



BOISE STATE UNIVERSITY

University Policy 5080

Biosafety

Effective Date

January 1992

Last Revision Date

June 29, 2021

Responsible Party

Office of Research Compliance, (208) 426-5401

Scope and Audience

This policy applies to sponsored and unsponsored research, academic, and core facility activities involving biohazardous material when using University facilities or equipment or when conducted by, or on behalf of, University employees, students, affiliates, volunteers, or visitors.

Additional Authority

- American Society of Tropical Medicine and Hygiene – Arthropod Containment Guidelines
 - Centers for Disease Control and Prevention – Biosafety in Microbiological and Biomedical Laboratories – 5th edition and subsequent revisions
 - Idaho Division of Building Safety
 - National Institutes of Health – NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines) – 59 FR 34472 and subsequent amendments
 - Occupation Safety and Health Administration – Bloodborne Pathogens, 29 CFR 1910.1030
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1. Policy Purpose

To establish the authority and responsibilities of the university, Institutional Biosafety Committee, and Principal Investigators conducting sponsored and unsponsored research, academic, and core facility activities involving biohazardous material.

2. Policy Statement

The possession and utilization of biohazardous materials is essential to Boise State University's research enterprise. Therefore, Boise State is committed to following the guidance of and fulfilling the obligations set forth by the National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), and other applicable agencies regarding the safe handling of biohazardous material.

3. Definitions

3.1 Biohazardous Material

An infectious agent or biological material presenting a risk to the health of humans, animals, or other forms of life such as DNA, recombinant and synthetic nucleic acid molecules, bloodborne pathogens, infectious organisms, viruses, select agents, and biological toxins.

3.2 Recombinant and Synthetic Nucleic Acid Molecules

The NIH Guidelines define recombinant and synthetic nucleic acid molecules as:

- a. Molecules that a.) are constructed by joining nucleic acid molecules, and b.) that can replicate in a living cell, i.e., recombinant nucleic acids;
- b. 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
- c. Molecules that result from the replication of those described in a.) or b.) above.

4. Responsibilities and Procedures

4.1 Vice President for Research and Economic Development

The Vice President for Research and Economic Development has delegated certain responsibilities to the Institutional Biosafety Committee (IBC) to ensure compliance with the

University's regulatory obligations and to the Office of Research Compliance for support and oversight of the IBC. The Vice President for Research and Economic Development appoints IBC members to ensure appropriate composition and representation in accordance with federal guidelines and committee effectiveness.

4.2 The Institutional Biosafety Committee (IBC)

- a. Generally, the IBC is responsible for the review and approval of sponsored and unsponsored research, academic, and core facility activities involving biohazardous material to assist the University and Principal Investigators (PIs) in adhering to these regulatory requirements and guidelines.
- b. Specifically, the IBC has the following authority and responsibilities:
 - Review activities involving biohazardous material and determine appropriate level of review based upon the material, activity, and associated risk as outlined in the IBC Program Guide;
 - Approve, not approve, or require modification of activities involving biohazardous material to ensure compliance with regulatory obligations and University policies and programs; and will notify the investigator in writing of this status. Should the IBC disapprove or terminate a research project, the investigator may request to present more information either in person or in writing to the IBC, explaining why they believe the project should be approved or continued. However, a final IBC decision to require modifications in, disapprove, suspend, or terminate a project is incontrovertible. No other committee or official, either University or federal, can override these IBC's decision. Further, no committee or person can approve an investigator to conduct any research that an IBC has not approved.
 - Report approval status in accordance with agency requirements; and
 - Report non-compliance to the Vice President for Research and Economic Development (through the Office of Research Compliance) and appropriate agencies as required;
 - Suspend or terminate activity approval based upon non-compliance with regulatory obligations and University policies and programs; and

- Advise the Vice President for Research and Economic Development and the Office of Research Compliance Director on facilities, guidelines, procedures, training, and education for handling biohazardous materials.

4.3 Office of Research Compliance

The Office of Research Compliance provides administrative support and oversight of the IBC and its program, which includes maintaining official records and developing program guidance, forms, and procedures.

4.4 Principal Investigator

The Principal Investigator serves as the lead person with responsibility and authority over activities involving biohazardous materials and has the responsibility to:

- a. Adhere to federal and state regulations and University policy and programs for biohazardous materials;
- b. Sufficiently complete and submit applicable forms to the IBC for activities requiring review;
- c. Abstain from performing activities requiring IBC approval where approval is not granted;
- d. Ensure activities under their direction adhere to the scope and procedures approved by the IBC; and
- e. Communicate risks associated with the activity to individuals with potential exposure to any associated hazards.

5. Related Information

IBC Program Guidance
boisestate.edu/research-compliance/ibc

University Policy 5020 (Principal Investigator Eligibility)

Revision History

July 1995; November 1999; January 2014; June 29, 2021

Last Review Date

August 03, 2023