

University of Massachusetts/Amherst

Use of Biohazardous Materials in Research and Instruction



PURPOSE

The University of Massachusetts Amherst (the University) is committed to ensuring the safe handling, storage, and disposal of potentially biohazardous materials, as defined below, used in University research or instructional projects. This policy is designed to ensure that employees, students and visitors follow safe practices when working with or near potentially biologically hazardous materials, synthetic nucleic acid molecules or recombinant DNA. The University will pursue biological safety through ensuring prudent practices to protect people and the environment from biological hazards and will conform to state and federal biosafety directives and guidelines. Implementation of this policy by the University is intended to provide a safe working atmosphere and a well-controlled research environment. The University's concern is for all biosafety issues but in particular it is concerned with activities involving

- Infectious agents
- Recombinant DNA research
- Synthetic nucleic acid molecule research
- Agents on the list of Select Agents
- Potentially biologically hazardous materials

This policy statement describes the role of the University and the Director of Research Compliance in the Office of Research and Engagement, the Environmental Health and Safety Executive Director (who is the Responsible Official with oversight over biosafety issues) and Assistant Director for Academic Safety & Environmental Health and the Institutional Biological Safety Officer (BSO) in EHS, the Institutional Biosafety Committee (IBC), and the IBC's structure and function. The Biological Safety Officer and IBC are charged with reviewing and approving projects that need to comply with federal regulations on the use of recombinant DNA, synthetic nucleic acid molecules and Select Agents. The review process is described below.

DEFINITION

Biosafety promotes safe laboratory practices, procedures and proper use of containment equipment and facilities among University staff and visitors.

Biohazardous Material -

The following categories represent the areas of primary concern with respect to biosafety. Projects involving material(s) included in any of these categories should be submitted to the BSO for initial review and may require IBC approval.

1. Chemical Carcinogens used in conjunction with animals.
2. Toxic/Infectious agents used in conjunction with animals and plants.
3. Oncogenic viruses used in conjunction with animals.
4. Infectious agents requiring handling conditions above Biosafety Level-1. (Biosafety Level determinations are based on the recommendations outlined by the CDC-NIH publication Biosafety in Microbiological and Biomedical Laboratories.
5. Recombinant DNA
6. Synthetic nucleic acid molecules
7. Human blood and blood products, human body fluids, human tissue, and/or human cells.
8. Biological toxins.
9. Agents regulated by CDC or USDA (e.g. on the list of Select Agents)
10. Whenever a contractual agreement or grant proposal requires Institutional Biosafety Committee approval for the safe handling of a biological or chemical product.
11. Any research that requires a permit from USDA Animal and Plant Health Inspection Service (APHIS).
12. Wild Poliovirus or materials that may contain wild poliovirus [contact Environmental Health and Safety (413) 545-2682 for additional information on this subject].

POLICY

This policy applies to all research and instructional activities, sponsored and unsponsored, conducted under the auspices of the University. This policy is applicable to all University locations. University projects involving the use of biohazardous materials at other institutions should receive Institutional Biosafety Committee (IBC) approval from the cooperating institution. Copies of approvals from cooperating institutions should be forwarded to the Office of Grant and Contract Administration (OGCA) and the Office of Research and Engagement.

All University research and instructional activities involving biohazardous materials must be reviewed and approved by the Biosafety Officer and, as required, the Institutional Biosafety Committee (IBC). Projects submitted for sponsorship by external agencies will be submitted for review prior to acceptance of funding. The review process is coordinated by Research Compliance Staff in the Office of Research and Engagement in Research Administration Building (545-5283).

RESPONSIBILITY

Administrative heads of departments and other units have responsibility for the biosafety of people, animals and the environment within their jurisdiction. Appropriate planning, provision of appropriate space and equipment, and training of personnel are essential in potentially biohazardous activities.

Principal investigators (PIs), instructors, supervisors and other personnel in charge of potentially hazardous activities are critical to the biosafety effort. PIs must set an example by their own actions to ensure compliance with the regulations and the University's biosafety policy, directives and guidelines regarding the work they supervise. They must report biologically hazardous incidents to the Biosafety Officer (BSO) promptly and assist in any resulting decontamination; investigation and/or reporting that may be required. They are responsible for posting biohazard warning signs at the entrance to the laboratory. They are responsible for notifying the Office of Research and Engagement of any proposed activity using biohazards by indicating so on the Internal Processing Form IPF form that accompanies a grant proposal submitted to the Office of Grants and Contracts (OGCA). They are responsible for making the initial determination of the required level of physical and biological containment in accordance with National Institute of Health (NIH) and Center for Disease Control (CDC) Guidelines. Once the project starts they are responsible for reporting any significant problems to the appropriate authorities (BSO, and/or Greenhouse or Animal Care Director as appropriate). It is the responsibility of the PI to ensure that copies of approval letters are properly directed to any funding agency or sponsor. It is also the PI's responsibility to renew approved projects with the Office of Research and Engagement and provide a current listing of personnel involved in approved projects as well.

All personnel involved in potentially biologically hazardous activity share biosafety responsibility and must follow specified procedures, take appropriate training, act responsibly, and report incidents and hazardous circumstances. They should inform their supervisor of any personal condition such as illness, medications, pregnancy, or reduced immunity which could make their work more hazardous to themselves and others.

