

**THE UNIVERSITY OF MASSACHUSETTS AMHERST
ADMINISTRATIVE POLICIES AND PROCEDURES**

Office of Primary Responsibility:
Vice Chancellor for Research and Engagement
Committee

Subject:
Institutional Biosafety

1.0 Purpose

The University of Massachusetts Amherst (the University) has an Institutional Biosafety Committee (IBC) in compliance with the *NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines, 2002)* and in accordance with *Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th Edition, 2007*. The following sections describes the University's policy and procedures for the IBC

2.0 Policy

The IBC follows *NIH Guidelines* for practices for reviewing projects that require constructing and handling: (i) rDNA molecules, and (ii) organisms and viruses containing rDNA molecules. The IBC also reviews activities involving use of Select Agents and Toxins and other biohazardous agents that must be handled at BSL3 and 4. The IBC will assist the Biosafety Officer (BSO) in the Department of Environmental Health & Safety (EH&S) in formulating policies and procedures related to the use of biohazards. The IBC is also charged with reviewing the biological and medical waste management program annually according to The Department of Public Health's regulation on the minimum requirements for the management of medical and biological waste CMR 480.000 The IBC may advise the institution and the Principal Investigator (PI) concerning management of research that is classified as "dual use".

3.0 Procedure

- 3.1 IBC members are appointed by the Vice Chancellor for Research and Engagement for 3-year terms. At the end of a member's term he/she may be reappointed for a further term.
- 3.2 IBC membership conforms to *NIH Guideline IV-B-2-a-(3)*.
- 3.3 The IBC meets no less than four times a year for review of projects using rDNA that require review at NIH review level IIIE and higher, or for any other matter within the scope of the committee. A meeting is conducted in person or via conference call. A quorum is a majority of the membership. When possible, and consistent with the protection of privacy and proprietary interests, IBC meetings are open to the public.
- 3.4 The Research Compliance Coordinator serves as Executive Secretary to the IBC including preparation of IBC minutes and filing reports with OBA. Annual Reports to OBA are filed on or before the anniversary of the previous Annual Report. Reports of significant problems or violations are reported to OBA within 30 days of the incident
- 3.5 An IBC member may not be involved in the review of any project in which he/she or a close relative or spouse has a personal or financial interest.

- 3.6 The IBC may approve a registration for a period of up to 5 years.
- 3.7 The PI is notified in writing that a registration has been approved by the IBC. The approval letter includes the registration number, expiration date, and any other pertinent information and special approval conditions. Approval letters for reviews conducted at NIH review level III E may be signed by the Executive Secretary. All other approval letters are signed by the IBC Chair.
- 3.8 The IBC has been granted authority to investigate potential violations or compliance problems related to its area of oversight
- 3.9 Requests from members of the public for documents relating to IBC activities are handled in accordance with provisions of the Massachusetts Open Records Law (M.G.L. c. 66, § 10) and University policy for handling requests for documents related to research. The University policy documents a process for review and redaction of research records before they are sent to a requestor. The institution's response to a request for records is handled in consultation with Legal Counsel. The Vice Chancellor for Research and Engagement responds to the request.

Approved by Vice Chancellor for Research and Engagement Michael Malone

University of Massachusetts/Amherst 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 Biosafety Officer in the Office of Environmental Health and Safety (EHS) (545-2682).

Note: In the past the University had two standing committees to oversee recombinant and synthetic nucleic acid molecules, and pathogens, oncogenes, carcinogens and toxins. These activities are now combined, as reflected by the **IBC's charge** which encompasses:

- Review of policies, programs and directives regarding biological hazards in academic, research, clinical and animal care activities.
- Review and approval of research that involves potentially biohazardous materials (plant and animal pathogens, oncogenes, carcinogens, toxins, recombinant and synthetic nucleic acid molecules, as required by University, State and Federal directives. Review includes: (i) an independent assessment of the containment levels required by the NIH guidelines for the proposed research, (ii) assessment of the facilities, procedures, practices and training and expertise of the personnel involved in rDNA research, and (iii) ensuring compliance with all reporting and adverse event reporting required by the NIH guidelines. The committee may approve, disapprove, or request revisions which would lead to approval.
- Advising the Administration regarding problems of a biologically hazardous nature and recommending actions. Recommendations include: denial of proposed activities where adequate facilities, equipment or personnel are not available; sanctions against individuals who are non-cooperative in biosafety matters; suspension of any biohazardous activity judged to pose a significant risk to health of safety.
- Review of emergency plans covering spills and personnel contamination resulting from rDNA research and research using biohazards.

