



**Institutional Biosafety Committee  
Policies and Procedures**

**Revision 4, October  
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## 1.0 INTRODUCTION

The purpose of this document is to outline the responsibilities, policies, and procedures for the Institutional Biosafety Committee (IBC) at the University Massachusetts Lowell (UMass Lowell). The IBC is a university-wide review body that oversees activities involving recombinant DNA (rDNA) molecules and potentially biohazardous materials. The IBC ensures that research activities using these materials and conducted at UMass Lowell are in compliance with the Federal [NIH Guidelines, Biosafety in Microbiological and Biomedical Laboratories (BMBL)], State and local laws and regulations. UMass Lowell is committed to ensuring the safe handling, storage, and disposal of potentially harmful biohazardous materials for research and instructional projects. IBCs are established specifically for the review of rDNA research but also review other research that includes biohazardous risks to the environment or public health. The broader purview of the committee is at the discretion of the Institution. Compliance reporting (adverse events reporting) is also a responsibility of the IBC. The IBC must at times communicate and coordinate review and approval of research projects with the Institutional Animal Care and Use Committee (IACUC) and the Institutional Review Board (IRB). The IBC may also provide recommendations for education and training related to biosafety for all UMass Lowell faculty, staff, and students that may be involved in the use of such materials.

The National Institutes of Health (NIH) require that an IBC be established at institutions that receive federal funding for research involving the use of biologically derived molecules. IBCs have been established in part as a result of public concern about the use and risks of these materials. NIH also requires that institutions receiving federal funds for rDNA research must establish and register an IBC. To be effective, the IBC must have the support of the senior administration.

The NIH Guidelines for Research Involving Recombinant DNA Molecules (referred to hereafter as the NIH Guidelines) were established to specify practices for constructing and handling rDNA molecules and organisms and viruses containing rDNA molecules. The Guidelines specifically apply to research at or sponsored at an institution that receives any NIH or United States Department of Agriculture (USDA) funding for rDNA research. The guidelines are **not** optional and are a term and condition of NIH and USDA funding for rDNA research. The Guidelines cover specific practices for handling rDNA, safety considerations, types of experiments covered, and roles and responsibilities of the IBC and its members. Due to the expanding nature of this field of research, the NIH Guidelines will never be complete or final as all conceivable experiments involving these materials cannot be foreseen. It is the responsibility of each institution and those associated with it to adhere to the intent of the NIH Guidelines as well as the specifics outlined therein. For more information on NIH Guidelines, go to <https://osp.od.nih.gov/biotechnology/nih-guidelines/>.

Each institution conducting or sponsoring rDNA research covered by NIH Guidelines is responsible for ensuring that the research conforms to the provisions set forth in the NIH Guidelines. The Institution is responsible for appointing and registering the committee and filing an annual report with NIH/OSP. Annual membership updates must be filed and include a roster of the members with the role and biographical sketch of each member. The registration and annual update provides NIH with the assurance of local review and biosafety risk and verifies to OSP that the IBC expertise meets NIH Guidelines. It also provides contact information for the

institution and a census of where DNA research is being conducted. IBCs are encouraged to open meetings to the public.

There are various levels of safety considerations, risk assessment, and approval levels based on the types of biological agents used and the research conducted. Experiments covered range from Level III-A, which require intense review and approval, to Level III-F for projects that are exempt from IBC review. Agents are classified into risk groups that range from RG-1, agents that are not associated with disease in healthy adults, to RG-4 for agents that are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are not usually available. While various types of studies may be exempt from review by the NIH, **only the IBC has the authority to exempt studies from review.**

## 2.0 INSTITUTIONAL BIOSAFETY POLICY

The UMass Lowell IBC policy applies to all research and teaching activities conducted at UMass Lowell regardless of funding for work that involves **rDNA, transgenic plants, animals, and microbes and/or biohazardous or infectious agents** (see page 8 for the definition of what are considered biohazardous materials). The work is approved through review of registration information submitted to the IBC. The submission and review includes assessment of the biosafety containment level proposed for the work; assessment of facilities, procedures, practices, and training; and expertise of personnel involved in research that involves the use of rDNA, infectious or biohazardous substances, and Select Agents and biologically derived toxins. All persons involved in activities using rDNA or biohazardous materials (also referred to as biological agents) at UMass Lowell must abide by the regulatory and policy requirements pertaining to the acquisition and use of these materials for research, teaching, and testing activities. The safe use of biological agents depends on the individual directing and conducting such activities. Every possible situation that could occur cannot be anticipated. Thus, this policy, in addition to the use of good judgment, is intended to help provide a safe work environment, well-controlled research study areas, and protection for the local community.

Projects that involve the use of biohazardous materials at other institutions may need to receive IBC approval from the UMass Lowell faculty and cooperating institution, depending on the nature of the project. Copies of approvals from the cooperating institutions should be forwarded to the Office of Research Integrity (ORI). All research and instructional activities involving biohazardous materials at UMass Lowell must be reviewed and approved by the IBC and the Biosafety Officer (BSO). The IBC also works in close cooperation with the Institutional Review Board (IRB) and the Institutional Animal Care and Use Committee (IACUC) to coordinate approval for protocols that also involve human subjects or animal research in which biologically derived materials are used. The use of stem cells requires both IBC and IRB review and approval. UMass Lowell is registered with the MA Department of Public Health for human embryonic stem cell research.

For more information, go to [www.uml.edu/Research/Integrity](http://www.uml.edu/Research/Integrity) or <https://www.uml.edu/EEM/Policies-and-Procedures/> for specific questions.

### **3.0 LAWS, REGULATIONS, AND GUIDELINES**

UMass Lowell faculty, students, staff, and any other persons involved in the use of biological agents at UMass Lowell will follow the regulatory guidelines set forth in the most recent versions of the following documents:

- NIH Recombinant DNA Guidelines (2001)
- CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL 5<sup>th</sup> edition)  
<http://www.cdc.gov/biosafety/publications/bmb15/>
- Public Health Security and Bioterrorism Preparedness and Response Act of 2002
- UMass Lowell IBC Policies and Procedures  
[www.uml.edu/Research/Integrity](http://www.uml.edu/Research/Integrity)
- UMass Lowell Environmental Health and Safety Office  
<https://www.uml.edu/EEM/Policies-and-Procedures/>
- All other relevant policies of the University of Massachusetts
- Office for Human Research Protection – Use of embryonic stem cells  
<http://www.hhs.gov/ohrp/policy/stemcell.pdf>

The policies and procedures outlined in this document are based on the federal regulatory guidelines.

## 4.0 CLASSIFICATION AND REGISTRATION

The type of physical containment depends upon standard practices generally used in microbiological laboratories including the application of special procedures, equipment, and laboratory installations that provide physical barriers. There are four biosafety levels that consist of combinations of laboratory practices and techniques, safety equipment, and facilities based on the potential hazard imposed by the agent(s) used and for the laboratory function and activity. Table 1 outlines the biosafety levels (BL) and the types of materials that are suitable for working under that classification. A risk assessment must also be made based on the Risk Group (RG) of an agent. Agents are classified into four Risk Groups according to their pathogenicity for healthy adult humans. Table 2 outlines the risk group classification information. (Tables 1 and 2 apply to all IBC related projects, Tables 3 and 4 apply to projects using rDNA.) Factors considered for determining containment levels include agent-specific factors such as virulence, pathogenicity, infectious dose, environmental stability, route of spread, communicability, operations, quantity, availability, and gene product characteristics such as toxicity, physiological activity, and allergenicity.

