories receive policies and guidance for the safe operation of such;

f. reviewing annual UC Location HCLOG reports;

g. preparing a triennial report on High-Containment Laboratory management practices submitted to the UC President; and

h. enforcing this Policy.

C. Chancellors, Health System Chief Executive Officers, the Vice President of Agriculture and Natural Resources, the Executive Director of the Natural Reserve System, and the Director of Lawrence Berkeley National Laboratory are responsible for:

a. overall local implementation of this Policy;

b. establishing a HCL Program;

c. forming a HCLOG; and

d. designate a HCLD.

D. High-Containment Laboratory Oversight Groups (HCLOGs) are responsible for:

a. reviewing UC Location High-Containment Research activities for compliance with this Policy;

b. ensuring the development and implementation of UC Location High-Containment Research and Laboratory policies and procedures;

c. having the authority to halt research in High-Containment Laboratories, in consultation with the HCLD, when necessary;

d. establishing a local HCLOG charter that includes the specific duties of the committee;

e. approving UC Location HCL Plan; and

f. submitting annual High-Containment Laboratory compliance report to UC HCLOC.

E. HCLD is responsible for:

a. overseeing all aspects of the UC Location High-Containment Laboratory operations and management;

b. developing and maintaining UC Location HCL Plan;

c. coordinating with UC Location compliance groups and/or individuals, including but not limited to IBC, IRE, IACUC, HCLOG, RO, BSO, and/or Export Control, based on the ongoing activities of the High-Containment Laboratories;

d. reviewing proposed research and providing Biosafety and Laboratory Biosecurity recommendations for High-Containment Research to UC Location compliance committees, such as IBC, IRE and/or IACUC; and

e. maintaining a record of High-Containment Laboratory operations.

F. Responsible Official for Select Agents and Toxins is responsible for:

a. overseeing all work with Select Agents and/or Toxins at the UC Location; and

b. coordinating with HCLD on research with Select Agents and/or Toxins that occurs in High-Containment Laboratories.

G. Biosafety Officer is responsible for:

a. reviewing proposed research with biological materials and/or Recombinant or Synthetic Nucleic Acid Molecules at the UC Location; and

b. coordinating with HCLD on research that occurs in High-Containment Laboratories.

H. UC Location IACUC is responsible for:

a. reviewing and approving research with laboratory animals conducted in High-Containment Laboratories.

I. UC Location IBC is responsible for:

a. reviewing and approving all applicable High-Containment Research protocols;

b. establishing appropriate biosafety levels and risk reduction measures; and

c. verifying appropriate High-Containment Laboratories are available for the proposed scope of research before the initiation of experiments.

J. UC Location IRE is responsible for:

a. assessing proposed High-Containment Research to determine if it falls within the scope of the United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential;

b. evaluating the risks and benefits of the proposed research; and

c. reviewing the risk mitigation plan for the safe and responsible conduct of High-Containment Research, if applicable.

K. Principal Investigators using High-Containment Laboratories are responsible for:

a. obtaining all proper approvals before the initiation of High-Containment Research;

b. maintaining an inventory of their pathogens in the High-Containment Laboratory;

c. immediately reporting any accident that results in a potential exposure, injury/illness, or property damage to the HCLD and/or other appropriate institutional officials (e.g. the HCLOG, RO, Occupational Health Physician, etc.); and

d. requiring all staff under their supervision who use High-Containment Laboratories to comply with applicable standards, policies, and procedures.

L. Laboratory and/or Animal Care Supervisors overseeing personnel in High-Containment Laboratories are responsible for:

a. immediately reporting any accident that results in a potential exposure, injury/illness or property damage to the HCLD and/or other appropriate institutional officials ((e.g. the HCLOG, RO, Occupational Health Physician, etc.); and

b. ensuring all staff under their supervision who use High-Containment Laboratories comply with applicable standards, policies, and procedures.

V. PROCEDURES

A. Systemwide High-Containment Oversight

a. All High-Containment Laboratories must be operated in accordance with all applicable laws, regulations, and requirements.

b. The Office of the President, Office of Risk Services facilitates the UC HCLOC following the UC HCLOC charter to establish High-Containment Laboratory policies, standards and guidance. If a local HCLOG needs to escalate a High-Containment Laboratory concern or request guidance, it should bring the matter to the UC HCLOC. This requirement attempts to maintain consistency in practices across the High-Containment Laboratories and to provide a conduit for sharing High-Containment Laboratory- and Research-related information with the Office of the President.

c. Plans to construct a new High-Containment Laboratory must be reported to the UC HCLOC during the design and construction phase of the project.

d. All High-Containment Laboratories must be identified within the scope of the annual reports from the HCLOGs.

