
BIOSAFETY POLICY

PURPOSE: To establish policies and procedures to ensure that University research, instruction and occupational staff activities of a potentially biohazardous nature are safely conducted; to protect the public, employees, students and the environment from biohazards; to assure a favorable climate for the conduct of scientific inquiry; and to protect the interests of Boise State University when conducting activities involving potentially biohazardous materials. The University's concern is for all biosafety efforts, including but not limited to activities involving human and animal blood, tissues, fluids, recombinant DNA products or organisms; chemical carcinogens, teratogens, mutagens, neurotoxins and other toxins; bioengineering research materials and equipment; and disposal of potentially biohazardous materials.

I. Introduction

- A. The following general guidelines apply equally to research and teaching activities involving potentially biohazardous activities. No distinction in the monitoring or coverage of activities will be drawn between funded and unfunded projects, sponsored or unsponsored projects, or between activities carried out by students, faculty, or other University employees on-campus or off-campus. The University assumes responsibility for communicating and explaining this policy to affected employees and students and for providing procedures or programs to effect its observance.
- B. For research, teaching and other activities involving the use of or exposure to potentially biohazardous materials the University uses as its guide the following documents:
 1. NIH Guidelines for Research Involving Recombinant DNA Molecules (59 FR 34496), published July 5, 1994 and all subsequent amendments issued by the Secretary, Department of Health and Human Services (DHHS). This document will hereinafter be referred to as "NIH Guidelines." Current amendments may be obtained on the NIH Office of Recombinant DNA Activities Home Page at <http://oba.od.nih.gov/oba/>
 2. DHHS Guidelines for Biosafety in Microbiological and Biomedical Laboratories, 4th Edition May 1999, HHHS Publication No. (CDC) 93-8395) and all subsequent regulations and amendments issued by the Secretary, DHHS. This document will hereinafter be referred to as "BMBL Guidelines."
 3. BSU Hazardous Waste Management Manual
 4. OSHA Bloodborne Pathogens Standard, 29 CFR 1910.1030; available at OSHA's home page at <http://www.osha.gov/>

5. BSU Bloodborne Pathogens (BBP) Exposure Control Master Plan

II. Institutional Biosafety Committee

- A. In accordance with NIH Guidelines, the University has established an Institutional Biosafety Committee (IBC) charged with reviewing all research activities of a potential biohazardous nature. Its primary responsibilities are to: 1) Review all projects involving, the use of recombinant DNA molecules, carcinogens, infectious disease agents, and other potentially dangerous materials which are not exempt from such reviews; 2) Report approvals in accordance with federal and agency requirements; 3) Report non-compliance to the Provost and Vice President for Academic Affairs (through the Director ORA) and other appropriate persons; and 4) Recommend training of investigators and laboratory personnel engaged in such research.
- B. The Institutional Biosafety Committee (IBC) shall be constituted of a minimum of five (5), members and a maximum of ten (10) voting members. Collectively, the membership shall have experience and expertise in research with microbial pathogens, chemical toxicology, and recombinant DNA and be cognizant of any potential risks to public health and the environment. At least two members shall not be affiliated with the institution (apart from their membership on the committee) and shall represent the interest of the surrounding community with respect to health and protection of the environment. The Institutional Biological Safety Officer (BSO) shall be a permanent voting member of the committee. The Director of the Office of Research Administration and/or the Coordinator/Secretary to the Committee shall be permanent ex officio members of the Committee. All appointments to the Committee shall be for a three-year term. Members shall be appointed by the Provost and Vice President for Academic Affairs, and the Committee shall nominate qualified successors as required.
- C. A designated person from the Office of Research Administration will provide administrative support to the Committee, serve as Coordinator/Secretary to the Committee, and maintain the official records.
- D. Some sponsoring agencies require approval certification from the IBC even before the proposal will be reviewed; therefore it is suggested that researchers submit their research biosafety protocols (Appendix A) to the IBC prior to submitting the proposal to the sponsor. For research covered under this policy, IBC review and approval must occur prior to initiation of experiments.

III. Responsibilities

- A. Administrative heads of colleges, departments and other units have primary responsibility for the biosafety of people, animals and the environment within their jurisdiction. Appropriate planning, equipment and trained personnel are essential in all potentially biohazardous activities. No activity of a potentially biohazardous nature is to be permitted unless there is a commitment of effort and expense to insure that it can be safely accomplished.
- B. Principal investigators, instructors, clinical supervisors and others in charge of potentially biohazardous activities are key persons in this biosafety effort. They are expected to set a proper example by their own actions and to ensure compliance with the intent of the University's Biosafety Policy, directives and guidelines regarding work supervised. Each must promptly report biohazard incidents to the Biological

Safety Officer and assist in any resulting decontamination, investigations and/or reporting which may be required.

