Institutional Biosafety Committee
Guidelines
Revision 3, September 2010

Institutional Official (IO): Dr. Louis Petrovic
Director of Institutional Compliance: Andrew Karberg Esq.

Committee Composition

Chair: Dr. Erin Bromage
Responsible Officer (RO): Andrew Karberg Esq.
University BioSafety Officer: Dr. Sheldon Cooper (Interim)
Recombinant Protein Dr. Tracie Ferreira
Plant Dr. Cathy Neto
Select Agent Dr. Shuowei Cai
Facilities (alternate responsible official) Sal Filardi
Additional Members Dr. Shanka Bhowmick
Community Member Dr. Pingguo He
Community Member Dr. Paul Calvert
Community Member To be named
Community Member To be named

Total committee = 12
Quorum = 7
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INTRODUCTION

This document outlines the responsibilities and guidelines for the Institutional Biosafety Committee (IBC) at the University Massachusetts Dartmouth (UMD). 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. It also requires that any institution that receives federal funds for rDNA research must establish and register an IBC.

The UMD IBC is a university faculty committee that oversees activities involving recombinant DNA (rDNA) molecules, biohazardous agents, materials and toxins in all research and teaching activities conducted by University faculty or research personnel. The UMD IBC ensures that research activities utilizing these materials conducted at UMD are in compliance with the Federal [i.e. NIH Guidelines, Biosafety in Microbiological and Biomedical Laboratories BMBL], State, and Local laws and regulations and university guidelines. For more information on Biosafety in Microbiological and Biomedical Laboratories, go to http://www.cdc.gov/OD/ohs/biosfty/bml5/bml5toc.htm. UMD is committed to ensuring the safe handling, storage, and disposal of potentially harmful biohazardous materials for research or instructional projects. Federal regulations mandate IBC review of rDNA research, however near universal best practices at research universities expand the IBC’s purview to include biohazards and their associated risks to the environment and public health. UMD has elected to embrace these best practices.

Other IBC responsibilities include compliance reporting (adverse events reporting) and coordinating review of “overlap” research with the Institutional Animal Care and Use Committee (IACUC) and the Institutional Review Board (IRB). The IBC also provides recommendations for education and training related to biosafety of rDNA, biohazardous agents, materials and toxin research for all UMD faculty, staff, and students.

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. Instead they are the terms and conditions of NIH and USDA funding for rDNA research. The Guidelines cover specific practices for handling rDNA (e.g., safety considerations, types of experiments covered, and roles and responsibilities of the IBC and its members). However, 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.

The Institution is responsible for appointing and registering the committee and filing an annual report with NIH/OBA. 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 assessment, and verifies to OBA that the IBC expertise meets NIH Guidelines. It also 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.

While various types of studies may be exempt from review by the NIH, only the IBC has authority to exempt studies from review.
Mission Statement

Ensure the University safeguards human health and the environment by maintaining an adherence with the NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines) and the Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th ed. through a balance of outreach and support for research personnel, the IBC will:

- Assure activities meet the ethical and legal requirements for the responsible use of rDNA, biohazardous agents, materials and toxins;
- Establish policies and make recommendations to the University regarding such activities;
- Minimize risks to the research personnel, community and the environment by educating the University community regarding the regulatory requirements for the use of rDNA, biohazardous agents, materials and toxins.

Charge and Authority of the IBC

The Chancellor and Institutional Officer (IO) have charged the committee with review, approval and oversight of research involving rDNA and biohazardous materials, agents and toxins in research and teaching activities. Responsibilities of the IBC include assessment of facilities, procedures, practices and training of research personnel to assure compliance with NIH/OBA and other pertinent guidelines and regulations. To successfully carry out these responsibilities, the IBC is appointed to achieve sufficient knowledge and expertise in biomedical research and biosafety. The IBC has the authority to approve, require modifications to secure approval, disapprove, suspend or terminate research activities as required to assure adherence to the appropriate regulations and guidelines.

The IBC has been charged in the planning and implementation of the campus biosafety program to ensure the health and safety of all personnel working with rDNA and biohazardous materials, agents and toxins. The IBC makes certain that research conducted at the Institution is in compliance with the NIH Guidelines, the BMBL, and CDC and USDA regulations. It also drafts campus guidelines, and reviews individual research proposals that use rDNA and biohazardous materials, agents and toxins. Because the University receives NIH funding for rDNA research, all activities involving rDNA must follow the NIH Guidelines. Failure to adhere to these guidelines can result in the suspension or termination of NIH funding, or to the imposition of prior NIH approval of all rDNA projects at the institution. The IBC is therefore responsible for establishing and implementing guidelines that provide for the safe conduct of research involving rDNA and biohazardous materials, agents and toxins to ensure adherence with NIH Guidelines, the BMBL 5th ed., and state and local laws. Also, as delineated in the IO’s charge to the IBC, the committee is given authority to oversee all research involving rDNA and biohazardous materials, agents and toxins including suspension or termination of research that does not comply with UMD IBC guidelines.
INSTITUTIONAL BIOSAFETY POLICY