<b>Table 1. Laboratory Classifications- Containment Levels</b>	
BL1	Suitable for work with agents of unknown or minimal potential hazard to lab personnel and the environment. Not separated from general traffic patterns in the building and work generally conducted on open bench tops. Special containment equipment not required or generally used.
BL2	Similar to level 1 and suitable for work with agents of moderate potential hazard. Requires 1) lab personnel have specific training in handling pathogenic agents and are directed by competent scientists, 2) limited access to lab when work is being conducted, 3) procedures using infectious aerosols must be conducted in biosafety cabinets or other physical containment.
BL3	Applicable to clinical, diagnostic, teaching, research, or production facilities in which work is conducted with indigenous or exotic agents which may cause serious or potentially lethal disease as a result of exposure by inhalation. Personnel must have specific training in handling pathogenic and potentially lethal agents and must be supervised by competent scientists who are experienced working with these agents. All procedures are conducted within biosafety cabinets or other physical containment devices and personnel must wear appropriate personal protective equipment.
BL4	Strictest level of containment for working with extremely biohazardous materials. Only authorized persons are allowed to enter and work in the area and must follow stringent guidelines for safety.

<b>Table 2. Risk Group Classifications</b>	
RG1	Agents that are not associated with disease in healthy adult humans (BSL-1)
RG2	Agents that are associated with human disease, which is rarely serious and for which preventative or therapeutic interventions are often available (BSL-2)
RG3	Agents that are associated with serious or lethal human disease for which preventative or therapeutic interventions may be available (high individual risk but low community risk (BSL-3)
RG4	Agents that are likely to cause serious or lethal human disease for which preventative or therapeutic interventions are not usually available (high individual risk and high community risk (BSL-4)
For a complete listing of agents, see "Appendix B-Classification of Human Etiologic Agents on the Basis of Hazard" in the NIH Guidelines for Research Involving Recombinant DNA Molecules, April 2002.	

## 5.0 DEFINITIONS

**Animal Research Compliance Manager:** The Animal Research Compliance Manager is responsible for management of the animal facility, oversight of animals there, and their well-being. For activities that involve IBC approved materials, the facility manager should be informed of all materials to be used and informed of appropriate PPE for personal safety.

**Biosafety:** A complete program of administrative controls, medical surveillance, vaccination, and containment strategies for promoting safe laboratory practices, procedures, and containment equipment to reduce the risk of disease to all persons handling such materials at UMass Lowell from potential occupational exposure to infectious agents or other biologically derived molecules.

**Biohazardous Material:** Biohazardous materials and organisms include all infectious agents or biologically derived infectious materials that present either a risk or a potential risk to the health of humans or animals, either directly through infection or indirectly through damage to the environment. An IBC Registration Form must be submitted to the IBC prior to initiation of any project involving use of any such materials or agents. The list of materials and agents includes:

- Human, animal, and plant pathogens including viruses, oncogenic and defective viruses (viral vectors), Rickettsiae, Chlamydiae, bacteria (including those with drug resistance plasmids), fungi, parasites, undefined or other infectious agents, such as prions, and toxins (bacterial, fungal, plant)
- All human blood, blood components and products, human tissues and body fluids
- Cultured cells (all human and non-human primates), including human embryonic stem cells (HESC), and potentially infectious agents these cells may contain (please note that the use of HESC also requires IRB review and approval)
- Infected animals and animal tissues
- Non-human primates and any tissues derived therefrom (can transmit Herpes B virus)
- Sheep and any tissues derived therefrom (can transmit *Coxiella burnetii*, the causative agent of Q-fever)
- Recombinant DNA or transgenic plants, animals or microbes
- Agents regulated by HHS, CDC or USDA (Select Agents or Toxins). See Appendix B.
- Synthetic nucleic acids

**Biosafety Level (BL):** A description of the degree of physical containment being employed to confine biohazardous materials and to reduce the potential for exposure of laboratory workers, persons outside of the laboratory, and the environment. In Appendix G of the *NIH Guidelines*, these are graded from BL-1 (the least stringent) to BL-4 (the most stringent) and are applicable to Select Agents and biotoxins.

**Biosafety violation:** Actions that pose substantive harm to the health or safety of personnel, students, the public or the environment or a serious deviation from either the established research protocol or those practices that are commonly accepted by the scientific community or could result in an adverse biosafety event. A violation may also occur when a researcher demonstrates other serious or continued noncompliance with federal, state, or local laws, regulations, or policies.

**Biological Safety Officer (BSO):** An individual appointed by an institution to oversee management of biosafety risks. The *NIH Guidelines* require that a BSO be appointed when the institution is engaged in large-scale research or production activities, or in research requiring containment at BL-3 or BL-4. The duties of the BSO are described in the *NIH Guidelines*.

**Centers for Disease Control and Prevention (CDC):** The federal agency requiring registration before any transfer or use of Select Agents can occur. The BSO and the EHS Director are the UMass Lowell officials with the responsibility for ordering Select Agents.

**Export Controls:** Some materials that are registered with the IBC are also controlled by U.S. Export Control regulations. These laws and regulations may require federal agency approval or a license before any controlled materials may be exported out of the U.S. or transferred to foreign persons within the U.S. The three federal government agencies responsible for implementing the export control regulations include

- The Department of Commerce
- The Department of State
- The Department of Treasury

**Human Embryonic Stem Cells (HESC):** An undifferentiated cell of a multicellular organism that is capable of giving rise to indefinitely more cells of the same type, and from which certain other kinds of cell arise by differentiation. Stem cells are cells found in all multi cellular organisms and are characterized by the ability to renew themselves through mitotic cell division and differentiate into a diverse range of specialized cell types. Research with HESC is considered human subject research and additional federal and state laws apply to the research. UMass Lowell is now registered with the state to conduct such activities. Please be aware that the work must have an ethical review (independent of IRB, IBC and/or IACUC) before these materials are received or used at UMass Lowell.

**Infectious Agents:** An agent capable of producing infection. Several factors are taken into consideration when evaluating risk, which include pathogenicity of the organism, mode of transmission and host range, availability of effective measures, and availability of treatment.

**Institution:** A public or private entity, including federal, state, and local governments.

**Institutional Animal Care and Use Committee (IACUC):** The IACUC is responsible for overseeing all animal care and use at UMass Lowell and has adopted policies and procedures that apply to all vertebrate animals used for research and teaching.

**Institutional Biosafety Committee (IBC):** A committee responsible for reviewing research involving recombinant DNA, biohazardous materials, Select Agents, biologically derived toxins and other forms of research that include biohazardous risks.

**Institutional Official (IO):** An individual who signs, and has the authority to sign, on behalf of the Institution and make a commitment that the appropriate regulatory requirements will be met. The IO at UMass Lowell is the Vice Provost of Research. (The IO may sometimes be referred to as Responsible Official.)

**Institutional Review Board (IRB):** The IRB is responsible for protecting the rights and welfare of all human participants involved in research. Human participants are defined as “living individuals about whom an investigator (whether professional or student) conducting research obtains data or identifiable private information through intervention or interaction with the individual.”

