
UCLA Policy 992: Use of Biohazardous Materials and Recombinant or Synthetic Nucleic Acid Molecules in Research and Teaching Activities

Issuing Officer: Vice Chancellor for Research and Creative Activities

Responsible Dept: Research Policy & Compliance

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I. PURPOSE & SCOPE

As a recipient of National Institute of Health (NIH) support for research involving Recombinant or Synthetic Nucleic Acid Molecules, UCLA must comply with the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)*. All activities involving the use of Recombinant or Synthetic Nucleic Acid Molecules conducted at or sponsored by UCLA must comply with the NIH Guidelines irrespective of the source of funding.

UCLA is further required to ensure that research and teaching activities conducted at or sponsored by UCLA that involve the use of Biohazardous Materials, comply with all applicable federal, state, and local regulations and industry standards. This includes but is not limited to, the Center for Disease Control and Prevention (CDC) *Biosafety in Microbiological and Biomedical Laboratories (BMBL)*, the Federal Select Agent Program (FSAP) Regulations, the California Division of Occupational Safety and Health (known as Cal/OSHA) Bloodborne Pathogen (BBP) Standard, and the Cal/OSHA Aerosol Transmissible Disease (ATD) Standard. These requirements apply regardless of the funding source.

This Policy outlines the shared roles and responsibilities of the individuals, offices, and committees responsible for ensuring compliance with all appropriate regulations and guidelines covering Biohazardous Materials and Recombinant or Synthetic Nucleic Acid Molecules.

II. DEFINITIONS

For the purposes of this Policy:

Biohazardous Material is an agent of biological origin that has the capacity to produce harmful effects in healthy individuals, animals, or plants. This may include a) infectious agents (e.g., bacteria, fungi, parasites, prions, viruses) that can cause disease in healthy humans and/or significant environmental or agricultural impact; b) human or nonhuman primate tissues, fluids, cells, or cell cultures; c) animals or animal specimens known to be vectors/reservoirs of zoonotic diseases; and d) Select Agents and Toxins identified by the Federal Select Agent Program (FSAP).

Institutional Biosafety Committee (IBC) is the local review body responsible for oversight of all research and teaching activities involving the use of Biohazardous Materials and Recombinant/Synthetic Nucleic Acid Molecules.

Principal Investigator (PI) is a UCLA employee (normally an academic appointee) who has primary responsibility for the scientific and technical conduct, reporting, fiscal, and programmatic administration of a research or teaching Project. The PI performs and/or oversees activities that utilize or produce Biohazardous Materials and/or Recombinant or Synthetic Nucleic Acid Molecules. Criteria for PI eligibility and exceptions to the requirements are defined in UCLA Policy 900.

Project means research or teaching activities involving the use, transfer, storage, shipping, and/or disposal of Biohazardous Materials and/or Recombinant or Synthetic Nucleic Acid Molecules.

Recombinant or Synthetic Nucleic Acid Molecules (r/sNAs) are (i) molecules that a) are constructed by joining nucleic acid molecules and b) that can replicate in a living cell (i.e., recombinant nucleic acids); (ii) nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base-pair with naturally occurring nucleic acid molecules (i.e., synthetic nucleic acids); or (iii) molecules that result from the replication of those described in (i) or (ii) above.

Select Agents and Toxins are a subset of biological agents and toxins that the federal Department of Health and Human Services (HHS) and Agriculture (USDA) have determined to have the potential to pose a severe threat to public health and safety, to animal or plant health, or to animal or plant products. The possession, use, and transfer of Select Agents and Toxins are strictly regulated by the FSAP, which comprises the CDC Division of Select Agents and Toxins (CDC DSAT) and the Animal and Plant Health Inspection Services (APHIS) Agricultural Select Agent Program.

Significant Incidents or Events that occur in a research or teaching environment include, but are not limited to:

- any exposure of individuals to Biohazardous Materials or r/sNAs; or
- any illness or injury resulting from exposure to Biohazardous Materials or r/sNAs; or
- known or potential loss of containment, and any release of Biohazardous Materials or r/sNAs into the environment; or
- all problems (identified limitations or failures) pertaining to implementation of safety procedures, operation of safety equipment, operation of HVAC systems, or facility security; and
- suspected or alleged violations of protocols, external regulations, or University policies that involve materials covered by this Policy.