The UMD IBC policy applies to all research and teaching activities conducted at UMD regardless of the funding source for work that involves rDNA, biohazardous or infectious agents, select agents, and toxins. The UMD IBC must grant approval prior to the acquisition, use, or transfer of biohazardous materials, infectious agents, select agents, or toxins. Research is approved through review of registration information submitted by the PI or course instructor to the IBC. The 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 the research. All persons involved in activities using rDNA or biohazardous materials (also referred to as biological agents) at UMD must abide by the regulatory and policy requirements pertaining to the acquisition and use of these materials for research, teaching, or 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 should receive IBC approval from the cooperating institution. Copies of approvals from cooperating institutions should be forwarded to the Office of Institutional Compliance. All UMD research and instructional activities involving biohazardous materials must be reviewed and approved by the IBC in conjunction with the Biosafety Officer (BSO). The IBC works in close cooperation with the Institutional Review Board (IRB) and the Institutional Animal Care and Use Committee (IACUC) to approve and oversee protocols submitted for human or animal research, which involve the use of biologically derived materials.
Experiments Requiring IBC Review

Experiments that required IBC review include, but are not limited to:

- Recombinant studies that are exempt from the NIH Guidelines.
- The deliberate transfer of a drug resistance trait to micro-organisms that are not known to acquire the trait naturally.
- The deliberate transfer of rDNA or DNA or RNA derived from rDNA into human research participants (human gene transfer).
- The deliberate formation of rDNA containing genes for the biosynthesis of toxin molecules.
- The use of RG-2 or RG-3 agents as host-vector systems.
- Infectious agents [pathogenic or infectious bacteria, viruses, fungi or parasites or nucleic acids (prions) or agents of unknown pathogenicity to humans, plants or animals]
- The cloning of DNA from RG-2 or greater agents into non-pathogenic prokaryotes or lower eukaryotic host-vector systems.
- The use of infectious or defective RG-2 or greater agents.
- Whole animals in which the animal’s genome has been altered by stable introduction of rDNA or DNA derived into the germ-line (transgenic animal).
- Viable rDNA-modified micro-organisms or cell lines tested on whole animals.
- More than 10 liters of rDNA culture in a single vessel.
- The formation of rDNA molecules containing one-half or more of the genome of a eukaryotic virus or from the same virus family.
- Experiments using BSL-2 or BSL-3 containment.
- Non-recombinant research using biohazardous materials, agents or toxins.
- All research using biological toxins or bioactive derivatives or subunits of toxins.
- Research collecting or analyzing human or non-human primate cell lines, tissues, fluids or other potentially infectious material.
- Xenotransplantation

For more information, email biosafetyofficer@UMD.edu for specific questions.
LAWS, REGULATIONS, AND GUIDELINES
UMD faculty, students, staff, and other persons involved in the use of biological agents at UMD 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 5th edition)
  http://www.cdc.gov/OD/ohs/biosfyt/bmb15/bmb15toc.htm
- Public Health Security and Bioterrorism Preparedness and Response Act of 2002
- Federal, State, and local laws related to biological agents
  Boston Public Health Commission
  http://www.bphc.org/programs/cib/environmentalhealth/biologicalsafety/Pages/Home.aspx
- UMD IBC Guidelines: http://www.atmc.umassd.edu/institutional_compliance/compliance.cfm
- UMD Environmental Health and Safety Office
  http://www.UMD.edu/EHS/policies_and_procedures/pandp.html
- All other relevant policies of the University of Massachusetts

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

Table 1. Laboratory Classifications- Containment Levels

<table>
<thead>
<tr>
<th>BL</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>BL1</td>
<td>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.</td>
</tr>
<tr>
<td>BL2</td>
<td>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.</td>
</tr>
<tr>
<td>BL3</td>
<td>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.</td>
</tr>
<tr>
<td>BL4</td>
<td>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.</td>
</tr>
</tbody>
</table>

Table 2. Risk Group Classifications

<table>
<thead>
<tr>
<th>RG</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>RG1</td>
<td>Agents that are not associated with disease in healthy adult humans (BSL-1)</td>
</tr>
<tr>
<td>RG2</td>
<td>Agents that are associated with human disease, which is rarely serious and for which preventative or therapeutic interventions are often available (BSL-2)</td>
</tr>
<tr>
<td>RG3</td>
<td>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))</td>
</tr>
<tr>
<td>RG4</td>
<td>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))</td>
</tr>
</tbody>
</table>
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.

**Table 3. Summary of Recombinant DNA/Infectious Agent Registration Requirements**
From Section III, Experiments Covered by the NIH Guidelines for Research Involving Recombinant(r) DNA Molecules (http://www4.od.nih.gov/oba/)

