I. PURPOSE AND SCOPE

Institutions that receive National Institute of Health (NIH) support for research involving Recombinant or Synthetic Nucleic Acid Molecules must comply with the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*), unless such research is specifically designated as exempt. As UCLA receives NIH support for research that falls under the purview of the *NIH Guidelines*, it is required to ensure that all activities involving the use of Recombinant or Synthetic Nucleic Acid Molecules conducted at or sponsored by UCLA, irrespective of the source of funding, comply with the *NIH Guidelines*.

UCLA is further required to ensure that research and teaching activities involving the use of Biohazardous Materials that are conducted at or sponsored by UCLA, irrespective of the source of funding, comply with all applicable federal, State, and local regulations and industry standards including, but not limited to, the Center for Disease Control and Prevention (CDC)/NIH *Biosafety in Microbiological and Biomedical Laboratories* (*BMBL*), Departments of Health and Human Services and Agriculture (HHS/USDA) Select Agents and Toxins 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.

This Policy outlines the roles and responsibilities of the individuals, offices, and committees that are responsible for ensuring that all appropriate regulations and guidelines covering Biohazardous Materials and Recombinant or Synthetic Nucleic Acid Molecules are adhered to and outlines the authority to impose disciplinary measures for non-compliance.

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 Toxins.
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 or Synthetic Nucleic Acid Molecules, as required and outlined in the NIH Guidelines and the BMBL.

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/Synthetic Nucleic Acid Molecules.

Recombinant or Synthetic Nucleic Acid Molecules 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 HHS and 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 current list of Select Agents and Toxins can be found at https://www.selectagents.gov/SelectAgentsandToxinsList.html. The possession, use, and transfer of Select Agents and Toxins are strictly regulated by the Federal Select Agent Program, 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 include, but are not limited to (i) all accidents that result in a) exposure of individuals to Biohazardous Materials and/or Recombinant or Synthetic Nucleic Acid Molecules, b) an illness, or c) known or potential loss of containment; (ii) all problems (identified limitations or failures) pertaining to implementation of safety procedures, operation of safety equipment, operation of HVAC systems, or facility security; and (iii) suspected or alleged violations of protocols, external regulations, or University policies that involve materials covered by this Policy.

III. STATEMENT

UCLA has established an Institutional Biosafety Committee (IBC) to ensure that campus investigators adhere to all appropriate regulations and guidelines covering Biohazardous Materials and Recombinant or Synthetic Nucleic Acid Molecules. The IBC has oversight of research and teaching activities that include the use of Biohazardous Materials and Recombinant or Synthetic Nucleic Acid Molecules conducted at or sponsored by UCLA; the EH&S Biosafety Office oversees the day-to-day operations of the EH&S Biosafety Program in support of the IBC.

Policies and procedures have been established and implemented at UCLA to ensure that all research and teaching Projects involving Biohazardous Materials and/or Recombinant or Synthetic Nucleic Acid Molecules are conducted safely and comply with all applicable federal, state, and local regulations and guidelines. These policies and guidelines are available on the IBC website: http://ora.research.ucla.edu/RSAWA/IBC/Pages/index.aspx.

A. Institutional Biosafety Committee (IBC)

The IBC is an advisory committee that reports to the Vice Chancellor for Research (VCR) on all matters relating to research and teaching activities involving Biohazardous Materials and
Recombinant or Synthetic Nucleic Acid Molecules, including use, storage, transport, and/or disposal.

The IBC is a faculty-led committee and consists of experts in various fields, including biosafety, human gene transfer, infectious diseases, Recombinant or Synthetic Nucleic Acid Molecules, animal containment, plant containment, and occupational health.

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:

- Recombinant or Synthetic Nucleic Acid Molecules, including genetically modified animals and whole plants, as covered by the *NIH Guidelines*
- 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)

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

- Animals or animal specimens known to be reservoirs/vectors of zoonotic diseases
- Exotic and/or invasive plant species

The use of Biohazardous Materials requiring BSL-4 containment by the *NIH Guidelines* or other recognized public health classification (e.g., World Health Organization) is not reviewed by the IBC, as such agents require specific containment, practices, and security requirements not available at the UCLA campus.

