Institutional Biosafety Committee
Guidelines
Revision 3, September 2010

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

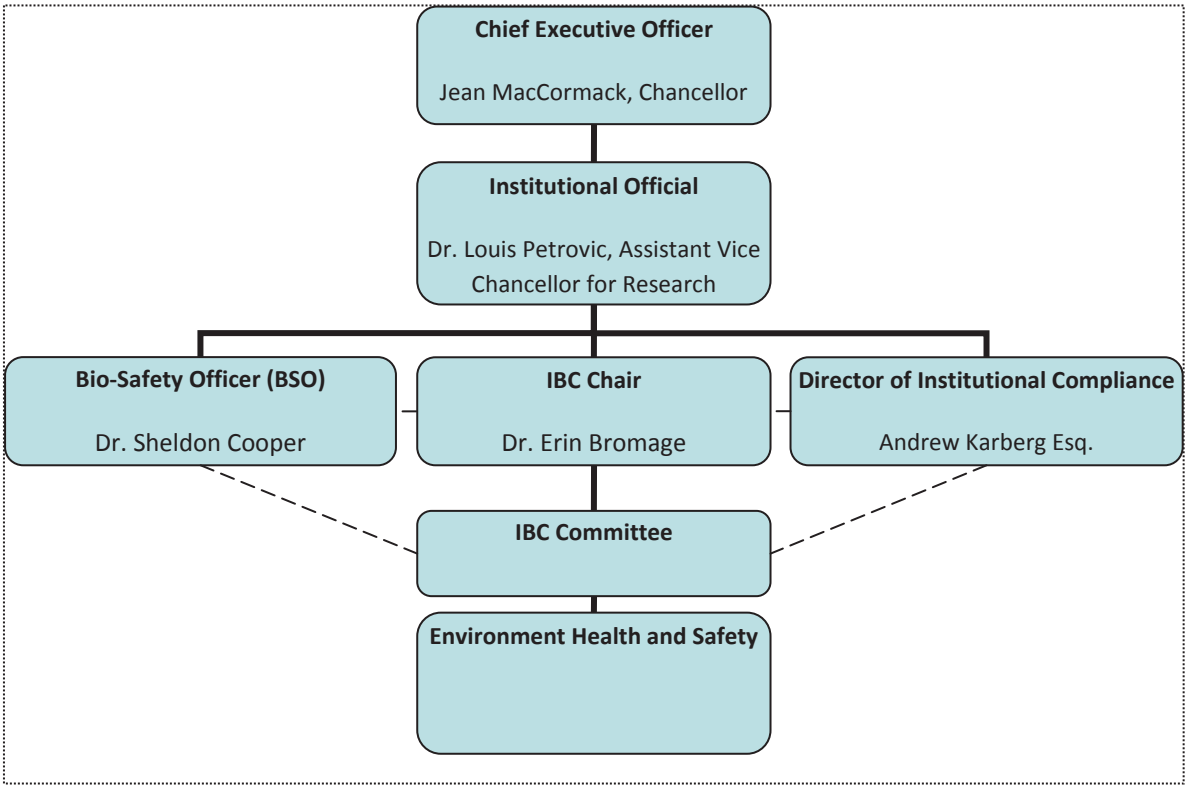
Committee Composition

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.ShankaBhowmick
	Dr. Pingguo He
	Dr. Paul Calvert
Community Member	To be named
Community Member	To be named

Total committee = 12

Quorum = 7

IBC Organizational Chart



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INTRODUCTION

This document outlines the responsibilities and guidelines for theInstitutional Biosafety Committee (IBC) at the University MassachusettsDartmouth (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/bmbl5/bmbl5toc.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 theyare 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 rDNAresearch, 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 for 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/biosfty/bmbl5/bmbl5toc.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 regulatoryguidelines.

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

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.