- C. All persons involved in a potentially biohazardous activity must share biosafety responsibility by mindful conduct and reporting of incidents and biohazardous circumstances. They must also keep the supervisor or administrative department head informed of any personal condition such as an illness, use of medication, pregnancy, or reduced immunity which could make the work more hazardous to themselves or others.
- D. The Biological Safety Officer: The University will appoint a Biological Safety Officer (BSO) who will be responsible for: 1) advising the Biosafety Committee, faculty and staff concerning biohazards and their control, performance of surveys, reviews and inspections of biohazardous activities; 2) those specific duties required of BSU in Federal and State regulations or directives; 3) coordination of biosafety efforts with other applicable state agencies; and 4) the day-to-day administration of activities for the Biosafety Committee.

IV. Specific Procedures

A. Recombinant DNA

1. For projects involving the use of recombinant DNA, a research biosafety protocol (Appendix A) must be submitted to the IBC for review, in accordance with requirements of NIH Guidelines and BSU policy.
2. According to the NIH Guidelines:
 - a) All experiments employing recombinant DNA technology, which are covered under the NIH Guidelines (Section III - Experiments Covered by the NIH Guidelines, Subsections III-A through III-D) must be registered with the IBC. BSU campus policy dictates that registration must occur prior to initiation of experiments. Exempt experiments are covered under Subsection III-E of the NIH Guidelines.
 - b) For competing and noncompeting applications (all series), the box "YES" under "RECOMBINANT DNA RESEARCH SUBJECT TO NIH GUIDELINES" is to be checked. No additional information for registration of the recombinant DNA aspects of the proposal need be submitted to NIH. (If the application does not have the above-mentioned box, the following statement should be typed at the bottom of the face page of the application: "RECOMBINANT DNA RESEARCH SUBJECT TO NIH GUIDELINES.")
 - c) Containment levels not specified by the NIH Guidelines: The setting of containment levels for projects for which containment levels are not explicitly specified by the NIH Guidelines or NIH, will require review by NIH, usually involving recommendation by the NIH's Recombinant DNA Advisory Committee (RAC). Hence, investigators are urged to provide to the Office of Recombinant DNA Activities (ORDA), in writing, full information on the proposed experiments prior to submission of a registration document to the IBC.
3. On behalf of the institution, the Principal Investigator (PI) is responsible for complying fully with NIH Guidelines in conducting any recombinant DNA research. As part of the general responsibility, the PI shall:

- a) Initiate or modify no recombinant DNA research requiring approval by the IBC (Sections III-A and III-B, NIH Guidelines), prior to initiation, until that research or the proposed modification thereof has been approved by the IBC and has met all other requirements of the NIH Guidelines;
 - b) Determine whether experiments are covered by Section III-C, NIH Guidelines and follow the appropriate procedures;
 - c) Report within 30 days to the IBC and NIH (ORDA) all significant problems with and violations of the NIH Guidelines and all significant research-related accidents and illnesses;
 - d) Report to the IBC and to NIH (ORDA) new information bearing on the NIH Guidelines;
 - e) Be adequately trained in good microbiological techniques;
 - f) Adhere to IBC approved emergency plans for dealing with accidental spills and personnel contamination;
 - g) Comply with shipping requirements for recombinant DNA molecules, as outlined in the Appendix H, NIH Guidelines; and
 - h) Comply with all other relevant areas of responsibility of the NIH Guidelines.
4. To register an experiment with the BSU/IBC
- a) The investigator should obtain a research biosafety protocol form (Appendix A) from the IBC Coordinator. NOTE: Appendix A may be copied and used.
 - b) At the same time, the BSO should be contacted and arrangements made for a facility inspection.
 - c) The registration document, with the facility inspection attached, should then be submitted to the IBC Coordinator who will arrange IBC review.
 - d) Containment levels for exempt experiments: The current list of procaryotic organisms for which recombinant DNA experiments are exempt from the guidelines contains several species that are potentially pathogenic for humans. Investigators using those species should adhere to appropriate biosafety procedures. These procedures can be found in the BMBL Guidelines.
5. Investigator Training - The IBC considers training of personnel an integral part of the approval process. This will be achieved in two stages. During the facility's certification, the principal investigator and co-investigator(s) will review with the BSO a detailed list of laboratory practices commensurate with the recombinant DNA experiments to be performed. Secondly, training sessions covering the guidelines and laboratory practices will be recommended for new investigators on an "as needed" basis. Copies of the latest NIH guidelines are available from the IBC Coordinator's office.
- B. Chemical Carcinogens - A research biosafety protocol form (Appendix A) for projects involving the use of regulated carcinogens must be submitted for IBC review and approval. Investigators will be required to file a safety plan for this use as well.
- C. Infectious Disease Agents