**Large Scale:** Indicates the use of 10 liters or more of any one cell line.

**National Institutes of Health (NIH):** It is comprised of 27 separate Institutes and Centers, and is one of eight health agencies with the Public Health service within the U.S. Department of Health and Human Services. The goal of NIH research is to acquire new knowledge to help prevent, detect, diagnose, and treat disease and disability.

**NIH Guidelines for Research Involving rDNA Molecules (NIH Guidelines):** Outlines principles for the safe conduct of research employing recombinant DNA technology (created in 1976 and recently updated in May 2011). The NIH Guidelines detail practices and procedures for the containment of various forms of rDNA research, for the proper conduct of research involving genetically modified plants and animals, and for the safe conduct of human gene transfer research. It is a constantly changing document to keep pace with the changing state of science.

**Office of Science Policy** The NIH office responsible for developing, implementing, and monitoring NIH policies and procedures for the safe conduct of rDNA activities, including human gene transfer.

**Principal Investigator (PI):** Any UMass Lowell faculty member, or other authorized individual, who may serve as a project director/leader for activities that involve biological agents. The PI accepts full responsibility for all aspects of the project.

**Recombinant DNA Advisory Committee (RAC):** An NIH advisory committee whose principal role is to provide advice and recommendations to the NIH Director on 1) the conduct and oversight of research involving recombinant DNA, including the content and implementation of the *NIH Guidelines*, and 2) other NIH activities pertinent to recombinant DNA technology. A major element of this role is to examine the science, safety, and ethics of clinical trials that involve the transfer of rDNA to humans.

**Recombinant DNA Molecules:** Molecules constructed outside of living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or molecules that result from their replication.

**Select Agent:** Microorganisms or related toxins that have been specifically identified by the Federal Government as presenting a potential public health threat as agents of bioterrorism. Identified and regulated as such, these agents carry additional regulatory burdens for safety and security. See Appendix B for the list. Select agents are also controlled for export control purposes. In addition to IBC approval, ORI must be consulted before any quantities of Select Agents may be acquired or used at UMass Lowell.

## **6.0 COMMITTEE COMPOSITION**

The IBC must be composed of at least 5 members, two whom are not affiliated with the institution in any way other than serving on the IBC and represent the interest of the surrounding community with respect to health and protection of the environment. The chair and all members of the Institutional Biosafety Committee shall be appointed by the IO. The IBC should include members with experience and expertise in rDNA technology and biosafety and physical containment. The committee should have collective knowledge of institutional commitments and policies, applicable laws, standards of professional conduct and practice, community attitudes, and the environment with the ability to assess the safety of rDNA research and identify potential risks to public health and safety.

The IBC is required to have:

- 2 members not affiliated with the institution
- Biosafety Officer (if a BSL3 facility is required or large scale research is conducted)
- Plant expert
- Animal Expert

It is recommended that the IBC have experts in biosafety and containment, persons with knowledge of institutional policies and applicable laws, and individuals who reflect community attitudes and at least one member who serves as laboratory technical staff.

## 7.0 ROLES AND RESPONSIBILITIES

All personnel working at UMass Lowell and involved in the use of biohazardous materials share biosafety responsibility and must follow specified procedures, complete required training, act responsibly, and report any incidents involving registered materials that could be considered biohazardous. All personnel should inform their supervisors of any health conditions that could make work or exposure to such substances more hazardous to themselves or others. Roles and responsibilities are outlined based on the October 2011 NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines). For the complete NIH Guidelines, go to <https://osp.od.nih.gov/biotechnology/nih-guidelines/>

### **University of Massachusetts Lowell**

The Institution is responsible for appointing and registering the committee and filing an annual report with NIH/OSP. ORI files the annual membership update with a roster of the members, their role, and a biographical sketch of each member. The registration and annual update provides NIH with the assurance of local review and biosafety risk and verifies to OSP that the IBC expertise meets NIH Guidelines. The update provides contact information for the institution and a census of where rDNA research is being conducted. IBCs are encouraged to open meetings to the public. UMass Lowell is responsible for

- Supporting IBC policies and procedures that provide for the safe conduct of rDNA research and ensure compliance with the NIH Guidelines
- Establishing an IBC composed of individuals with the appropriate expertise and appointing a Committee Chair
- Appointing a BSO to the IBC (if rDNA research is conducted at level BSL-3 or BSL-4 or the institution engages in large scale research [any one culture in volume >10L])
- Ensuring that PIs conducting research comply with the NIH Guidelines
- Upon request, making all IBC meeting minutes and any documents submitted to or received from funding agencies available to the public
- Ensuring appropriate approved training is provided for IBC members, PIs, and laboratory staff

### **Institutional Biosafety Committee (IBC)**

The IBC is charged with determining the adequacy of the facilities, Standard Operating Procedures (SOPs), and safety training in relation to the use of biohazardous materials. Compliance reporting (adverse events reporting) is also a responsibility of the IBC.

For basic and preclinical research, IBCs have the responsibility to

- Review policies, programs, and directives regarding the use of biohazardous materials in academic, research, clinical, and animal care activities
- Review rDNA research for compliance with NIH Guidelines including
  - assessment of the containment levels required for the proposed research
  - assessment of the facilities, procedures, practices, and training and expertise of personnel involved in rDNA research
  - ensure compliance with all surveillance, data reporting, and adverse event reporting
- Review all IBC Registration applications and notify the PI of the results of the review

- Approve lower containment levels for certain experiments in which DNA from Risk Group 2-4 is cloned in non-pathogenic organisms
- Set containment levels for experiments involving biohazardous materials
- Periodically review institutional compliance with NIH Guidelines
- Report any significant problems with or violations of the NIH Guidelines and any significant research-related accidents or illnesses to the appropriate institutional official and NIH/OSP within 30 days

For human gene transfer research, IBCs must ensure:

- No participant enrolled is enrolled until NIH-RAC review is completed and IRB and IBC approval is obtained
- Issues raised by NIH-RAC in public review are considered
- Final IBC approval occurs only after NIH-RAC review
- Compliance with surveillance, data reporting, and adverse event reporting is maintained

IBC's may not authorize initiation of rDNA experiments NOT explicitly covered by the NIH Guidelines until NIH (with the advice of the RAC when required) establishes the containment requirement. The IBC must at times communicate and coordinate review and approval of research projects with the Institutional Animal Care and Use Committee (IACUC) and the Institutional Review Board (IRB). The IBC may also require education and training related to biosafety for all UMass Lowell faculty, staff, and students that may be involved in the use of such materials.

### **Environmental Health and Safety (EHS) Department**

EEM-EHS monitors compliance with University safety policies and procedures regarding potentially infectious and biohazardous materials and their use on campus. The Department assists PI's in the selection of appropriate laboratory practices, equipment, and controls based on the needs of the PI and their individual laboratories in addition to providing technical guidance to all personnel on matters related to laboratory safety. EEM-EHS develops and conducts appropriate training programs to promote techniques for the safe handling and disposal of biohazardous materials in accordance with IBC authorized use and NIH or BMBL safety criteria for the handling of such materials. All reported accidents which may result in personnel or environmental exposure to biohazardous materials are investigated by EEM-EHS and in response makes recommendations to all appropriate authorities about continuing practices in the affected location and how to address the prevention of future accidents. EEM-EHS also oversees the infectious waste disposal program. Purchase of any biological agents and products are reviewed and approved through the Department to identify and track all of these materials proposed for use on campus.