Table 2. Risk Group Classifications

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 ortherapeutic interventions are often available (BSL-2)
RG3	Agents that are associated with serious or lethal human disease for which preventative or therapeuticinterventions 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 therapeuticinterventions 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 ofHazard" 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/)

Level	Approval/Review Required	Experiments Covered
III-A	IBC and NIH Director Approval, RAC Review*	Transfer of a gene encoding drug resistance into microorganisms that are not known to acquire the trait naturally
III-B	NIH/OBA, IBC Approvals*	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 *Shigelladysenteriae*neurotoxin)
III-C	IBC, IRB Approvals and NIH/OBA Registration*	Proposals involving the deliberate transfer of rDNA, or DNA or RNA derived from rDNA, into human subjects (human gene transfer)
III-D	IBC Registration and Approval*	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 hostvector 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 >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.
III-E	IBC Notification**	Experiments involving formation of rDNA with no more than 2/3 of the genome of any eukaryotic virus; experiments involving whole plants, transgenic rodents
III-F	Exempt- IBC Registration Still Required**	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).

*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).

Sec III-F-1	Those molecules that are not in organisms or viruses
Sec III-F-2	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.
Sec III-F-3	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.
Sec III-F-4	Those molecules that consist entirely of DNA from an eukaryotic host including its chloroplasts, mitochrondria, or plasmids (but excluding viruses) when propagated only in that host (or closely related strain of the same species).
Sec III-F-5	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*.
Sec III-F-6	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*.

DEFINITIONS

Biosafety: A complete program of administrative controls, medical surveillance, vaccination,and containment strategies for promoting safe laboratory practices, procedures, and containmentequipment to reduce the risk of disease to employees from potential occupational exposure toinfectious agents or other biologically derived molecules.

Biohazardous Material: Biohazardous materials and organisms include all infectious agents orbiologically derived infectious materials that present either a risk or a potential risk to the healthof humans or animals, either directly through infection or indirectly through damage to theenvironment. An IBC Research Registration Form must be submitted to the IBC prior toinitiation of any project involving use of these materials or agents. The following is a list of thepotentially hazardous biological materials and agents.

- Human, animal, and plant pathogens including viruses, oncogenic and defective viruses(viral vectors), Rikettsiae, Chlamydiae, bacteria (including those with drug resistanceplasmids), fungi, parasites, undefined or other infectious agents, such as prions, andtoxins (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 agentsthese 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 *Coxiellaburnetii*, the causativeagent 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 toconfine 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 applicableto 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 researchprotocol or those practices that are commonly accepted by the scientific community or couldresult in an adverse biosafety event. A violation may also occur when a PI demonstrates otherserious or continued noncompliance with federal, state, or local laws, regulations, or policies.

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

Centers for Disease Control and Prevention (CDC): The federal agency requiring registrationbefore any transfer or use of select agents can occur. The BSO and the EHS Director are theUMD officials with the responsibility for ordering Select Agents.

Infectious Agents: An agent capable of producing infection. Several factors are taken intoconsideration when evaluating risk, which include pathogenicity of the organism, mode oftransmission 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 foroverseeing all animal care and use at UMD and has adopted policies and procedures that apply toall vertebrate animals used for research and teaching.

Institutional Biosafety Committee (IBC):A committee created to review research involvingrecombinant 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 assignedresponsibilities.

Institutional Official (IO): An individual who signs, and has the authority to sign, on behalf ofthe 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 welfareof all human subjects involved in research. Human subjects are defined as “a living individualabout whom an investigator (whether professional or student) conducting research obtains datathrough 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, andis 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 newknowledge to help prevent, detect, diagnose, and treat disease and disability.

NIH Guidelines for Research Involving rDNA Molecules (NIH Guidelines): Outlinesprinciples for the safe conduct of research employing recombinant DNA technology (created in1976). The NIH Guidelines detail practices and procedures for the containment of various formsof rDNA research, for the proper conduct of research involving genetically modified plants andanimals, and for the safe conduct of human gene transfer research. It is a constantly changingdocument 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 rDNAactivities, including human gene transfer.

Principal Investigator: Any UMD faculty member, or other authorized individual, who mayserve as a project director/leader for activities that involve biological agents. The PI accepts fullresponsibility for all aspects of the project.

Recombinant DNA Advisory Committee (RAC): An NIH advisory committee whoseprincipal role is to provide advice and recommendations to the NIH Director on 1) the conductand oversight of research involving recombinant DNA, including the content and implementationof the *NIH Guidelines*, and 2) other NIH activities pertinent to recombinant DNA technology. Amajor element of this role is to examine the science, safety, and ethics of clinical trials thatinvolve the transfer of rDNA to humans.

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

Select Agent: Microorganisms or related toxins that have been specifically identified by theFederal 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 andsecurity. See Appendix B for the list.