The IBC receives administrative support from the IBC administrative staff in the Research Safety & Animal Welfare Administration (RSAWA). The EH&S Biosafety Office reports to the Assistant Vice Chancellor – Environment, Health & Safety.

**B. Responsibilities**

Compliance is a shared responsibility. The IBC, RSAWA, EH&S Biosafety Office, PIs, and research teams work together to ensure that all research and teaching activities conducted at or funded by UCLA involving Biohazardous Materials and/or Recombinant or Synthetic Nucleic Acid Molecules 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 (https://ucla.app.box.com/v/UCLA-Biosafety-Plan).

In addition to ensuring compliance with this Policy and all appropriate guidelines, laws, and regulations, the following individuals, offices, and committees have the following responsibilities:

1. **The IBC** is responsible for establishing, monitoring, and enforcing policies and procedures involving Biohazardous Materials and Recombinant or Synthetic Nucleic Acid Molecules and for conducting risk assessments and evaluating proposed containment/mitigation measures for Project proposals involving Biohazardous Materials and/or Recombinant or Synthetic Nucleic Acid Molecules. Through the aforementioned activities, the IBC determines the level of acceptable biological risk for UCLA.

2. **The RSAWA** is responsible for 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 and practices. The EH&S Biosafety Office provides subject-matter expertise in consultation on risk assessments and best practices with the UCLA research and teaching communities, compliance offices and committees, and UCLA staff.

4. The PI is responsible for full compliance with University policies and all government regulations and guidelines as applicable to overseen Project(s). These responsibilities extend to all aspects of biosafety including 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. Although PIs may designate aspects of their biosafety program under their BUAs to other laboratory or teaching staff, they are ultimately responsible for all activities occurring in their facilities.

The PI’s responsibilities include, but are not limited to, the following:

a) Completing and submitting a BUA and associated documents, when appropriate, and amending these documents when there are any changes in materials, procedures, personnel, locations, etc.

b) Ensuring all personnel under their oversight are adequately trained and competent in
   - 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) Complying with all applicable reporting requirements, including reporting of the following immediately to the IBC:
   - Any Significant Incidents or Events
   - Any new information relating to the Project and that 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 may result in suspension of IBC approval, limitation or termination of financial assistance for the non-compliant Project, regardless of whether it is NIH-funded, and/or termination of NIH funds for other research at UCLA involving Biohazardous Materials and/or Recombinant or Synthetic Nucleic Acid Molecules.

The EH&S Biosafety Office, 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 activities or access must immediately be reported to the IBC Chair 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 to its satisfaction.
The IBC has the authority to impose disciplinary measures for reportable Significant Incidents or Events that are not consistent with UCLA’s established biosafety practices and procedures, including non-compliance with applicable regulations and guidelines. All sanctions will be determined by the IBC on a case-by-case basis, giving the PI of the Project the opportunity to respond to any potential violations and to propose applicable corrections.

IV. REFERENCES


2. Biosafety in Microbiological and Biomedical Laboratories (BMBL) by CDC and NIH, Department of Health and Health Services (current version) <https://www.cdc.gov/biosafety/publications/bmbl5/index.htm>

3. Department of Human and Health Services (HHS): Possession, Use, and Transfer of Select Agents and Toxins, Final Rule (42 CFR 73) <https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=8a4be60456973b5ec6bef5dfeafffd49a&r=PART&n=42y1.0.1.6.61>

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) <https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=b9126e9fba23e3e7933354a1d2630d72&ty=HTML&h=L&n=9y1.0.1.5.58&r=PART and https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=b9126e9fba23e3e7933354a1d2630d72&ty=HTML&h=L&n=7y5.1.1.1.9&r=PART>


9. UCLA Policy 905, Research Laboratory Personal Safety and Protective Equipment <http://www.adminpolicies.ucla.edu/APP/Number/905>


14. National Research Council: Occupational Health and Safety in the Care and Use of Nonhuman Primates [https://www.nap.edu/read/10713/chapter/1](https://www.nap.edu/read/10713/chapter/1)


Issuing Officer

/\s/ Roger M. Wakimoto

Vice Chancellor for Research

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