<table>
<thead>
<tr>
<th>Level</th>
<th>Approval/Review Required</th>
<th>Experiments Covered</th>
</tr>
</thead>
<tbody>
<tr>
<td>III-A</td>
<td>IBC and NIH Director Approval, RAC Review*</td>
<td>Transfer of a gene encoding drug resistance into microorganisms that are not known to acquire the trait naturally</td>
</tr>
<tr>
<td>III-B</td>
<td>NIH/OBA, IBC Approvals*</td>
<td>Deliberate formation of rDNA containing genes for the biosynthesis of toxin molecules lethal for vertebrates at an LD50 of less than 100ng/kg of body weight (e.g. microbial toxins such as botulinum, tetanus, diphtheria, and <em>Shigelladysenteriaeneurotoxin</em>)</td>
</tr>
<tr>
<td>III-C</td>
<td>IBC, IRB Approvals and NIH/OBA Registration*</td>
<td>Proposals involving the deliberate transfer of rDNA, or DNA or RNA derived from rDNA, into human subjects (human gene transfer)</td>
</tr>
<tr>
<td>III-D</td>
<td>IBC Registration and Approval*</td>
<td>Experiments using Risk Group 2, 3, and 4 restricted agents as host-vector systems; experiments in which DNA from risk group 2, 3, 4, or restricted agents is cloned into nonpathogenic prokaryotic or lower eukaryotic host-vector systems; experiments involving the use of infectious DNA or RNA viruses or defective DNA or RNA viruses in the presence of helper virus in tissue culture systems; experiments involving whole animals or whole plants; experiments involving &gt;10 liters of culture. Construction of transgene(s) to generate transgenic animals requires IBC approval. The use of transgenic animals does not but may require IACUC approval.</td>
</tr>
<tr>
<td>III-E</td>
<td>IBC Notification**</td>
<td>Experiments involving formation of rDNA with no more than 2/3 of the genome of any eukaryotic virus; experiments involving whole plants, transgenic rodents</td>
</tr>
<tr>
<td>III-F</td>
<td>Exempt- IBC Registration Still Required**</td>
<td>Experiments using rDNA not found in organisms or viruses; DNA segments entirely from a single non-chromosomal or viral DNA source; DNA entirely from a prokaryotic host or host DNA transferred to the same host or related species; entirely segments from different species that exchange DNA by known physiologic processes; those that do not pose a significant risk to health or the environment as determined by the NIH Director (e.g. purchase of transgenic animals with no further genetic manipulations).</td>
</tr>
</tbody>
</table>

*Approval required before initiation. ** Notify IBC simultaneous with project initiation, approval still required.
Table 4. rDNA exemptions from the NIH Guidelines (IBC registration is still required).

<table>
<thead>
<tr>
<th>Section III-F-1</th>
<th>Those molecules that are not in organisms or viruses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Section III-F-2</td>
<td>Those molecules that consist entirely of DNA segments from a single non-chromosomal or viral DNA source, though one or more of the segments may be a synthetic equivalent.</td>
</tr>
<tr>
<td>Section III-F-3</td>
<td>Those molecules that consist entirely of rDNA from a prokaryotic host including its indigenous plasmids or viruses when propagated only in that host (or a closely related strain of the same species), or when transferred to another host by well-established physiological means.</td>
</tr>
<tr>
<td>Section III-F-4</td>
<td>Those molecules that consist entirely of DNA from an eukaryotic host including its chloroplasts, mitochondria, or plasmids (but excluding viruses) when propagated only in that host (or closely related strain of the same species).</td>
</tr>
<tr>
<td>Section III-F-5</td>
<td>Those molecules that consist entirely of DNA segments from different species that exchange DNA by known physiological processes, though one or more of the segments may be synthetic equivalent. A list of such exchangers will be prepared and periodically revised by the NIH Director with the advice of the RAC after appropriate notice and opportunity for public comment (see Sec IV-C-1-b-(1)(c), Major actions). See Appendices A-I through A-VI, Exemptions Under Section III-F-4-Sublists of Natural Exchangers, for a list of natural exchangers that are exempt from the NIH Guidelines.</td>
</tr>
<tr>
<td>Section III-F-6</td>
<td>Those molecules that do not present a significant risk to health or the environment (see Section IV-C-1-b-(1)-(c), Major actions), as determined by the NIH Director, with the advice of the RAC, and the following appropriate notice and opportunity for public comment. See Appendix C, Exemptions under Section III-F-6 for other classes of experiments which are exempt from the NIH Guidelines.</td>
</tr>
</tbody>
</table>
DEFINITIONS

**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 employees 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 Research Registration Form must be submitted to the IBC prior to initiation of any project involving use of these materials or agents. The following is a list of the potentially hazardous biological materials and agents.

- 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, tissues and body fluids
- Cultured cells (all human and non-human primates) and potentially infectious agents these cells may contain
- 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
- Agents regulated by HHS, CDC or USDA (Select Agents or Toxins). See Appendix B.

**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 could result in an adverse biosafety event. A violation may also occur when a PI 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 sections IV-B-3 of 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 UMD officials with the responsibility for ordering Select Agents.

**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 UMD and has adopted policies and procedures that apply to all vertebrate animals used for research and teaching.

**Institutional Biosafety Committee (IBC):** A committee created to review research involving recombinant DNA, biohazardous materials, select agents, and biologically derived toxins. The IBC also reviews other forms of research that include biohazardous risks as part of the assigned responsibilities.

**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. May also be referred to as Responsible Official.

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

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

**National Institutes of Health (NIH):** It is comprised on 27 separate Institutes and Centers, and is one of eight health agencies with the Public Health service, which is an agency 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). 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 Biotechnology Activities (OBA):** 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:** Any UMD 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.