COMMITTEE COMPOSITION

The IBC must be composed of at least 5 members, two whom are not affiliated with theinstitution in any way other than serving on the IBC and represent the interest of the surroundingcommunity with respect to health and protection of the environment. The chair and all membersof the Institutional Biosafety Committee shall be appointed by the Associate Vice Chancellor for Research and Development (InstitutionalOfficial). The IBC should include members with experience and expertise in rDNA technologyand biosafety and physical containment. The committee should have collective knowledge ofinstitutional commitments and policies, applicable laws, standards of professional conduct andpractice, community attitudes, and the environment with the ability to assess the safety of rDNAresearch 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 withknowledge of institutional policies and applicable laws, and individuals who reflect communityattitudes, and at least one member from laboratory technical staff.

ROLES AND RESPONSIBILITIES

All personnel involved in potentially biohazardous activities share biosafety responsibility andmust follow specified procedures, complete required training, act responsibly, and reportincidents involving hazardous circumstances. All personnel should inform their supervisors ofany health conditions that could make work or exposure to such substances more hazardous tothemselves or others. Roles and responsibilities are outlined based on the April 2002 NIHGuidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines). For thecomplete 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 userDNA 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) isalso 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 inacademic, 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 ofpersonnel involved in rDNA research;
    - ensure compliance with all surveillance, data reporting, and adverse eventreporting.
- 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 anysignificant research-related accidents or illnesses to the appropriate institutional officialand 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 containmentrequirement. The IBC must at times communicate and coordinate review and approval ofresearch projects with the Institutional Animal Care and Use Committee (IACUC) and theInstitutional Review Board (IRB). The IBC may also provide recommendations for educationand training related to biosafety for all UMD faculty, staff, and students that may be involved inthe 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 containingrDNA molecule of 10 liters or more of any one cell line or if the institution engages in rDNAresearch that requires use of BSL3 or BSL4 facilities. The BSO reports to the EHS Director andhas responsibility for oversight of research and other activities involving the use of biohazardousmaterials. In the absence of a BSO, staff from the Environmental Health and Safety Office willfulfill this role. Containment levels are set in accordance with the NIH Guidelines and theCenter for Disease Control and Prevention. The BSO reports violations of the NIH Guidelinesand UMD guidelines to the responsible Institutional Official and the IBC. The BSOmust 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 andpractices for working with potentially biohazardous materials;
- Reviewing or pre-reviewing registrations for the IBC and providing recommendations toensure safe practices are followed;
- Inspecting facilities and reporting results to the IBC on an annual basis;
- Reviewing and inspecting activities involving biohazardous materials in coordinationwith other EHS personnel, the Office of Research Services Facility Manager, and theDirector of Institutional Compliance;
- Reporting to the IBC and the Institution any significant concerns, violations of the NIHGuidelines 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 personnelcontamination;
- Determining the necessity for health surveillance of personnel involved in projects thatinvolve 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 Chairwith 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 thatresearch with biohazardous materials and organisms at the UMD is conducted in accordance withall applicable local, state, and federal regulations. With respect to the IBC, the Director ofInstitutional 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 forregistration 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 IBCoversight;
- Interfacing and communicating relevant information between the BSO, IBC, IRB, andIACUC and attending meetings of all three committees;
- Make available biosafety training materials for PIs, IBC members, students and staff atUMD 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. Policychange recommendations are brought to the IBC for discussion and action. The Director ofInstitutional Compliance or University of Massachusetts System General Counsel may revisepolicies 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 exampleby 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 beforecommencing 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 ofthe materials they are working with;
- Ensuring compliance with the regulations and theUMD IBC guidelines and providing directives and guidelines for the workthey 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 ofany proposed research;
- Coordinating use and transport of biohazardous materials with EHS and refer to EHSPolicies and Procedures as necessary;
- Immediately reporting any significant problems or incidents to the appropriate authorities (EHS, BSO, or Director ofInstitutional 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/biohazardouswaste, or do work beyond classes in laboratories are required to attend the EHS LaboratorySafety Training on an annual basis. The training providesinformation about the EHS staff and responsibilities, right-to-know law, emergency spillresponse notification, blood borne pathogens/biohazards, personal protective equipment (PPE),hazardous waste management, fire response procedures, and laboratory practices and policies. Itis the responsibility of the faculty member or laboratory manager that oversees the laboratory toensure 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 berequired to complete the online Collaborative Institutional Training Initiative (CITI) atwww.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 customizetraining to the user's needs. Certificates are sent electronically to the Institutional ComplianceOffice, if linked to UMD during the registration process. The Office of Institutional Compliancetracks all training certification for personnel registered through the IBC. General conceptscovered in CITI biosafety training include: Introduction to Biosafety Concepts, Regulations andGuidelines 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 withthe IBC must complete one of the several approved options for the annual training certificationincluding 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 safehandling 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 encouragedto attend and answer any questions. Possible outcomes include approved, notapproved (modifications required), or tabled. The IBC approves protocols at maximum for a 3 year period. The IBC receives an annual report from the BSOregarding the annual inspections of all UMD biosafety facilities (including laboratories andsatellite 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 andsafety, or any activity not conducted in accordance with IBC requirements. No member of theIBC may vote on or be present for the review and discussion of a proposal in which the memberis involved or has a financial or institutional conflict of interest. In such instances the IBCmember will voluntarily recuse herself/himself from the meeting until the committee takes actionon the proposal. The vote will show the total number of members present, the total votes (yesand no), and members absent from room during vote because recused. This verifies that a quorum is present, even though the vote wasone less than that necessary for a quorum.