III. POLICY STATEMENT

The UCLA Institutional Biosafety Committee (IBC) was established to review applications for use of biohazardous materials in research and teaching activities to ensure that proposed work adheres to all appropriate regulations and guidelines covering Biohazardous Materials and r/sNAs. The IBC has oversight of academic research and teaching activities that include the use of Biohazardous Materials and r/sNAs conducted at or sponsored by UCLA. The EH&S Biosafety Office oversees the day-to-day operations of the EH&S Biosafety Program, which is responsible for ensuring compliance with applicable safety regulations and standards, and implements IBC policies and practices.

The IBC has established policies and procedures to ensure that all research and teaching Projects involving Biohazardous Materials and r/sNAs, conducted at UCLA or within UCLA facilities, are conducted safely and comply with all applicable federal, state, and local regulations and guidelines. These policies and procedures are available on the [IBC website](#).

The use of Biohazardous Materials requiring containment and facilities assigned as Biosafety Level 4 (BSL-4) by the *NIH Guidelines*, *CDC BMBL*, or other recognized public health classification (e.g., World Health Organization) is not allowed at the UCLA campus.

A. Institutional Biosafety Committee (IBC)

The IBC is a faculty-led committee that advises the Vice Chancellor for Research and Creative Activities (VCR) on all matters relating to academic research and teaching activities involving Biohazardous Materials and r/sNAs, including use, storage, transport, and/or disposal.

The IBC membership consists of experts in various fields, including biosafety, human gene transfer, infectious diseases, r/sNAs, animal containment, and plant containment.

The IBC reviews and approves biological use applications (BUAs), as well as institutional policies and procedures, for academic research and teaching activities involving the following materials:

- r/sNAs, as covered by the *NIH Guidelines*. This includes genetically modified organisms, animals, insects, whole plants, and clinical research studies that involve the deliberate transfer of r/sNAs into human research participants.
- Infectious agents (e.g., bacteria, viruses, fungi, parasites, and prions) that can cause disease in healthy humans and/or significant environmental or agricultural impacts
- Select Agents and Toxins
- Human and nonhuman primate materials (all fluids, tissues, excretions, secretions, cells, or cell cultures)

The IBC only reviews clinical research studies if they include any of the following:

- Work with r/sNAs, as described by the *NIH Guidelines*.
- An academic research laboratory component.
- Hazards or risks above the clinical standards typically managed by UCLA Health Infection Control, ATD, and BBP programs.

At its discretion, the IBC may also review BUAs involving:

- Animals or animal specimens known to be reservoirs/vectors of zoonotic diseases
- Arthropods, parasites, and other organisms that cause disease in humans, animals, plants, or serve as vectors of disease transmission
- Exotic and/or invasive plant species

B. Responsibilities

The IBC, IBC administrative staff, EH&S Biosafety Office, PIs, and research teams work together to ensure that all research and teaching activities conducted at or sponsored by UCLA involving Biohazardous Materials and r/sNAs as defined above are compliant with the standards contained in the *NIH Guidelines*, *BMBL*, and applicable federal, state, and local regulations. Responsibilities are fully delineated in [The UCLA Institutional Biosafety Plan](#).

In addition to ensuring compliance with this Policy and all appropriate guidelines and regulations, the following individuals, offices, and committees are responsible for:

1. The IBC is responsible for establishing, monitoring, and enforcing policies and procedures related to the use of Biohazardous Materials and r/sNAs, and for conducting risk assessments and evaluating proposed containment/mitigation measures for Projects involving these materials. Through the aforementioned activities, the IBC determines the level of acceptable biological risk for UCLA.
2. IBC administrative staff provide support to the IBC, communicate IBC decisions to investigators, and ensure timely submission of annual and incident reporting to the NIH Office of Science Policy.

3. The EH&S Biosafety Office ensures compliance with applicable safety regulations and standards and implements IBC policies. Staff of the EH&S Biosafety Office provide subject-matter expertise and consults with the campus research and teaching communities, compliance offices and committees, and support staff on issues such as safety/mitigation measures, appropriate containment based on agent risk level, the use of Personal Protective Equipment (PPE), and best practices.
4. The PI is responsible for compliance with all applicable University policies and government regulations and guidelines to oversee Project(s). These responsibilities extend to all aspects of biosafety and basic laboratory safety for all individuals who enter or work in the PI's laboratory, clinic, or classroom, or are involved in activities that fall under the PI's BUA.