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 Associate Vice Chancellor for Research and Development (Institutional Official). 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 BSL3 facility required or large scale research is conducted)
- rDNA expert
- Plant, plant pathogen, plant pest containment expert
- Animal Containment Expert
- Select Agents 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 from laboratory technical staff.

ROLES AND RESPONSIBILITIES

All personnel involved in potentially biohazardous activities share biosafety responsibility and must follow specified procedures, complete required training, act responsibly, and report incidents involving hazardous circumstances. 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 April 2002 NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines). For the complete NIH Guidelines, go to http://oba.od.nih.gov/rdna/nih_guidelines_oba.html
**Institutional Official**

The UMD Institutional Official is the Associate Vice Chancellor for Research Development. The I/O is responsible for:

- Supporting IBC policies and procedures that provide for the safe conduct of rDNA research
- Ensuring compliance with the NIH Guidelines, BMBL, and university policies and procedures;
- Establishing an IBC composed of individuals with the appropriate expertise;
- 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;
- Ensuring appropriate approved training is provided for IBC members, PIs, and laboratory staff;
- Providing and maintaining adequate facilities for biohazardous research;
- Annually evaluating IBC members with input from the IBC Chair and OIC Director;
- Overseeing the IBC and research personnel who obtain, possess or use rDNA and biohazardous materials, agents and toxins;
- Annually evaluating allocation of resources to the IBC and adjusts as necessary.

The IO and the Chancellor have charged the IBC (See Section) to review, approve and provide oversight and guidance to those research personnel who seek to use rDNA and biohazardous materials, agents and toxins in experiments or teaching. Any possession and/or use of rDNA and biohazardous materials, agents and toxins at the University must be conducted with appropriate safeguards and in accordance to with University policies and federal guidelines and regulations.

**IBC**

The IBC is charged with determining the adequacy of the facilities, 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 RiskGroup 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/OBA within 30 days;
IBCs 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 provide recommendations for education and training related to biosafety for all UMD faculty, staff, and students that may be involved in the use of such materials.

**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 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 UMD guidelines 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;
- Reviewing or pre-reviewing registrations for the IBC and providing recommendations to ensure safe practices are followed;
- Inspecting facilities and reporting results to the IBC on an annual basis;
- Reviewing and inspecting activities involving biohazardous materials in coordination with other EHS personnel, the Office of Research Services Facility Manager, and the Director of Institutional Compliance;
- Reporting to the IBC and the Institution any significant concerns, violations of the NIH Guidelines or UMD guidelines, 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 EHS staff.

**Director of Institutional Compliance**

The Director of Institutional Compliance is a professional staff member reporting to the Associate Vice Chancellor for Research who works closely with the BSO and the EHS Office to ensure that research with biohazardous materials and organisms at the UMD is conducted in accordance with all applicable local, state, and federal regulations. With respect to the IBC, the Director of Institutional Compliance is responsible for:

- Filing the IBC registration, biographical sketches and the annual report with NIH/OBA;
- Managing the registration intake, review process, and working with the BSO and IBC for registration reviews;
- Drafting and distributing IBC minutes;
- Maintaining records of registrations submitted and actions taken;
Notifying the PI of the outcome of a registration review;
Providing administrative support to the IBC and BSO;
Reporting oversight activity to the IBC when the activity does NOT require IBC oversight;
Interfacing and communicating relevant information between the BSO, IBC, IRB, and IACUC and attending meetings of all three committees;
Make available biosafety training materials for PIs, IBC members, students and staff at UMD in coordination with EHS staff or the BSO as necessary.

The Compliance Director is responsible for reviewing all guidelines outlined in this manual at least once a year. This allows for continued evaluation of the biosafety guidelines and ensures that all regulatory requirements and community needs are met. Policy change recommendations are brought to the IBC for discussion and action. The Director of Institutional Compliance 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. In lieu of appointing a chair, the Institutional Official may delegate appointment of the chair to the full IBC. Acting under such delegation, the IBC may elect a chair. The IBC chair serves a one year term. The Chair is responsible for:

- Developing meeting agendas;
- Convening and leading meetings;
- Determining exempt projects;
- Providing orientation for new members;
- Ensuring IBC members are properly trained;
- Assigning subcommittees as needed to review an issue prior to official committee decisions made at the convened meeting;
- Acting as liaison between the research personnel and IBC;
- Serving as one of three contacts for all regulatory agencies (in addition to IO who may delegate this function).

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 guidelines outlined by UMD in the conduct of research. PIs are expected to set an example by their own actions to ensure compliance with the regulations and the UMD IBC guidelines and provide directives and guidelines for the work they supervise. PIs responsibilities include:

- Identifying potentially infectious and biohazardous materials proposed for use;
- Providing adequate training and oversight for all CO-PIs, administrators, students, and staff working under their direction;
- Submitting research registration form(s) to the IBC for review and approval before commencing with any research activities using biohazardous substances or purchasing biohazardous substances;
Implementing necessary specific control procedures within their own laboratories and ensuring that students and staff working there receive proper instruction in the potential hazards of the materials they are working with;

Ensuring compliance with the regulations and the UMD IBC guidelines and providing directives and guidelines for the work they supervise;

Notifying the Offices of Institutional Compliance and Research Administration of any proposed activity using biohazards by indicating so on the Proposal Information Sheet accompanying a grant proposal;

Ensuring that reporting requirements are fulfilled;

Ensuring that copies of approval letters are received by the ORA to be forwarded to the funding agency or sponsor of any proposed research;

Coordinating use and transport of biohazardous materials with EHS and refer to EHS Policies and Procedures as necessary;

Immediately reporting any significant problems or incidents to the appropriate authorities (EHS, BSO, or Director of Institutional Compliance);

Assisting in any decontamination, follow-up investigation, or reporting that maybe required.

