

Boston Public Health Commission
Biological Laboratory Safety Permit Application

SECTION 11: BSL-3 AND BSL-4 MANAGEMENT COMMITMENTS

Boston University
National Emerging Infectious Diseases Laboratories

March 2014

Boston University (BU) and Boston Medical Center (BMC) are committed to conducting all research activities incorporating the highest levels of ethical and research integrity and complying with legal standards. BU/BMC fully understands and takes very seriously the responsibility to comply with city, state and national laws, contract and grant obligations, and standards of integrity, quality, and ethics.

The NEIDL operates as an Institute of the Boston University School of Medicine and includes Scientific and Operations Cores whose members serve the mission of the NEIDL while ensuring alignment with the operations of Boston University at large. NEIDL leadership members have responsibilities that are NEIDL-specific and responsibilities that are Medical Campus or Boston University wide. This organizational model reinforces the commitment of Boston University by ensuring alignment from leadership to operations and by providing resources in the development, management, and support of the NEIDL.

These core values foster a culture of responsibility and conscience in both science and scholarship. Complementing these research-related values is the commitment of leadership to the ongoing management of a safe environment, as reflected in the *Statement of Commitment to Environmental Health and Safety* below.

BU NATIONAL EMERGING INFECTIOUS DISEASES LABORATORIES

Section 11: BSL-3 and BSL-4 Management Commitments

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**BOSTON
UNIVERSITY**


**Statement of Commitment to
Environmental Health and Safety**

Boston University is committed to maintaining a healthy and safe environment for its students, faculty staff, visitors, and neighbors and to fostering a culture of safety among users of all campus facilities. Members of the Boston University community should therefore comply with all environmental health and safety laws and regulations and with current best practices, especially in laboratory settings. In addition, members of the community should commit to continuous improvement in their efforts to minimize adverse environmental impacts and safety risks and to supporting a culture of safety in the University's operations by:

- Accepting the critical role each person has in protecting his or her own safety as well as that of others.
- Recognizing the critical importance of adherence to the highest standards for safety and occupational health for our students, our staff, and the communities around us.
- Minimizing air and water pollution and waste generation.
- Incorporating safety as an integral aspect of all operations, including but not limited to experimental design, facility construction, and equipment specifications.
- Providing students and employees with safety education targeted to maximize safe work practices and to minimize the potential for injury or illness.
- Creating an environment where individuals are able to recognize and to report errors without fear of reprimand or punishment.
- Providing appropriate and timely information in response to questions or concerns about environmental health and safety issues.
- Investigating incidents, disseminating lessons learned in such reviews, and modifying programs, as appropriate, to incorporate any potential improvements identified.
- Creating an environment of collaboration among all stakeholder, including researchers, safety specialists, students, and staff from facilities management and public safety, to identify safety issues and to find solutions to safety problems.

The University's Environmental Health and Safety staff, working closely with oversight committees, has developed policies and procedures designed to further the above goals.

Deans, directors, department heads, managers and other supervisors at the University are responsible for implementing this commitment within their areas of responsibility. I ask every member of the Boston University community to cooperate in these important matters.


Robert A. Brown

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Academic and medical research at BU is subject to a myriad of laws, regulations, and/or other binding agreements that are both challenging and complex. Oversight of these activities is provided by the *Office of the Associate Vice President for Research Compliance (AVP-RC)*, who is the designated Responsible Official for the Boston Public Health Commission.

The compliance program at BU integrates and coordinates the significant requirements with which we must comply. Because multiple operational units are responsible for the overall effort to manage potential risk, the Research Compliance website (<http://www.bu.edu/orc/>) helps researchers and staff find the offices responsible for regulations and policy making and provides information related to ongoing efforts to ensure a culture of safety (<http://www.bu.edu/orc/culture-of-safety/>).

Responsibility for maintaining a culture of safety requires collaboration, communication, and coordination and belongs to all NEIDL staff. Initiatives such as daily safety meetings that include representatives of Environmental Health & Safety, Facilities Management & Planning, Public Safety, and NEIDL Administration are in place to confirm that all expectations related to working safely are met every day. Each representative of that group has the authority to stop work and to correct issues as a team, as opposed to as individual cores with overlapping responsibilities.

BU provides a number of mechanisms for reporting concerns from both internal and external sources addressing confidential reporting, research misconduct, and animal welfare as listed at <http://www.bu.edu/orc/about/reportingconcerns>. Additionally BU solicits information on near misses through a webpage <http://www.bu.edu/ehs/near-miss/> and uses the information collected to identify opportunities for improvement and training.