The PI's responsibilities include, but are not limited to:

- a) Maintaining an active and approved BUA(s) that describes all current Projects under the PI's purview and ensures that:
 - Amendments to previously approved Projects are submitted and approved prior to implementing changes in materials, procedures, personnel, locations, or documents
 - Lapses in BUA approval status are prevented for ongoing Projects
 - The PI or another responsible faculty member will be available on-site to oversee Project work occurring at BSL2 containment or higher
- b) Making available to all laboratory staff the protocols that describe potential biohazards and precautions to be taken. Ensuring all personnel under their oversight are adequately trained and knowledgeable about:
 - Good microbiological techniques, when applicable
 - Agent-specific hazards and applicable occupational health considerations
 - Safety practices
 - Emergency plans (e.g., for accidental spills and personnel contamination)
 - Transport and disposal procedures
 - Reporting requirements
- c) Ensuring that reports listed below, and any corresponding update to the BUA, are submitted immediately to EH&S Biosafety:
 - Any Significant Incidents or Events as defined in this Policy
 - Any new information relating to the Project that impacts the risk assessment or containment level of the Project, or bears on compliance with the *NIH Guidelines* or other applicable rules or regulations

C. Non-Compliance

Failure to comply with applicable University rules or federal or state regulations or guidelines related to the use of Biohazardous Agents and r/sNAs may result in suspension of IBC approval and limitation or termination of funding for the non-compliant Project, and/or termination of NIH funds for other research at UCLA involving Biohazardous Materials and r/sNAs.

The EH&S Biosafety Office, acting on behalf of the IBC, has the authority to immediately and temporarily suspend the conduct of specific research, teaching, or other activities and/or limit access of individuals to specific Biohazardous Materials or facilities in cases where there is (a) violation of UCLA's established biosafety practices and procedures, University rules, including this Policy, and/or applicable regulations and guidelines, or (b) a significant risk to safety and/or a threatened or actual environmental release. All Significant Incidents or Events leading to the suspension of Projects or access must immediately be reported to the IBC Chairperson for full committee review of the continuation or

termination of the suspension. The IBC has the authority to continue the suspension until the conditions leading to the suspension have been resolved.

The IBC has the authority to impose disciplinary measures for any failures to follow the *NIH Guidelines*, policies, and regulations described here, as well as observed practices that are not consistent with UCLA's established biosafety practices and procedures, including non-compliance with applicable regulations and guidelines. Sanctions will be determined by the IBC on a case-by-case basis. The PI of the Project will have an opportunity to respond to any potential violations and to propose applicable corrections.

IV. REFERENCES

1. Department of Health and Human Services, National Institute of Health: Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules ([NIH Guidelines](#), the most current version).
2. [Biosafety in Microbiological and Biomedical Laboratories \(BMBL\)](#) by CDC and NIH, Department of Health and Human Services (current version)
3. Department of Human and Health Services (HHS): [Possession, Use, and Transfer of Select Agents and Toxins, Final Rule \(42 CFR 73\)](#)
4. Department of Agriculture (USDA): Agricultural Bioterrorism Protection Act of 2002: [Possession, Use, and Transfer of Biological Agents and Toxins; Final Rule \(9 CFR 121, 7 CFR 331\)](#)
5. Department of Labor Regulations 29 Code of Federal Regulations, Part 1910, Subpart J - [Occupational Safety and Health Standards, General Environmental Controls](#)
6. California Code of Regulations, Title 7, General Industry Safety Orders, Group 16. [Control of Hazardous Substances, Article 109. Hazardous Substances and Processes, § 5193. Bloodborne Pathogens](#)
7. California Code of Regulations, Title 7, General Industry Safety Orders, Group 16. [Control of Hazardous Substances, Article 109. Hazardous Substances and Processes, § 5199. Aerosol Transmissible Diseases](#)
8. [UCLA Policy 811](#), Environmental Health and Safety
9. [UCLA Policy 905](#), Research Laboratory Personal Safety and Protective Equipment
10. [Medical Waste Management Act: The CA Health and Safety Code, sections 117600 – 118360](#) (Division 104, Part 14 California Health and Safety Code)
11. Department of Transportation 49 Code of Federal Regulation Parts 171, 172, 173, 175 Hazardous Materials: Infectious Substances, Harmonization with United Nations Recommendations (current version)
12. National Research Council: [Occupational Health and Safety in the Care and Use of Research Animals](#)
13. National Research Council: [Occupational Health and Safety in the Care and Use of Nonhuman Primates](#)
14. [UCLA Institutional Biosafety Committee Policies and Guidance](#)
15. Federal Select Agent Program Select Agents and Toxins List: <https://www.selectagents.gov/SelectAgentsandToxinsList.html>

Issuing Officer

Roger Wakimoto
Vice Chancellor Research & Creative Activities

**Questions concerning this policy or procedure should be referred to
the Responsible Department listed at the top of this document.**