TRAINING REQUIREMENTS

All personnel involved in using biohazardous materials at UMD are required to complete the approved biosafety training program – www.citiprogram.org.

EHS Laboratory 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/biohazardous waste, or do work beyond classes in laboratories are required to attend the EHS Laboratory Safety Training on an annual basis. The training provides information about the EHS staff and responsibilities, right-to-know law, emergency spill response notification, blood borne pathogens/biohazards, personal protective equipment (PPE), hazardous waste management, fire response procedures, and laboratory practices and policies. It is the responsibility of the faculty member or laboratory manager that oversees the laboratory to ensure that all workers have completed the EHS laboratory safety training and are certified. Training certificates are kept on file at the EHS Office.

Online Training

All personnel involved in research activities or of training students that are registered with the IBC will be required to complete the online Collaborative Institutional Training Initiative (CITI) at www.citiprogram.org and submit copies of training certification(s) for personnel listed on theregistration forms. CITI training is free of charge and modules can be selected to customize training to the user’s needs. Certificates are sent electronically to the Institutional Compliance Office, if linked to UMD during the registration process. The Office of Institutional Compliance 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, Select Agents, Packaging and Shipping, and Animal Biosafety in addition to others.
**Training for Students in Courses that require IBC registration**

Students who are enrolled in courses that have laboratory activities that must be registered with the IBC must complete one of the several approved options for the annual training certification including CITI, or EHS.

**Research Specific Training**

Faculty, with support from the BSO, 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.

**IBC PROCEDURES**

The IBC discusses and reviews Registration Forms at regularly scheduled IBC meetings. PIs are notified of meetings during which a submitted registration is on the agenda and are encouraged to attend and answer any questions. Possible outcomes include approved, not approved (modifications required), or tabled. The IBC approves protocols at maximum for a 3 year period. The IBC receives an annual report from the BSO regarding the annual inspections of all UMD biosafety facilities (including laboratories and satellite facilities). The BSO may delegate this function to an appropriate Biosafety official. 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. 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 members absent from room during vote because recused. This verifies that a quorum is present, even though the vote was one less than that necessary for a quorum.

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, to review proposed biohazard research registrations. 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.

**Requirements for Quorum**

The conduct of official IBC business occurs at convened meetings that must include a quorum of members in order for the meeting to be held. The IBC defines a “quorum” as more than half the regular voting members. A protocol is approved only if a quorum is present, and if more than 50% of the quorum votes in favor or protocol approval. For reasons other than conflict of interest, abstentions from voting do
not alter the quorum or change the number of votes required. Members are expected to attend the convened meetings unless they have notified the IBC Chair or OIC Director in advance, that they are unable to do so. Members who fail to attend meetings on a regular basis may be removed from the committee.

**Meeting Frequency**

Convened meetings of the IBC occur monthly unless cancelled by the IBC Chair. Meeting schedules are typically set six months in advance and posted on the OIC website. The Chair may call an emergency meeting of the IBC as necessary to address such issues as noncompliance or serious and/or unexpected events involving rDNA and biohazardous materials, agents and toxins.

**Meeting Protocol**

At the scheduled time and upon reaching a quorum, the IBC Chair will call the meeting to order and follow an agenda prepared prior to the meeting. The typical order of the agenda is as follows:

- Call to order.
- Chair’s reminder to members of conflict of interest requirements.
- Approval of the previous month’s meeting minutes.
- IBC related announcements.
- Educational items for discussion.
- Next meeting announcement.
- Protocol Review.
- Meeting adjournment.

When reviewing protocols for initial review or periodic review of ongoing research activities, there are several activities that the IBC must carry out on behalf of the University:

- Conduct assessment of the containment levels required by the *NIH Guidelines*.
- Assess the facilities, procedures, practices, and training and expertise of personnel involved in research with rDNA and/or biohazardous materials, agents or toxins.
- Ensure compliance with the *NIH Guidelines*, the BMBL, and UMD guidelines.

In reviewing proposed rDNA research, the *NIH Guidelines*, in Sections II and III, cite a number of matters that the IBC should consider that include:

- Agent characteristics (e.g. virulence, pathogenicity, environmental stability).
- Types of manipulations planned.
- Source(s) of the inserted DNA sequences (e.g., species).
- Nature of the inserted DNA sequences (e.g., structural gene, oncogene).
- Host(s) and vector(s) to be used.
- Whether an attempt will be made to obtain expression of a foreign gene, and if so, the protein that will be produced.
- Containment conditions to be implemented.
- Applicable section of the *NIH Guidelines* (e.g., Section II-D-1. Section III-E-1, etc.).