The Biosafety Officer (BSO) is appointed by the University and is a member of the EHS staff. The BSO reports to the **Assistant Director for Academic Safety & Environmental Health** who in turn reports to the **Executive Director of Environmental Health and Safety** who is charged with oversight of research and other activities involving the use of biohazardous materials. The EHS Executive Director is the **Responsible Official** for biosafety issues and the Assistant Director and the BSO is his/her Alternate Responsible Officials as required by the Homeland Security Act. The Executive Director, Assistant Director and the BSO set containment levels in accordance with the National Institute of Health Guidelines and the Center for Disease Control Prevention. The BSO reports any violations of the NIH Guidelines to the other Responsible Officials and the Institutional Biosafety Committee. The BSO and other EHS personnel maintain an inventory of all potentially biologically hazardous materials, including Select Agents. EHS records include a biohazard's nature, location, and the Principal Investigator(s) involved. The BSO is responsible for:

- advising and training the Institutional Biosafety Committee members, faculty and staff concerning biologically hazardous materials and their control
- reviewing (or pre-reviewing for the IBC) registrations of rDNA and Select Agents
- inspecting facilities

- reviewing and inspecting biologically hazardous activities in coordination with other EHS personnel and activities, the Animal Care Director, Greenhouse Managers, and the Director of Research Compliance in the Office of Research and Engagement
- providing technical advice to investigators on laboratory containment facilities, safety equipment, security and research safety procedures
- developing emergency plans for containment and handling spills and personnel contamination
- investigating accidents involving biologically hazardous materials.

The Director of Research Compliance is a professional staff member in the Office of Research and Engagement. The DRC works closely with the BSO and EHS Directors to ensure that research with biologically hazardous materials and organisms at the University is conducted in accordance with all applicable local, state and federal regulations. The DRC and staff in the Office of Research and Engagement have responsibility for:

- managing the rDNA and Select Agent registrations database
- managing the registration review process and interfacing with the BSO and the IBC for registration review
- taking IBC meeting minutes
- recording registrations submitted and actions taken
- providing administrative support to the IBC and BSO
- notifying the principal investigator of the outcome of a registration review
- filing the IBC Annual Report for the University of Massachusetts Amherst with the NIH/Office of Biotechnology Activities
- reporting oversight activity to the IBC when, according to State and Federal Regulations, the activity does not require the committee's direct oversight
- interfacing between the BSO and the IBC and other University oversight committees like the Institutional Animal Care and Use Committee (IACUC) and the Institutional Review Board (IRB).

The University is responsible for

- establishing an IBC and appointing the IBC Chair
- ensuring that the IBC members, the BSO, the DRC, PIs and laboratory staff have appropriate expertise and training
- ensuring that an Annual Report is filed with the NIH Office of Biotechnology Activities and that the report includes (1) a roster of IBC members indicating their expertise; and (2) bio-sketches of the members. [The Institution has an Approval on file with the NIH/Office of Biotechnology Activities. The Approval must be renewed annually.]
- establishing procedures for the IBC
- making available to the public, on request, IBC meeting minutes and any documents submitted to, or received from, funding agencies that those agencies must make available to the public.

THE INSTITUTIONAL BIOSAFETY COMMITTEE

The Institutional Biosafety Committee (IBC) is a University-wide review body appointed by the Vice Chancellor for Research and Engagement to review and approve potentially

biohazardous research. When it is unclear as to whether a material constitutes a potential biohazard, questions should be directed to the BSO in the Office of Environmental Health and Safety (EHS) (545-2682).

When the research involves work with rDNA, synthetic nucleic acid molecules and/or Select Agents the DRC assistant contacts the PI and requests that he/she submit the appropriate form (rDNA registration or Select Agent registration) to register the work with the IBC. For **rDNA registrations** the PI must indicate the Biohazard level according to the NIH Recombinant DNA/Infectious Agent registration Guidelines and should clearly identify projects that involve more than one biohazardous material. The completed rDNA or Select Agent registration is returned to the Office of Research and Engagement, (Research Administration Building) where the information is entered into a database then forwarded to the BSO together with a copy of the proposal. For work registered at Levels III-D through III-A formal written approval by the BSO, the IBC and appropriate federal agencies must be received before the project can be started.

For Select Agents registration the BSO follows up with the PI to ensure that all aspects of Homeland Security and the Patriot Act and other regulations are complied with.

DISPOSAL OF BIOHAZARDOUS WASTE

All biohazardous waste must be disposed of in accordance with local, state and federal regulations. Biohazardous waste must be collected in a sturdy, clear plastic bag. Bags must be kept in a sturdy, covered, leak-proof container. Biohazardous waste must be decontaminated by autoclaving, disinfection, or incineration. Waste that cannot be decontaminated by laboratory personnel will be removed from the area by EHS personnel for disposal, shipment, or destruction in accordance with applicable regulations. Sharps waste must be collected in “sharps” containers and removed by EH&S personnel in accordance with applicable regulations. Refer to the EH&S Biohazardous Waste treatment, packaging, and disposal guidelines at <http://www.ehs.umass.edu>