### **Biosafety Officer**

A Biological Safety Officer (BSO) must be appointed by the Institution if it engages in large scale research, which is indicated if production activities involving viable organisms containing rDNA molecule of 10 liters or more of any one cell line or if the institution engages in rDNA research that requires use of BSL3 or BSL4 facilities. The BSO reports to the EEM-EHS Director and has responsibility for oversight of research and other activities involving the use of biohazardous materials. In the absence of a BSO, staff from the Environmental Health and

Safety Office will fulfill this role. Containment levels are set in accordance with the NIH Guidelines and the Center for Disease Control and Prevention. The BSO reports violations of the NIH Guidelines and UMass Lowell policies and procedures to the responsible Institutional Official and the IBC. The BSO must be a voting member of the IBC. BSO duties include but are not limited to

- Advising and training the IBC members, faculty, and staff as necessary in safe use and practices for working with potentially biohazardous materials
- Pre-reviewing activities and registrations for the IBC and providing recommendations to ensure safe practices are followed and to facilitate IBC approval
- Inspecting facilities and reporting results to the IBC on an annual basis
- Reviewing and inspecting activities involving biohazardous materials in coordination with other EEM-EHS personnel, and the Director of Research Integrity
- Reporting to the IBC and the Institution any significant concerns, violations of the NIH Guidelines or UML policies and procedures, and research-related accidents or illnesses
- Providing assistance, input, and support required for emergency response
- Developing emergency plans for containment, handling accidental spills, and personnel contamination
- Determining the necessity for health surveillance of personnel involved in projects that involve biohazardous substances
- Providing technical advice to PIs on laboratory containment facilities, safety equipment, security, and research safety procedures
- If a biosafety violation occurs, then an investigation will be initiated by the IBC Chair with assistance from the Biosafety Officer and/or EEM-EHS staff.

### **ORI Director**

The ORI Director is a professional staff member reporting to the Associate Vice Chancellor for Research Administration and Research Integrity. The ORI Director works closely with the BSO and the EHS Office to ensure that research with biohazardous materials and organisms at the UMass Lowell is conducted in accordance with all applicable local, state, and federal regulations. The ORI Director is responsible for attending committee meetings and supporting and providing oversight for the IBC Administrator. ORI operations related to IBC activities include:

- Filing the annual report with NIH/OSP and updating with new members and biographic sketches
- Oversight of registration intake and processing, preparation and record keeping for committee meetings, and communication to faculty regarding IBC actions
- Assists with reviews of registrations, concerns memos, and final IBC approval communications, IBC agendas, meeting minutes and their distribution
- Maintaining records of registrations submitted and actions taken
- Reviewing space lease agreements for ORI requirements and reporting information back to the IBC and BSO
- Interfacing and communicating relevant information between the BSO, IBC, IRB, and IACUC

- Provide information about biosafety training options for PIs, IBC members, students and staff to meet IBC requirements

The ORI Director is responsible for reviewing all policies and procedures periodically. This allows for continued evaluation of the biosafety policies and procedures and ensures that all regulatory requirements and community needs are met. Policy change recommendations are brought to the IBC for discussion and a vote for approval. The ORI Director, BSO or University of Massachusetts System General Counsel may revise policies and procedures as necessary to comply with new statutory or regulatory requirements.

### **IBC Chair**

The primary responsibility of the Chair is to provide leadership to the IBC. The Chair is responsible for:

- Assisting in development of meeting agendas
- Convening and leading meetings
- Determining exempt projects
- Providing orientation for new members
- Ensuring IBC members are properly trained

The Chair is involved in the assessment of Biosafety misconduct, investigating any biosafety violations, and determining and recommending subsequent actions.

### **Principal Investigator**

PIs are responsible for full compliance with the NIH Guidelines and the IBC Policies and Procedures in the conduct of research. PIs are expected to set an example by their own actions to ensure compliance with the regulations and the UMass Lowell IBC Policies and Procedures and provide directives and guidelines for the work they supervise. PIs are responsible to:

- Identify potentially infectious and biohazardous materials proposed for use in research and teaching activities
- Submit research registration form(s) to the IBC for review and approval before commencing with any research activities using biohazardous substances
- Implement necessary specific control procedures within their own laboratories and ensure that students and staff working there receive proper instruction in the potential hazards of the materials they are working with
- Set an example by their own actions to ensure compliance with the regulations and the UML IBC Policies and Procedures and provide directives and guidelines for the work they supervise
- Notify the ORI and Office of Research Administration of any proposed activity using biohazards by indicating so on the Proposal Information Sheet that accompanies grant proposals.
- Ensure that reporting requirements are fulfilled and be accountable for any reporting lapses
- Ensure that copies of approval letters are received by the funding agency or sponsor of any proposed research

- Coordinate use and transport of biohazardous materials with EHS and refer to EHS Policies and Procedures as necessary
- Report any significant problems to the appropriate authorities (EHS, BSO, or ORI Director) after the project is initiated
- Report incidents promptly to the BSO and/or EHS office
- Assist in any follow-up investigation or reporting that may be required in the case of an incident.

### **Shipping and Receiving**

The Shipping and Receiving Department is under the direction of the Vice Chancellor for Finance and Operations. All **rDNA, transgenic plants, animals, and microbes and/or biohazardous or infectious agents** should be shipped in appropriate DOT approved containers and labeled and shipped to EHS for receiving the materials. They will contact the PI upon receipt of the materials. For more information, go to [www.uml.edu/eem/ehs](http://www.uml.edu/eem/ehs).

Any and all international shipments involving chemical or biological materials must be vetted and approved by ORI before being sent. A Request to Ship Materials Out of the U.S. form should be submitted to ORI for review. In some cases, a license may be necessary to ship the material. Contact the ORI Export Control Compliance Manager for assistance.

## 8.0 TRAINING REQUIREMENTS

All personnel involved in using biohazardous materials at UMass Lowell are required to complete program both Lab Safety and OSHA Bloodborne Pathogens (BBP)/Biosafety Training.

### **EHS Lab Safety Training**

All faculty, staff, graduate students, teaching assistants, and researchers that use chemicals, biological materials (including those with potential blood borne pathogens), generate hazardous waste, or work in laboratories (other than course work) are required to attend EHS Lab Safety and OSHA BBP/Biosafety Training on an annual basis. Both trainings are offered monthly throughout the year and the certification must be kept current to work in any UMass Lowell laboratory. The training provides information about the EHS staff and responsibilities, right-to-know law, emergency spill response notification, bloodborne pathogens/biohazards, personal protective equipment (PPE), biohazardous waste management, fire response procedures, and laboratory practices and policies. It is the Faculty members or laboratory manager should ensure that all lab workers have completed both EHS lab Safety and OSHA BBPB/Biosafety training. Training certificates are kept on file at the EHS Office.

### **OSHA BBP/Biosafety Training**

The EEM-EHS Department offers OSHA-BBP training to all employees, students, faculty and staff that will work in laboratories or potentially will be in contact with blood, body fluids, tissues, biopsies, cell lines, or other potentially infectious materials of human origin. These workers are considered at risk for occupational exposure to BBP and require training, adequate personal protective equipment (PPE), and are offered the Hepatitis B vaccination at no cost to them. OSHA- BBP training is valid for one year and lab workers must attend training annually.