**Meeting Documentation**

The Director of Institutional Compliance is responsible for the administrative aspects of IBC meetings including coordinating with the Chair to set the meeting agenda, disseminating materials, scheduling meeting locations, and recording and distributing minutes and submitted registration forms. 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 drafted and 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 a summary of discussions and actions.

**Undue Influence or Coercion of IBC Committee Members or OIC Staff**

In cases in which an IBC member or an OIC staff person experiences either direct or indirect undue influence or coercion to make a ruling for a specific research study or investigator, the following process should be used. The IBC member or OIC staff person is asked to document the issues related to the case in writing to both the Director of the OIC and the IO in order to open a formal report. The IO will formally review the information and may convene a meeting and/or otherwise obtain additional information as necessary. The Director of OIC will then subsequently inform the IBC of the findings. Based upon these findings the IO in conjunction with the IBC have the authority to take any and all necessary corrective actions.

**Identification of Conflict of Interest**

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 Director of Institutional Compliance to ensure:

- the responsible conduct and integrity of decisions made by the Committee;
- to protect the Committee membership and the University from unnecessary and avoidable litigation and;
- to ensure the committee membership complies 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 Director of Institutional Compliance 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 from discussion related to voting and approval. Members with a declared conflict of interest cannot be physically present for the IBC vote on the conflicted-item.

**REGISTRATION SUBMISSIONS**

**Who Should Register**
All PIs using biohazardous materials must register with the IBC. All activities at UMD that involve the use of biohazardous materials, rDNA, or Select Agents must submit IBC registrations. This includes grant-funded research, non-funded research, and teaching activities. Registration forms are available at www.UMD.edu/ora/institutionalcompliance. Typically, an IBC protocol directly parallels a funded research project overseen by the PI. The PI submits a Biological Research Registration Form to the Director of Institutional Compliance 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 or its 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 the Director of Institutional Compliance and EHS (or BSO). The registration form has specific separate sections for more information regarding research with recombinant DNA, infectious agents, involving human or non-human primate source materials, involving animal subjects, and select agents. These sections are described briefly below.

**Materials that Require Registration**
In order to approve proposed activities or changes in ongoing biohazardous activities, the IBC reviews components related to biosafety, determines if the proposed activities are in accordance with UMD guidelines, and may make recommendations to clarify processes or suggest improved handling procedures. The IBC also verifies that the activities will be conducted in accordance with NIH Guidelines, CDC guidance, and all Federal, State and local laws and regulations and that the activity is consistent with these requirements unless acceptable justification for a departure is presented and proper federal approval is obtained. Projects that use the types of materials outlined below must be reviewed by the IBC before approval is granted for research, teaching, or testing activities. These include:

- Recombinant studies that are exempt from the *NIH Guidelines*.
- The deliberate transfer of a drug resistance trait to micro-organisms that are not known to acquire the trait naturally.
- The deliberate transfer of rDNA or DNA or RNA derived from rDNA into human research participants (human gene transfer).
- The deliberate formation of rDNA containing genes for the biosynthesis of toxin molecules.
- The use of RG-2 or RG-3 agents as host-vector systems.
- Infectious agents [pathogenic or infectious bacteria, viruses, fungi or parasites or nucleic acids (prions) or agents of unknown pathogenicity to humans, plants or animals]
- The cloning of DNA from RG-2 or greater agents into non-pathogenic prokaryotes or lower eukaryotic host-vector systems.
- The use of infectious or defective RG-2 or greater agents.
- Whole animals in which the animal’s genome has been altered by stable introduction of rDNA or DNA derived into the germ-line (transgenic animal).
- Viable rDNA-modified micro-organisms or cell lines tested on whole animals.
- More than 10 liters of rDNA culture in a single vessel.
- The formation of rDNA molecules containing one-half or more of the genome of a eukaryotic virus or from the same virus family.
- Experiments using BSL-2 or BSL-3 containment.
- Non-recombinant research using biohazardous materials, agents or toxins.
- All research using biological toxins or bioactive derivatives or subunits of toxins.
- Research collecting or analyzing human or non-human primate cell lines, tissues, fluids or other potentially infectious material.
- Xenotransplantation
- Pathogenic or infectious bacteria, viruses, fungi, parasites, nucleic acids (prions) or agents of unknown pathogenicity to humans, plants, or animals
- Drug resistant bacteria, including those with drug resistant plasmids
- Human & nonhuman primate materials that include all blood, blood components, tissues and body fluids or cultured human or animal cells that are potentially infectious
- Recombinant DNA or transgenic plants, animals and microbes
- Infected animals or animal tissues
- Select agents
- Biotoxins
Using rDNA, Infectious Agents, Human or Non-Human Primate Source Materials, Animal Subjects, and Select Agents

The Registration Form has specific sections that must be completed for work with each of these 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 [http://oba.od.nih.gov/oba/index.html]. 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 Agents registration, EHS staff (or the BSO) works closely with the PI to ensure compliance with UMD policies, CDC, Homeland Security, 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;
- Conducting risk assessments.

If the project is to be conducted in a UMD laboratory, 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.

Completing the Registration Form

It is important that registration forms include as much detail as possible. Registration forms should only be submitted that are fully complete. This helps to maximize the time and effort spent by the committee members. 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 an exposure both for personnel and for cleanup of a spill.