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

Meetings

The IBC meets monthly, to review proposed biohazard research registrations. The NIHGuidelines do not prescribe how IBCs should be convened. Minority views are recorded in theminutes.

Meetings may be conducted by teleconferencing as long as a written record of the meeting iscreated to document committee actions and fulfill its duties and meeting requirements. Emailmay be used to distribute protocols, conduct pre-meeting reviews, approve meeting minutes, andto 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 that 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*.
- Assessthe 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 avoidablelitigation and;
- to ensure the committee membership complies with agreements entered into with third-partyfunding organizations for whom the committee approves facilities, protocols, activities orresearch 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 directfinancial interest or benefit, directly or through relatives by blood or marriage, in the subjectmatter 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 researcherundertaking a protocol or registration considered by the committee;
- is a research competitor or has a personal conflict with the project or the investigators, so couldbe 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 orpotential conflict of interest. If a committee member is unaware of any conflict of interest orpotential conflict of interest at the time they sit in a meeting in which they later discover they arein a conflict situation, they should let the Chair of the Committee or the Director of InstitutionalCompliance know immediately once the conflict comes to, or is brought to, their attention. If acommittee 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. Facultymembers residing in the same Department are allowed to review protocols and registrationscoming from the same Department as long as the Committee member does not

have a personalinterest or stake in the research being proposed. If a conflict is identified, the member may bepresent 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. Thisincludes grant-funded research, non-funded research, and teaching activities. Registration formsare available at www.UMD.edu/ora/institutionalcompliance. Typically, an IBC protocol directlyparallels a funded research project overseen by the PI. The PI submits a Biological ResearchRegistration Form to the Director of Institutional Compliance for dissemination to the full IBCfor review. The project may not commence until the PI has received official approvalnotification in writing from the IBC or its authorized representative. The lifespan of an approvedprotocol is three years and parallels the life of a typical research grant. After approval, all formsare kept on file with the Director of Institutional Compliance and EHS (or BSO). Theregistration form has specific separate sections for more information regarding research withrecombinant 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 accordancewith UMD guidelines, and may make recommendations to clarify processes orsuggest improved handling procedures. The IBC also verifies that the activities will beconducted in accordance with NIH Guidelines, CDC guidance, and all Federal, State and locallaws and regulations and that the activity is consistent with these requirements unless acceptablejustification for a departure is presented and proper federal approval is obtained. Projects thatuse the types of materials outlined below must be reviewed by the IBC before approval isgranted 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) oragents 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, tissuesand 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 Guidelineshttp://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 forcompleteness 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 theappropriate 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 ensurecompliance with UMD policies, CDC, Homeland Security, the Patriot Act and other regulations. Thismay 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 asrequired;
- 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 notalready 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 rangeand information about whether the agent may synthesize toxins. Procedures should be describedin detail and include activities related to culture, volume of material expected for use, andconcentrations. An explanation should be provided as to how the agent is inactivated or lysedand at what stage of the experiment this will occur.