In addition, EEM-EHS offers Biosafety training to all laboratory workers that will handle any kind of biological agents and work at BSL-1 and/or BSL-2 laboratories.

All personnel involved in research and teaching activities the registered with the IBC are required to complete - the annual Lab Safety and BBP/Biosafety Training,. Both trainings are offered monthly and the schedule can be find at <https://www.uml.edu/EEM/EHS/ehs-training/>. Training certification(s) must be provided for all personnel listed on the registration forms before the registration may be approved.

Every year after the initial training, personnel can update their annual training by taking the EHS monthly classes (<https://www.uml.edu/EEM/EHS/ehs-training/>), taking the online refresher training

(<https://www.uml.edu/sso/Auth/Login?returnUrl=%2Fservice%2FApps%2FSafetyCertification%2FLabStaff%2FStatus>) and or using the online Collaborative Institutional Training Initiative (CITI) at [www.citiprogram.org](http://www.citiprogram.org).

**CITI Training** CITI training is free of charge and modules may be selected to customize the training to the user's needs. Certificates are sent electronically to ORI, if linked to UMass Lowell during the registration process and are valid for three years. ORI tracks all training certification for personnel registered through the IBC. General concepts covered in CITI biosafety training include: Introduction to Biosafety Concepts, Regulations and Guidelines

Overview, OSHA Bloodborne Pathogens Standard, Laboratory Acquired Infections, Risk Management, and Animal Biosafety in addition to others.

Specific training modules are required depending on the nature of the materials to be used and the work to be conducted. Blood borne pathogen training is required annually. Personnel who work with these materials can update their BBP training annually by taking either the EHS training in person held monthly or the CITI online BBP module. The Clinical Laboratory and Nutritional Sciences Department has additional required modules through the CITI training program.

### **Research Specific Training**

Faculty are responsible to develop protocols and provide training for staff and students in safe handling and accidental exposure procedures for their specific research-related activities.

## **9.0 IBC ADMINISTRATIVE PROCEDURES**

The IBC discusses and reviews Registration Forms at regularly scheduled monthly meetings. PIs are notified when their registration is on the agenda and are encouraged to attend the meeting to be available to answer any questions. Possible outcomes include approved, requires modifications to secure approval, tabled or disapproved. The IBC receives an annual report from the BSO regarding the annual inspections of all UMass Lowell biosafety facilities (including laboratories and satellite facilities). The IBC may suspend any activity considered unsafe, a threat to public or employee health and safety, or any activity not conducted in accordance with IBC requirements.

Transparency and public participation are founding principles of the NIH Guidelines. Public access to meetings is encouraged. Minutes are not for general distribution or public access but they may, upon written request, be made available to the public. Information released to the public must be balanced with the need for security. Information vital to institutional or national security may be redacted from IBC minutes. Information about the location of Select Agents may not be released. Reasonable charges for photocopying of documents may be passed on to the organization or person requesting such information.

### **Meetings**

The IBC meets monthly, or as necessary to review proposed rDNA and registrations. A simple majority of members must be present at these meetings in order to conduct business. A passing vote is a simple majority of the members present. The NIH Guidelines do not prescribe how IBCs should be convened. Minority views are recorded in the minutes.

Meetings may be conducted by teleconferencing as long as a written record of the meeting is created to document committee actions and fulfill its duties and meeting requirements. Email may be used to distribute protocols, conduct pre-meeting reviews, approve meeting minutes, and to poll members about particular matters. Faculty or new researchers are invited to attend the meetings to answer questions and explain their research when appropriate.

### **Identification of Conflict of Interest**

No member of the IBC may vote on or be present for the review and discussion of a proposal in which the member is involved or has a financial or institutional conflict of interest. In such instances the IBC member will voluntarily recuse herself/himself from the meeting until the committee takes action on the proposal. The vote will show the total number of members present, the total votes (yes and no), and one abstention. This verifies that a quorum is present, even though the vote was one less than that necessary for a quorum.

A conflict of interest must be disclosed at the beginning of any meeting or before review of any documents to the Committee Chair or to the ORI Director to ensure:

- the responsible conduct and integrity of decisions made by the IBC;
- to protect the IBC member and the University from unnecessary and avoidable litigation and;
- to ensure the IBC members comply with agreements entered into with third-party funding organizations for whom the committee approves facilities, protocols, activities or research projects.

A conflict of interest is considered to be a committee member who has any of the following:

- an affiliation with any organization, company, venture or other body that involves a direct financial interest or benefit, directly or through relatives by blood or marriage, in the subject matter or materials of a protocol or registration for review by the committee;
- direct involvement in the research subject matter under review by the committee;
- is related, by blood or marriage, or a business partner of a person who is a researcher undertaking a protocol or registration considered by the committee;
- is a research competitor or has a personal conflict with the project or the investigators, so could be perceived as having a potential bias.

The meeting agenda will include the item "identification of conflict of interests'. A committee member is obliged to disclose, as soon as it comes to their attention, any conflict of interest or potential conflict of interest. If a committee member is unaware of any conflict of interest or potential conflict of interest at the time they sit in a meeting in which they later discover they are in a conflict situation, they should let the Chair of the Committee or the ORI Director know immediately once the conflict comes to, or is brought to, their attention. If a committee member is in any doubt about whether or not they are in a potential conflict situation, they must state this to the committee members at the commencement of the meeting.

Faculty members residing in the same Department are allowed to review protocols and registrations coming from the same Department as long as the Committee member does not have a personal interest or stake in the research being proposed. If a conflict is identified, the member may be present for discussion and to answer questions but will recuse themselves for discussion related to voting and approval.

### **Meeting Documentation**

The ORI is responsible for the administrative aspects of IBC meetings including coordinating with the Chair and BSO to set the meeting agenda, disseminating materials, scheduling meeting locations, and recording and distributing minutes and submitted registration forms tracking registration information and tracking training certificates. The agenda must include time to review and approve the previous meeting minutes, summarize activities reviewed or exempted since the last meeting, and provide administrative updates. Meeting minutes are distributed to all IBC members before the next meeting. Minutes include the meeting date, attendance, general registration form information (number, project title, PI, type of material, and recombinant methodology, containment level), motions, voting results, and committee actions on each registration reviewed.

### **Registration Approval and Documentation**

Meeting minutes and concerns memos are prepared by staff in the ORI and circulated to the IBC if necessary before finalizing. Concerns memos or approvals are sent to the PIs as soon as possible after the IBC meeting. After the PI responds to the concerns and revises the registration form, the IBC Chair, BSO or ORI Director reviews the information to ensure all concerns have been addressed. The final approval may be issued if all concerns have been addressed. The date of final approval is reported on the meeting agenda for the next scheduled IBC meeting. Approval memos include the name of the PI, title of the project, IBC registration number, biosafety level to be followed, and the list of all materials approved under the registration.