The NEIDL, in addition to the Boston University-wide mechanisms for reporting listed above, has instituted a program for ongoing monitoring that is addressed in the NEIDL Personnel Suitability and Reliability Policy. This policy addresses requirements for access to the building, for continued work in the building, and for the maintenance of a safe working environment, as well as processes for both reporting concerns or opting out of work in the event that doing so is conducive to the maintenance of a safe environment.

The oversight of research compliance at NEIDL is integral to the facility's existing programs, and appropriate site-specific programmatic enhancements have been made to facilitate the unique requirements of the NEIDL research programs.

The Office of the AVP-RC has developed a comprehensive research safety and oversight program that includes the following:

1. Environmental Health & Safety (EHS)

- 1.1. Environmental Health & Safety's mission is to provide a safe environment for employees, faculty, and staff, as well as patients and others visiting our facilities. Established programs not only provide for a safe environment but also help to ensure compliance with federal, state, and local codes and regulations. EHS provides a full range of environmental, health, and safety services to the BU communities.

EHS has five divisions that establish the BU comprehensive safety management structure. These divisions include: Research Safety, Emergency Response Planning, Campus and Clinical Safety, Medical Physics and Radiation Safety, and Environmental Management. Technical areas that make up these divisions include: biosafety, laboratory safety, chemical safety, controlled substances, industrial hygiene, fire safety, construction safety, hospital safety, workplace safety, radiation protection, medical physics, laser safety, non-ionizing radiation, pollution prevention, environmental regulatory compliance, and hazardous materials management. EHS provides training, conducts inspections, and manages specific programs in these areas. BU policies regarding environmental health and safety issues are outlined in division-specific management plans that can be viewed on the EHS website at <http://www.bu.edu/ehs/>.

EHS assigns staff as Departmental Safety Advisors (DSA) to laboratories and departments in order to provide support to users throughout BU. DSAs work with Principal Investigators and lab-specific Laboratory Safety Coordinators to conduct risk-based inspections, provide education, training and regulatory updates, and to serve as liaison to all compliance-related issues. Services and support are outlined in the Lab Safety Coordinator toolkit at <http://www.bu.edu/ehs/toolkits/lsc-toolkit/>.

EHS is staffed by skilled and highly trained professionals who are available during normal business hours to address questions and concerns. Staff is also available 24 hours a day to respond to safety-related emergencies.

Within NEIDL, the *EHS Core* is staffed by individuals with training experience in high (BSL-3) and maximum (BSL-4) containment facilities and is charged with the oversight of health and safety programs within the facility.

1.2. Emergency Response Planning (ERP)

ERP is responsible for the maintenance, review, and revision to the University's Emergency Response Plans. ERP also provides recommendations related to emergency management planning, training, and response coordination for others within EHS, Facilities Management & Planning, Public Safety, and members of Emergency Response Teams. In addition, the ERP participates in the development and implementation of new emergency response plans, risk reduction initiatives, risk prevention measures, and serves as a liaison to local, state, and federal emergency management agencies.

ERP works closely with other EHS divisions to ensure that emergency notifications and bio-safety and laboratory safety training and requirements are consistently updated.

2. Research Occupational Health Program

The Research Occupational Health Program (ROHP) was established in response to the growth in research programs and the need for a comprehensive program to address that growth. ROHP was created to enhance the health and safety of BU/BMC researchers and to ensure that occupational health is an integral part of our overall health and safety programs.

ROHP is part of the Research Compliance office and is focused on the health, wellness, and safety of the research community and those that support that research. ROHP promotes a culture of safety in research by utilizing comprehensive best practices to perform medical surveillance, workplace risk assessments, biosafety and agent training, psychological evaluation of all NEIDL investigators and staff, and clinical occupational health services led by board-certified Occupational Medicine physicians.

Emergency Response Planning, Environmental Health & Safety, and the Research Occupational Health Program report to the AVP-RC through the Executive Director for Research Compliance.

3. Committee Oversight

The committees charged with overseeing research are in place to facilitate communication and compliance within and between the research staff and to ensure that federal, state, local, and voluntary standards are being met by the institution. Committees are staffed to ensure smooth and efficient operations that maintain the institution's compliance with all regulations and standards of recombinant DNA (rDNA) and biohazardous materials in research, radiation, animal research, and lab safety.

3.1. Institutional Biosafety Committee (IBC)

The Institutional Biosafety Committee (IBC) is a University-wide committee responsible for reviewing and approving recombinant DNA research and biohazard research projects. The IBC has overall oversight responsibility for the Biosafety Program at BU/BMC. The committee sets containment levels in accordance with the National Institutes of Health (NIH) guidelines and the Centers for Disease Control and Prevention (CDC). It also periodically reviews previously approved research projects for changes that may necessitate increasing or decreasing the Biological Safety Levels. Once a project has been approved, an approval letter is sent to the Principal Investigator; this letter lists the project's IBC approval number(s), containment levels set by the IBC, project titles, and any additional requirements.