For work with human or non-human primate source materials, information such as the type ofmaterial and its source, pathogen testing already available for the material, precautions andtraining provided to staff working with these materials, and if the materials used for the projectare 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 formsshould only be submitted that are fully complete. This helps to maximize the time and effortspent by the committee members. General information should include the purpose and goals ofthe project, descriptions of all protocols and techniques to be used, and detailed informationabout the types of materials, volumes to be used, and risks to personnel for each material. Inaddition to laboratory and personnel information, the

registration should include details aboutsafety procedures, precautions taken when using the materials registered, and a plan in the eventof an exposure both for personnel and for cleanup of a spill.

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

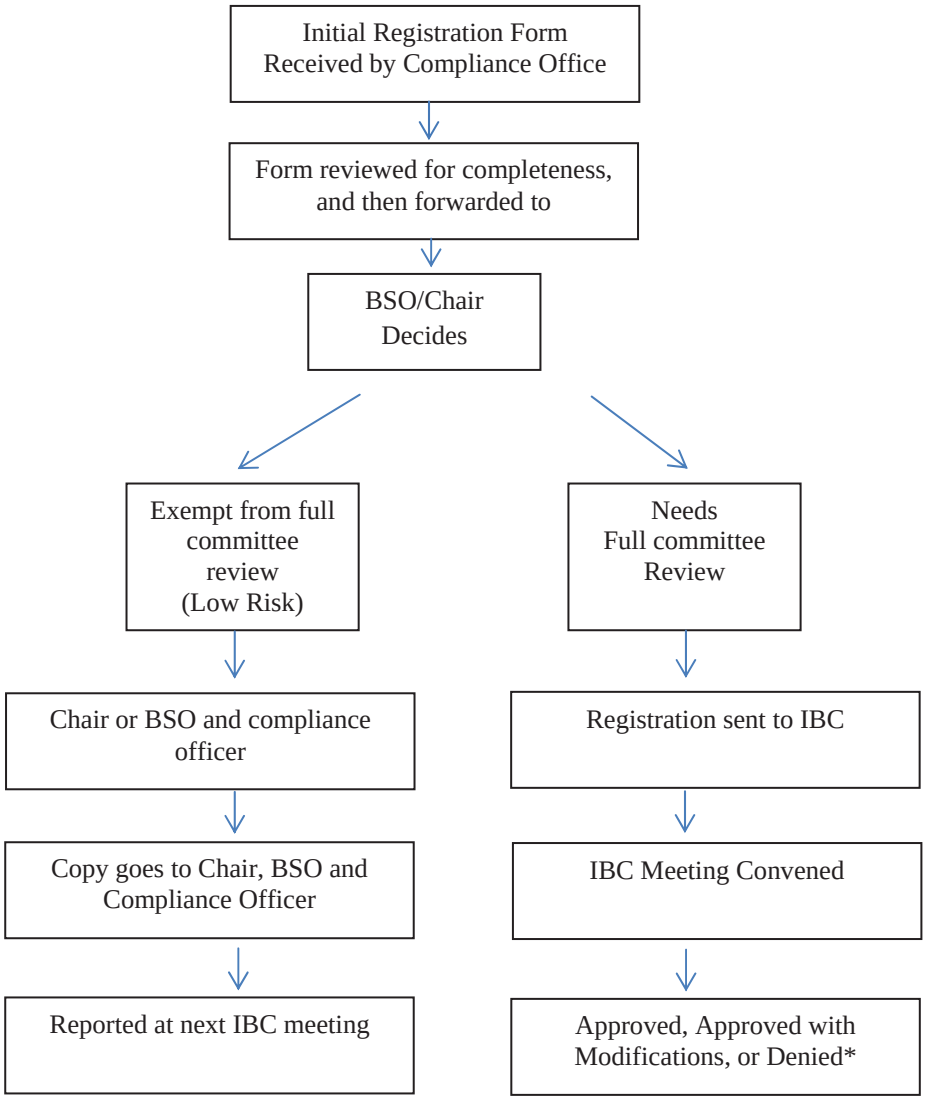
Some projects that use biohazardous materials and require IBC review may also require the useof animal or human test subjects. In addition to providing the IBC with information about howthe agents will be used and protections in place for personnel handling the materials, humansubjects, and animal facility workers, these projects also must be reviewed by the respectiveoversight committee. The approval of each committee involved is required before the projectcan proceed. The Director of Institutional Compliance serves on each oversight committee tocoordinate projects that require oversight by more than one committee. For projects that involvehuman 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 Formmust 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 athttp://www.atmc.umassd.edu/institutional_compliance/compliance.cfm