## 10.0 REGISTRATION SUBMISSIONS

### Who Should Register

PIs using biohazardous materials must register with the IBC. All activities at UMass Lowell that involve the use of **rDNA, transgenic plants, animals, and microbes and/or biohazardous or infectious agents** must submit IBC registrations. This includes grant-funded research, non-funded research, and teaching activities. Registration forms are available at [www.uml.edu/Research/Integrity](http://www.uml.edu/Research/Integrity). Typically, an IBC registration should directly parallel a funded research project overseen by the PI. The PI submits a Biological Research Registration Form to ORI for dissemination to the full IBC for review. The project may not commence until the PI has received official approval notification in writing from the IBC's authorized representative. The lifespan of an approved protocol is three years and parallels the life of a typical research grant. After approval, all forms are kept on file with ORI and the BSO. The registration form has separate sections for information regarding research with recombinant DNA, infectious agents, human or non-human primate source materials, animals, Select Agents, and classroom activities. These sections are described briefly below.

### Specific Regulated Material Requirements

The Registration Form has sections that must be completed for work with rDNA, Infectious Agents, Human or Non-Human Primate Source Materials, Animals or Select Agent materials. For rDNA registration, the PI must indicate the highest biohazard level required for the project according to the NIH Recombinant DNA/Infectious Agent Registration Guidelines <https://osp.od.nih.gov/biotechnology/nih-guidelines/>. The registration should clearly list and describe all biohazardous materials proposed for use. For rDNA registration, the form is reviewed for completeness and then forwarded to the Chair (or BSO), and depending on the biohazard level, may either be approved by the Chair at the suggested level (Level III-F, E, BSL1) with the appropriate biosafety requirements, or submitted for full IBC review (levels III- A, B, C, D; BSL>1).

For Select Agent registration, EHS staff or the BSO works closely with the PI to ensure compliance with UMass Lowell policies, Homeland Security, Export Controls Compliance, the Patriot Act and other regulations. This may include

- Determination of whether 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 unauthorized persons will not have access to the Select Agents
- Registers Select Agent(s) with appropriate federal, state, or municipal agencies as required
- Locations where the Select Agents will be stored and used
- How the Select Agents will be secured and be controlled when not in storage
- Disinfection and disposal methods
- Emergency response procedures
- Training recommendations for PIs

If the project is to be conducted in any UMass Lowell laboratory or space, EHS staff (or BSO) may inspect the site(s) where the research will be conducted. A written Safety Protocol may be required, if one is not already available, where biohazardous materials are used.

For work with infectious agents, the registration form should include the hazard of working with each agent, the source of the agent, whether it may have any antibiotic resistance, the host range and information about whether the agent may synthesize toxins. Procedures should be described in detail and include activities related to culture, volume of material expected for use, and concentrations. An explanation should be provided as to how the agent is inactivated or lysed and at what stage of the experiment this will occur.

For work with human or non-human primate source materials, information such as the type of material and its source, pathogen testing already available for the material, precautions and training provided to staff working with these materials, and if the materials used for the project are collected from human subjects, IRB approval will also be necessary.

## 11.0 COMPLETING THE REGISTRATON FORM

Registration forms should include as much detail as possible and should be complete. This helps to minimize the time and effort spent by the committee members for reviews. Incomplete or unclear documents will be returned to the PI for more detail to avoid wasting the committee members' time. General information should include the purpose and goals of the project, descriptions of all protocols and techniques to be used and detailed information about the types of materials, volumes to be used, and risks to personnel for each material. In addition to laboratory and personnel information, the registration should include details about safety procedures, precautions taken when using the materials registered, and a plan in the event of exposure to personnel and to cleanup a spill.

### **Research with Dual Committee Review (IBC and Animals or Human Subjects)**

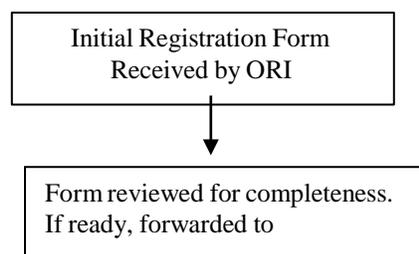
Some projects that require IBC review may also require the use of animal or human test subjects. In addition to providing the IBC with information about how the agents will be used and protections in place for personnel handling the materials, human subjects involved in analyzing materials, and animal facility workers, these projects also must be reviewed by the respective oversight committee. The final approval of each committee involved is required before a project requiring dual committee review can proceed. The Director of Research Integrity serves on each oversight committee to coordinate projects that require oversight by more than one committee. For projects that involve human participants, an IRB application must be completed and submitted to the IRB for review. For projects that involve animal test subjects, an Animal Care and Use Protocol must be completed and submitted to the IACUC for review and approval. These forms are available at <http://www.uml.edu/Research/Integrity/>.

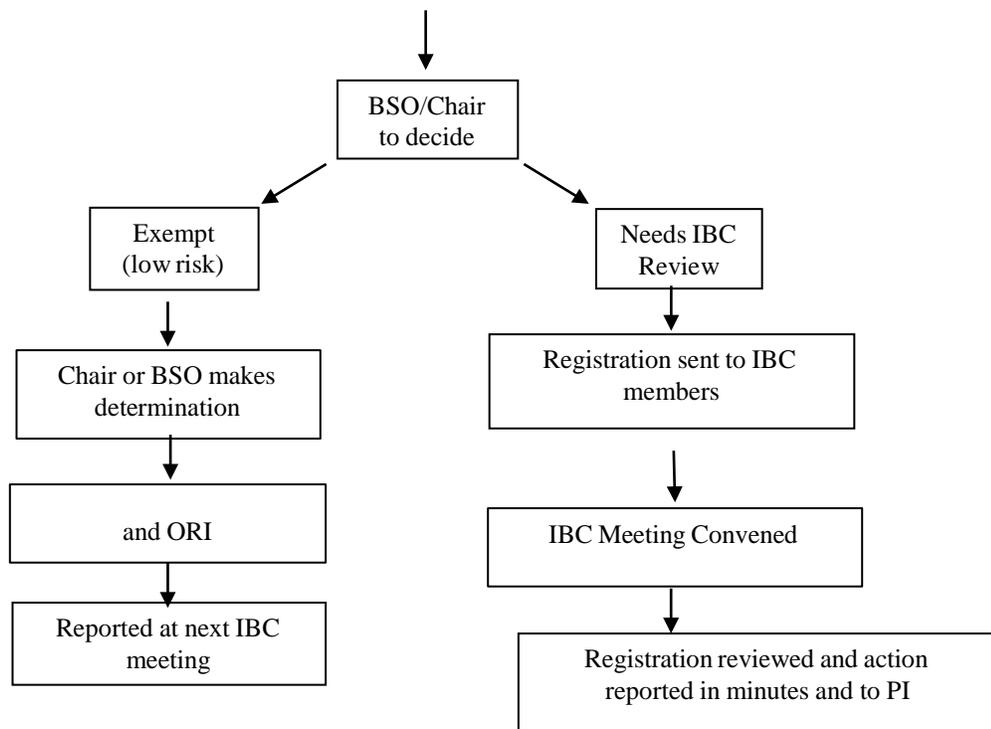
### **Risk Assessment**

It is the responsibility of all laboratory directors, laboratory supervisors and PIs to provide an initial assessment of the risk factors and risk levels involved in the proposed activities. In many instances the PI/Supervisor has significant experience working with similar biological agents or rDNA and are, therefore, in the best position to estimate appropriate biosafety levels for the laboratory and their immediate work environment. This assessment must be done in collaboration with the BSO, Environmental Health and Safety (EHS) staff, and the IBC.