The IBC currently has eleven members appointed for three-year terms to provide oversight over University operations and activities of a potentially biologically hazardous nature. Membership of the IBC is consistent with NIH guidelines (sections IV-B-2-a and IV-B-2-b) on the review of

projects involving the use of recombinant and synthetic nucleic acid molecules and its make-up has been reviewed and approved by the NIH/Office of Biotechnology Activities. The BSO is a member of the committee and the other members work closely with the BSO to recommend actions necessary to maintain and/or improve biosafety on the campus. The IBC meets at least four times a year. A quorum consists of a simple majority. A passing vote is a simple majority of members present. Minority views are recorded in the minutes. A member of the Research and Engagement Compliance staff attends the meetings and takes the minutes.

Procedures

PIs conducting research with biohazardous materials must register with the IBC.

Grant-funded research: PIs proposing research that uses biohazardous materials must indicate the category on the Internal Processing Form (IPF). When one or more of the following items are checked:

- biohazardous substances
- carcinogenic substances
- recombinant DNA
- synthetic nucleic acid molecules
- Select Agents

A copy of the proposal is forwarded from the Office of Grants and Contracts to the Office of Research and Engagement for action. When the research involves biohazardous or carcinogenic substances a copy of the proposal is forwarded to the BSO for review. The BSO contacts the PI and requests that he/she submit the appropriate form to register the work with the IBC and to ensure that the procedures are in compliance with all relevant regulations.

Non-funded research and teaching activities: If there is no grant proposal the registration must also include an outline of the parts of the experimental procedure that involve the use of rDNA, synthetic nucleic acid molecules or Select Agents.

When the research involves work with rDNA, synthetic nucleic acid molecules and/or Select Agents the Research and Engagement Compliance assistant contacts the PI and requests that he/she submit the appropriate form (rDNA and synthetic nucleic acid molecules registration or Select Agent registration) to register the work with the IBC. For **rDNA and synthetic nucleic acid molecules registrations** the PI must indicate the Biohazard level according to the NIH Recombinant DNA/Infectious Agent registration Guidelines <http://www4.od.nih.gov/oba/> 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 where the information is entered into a database then forwarded to the BSO together with a copy of the proposal. For rDNA registrations the BSO reviews the registration and, depending on the biohazard level, either approves the registration (Level III-F, E, BSL1) and determines the appropriate biosafety requirements for the PI, or submits the project for consideration by the full IBC (levels III-A, B, C,D; BSL>1). For work registered at Levels III-F and III-E the PI may begin the project without receipt of formal approval from the BSO and/or IBC. 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 including:

- whether or not the Select Agents are exempt from registration with the CDC
- justification of the type of Biological Agent, Toxin or Delivery system to be used
- assurance that “Restricted Persons” and/or unauthorized persons will not have access to the Select Agents
- how the Select Agents will be secured and be controlled when not in storage
- the locations where the Select Agents will be stored and used
- disinfection and disposal methods

If the project is to be conducted in a University laboratory, the BSO contacts the PI and schedules an inspection of the site(s) where the research will be conducted. If the research also needs review and approval by the IACUC or IRB, approval by these committees is withheld pending approval of the project by the BSO/IBC and an assurance from the BSO that procedures are in place to ensure the safety of any personnel that will come in contact with the biohazardous materials, including laboratory staff and students, and animal care or greenhouse technicians.

Note: When contacted by the BSO the PI should discuss the need for a written Safety Protocol. A written Safety Protocol is required for projects where the biohazardous material comes in contact with animals and animal care staff.

Upon receiving a positive recommendation from the BSO (and the IBC chair if the protocol received full committee review), the IBC Chair informs the principal investigator. Approvals are for the life of the project or for a maximum of five years.

Records for the IBC and a database of BSO-approved protocols are maintained in the ORA in accordance with federal standards. Laboratory inspection records, training records, and the inventory are maintained by EHS in accordance with applicable federal regulations.