B. UC Location High-Containment Laboratory Oversight Program (HCL Program)

a. Each UC Location is responsible for developing and maintaining a HCL Program.

b. UC Locations must solicit stakeholder engagement in the HCL Program development and revision process.

c. UC Locations must have individuals with expert knowledge of High-Containment Laboratories and Research serving on compliance groups (e.g., IACUC, IBC, IRE, HCLOG and Select Agent program), to review High-Containment Research proposals. A risk assessment for each project must be documented and maintained per the UC Records Retention and Disposition Policy.

d. UC Locations must establish a sustainable mechanism to support the ongoing operation and maintenance needs of High-Containment Laboratories, including procedures for rapid resource distribution during emergencies. UC Locations must have procedures for distribution of resources during emergencies affecting High-Containment Laboratories.

e. HCL Programs must include the following elements:

i. High-Containment Laboratory Oversight Group (HCLOG)

1. UC Locations must maintain a HCLOG, which acts as the local authority for it's High-Containment Laboratories. The committee is responsible for overseeing the management, operations, preventative maintenance, emergency management, testing and verification of and provide training for personnel associated

with existing, new and renovated High-Containment Laboratories.

2. HCLOGs must include technical and/or faculty experts and staff responsible for High-Containment Laboratories and Research.
3. A faculty member must chair the HCLOG..
4. The HCLOG must include the HCLD.
5. Additional membership may be drawn from units such as Facilities Management, Environmental Health & Safety, Occupational Health, Police, Finance, Research, Export Control, Information Technology, Planning and Administration. UC Locations may designate an existing committee to serve this function, if it includes representation from the relevant areas as specified.

ii. High-Containment Laboratory Director (HCLD)

1. Each UC Location must designate a HCLD. The staff hours dedicated to this position should be commensurate with the size of the High-Containment Research program at the UC Location.
2. The designee must be properly qualified and trained in High-Containment Laboratory operations.
3. The HCLD must develop and implement policies and/or procedures for the UC Location High-Containment Laboratories.
4. The HCLD must implement and maintain the HCL Plan.
5. The HCLD oversees High-Containment Laboratory design, construction, maintenance, certification, performance verification, and training.

iii. High-Containment Laboratory Management Plan (HCL Plan)

1. The HCL Plan may apply to all High-Containment Laboratories at a UC Location or separate plans may be developed for individual High-Containment Laboratories.
2. The HCL Plan must consider the safety and protection of UC students, staff, visitors, community, and environment.
3. The HCL Plan must be available to all High-Containment Laboratory-associated personnel groups.
4. HCL Plans must include the following components
    a. Roles and responsibilities of all High-Containment Laboratory-associated personnel groups
    b. Laboratory risk assessments with established review criteria

c. Biosafety including identification of practices, procedures, safety equipment, and specialized biocontainment facilities

d. Laboratory Biosecurity

e. Facility operations & maintenance

f. Occupational health requirements for High-Containment Laboratory access and medical surveillance

g. Incident response and reporting

h. Training requirements

5. The HCL Plan may be a collection of UC Location documents and must collectively contain the required information.

C. Annual HCL Program Report

a. HCLOGs must prepare an annual report on UC Location High-Containment Laboratory activities to be submitted to the UC HCLOC. The report will summarize the status of the UC Location HCL Program, including but not limited to:

i. Designated HCLD

ii. HCLOG Activities

iii. RG3 agents being researched or stored at the UC Location

iv. Biological materials that are identified to be handled in a High-Containment Laboratory at the UC Location

v. High-Containment Laboratories: new, renovated, operational, inactive, and decommissioned

vi. High-Containment Research overview

vii. Number of personnel trained by roles identified in the HCL Plan

viii. Incidents

ix. Any additional information requested by the UC HCLOC

b. The UC HCLOC reviews the annual UC Location HCL Program reports.

c. The UC HCLOC prepares a triennial report which summarizes High-Containment Laboratory and Research activities to be submitted to the UC Office of the President.

VI. RELATED INFORMATION

Biosafety in Microbiological and Biomedical Laboratories (BMBL) Current Edition

United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with enhanced Pandemic Potential

UC ABSL-3 Laboratory Design Standards

UC BSL-3 Laboratory Design Standards

UC BSL-3 Training Standards

UC HCLOC Charter

UC Policy BDB-RMP-2: Records Retention and Disposition: Principles, Processes, and Guidelines

UC Policy: Dual Use Research of Concern

UC Policy on Export Control

UC Policy: Use of Animals in Research and Teaching

VII. FREQUENTLY ASKED QUESTIONS

Not applicable.

VIII. REVISION HISTORY

This is a new Policy that complies with the Web Content Accessibility Guidelines (WCAG) 2.0.