### **Review Process**

There are various levels of review based on the nature of the hazard(s) involved in a study and the IBC has the sole authority to determine the review category. Protocols may be designated as exempt from review by the Chair or BSO or require full committee review. The Review Process Diagram below outlines the typical process:





**Exempt** protocols are those that present only minor hazards with very low risk that may be reviewed by the IBC Chair or BSO to validate the Exempt status. Exempt protocols may be validated immediately upon review but require a signature approving it as exempt. Upon receipt of the application by ORI, the BSO or IBC Chair assesses the proposal as to eligibility for an exemption from IBC review. The IBC Chair or BSO may direct ORI to issue an exemption approval memo. Projects that are exempted from review will be reported to the full IBC at regularly scheduled meetings. If the activities do not meet requirements for an exemption, then the application and the pre-review analysis will be forwarded to the full IBC for review at the next scheduled meeting.

**Full Committee Review** is used for protocols that may present hazards to humans, animals or the environment. Examples of projects that require full committee review include non-exempt rDNA protocols, use of biohazardous materials requiring BSL2 containment facilities or practices (or greater), or projects that involve the release of genetically altered organisms. It is recommended that the PI allow a minimum of 10-15 working days for the full review, approval, and notification process. The PI must address all concerns raised by the IBC before final approval is granted.

### Minor Amendments

A minor amendment form must be submitted for minor proposed changes in an approved Registration before the changes can be initiated. For major changes to an approved registration, a new registration form must be submitted for review and approval. Minor amendments are appropriate for adding agents, vectors, or cell lines that require the same (or lower) biosafety levels; removing agents, vectors, or cell lines; and for changes to personnel involved in the work. Minor amendments are NOT for changes in any of the following: approved management of

biohazards, accidental exposure plans, changes in biosafety levels, changes in work location, or biocontainment and biosafety precautions.

### **Biosafety Registration Approval Criteria**

The IBC determines that research proposals conform to the UMass Lowell NIH Assurance and that

- Safety procedures are developed and monitored for hazards and risks associated with the project or activity (the BSO will assist PIs to develop SOPs)
- Risk to personnel, students or visitors is reasonable in relation to the threats and hazards associated with use of the materials
- Risk to community health and environment is reasonable
- Facilities are adequate to minimize risks and handle the approved materials
- Preventative medical measures are taken to minimize risks associated with breeches in safety procedures (including any required occupational health consultations)

Safety procedures will be developed in collaboration with EHS staff and in accordance with EHS laboratory safety standards. Routine monitoring of facilities may be conducted by the EHS Office, the Office of Research Integrity, or the BSO as available.

### **Committee Action Information**

All registrations (exempt, expedited, and approved) and committee actions are recorded in meeting minutes. The IBC may decide to

- approve,
- require modification to secure approval,
- table, or
- disapprove the registration.

Approval memorandums are typically drafted by the IBC Administrator and reviewed by another IBC member before sending to the PI. The approval memo will contain any elements that the IBC requested to be modified or clarified during the full review. Approval memos will also include the identifying registration number, list all materials registered, note the highest biosafety level required for carrying out the work, and include a note about the supporting documentation such as training certificates, product descriptions, and exposure control plans. The letter will clearly state the changes requested before final approval is granted. Official copies of approval letters will be kept on file with ORI.

Approvals and all forms related to the approved IBC registrations are kept on file for three years after the end date of the activity. IBC records and a database of approved protocols are maintained by the ORI in accordance with federal standards. Laboratory inspection records, training records, and inventory are maintained by the EHS Office in accordance with applicable municipal, state, and federal regulations.

### **Dispute Resolution**

For disputes with IBC decisions, the Vice Provost for Research and the IBC Chair may be petitioned to reconsider if the PI disagrees with the findings of the IBC. The Chair will review the findings, brief the Vice Provost for Research on the findings, consider any new evidence or changes in circumstances, and together will render a final decision. All requests for reconsideration must be submitted to the IBC Chair within 30 days of receipt of the IBC's

decision. This request must be in writing, signed by the PI, and include copies of material relevant to the case, including any new evidence. All decisions of the IBC are final.

## **12.0 ENVIRONMENTAL HEALTH AND SAFETY REQUIREMENTS**

Access to hazardous agents shall be limited to authorized personnel, in accordance with the safe handling, storage, and disposal practices of UMass Lowell. The use of appropriate ventilation such as chemical fume hoods or biological safety cabinets must be utilized to separate personnel from exposure to hazardous agents. Hazardous agents include biological, radiological, and chemical materials that may be used during a research project. The EHS Department oversees procurement, use, and chemical inventory and provides several types of safety training related to the use of these materials. The IBC reviews proposed experimentation, facility capabilities, institutional procedures, and PI training and expertise to ensure that projects using biohazardous materials are conducted safely and follow NIH guidelines. While the IBC reviews proposed research, the EHS staff oversees the facilities and use of various materials within each facility. Facilities used for animal experimentation with hazardous agents shall be separated from animal housing and support areas. Similarly, the Radiation Safety Committee reviews and approves projects that involve the use of radioactive materials.

### **Material Procurement**

The procurement of biological agents must be made through the established EHS Office chemical and biological product PeopleSoft purchasing program. No materials may be procured until the IBC approval has been granted. The PI must communicate any incidents or problems to the IBC and EHS throughout the duration of the project. Projects that use rDNA must have replication competence testing.

### **Human and Non-human Primate Source Material**

For projects that involve the use of human and nonhuman primate source materials, PIs must comply with the Blood Borne Pathogen Program and Exposure Control Plan at UMass Lowell. Transfer of these types of materials between institutions must also follow specific packaging and shipping requirements and EHS can assist by providing PIs with the appropriate information for transfer of such materials. This information is available from the EHS Office at 978-934-2618 or [www.uml.edu/eem/ehs](http://www.uml.edu/eem/ehs). If necessary, IRB review may also be required for the use of human source materials, depending on how and where the materials are acquired.

### **EHS Policies**

Depending on the specific work activity, research protocol, and/or procedure being conducted in a facility, the use of personal protection equipment (such as gloves, eye protection, laboratory coats, shoe covers, respirators, etc.) is required to properly protect individuals. Workers are advised to review and familiarize themselves with the specific SOP that is available at each laboratory facility that provides specific references and information regarding what PPE is to be worn and utilized during specific work processes.

Biohazardous materials shall be purchased and inventoried through the UMass Lowell EHS Hazardous Materials PeopleSoft purchasing program. All Material Safety Data Sheets (MSDS) and product safety information sheets are available from the EHS Office through the Hazardous Materials Manager, 978-934-2543. The disposal of hazardous materials including biological,

chemical and physical agents will be in accordance with the UMass Lowell EHS Office program and with applicable federal, state, and municipal regulations.

All accidents, injuries (including animal bites and needle sticks) and exposure incidents must be reported immediately to the individual's supervisor, the Environmental Health and Safety Office at 978-934-2618 and the Human Resources Office at 978-934-3560. For immediate medical emergency assistance, call the emergency number at 978-934- 2911. It is staffed 24 hours a day by the UMass Lowell Police and Emergency Medical Technicians.

All exposure incidents shall be reported, investigated, and documented on an Incident Report Form. Forms are available by contacting EHS at 978-934-2618, Human Resources at 978-934-3560, Student Health Services at 978-934-4991 or online at [www.uml.edu/eem/ehs](http://www.uml.edu/eem/ehs).