1. Any experiments or bioassays involving cells, tissues, or body fluids obtained from humans or animals known to contain, or suspected of harboring, infectious disease agents (e.g., bloodborne pathogens including but not limited to HIV or HBV) or from human tumor tissue are to be handled and disposed of in accordance with the standards outlined in the BMBL Guidelines. All research activities involving the culture, production, concentration, experimentation and manipulation of HIV or HBV shall also be conducted in compliance with section (e) of the OSHA Bloodborne Pathogens Standard, 29 CFR 1910.1030.
2. Experiments involving etiological agents of Risk Group 3 or higher as listed in the NIH Guidelines, "Classification of Human Etiologic Agents on the Basis of Hazard," and other activities which involve animals that are carriers of infectious agents (i.e., sheep: "Q" fever; chicken: Newcastle disease; etc.) must be approved by the IBC prior to commencement of work. Updates on the Appendix B lists may be obtained at the NIH Office of Recombinant DNA Activities Home Page at <http://www.nih.gov/od/oba/>

D. Bloodborne Pathogens (BBP) Exposure Control

1. The University shall provide education and exposure prevention guidelines to employees who may be exposed to bloodborne pathogens. This action and applicable definitions shall be described in detail in the *BSU Bloodborne Pathogens (BBP) Exposure Control Master Plan (Master BBP Plan)* and/or the respective *Department Bloodborne Pathogens (BBP) Plan*. Any University part- or full-time faculty, staff or student employees who have had an *exposure incident*^a involving human blood or *Other Potentially Infectious Material*^b (*OPIM*) shall follow the post-exposure medical follow-up procedures as described in their respective *Department BBP Plan*. All medical evaluation and treatment costs will be subject to payment under the University's Workers' Compensation policy and procedures.
2. Human *blood* and/or *OPIM*, primate blood and/or body fluids from primates, and clinical samples, including but not limited to feces, urine and respiratory secretions, shall not be used in undergraduate courses or laboratory work unless approved by the Biosafety Committee.
3. Before engaging in any activity where *occupational exposure*^c to human *blood* and/or *OPIM* has been determined to be probable, *covered employees* (as defined by the *Master BBP Plan*) must present either evidence of HBV immunization or serologic evidence of a protective antibody titer against hepatitis B virus disease (HBV) and undergo training to prevent or minimize exposure. Hepatitis B immunization is available without charge to University employees who have been determined to have *occupational exposure*. Employees who want to forego such immunization must sign a formal disclaimer statement as provided in the *Master BBP Plan*.

^a *Exposure incident*: Any specific eye, mouth, other mucous membranes, non-intact skin or parenteral contact with *blood* or *OPIM* that results from the performance of an

employee's duties (contact with intact skin does not necessarily constitute an *exposure incident* - see the BSU Master BBP Plan for details).

^b *Other Potentially Infectious Materials (OPIM)*: Any of the following human body fluids: semen; vaginal secretions; cerebrospinal, synovial, pleural, pericardial, peritoneal and amniotic fluids; fluid visibly contaminated with *blood*; all body fluids in situations where it is difficult or impossible to differentiate between fluids; any unfixed tissue or organ (other than intact skin) from a human (living or dead); HIV-containing cell, tissue and organ cultures; HIV- or HBV-containing culture medium, *blood* and organs; tissues from experimental animals infected with HIV or HBV.

^c *Occupational exposure*: Any reasonably anticipated skin, eye, mucous membrane or parenteral contact with *blood* or *OPIM* that results from the performance of an employee's duties - see the *BSU Master BBP Plan* for details.

[Appendix A](#)

You will need Adobe Acrobat Reader to view and print Appendix A. If you don't already have Adobe Acrobat Reader, [click here](#) for a free download of the program.