Risk Assessment

It is the responsibility of all laboratory directors, laboratory supervisors and PIs to provide aninitial assessment of the risk factors and risk levels involved in the proposed activities. In manyinstances the PI/Supervisor has significant experience working with similar biological agents orrDNA and are, therefore, in the best position to estimate appropriate biosafety levels for thelaboratory and their immediate work environment. This assessment must be done incollaboration with the BSO, Environmental Health and Safety (EHS) staff, Director ofInstitutional 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 asexempt from full committee review by the Chair or BSO or require full committee review. The Review ProcessDiagram below outlines the typical process:



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

Protocols that are exempt from full committee revieware 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 protocolsmay be validated immediately upon review but require a signature approving it asexempt 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 andprovides a preliminary assessment based on regulatory requirements. If the activities areeligible 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 regularlyscheduled meetings. If the activities proposed require full committee review, then theapplication and the preliminary analysis will be forwarded to the full IBC for review atthe next scheduled meeting.

Full Committee Reviewis used for protocols that may present significant hazards tohumans, animals or the environment. Examples of projects that require full committeereview include non-exempt rDNA protocols, use of biohazardous materials requiringBSL2 containment facilities or practices (or greater), or projects that involve the releaseof 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 areappropriate for adding agents, vectors, or cell lines that require the same (or lower) biosafetylevels, 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 ofbiohazards, accidental exposure plans, changes in biosafety levels, changes in work location, orbiocontainment 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 theproject or activity (the BSO will assist PIs to develop SOPs);
- Risk to personnel, students or visitors is reasonable in relation to the threats and hazardsassociated 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 breeches insafety 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. Approvalmemorandums will be drafted by the Director of Institutional Compliance and disseminated tothe IBC for review before sending to the PI. The approval memo will contain any elements thatthe IBC requested to be modified or clarified during the full review. Approval memos will alsoinclude the identifying registration number, list the materials registered, note the highestbiosafety level required for carrying out the work, and include a note about the supportingdocumentation such as training certificates, product descriptions, and exposure control plans.The letter will clearly state the changes requested before final approval is granted. Officialcopies 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 ofapproved protocols are maintained by the Office of Institutional Compliance in accordance withfederal standards. Laboratory inspection records, training records, and inventory are maintainedby 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 bepetitioned 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 reviewthe findings, brief the Vice Provost for Research on the findings, consider any new evidence orchanges 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 forreconsideration 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 materialrelevant 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 fromexposure to hazardous agents. Hazardous agents include biological, radiological, and chemicalmaterials that may be used during a research project. The EHS Department overseesprocurement, use, and chemical inventory and provides several types of safety training related tothe use of these materials. The IBC reviews proposed experimentation, facility capabilities,institutional procedures, and PI training and expertise to ensure that projects using biohazardousmaterials are conducted safely and follow NIH guidelines. While the IBC reviews proposedresearch, 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 mustcomply with UMDBloodborne Pathogen Program and Exposure Control Plan. Transferof these types of materials between institutions must also follow specific packaging and shippingrequirements and EHS can assist by providing PIs with the appropriate information for transferof such materials. This information is available from the EHS Office at extension 2618 orwww.UMD.edu/ehs.