The University's Blood Borne Pathogen Program and Exposure Control Plan ensures that appropriate "Post Exposure and Follow-Up" procedures are followed. All personnel including staff, faculty, students, and contract employees are required to adhere to the University's Blood Borne Pathogen Program and Exposure Control Plan.

### **Decontamination Practices**

The PI will be responsible to submit to the BSO for approval a Standard Operating Procedure for decontaminating an area after use of specific materials. The approved SOP shall be available in the lab and on file with the ORI Director and EHS Office.

## **13.0 ANNUAL REVIEWS AND OSP REPORTS**

IBC Policies and Procedures will be reviewed periodically and updated as necessary. EHS staff or the BSO are responsible for annual laboratory inspections or may delegate responsibility for inspection of facilities where rDNA and activities using hazardous agents occur. The annual review of facilities is to assess the overall biosafety at UMass Lowell and ensure that ongoing projects meet all regulatory requirements. Any deficits in policy will be brought to the IBC for comment and suggestions. The Director of ORI, BSO, or University of Massachusetts System General Counsel may revise policies and procedures in order to comply with new statutory or regulatory requirements.

Documentation in regards to the committee composition is compiled and submitted annually by the Director of ORI to the National Institutes of Health, Office of Science Policy. Annual reports must include a committee roster indicating the role and a bio-sketch of each member. The cover letter to NIH should indicate that the information submitted is for the annual report and note any changes from the previous year's submission.

## **14.0 BIOSAFETY VIOLATIONS**

A biosafety violation occurs when activities or use of materials are not followed as approved. Individuals who have concerns may contact the ORI Director or BSO. A Compliance Hotline has been established at 978-934-3100 for anonymous reporting. The IBC must review, and if warranted, investigate concerns involving biohazardous materials. All complaints must be reviewed but not all complaints may need to be investigated.

When registration violations are determined, the IBC will work to bring the registration and activities into compliance or take immediate action to stop any activities that may pose a hazard to any personnel. The IBC Chair is empowered to suspend any research or teaching activity immediately if violations are a threat to the health or safety of personnel

### **Investigations of Potential Biosafety Violations**

The IBC Chair, BSO, and Director of ORI will review the information and consult with other committee members to determine the seriousness of the complaint. If an investigation is necessary, the IBC may obtain additional information through:

- Unannounced visits to the location of the concern (laboratory/facility)
- Review of laboratory procedures, IBC registrations, and lab/facility documents (including records pertaining to material purchases and research records)
- Interview with the Principal Investigator (PI)
- Interviews with laboratory personnel, co-workers, etc.
- Letters or interviews with other individuals who might provide information for the investigation
- Assistance from other IBC members in collection of information

When necessary, the IBC may consult with experts in the particular area of research in order to make definitive, unbiased, and educated decisions regarding a potential violation. Recommendations regarding the seriousness of the violation will be presented to the IBC for further action as soon as possible.

If the IBC finds any of the following violations to be true,

- Actions that pose substantive harm to the health or safety of personnel, students, the public, or the environment,
- A deviation from the approved research activity,
- A deviation from the practices that are commonly accepted by the scientific community or could result in an adverse biosafety event, or
- If a PI demonstrates willful misconduct or other serious or continued noncompliance with federal, state, or local laws, regulations or policies.

Then the IBC Chair has the authority to immediately suspend the registration approval and research activity. (The IBC Chair may suspend activities in advance of the hearing if the Chair determines a significant threat to employees or public health and safety or regulatory compliance.)

If the investigation determines that the biosafety violations are minor, the IBC Chair will notify the PI in writing to indicate what action(s) must be taken to correct the problem and any required communication to the research participants.

Depending on the severity of the violation, enforcement or disciplinary actions may also include but not be limited to termination of privileges, suspension of privileges, probation, a letter of reprimand, mandatory training, or other actions deemed necessary by the IBC or IO. The IBC Chair will report to the full IBC a summary of the violation, review the information gathered, steps taken, and outcome at the next scheduled meeting.

Any protocol or investigator suspension will be reported directly to the ORI Director and BSO. The IO will be notified and report as necessary to the appropriate federal agencies or sponsors.

### **Misconduct**

If a PI continues research activities after notice of suspension by the IBC, or if a PI conducts research activities without registering with the IBC, it is considered to be misconduct. The misconduct is then forwarded to the ORI Director and the IO for administrative review and determination of action. Misconduct of this nature may also fall under the purview of the UMass Lowell Policy on Misconduct in Science.

### **Reporting Concerns**

Any employee, student, or agent of UMass Lowell reporting a concern will be protected against reprisal. There is a Compliance Hotline established at 978-934-3100 to file anonymous complaints or send an email to [Compliance\\_Hotline@uml.edu](mailto:Compliance_Hotline@uml.edu). Every effort will be made to protect the complainant's confidentiality, but UMass Lowell is an agency of the Commonwealth of Massachusetts and is therefore subject to the Massachusetts Public Records law, G.L. c.66, § 10. This law states the general rule that any record made or received by an officer of the Commonwealth is presumed to be a public record and must be released to "any person" who requests it. If appropriate, concerns involving the care and use of animals may fall under the purview of the UMass Lowell Policy on Misconduct in Science.

## 15.0 APPENDIX A – Resources

- American Biological Safety Association - <http://www.absa.org/>
- Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5<sup>th</sup> Ed. 2009. U.S. Government Printing Office, Washington, D.C. - <http://www.cdc.gov/biosafety/publications/bmb15/>
- Boston Public Health Commission – [www.bphc.org](http://www.bphc.org)
- Centers for Disease Control and Prevention - Atlanta, Georgia 30333 Telephone: (800) 232-4636 - [www.cdc.gov](http://www.cdc.gov)
- List of Select Agents - <https://www.selectagents.gov/SelectAgentsandToxinsList.html>
- Massachusetts Department of Public Health - <http://www.mass.gov/eohhs/gov/departments/dph/>
- Massachusetts State Regulations:
  - [105 CMR 480.000](#): Minimum Requirements for the Management of Medical or Biological Waste (state sanitary code chapter VIII)
  - <https://www.mass.gov/regulations/105-CMR-12000-the-control-of-radiation> Radiation Control Program
  - [105 CMR 300.000](#): Reportable Diseases, Surveillance, and Isolation and Quarantine Requirements
- National Animal Disease Center, U.S. Department of Agriculture, Ames, Iowa 50010 Telephone: (515) 862-8258 - [http://www.ars.usda.gov/main/site\\_main.htm?modecode=36-25-30-00](http://www.ars.usda.gov/main/site_main.htm?modecode=36-25-30-00)
- National Institutes of Health Guidelines - [https://osp.od.nih.gov/wp-content/uploads/NIH\\_Guidelines.pdf](https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf)
- Public Health Agency of Canada - [www.phac-aspc.gc.ca](http://www.phac-aspc.gc.ca)
- University of Massachusetts Lowell, Environmental Health & Safety <https://www.uml.edu/eem/ehs/>
- U.S. Department of Labor, Occupational Safety and Health Administration (Standards - 29 CFR Bloodborne pathogens.-1910.1030 <https://www.osha.gov/SLTC/bloodbornepathogens/standards.html>