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

Some projects that use biohazardous materials and 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, humansubjects, and animal facility workers, these projects also must be reviewed by the respective oversight committee. The approval of each committee involved is required before the project can proceed. The Director of Institutional Compliance serves on each oversight committee to coordinate projects that require oversight by more than one committee. For projects that involve human research participants, an IRB application must be completed and submitted to the IRB for review. For projects that involve vertebrate animal(s), an Animal Care and Use Protocol Review Form must be completed and submitted to the IACUC for review. If IRB or IACUC approval has not been given prior to review of the IRB application, the proposal can be approved contingent upon the approval of the dual committee review. These forms are available at [http://www.atmc.umassd.edu/institutional_compliance/compliance.cfm](http://www.atmc.umassd.edu/institutional_compliance/compliance.cfm)

**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, Director of Institutional Compliance, 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 full committee review by the Chair or BSO or require full committee review. The Review Process Diagram below outlines the typical process:

![Review Process Diagram]

*All forms are kept on file with the Director of Institutional Compliance and EHS (or BSO).

**Protocols that are exempt from full committee review** are those that present only minor hazards with very low risk. These low-risk protocols will 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 from full committee review. Every effort will be made to determine exemption status within 3 business days of receipt of the completed application. Upon receipt of the application from the Director of Institutional Compliance, the BSO or IBC Chair assesses the proposal for
completeness of information and provides a preliminary assessment based on regulatory requirements. If the activities are eligible for an exemption from full committee IBC review, the IBC Chair may issue an exemption. Every effort will be made to provide exemptions within 72 hours of submission. Projects that are exempt from full committee review will be reported to the full IBC at regularly scheduled meetings. If the activities proposed require full committee review, then the application and the preliminary 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 significant 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 already approved Registration before any 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 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 UMD 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 of using the materials;
- Preventative medical measures are taken to minimize risks associated with breaches 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 Compliance Office, or the BSO as available.

**Approval Information**
The IBC may decide to approve, approve with modifications, or not approve the registration. All registrations (exempt, expedited, and approved) are recorded in meeting minutes. Approval memorandums will be drafted by the Director of Institutional Compliance and disseminated to the IBC for review 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 the 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 in the Institutional Compliance Office. Approvals
from the IBC are for a maximum of three years. IBC records and a database of approved protocols are maintained by the Office of Institutional Compliance 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. All disapproval decisions of the IBC are final and cannot be overruled by the Institutional Official. However, all other decisions of the IBC may be appealed to the IO. 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. At the time of submission, the petitioner may request full committee review. This review will occur at the next scheduled IBC meeting. 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.

**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 UMD. 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.

**Human and Non-human Primate Source Material**
For projects that involve the use of human and nonhuman primate source materials, PIs must comply with UMDBloodborne Pathogen Program and Exposure Control Plan. 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 extension 2618 or www.UMD.edu/ehs.

**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 UMD EHS Hazardous Materials PeopleSoft purchasing program. All Material Safety Data Sheets (MSDS) and productsafety information sheets are available from the EHS Office. The disposal of hazardous materials including biological, chemical and physical agents will be in accordance with the UMD 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 their supervisor, Environmental Health and Safety Office and the Human Resources Office. For immediate medical emergency assistance, an emergency phone (ext. 9191) has been established and is staffed 24 hours a day in the UMD Public Safety Office.

All exposure incidents shall be reported, investigated, and documented on an Incident Report Form. Incident Report Forms are available by contacting EHS or through www.UMD.edu/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 Director of Institutional Compliance and EHS Office.

Additional information about UMD biosafety policies and procedures can be found in the UMD Biosafety Manual, Chemical Hygiene Plan, and the UMD Select Agents Manual.

**ANNUAL REVIEWS AND OBA REPORTS**

IBC guidelines will be reviewed on an annual basis and updated as necessary. Issues that arise during the year will be noted and addressed during the annual review of the guidelines. EHS staff (or BSO) are responsible for annual 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 UMD 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 Institutional Compliance or University of Massachusetts System General Counsel may revise policies and procedures inorder to comply with new statutory or regulatory requirements.

Documentation in regards to the committee composition is compiled by the Office of Institutional Compliance and submitted to the National Institutes of Health, Office of Biotechnology Activities. Annual reports must include a committee roster indicating the role and a biosketch of each member. The cover letter should indicate that the information submitted is for the annual report.
BIOSAFETY VIOLATIONS

Deviations from the Policies and Procedures set forth in this document, or biosafety/biosecurity-related incidents shall be documented by the Director of Institutional Compliance, and communicated to the IBC members. Individuals who have biosafety and/or biosecurity-related concerns may contact the Director of Institutional Compliance in person, by email (akarberg@umassd.edu), or phone (ext. 9880). 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 (or BSO) 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, Director of Institutional Compliance, and EHS representative 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 substantiated, the IBC Chair has the authority to immediately suspend the protocol and research activity. (The IBC Chair may suspend activities on the protocol in advance of the hearing if the Chair determines a significant threat to employees or public health and safety or regulatory compliance.)

- Actions that pose substantive harm to the health or safety of personnel, students, the public, or the environment;
- A deviation from the approved research protocol;
- 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 misconduct or other serious or continued noncompliance with federal, state, or local laws, regulations or policies.