Specifically, the IBC evaluates research projects that use recombinant DNA; agents that are infectious to humans, animals, and plants; other potentially infectious materials; select agents and biological toxins; human materials including blood, cells, unfixed human tissues and other body fluids; and xenotransplant and gene transfer clinical studies. The IBC coordinates its application procedures with two other departments that are described above, EHS and ROHP, in order to ensure that research personnel have adequate occupational health monitoring, training on safe work practices, exposure control in emergencies, and use of personal protective equipment. The IBC carries out these functions pursuant to requirements set forth by federal, state, and local agencies as well as BU/BMC.

The IBC is composed of faculty investigators from both campuses with expertise in recombinant DNA and biohazards research, as well as non-scientists and community members, and a Biosafety Officer. In conjunction with EHS and ROHP, the IBC oversees the Biosafety Program for laboratory research with recombinant DNA and biohazards. This includes the review and approval of all new research involving rDNA and biohazards, continued review of approved research projects, review of

laboratory inspection reports, investigation of complaints and concerns, and review of training and medical surveillance programs.

The Director of the EHS Research Safety division is the Responsible Official under the University's registration with the CDC/USDA Select Agents Program. The University's Select Agents Program manages the permitting, inventory, security, facility containment, and safety operations of all "select agents" at BU/BMC in accordance with federal and local regulations.

3.2. Radiation Safety Committee

The Radiation Safety Committee (RSC) has overall responsibility for the development and recommendation of comprehensive policies and guidelines for the safe use of all sources of radiation including all clinical and research uses of radioactive materials, and ionizing and non-ionizing radiation generating devices. As such, the RSC is charged to provide general review and audit of radiation safety programs to determine compliance with regulations and licenses issued on the local, state, and federal levels. The RSC establishes minimum initial and ongoing training requirements for use of radiation sources. The RSC also reviews, approves, disapproves, and requires changes in order to grant approval for any ionizing and non-ionizing radiation use in order to comply with regulations and to meet reasonable standards of safety and health.

The Chief Health Physicist of the EHS Medical Physics & Radiation Safety division is the Radiation Safety Officer under the University's registration with the NRC /Massachusetts Department of Public Health Program.

3.3. Laboratory Safety Committee

The Laboratory Safety Committee (LSC) is responsible for an annual review of BU/BMC Chemical Hygiene Plan (CHP), monitoring the status and implementation of the CHP, discussing safety-related incidents in laboratories, reviewing laboratory-related written guidelines and training programs, and providing a forum for the discussion of laboratory safety issues. The Laboratory Safety Committee is comprised of faculty and staff members from various science departments.

The Certified Industrial Hygienist of the EHS Campus & Clinical Safety division is the Chemical Hygiene Officer and serves on the Laboratory Safety Committee.

3.4. Institutional Animal Care and Use Committee (IACUC)

BU/BMC has sought to maintain the highest standards for the care and use of animals in research, and IACUC plays an important role in this regard. The members of the IACUC believe that the use of animals in research is necessary and provides important information that benefits both humans and animals. Nevertheless, while many uses of animals in research are ethical and important, it is important that animal use includes avoiding unnecessary pain and suffering as we have a moral obligation to ensure that their use is justified and that they are treated with care and respect. Accordingly, the mission of the IACUC is to consider the care and use of animals in research and teaching from an ethical perspective and to ensure institutional compliance with federal requirements through oversight of the laboratory animal care program. Research institutions are required to have an IACUC as a result of the Health Research Extension Act of 1985 (Public Law 99-158). Both the USDA and the Public Health Service promulgate principles, regulations, policies, and standards pertaining to the use of animals in research and teaching.

The Director of the BU Animal Services Center serves as the Institutional Attending Veterinarian and serves on the Institutional Animal Care and Use Committee

In consultation with BU provosts and deans as well the BMC leadership, the Associate Vice President for Research Compliance appoints various committee members. Research Compliance programs are guided and regulated by the federal Office of Biotechnology Activities, the federal Office of Laboratory Animal Welfare, CDC guidelines entitled *Biosafety in Microbiological and Biomedical Laboratories* (BMBL), federal Occupational Health & Safety Administration (OSHA), the United States Department of Agriculture (USDA), and the City of Boston Public Health Commission.

The oversight committees report to the AVP-RC through the Executive Director for Research Integrity and Assurance.