EHS Policies

Depending on the specific work activity, research protocol, and/or procedure being conducted ina facility, the use of personal protection equipment (such as gloves, eye protection, laboratorycoats, shoe covers, respirators, etc.) is required to properly protect individuals. Workers areadvised to review and familiarize themselves with the specific SOP that is available at eachlaboratory facility that provides specific references and information regarding what PPE is to beworn 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 andphysical agents will be in accordance with the UMD EHS Office program and with applicablefederal, 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 andthe 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 includingstaff, 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 maydelegate responsibility for inspection of facilities where rDNA and activities using hazardousagents occur. The annual review of facilities is to assess the overall biosafety at UMD andensure that ongoing projects meet all regulatory requirements. Any deficits in policy will bebrought to the IBC for comment and suggestions. The Director of Institutional Compliance orUniversity 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 ofInstitutional Compliance and submitted to the National Institutes of Health, Office ofBiotechnology Activities. Annual reports must include a committee roster indicating the roleand a biosketch of each member. The cover letter should indicate that the information submittedis 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 ifwarranted, investigate concerns involving biohazardous materials. All complaints must bereviewed 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 ahazard to any personnel. The IBC Chair (or BSO) is empowered to suspend any research or teachingactivity 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 thecomplaint. 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 (includingrecords 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 theinvestigationl
- 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 forfurther 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, thepublic, or the environment;
- A deviation from the approved research protocol;
- A deviation from the practices that are commonly accepted by the scientific communityor could result in an adverse biosafety event; or
- If a PI demonstrates misconduct or other serious or continued noncompliance withfederal, 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 ofreprimand, mandatory training, or other actions deemed necessary by the IBC or IO. The IBCChair 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 conductsresearch activities without registering with the IBC, it is considered to be misconduct. Themisconduct is then forwarded to the Director of Institutional Compliance and the IO foradministrative review and determination of action. Misconduct of this nature may also fall underthe 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 ofthe Commonwealth of Massachusetts and is therefore subject to the Massachusetts PublicRecords law, G.L. c.66, § 10. This law states the general rule that any record made or receivedby 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 mayfall 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*
Cercopithecineherpesvirus 1 (Herpes B virus)
*Clostridium perfringens*epsilon toxin
Coccidioidesposadasii/Coccidioidesimmitis
Conotoxins
Coxiellaburnetii
Crimean-Congo haemorrhagic fever virus
Diacetoxyscirpenol
Eastern Equine Encephalitis virus
Ebola virus
Francisellatularensis
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 (Reconstructed1918 Influenza virus)
Ricin
Rickettsia prowazekii
Rickettsia rickettsii
Saxitoxin
Shiga-like ribosome inactivating proteins
Shigatoxin

OVERLAP SELECT AGENTS AND TOXINS

Bacillus anthracis
Brucellaabortus
Brucellamelitensis
Brucellasuis
Burkholderia mallei (formerly *Pseudomonas mallei*)
Burkholderiapseudomallei(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
- Far Eastern Tick-borne encephalitis
- Kyasanur Forest disease
- Omsk Hemorrhagic Fever
- Russian Spring and Summer encephalitis

Variola major virus (Smallpox virus)
Variola minor virus (Alastrim)
Yersinia pestis

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
Ehrlichiaruminantium(Heartwater)
Foot-and-mouth disease virus
Goat pox virus
Japanese encephalitis virus
Lumpy skin disease virus
Malignant catarrhal fever virus (Alcelaphineherpesvirus type 1)
Menangle virus
*Mycoplasma capricolum*subspecies*capripneumoniae*(contagious caprinepleuropneumonia)
*Mycoplasma mycoides*subspecies*mycoides*small colony (*Mmm*SC)(contagious bovine pleuropneumonia)
Peste des petitsruminants virus
Rinderpest virus
Sheep pox virus
Swine vesicular disease virus
Vesicular stomatitis virus (exotic): Indiana subtypes VSV-IN2, VSV-IN3
Virulent Newcastle disease virus1

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

Peronosclerosporaphilippinensis(*Peronosclerospora sacchari*)
Phomaglycinicola(formerly *Pyrenochaetaglycines*)
*Ralstoniasolanacearum*race 3, biovar 2
Rathayibactertoxicus
Sclerophthorarayssiaevarzeae
Synchytriumendobioticum
Xanthomonasoryzae
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 virulentstrains of Newcastle disease virus. A failure to detect a cleavage site that is consistent with virulent strains does not confirm theabsence of a virulent virus.

Appendix C. Information Resources

Biosafety in Microbiological and Biomedical Laboratories (BMBL) 4th Ed. 1999. U.S. Government Printing Office, Washington, D.C.
http://www.cdc.gov/OD/ohs/biosfty/bmbl5/bmbl5toc.htm

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

University of Massachusetts Dartmouth, Environmental Health & Safety http://www.UMD.edu/ehs/
U.S. Department of Labor, Occupational Safety and Health Administration (Standards - 29 CFR Bloodborne pathogens.-1910.1030
http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10051

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