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 Director of Institutional Compliance. 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 Director of Institutional Compliance and the IO for administrative review and determination of action. Misconduct of this nature may also fall under the purview of the UMD Policy on Misconduct in Science.

**Reporting Concerns**
Any employee, student, or agent of UMD reporting a concern will be protected against reprisal. Every effort will be made to protect the complainant’s confidentiality, but UMD 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 may fall under the purview of the UMD Policy on Misconduct in Science.
APPENDICES

Appendix A. The following list of forms may be used for various purposes for PIs working with hazardous agents (available online at www.UMD.edu/research/institutionalcompliance)

Biological Research Registration Form Instructions

Biological Research Registration Form

Minor Amendment Form

Research Using Select Agents Form
Appendix B:

HHS SELECT AGENTS AND TOXINS

Abrin
Botulinum neurotoxins
Botulinum neurotoxin producing species of Clostridium
Cercopithecine herpesvirus 1 (Herpes B virus)
Clostridium perfringens epsilon toxin
Coccidioides posadasii/Coccidioides immitis
Conotoxins
Coxiella burnetii
Crimean-Congo haemorrhagic fever virus
Diacetoxyscirpenol
Eastern Equine Encephalitis virus
Ebola virus
Francisella tularensis
Lassa fever virus
Marburg virus
Monkeypox virus
Reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments (Reconstructed 1918 Influenza virus)
Ricin
Rickettsia prowazekii
Rickettsia rickettsii
Saxitoxin
Shiga-like ribosome inactivating proteins
Shigatoxin

OVERLAP SELECT AGENTS AND TOXINS

Bacillus anthracis
Brucella abortus
Brucella melitensis
Brucella suis
Burkholderia mallei (formerly Pseudomonas mallei)
Burkholderia pseudomallei (formerly Pseudomonas pseudomallei)
Hendra virus
Nipah virus
Rift Valley fever virus
Venezuelan Equine Encephalitis virus
South American Haemorrhagic Fever viruses
  Flexal
  Guanarito
  Junin
  Machupo
  Sabia
Staphylococcal enterotoxins
T-2 toxin
Tetrodotoxin
Tick-borne encephalitis complex (flavi) viruses
  Central European Tick-borne encephalitis

USDA SELECT AGENTS AND TOXINS

African horse sickness virus
African swine fever virus
Akabane virus
Avian influenza virus (highly pathogenic)
Bluetongue virus (exotic)
Bovine spongiform encephalopathy agent
Camel pox virus
Classical swine fever virus
Ehrlichia ruminantium (Heartwater)
Foot-and-mouth disease virus
Goat pox virus
Japanese encephalitis virus
Lumpy skin disease virus
Malignant catarrhal fever virus
  (Alcelaphine herpesvirus type 1)
Menangle virus
Mycoplasma capricolum subsp. capripneumoniae (contagious caprine pleuropneumonia)
Mycoplasma mycoides subsp. mycoides small colony
  (MmmSC) (contagious bovine pleuropneumonia)
Peste des petits ruminants virus
Rinderpest virus
Sheep pox virus
Swine vesicular disease virus
Vesicular stomatitis virus (exotic): Indiana subtypes
  VSV-IN2, VSV-IN3
Virulent Newcastle disease virus 1

USDA PLANT PROTECTION AND QUARANTINE (PPQ) SELECT AGENTS AND TOXINS

Peronosclerosporaphilippinensis (Peronosclerospora sacchari)
Phomaglycinicola (formerly Pyrenochaetaglycines)
Ralstoniasolanacearum race 3, biovar 2
Rathayibacter toxicus
Scleropithorarayssiae varzeae
Synchytrium endobioticum
Xanthomonas oryzae
Xylellafastidiosa (citrus variegated chlorosis strain)

11/17/2008

1 A virulent Newcastle disease virus (avian paramyxovirus serotype 1) has an intracerebral pathogenicity index in day-old chicks (Gallus gallus) of 0.7 or greater or has an amino acid sequence at the fusion (F) protein cleavage site
that is consistent with virulent strains of Newcastle disease virus. A failure to detect a cleavage site that is consistent with virulent strains does not confirm the absence of a virulent virus.
Appendix C. Information Resources


Centers for Disease Control and Prevention, Or External Activities Program, Atlanta, Georgia 30333 Telephone: (404) 639-4418

National Animal Disease Center, U.S. Department of Agriculture, Ames, Iowa 50010 Telephone: (515) 862-8258

National Center for Infectious Diseases http://www.cdc.gov/ncidod/

National Institutes of Health, Office of Biotechnology Activities http://www4.od.nih.gov/oba/ 6705 Rockledge Drive, Suite 750, Bethesda, Maryland 20892-7985 Telephone: (301) 496-9838


Massachusetts State Regulations:
- 105 CMR 480.000: Minimum Requirements for the Management of Medical or Biological Waste (state sanitary code chapter VIII)
  - 105 CMR 300.000: Radiation Control Program
  - 5 CMR 120.000: Radiation Control Program

Other Agencies Involved with specific Biological Agents: FBI

Websites
www.bphc.org
www.cdc.gov
www.phac-aspc.gc.ca
www.mass.gov/dph/
www.absa.org