Institutional Biosafety Committee (IBC)
Standard Operating Procedure (SOP)
Revision 4, June 2024

Table of Contents

Section 5: Elements for Consideration:

- Experimental Design
- Risk Assessment
- Biosecurity
- Containment and Safety Measures
- Personal Protective Equipment
- Decontamination Practices
- Emergency Procedures
- Long-Term Management of Biohazardous Materials
- Biohazardous Management Standard Operating Procedure (BHMSOP)
- External Collaborators
- Dual Use Research
- Biological Toxins and Select Agents
- Transgenic Animals
- Monitoring and Reporting of Adverse Events
- Impact on Human and Animal Subjects
- Environmental Impact
- Identification of Conflict of Interest
- Environmental Health and Safety ??
- Biosafety Violations and Reporting Procedures
- Reporting Requirements

Section 6: IBC Procedures

- Submission of IBC Registration
- Biosafety Review
- Non-Convened Review
- Committee Review Full Committee Review
  - Meeting Preparation
  - Meeting Review Procedures
  - Meeting Vote
- Administrative Process
  - Schedule and Distribution:
  - Agenda:
  - Minutes
  - Correspondence
  - Education and Training
  - Documentation and Record-Keeping
  - Monitoring Compliance and Audits
  - Review of Policies and Procedures
  - Post Review
  - IBC Follow Up
  - Consultant Review
  - IBC Record Requirements
  - Annual Reviews & OSP Reports

Section 6: Appendices

- Appendix A – Guide for Effective Safety
- Appendix B: HHS Select Agents & Toxins
- Table 1: Federal, State, and Local Regulations
- Table 2: Materials and Activities Requiring Additional Permits or Approvals
- Table 3. Summary of Recombinant DNA/Infectious Agent Registration Requirements

Section 1: Introduction

IBC Charter

The University is deeply committed to safety as a core institutional value, ensuring a secure environment for all faculty, staff, students, and the surrounding community. This commitment fosters an atmosphere where teaching, learning, service, outreach, discovery, and creativity can thrive without compromising safety standards. Every individual involved in potentially biohazardous activities share the responsibility for biosafety by adhering to specified procedures, completing required training, acting responsibly, and promptly reporting any incidents involving hazardous circumstances. The IBC is responsible for the safety, ethical conduct, and scientific integrity of biohazardous activities by ensuring the possession and utilization of biohazardous materials at the University comply with rigorous safeguards, guidelines, and regulations.
Adherence to NIH Guidelines Research Involving Recombinant DNA Molecules (referred to as the *NIH Guidelines*) is a cornerstone of the University's commitment to safety. The *NIH Guidelines* regulate the construction and handling of recombinant DNA (rDNA) and synthetic nucleic acid molecules (sDNA), as well as organisms or viruses that may contain these elements. Compliance with these guidelines is mandatory for institutions receiving NIH or USDA funding for rDNA research and is outlined as required per terms and conditions. The *NIH 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). The University acknowledges the evolving nature of research in this field, necessitating continual adaptation to emerging challenges. As such, the University has expanded the authority of the IBC beyond rDNA research to encompass oversight of all biohazardous materials which include biological agents, biologically derived toxins, and other materials that may pose risks to the environment and public health. This proactive expansion aligns with the best practices of research universities and reflects the University's commitment to fostering a culture of safety, ensuring that all activities—from teaching and learning to research and discovery—can thrive securely.

Acknowledging the pivotal role of the IBC in the planning and execution of the University's biosafety program, the Chancellor and Institutional Official (IO) charge the IBC with reviewing, approving, and overseeing activities (research and teaching) involving biohazardous materials, rDNA, biological agents, and biologic-derived toxins at UMassD; regardless of the funding source.

The IBC has the authority to approve, require modifications to secure approval, disapprove, suspend, or terminate research activities to assure adherence to safety protocols and regulations, including the authority to grant exemption from IBC oversight, where appropriate. During review, the IBC assess facilities, procedures, safety practices, personnel expertise and training to ensure proper biohazards management and assure compliance with applicable guidelines and regulations. Projects involving biohazardous materials at other institutions should receive IBC approval from the cooperating institution, corresponding approvals must be documented. The IBC must grant approval prior to the acquisition, use, or transfer of biohazardous materials. The IBC is responsible for establishing and implementing guidelines to facilitate the safe conduct of research involving biohazardous materials, rDNA, biological agents, and biologic-derived toxins while monitoring federal, state, and local regulations to ensure UMassD compliance.

Given the University's receipt of NIH funding for rDNA research, adherence to NIH Guidelines is imperative to maintain funding and ensuring institutional compliance. The University is responsible for registering the IBC with NIH's Office of Science Policy (OSP), including filing an annual report which includes a roster of IBC members, their roles, and a biographical sketch outlining their qualifications. The registration and reporting assure the NIH of the local review and oversight, verifies IBC expertise meets NIH standards, provides contact information for the institution, and a census of where rDNA research is being conducted.

Membership is composed to ensure the acquisition of adequate subject-matter knowledge and expertise in work being reviewed. To ensure impartiality and provide external oversight, at least two members of the IBC are not affiliated with the University. These external members represent the interests of the broader community, offering an important outside perspective on biosafety issues. The diversity of expertise within the IBC ensures thorough reviews and risk assessments of the research and teaching activities under its jurisdiction.

In alignment with best practices and NIH recommendations, the IBC is committed to transparency. Whenever feasible, IBC meetings will be open to the public to foster community engagement and ensure the accountability of the committee's decisions.

The purpose of this Charter is to outline the scope, responsibilities, and procedures of the IBC, and to ensure that all activities involving biohazardous materials at the University are conducted safely, ethically, and in compliance with applicable regulations. This document serves as a framework to promote a safe working environment, well-regulated research study areas, and protection for the local community.

Mission Statement

The IBC is dedicated to upholding the highest standards of biosafety and ethical conduct in research involving biohazardous materials. The IBC ensures that activities utilizing these materials adhere to ethical and regulatory requirements, including their safe handling, storage, and disposal. By ensuring compliance with the NIH Guidelines, Health and Human Services, Biosafety in Microbiological and Biomedical Laboratories (BMBL; 6th edition), and other relevant local, state, or federal regulations, the IBC strives to safeguard human health and promote responsible research practices.

In addition to its oversight responsibilities, the IBC establishes and implements policies that support the safe use and handling of biohazardous materials. This includes providing comprehensive training to faculty, staff, and students on proper handling practices and making informed recommendations to the University based on compliance reports, including adverse event reporting.

A key component of the IBC's mission is to educate the University community on the regulatory requirements surrounding the use of biohazardous materials to minimize risks to research personnel, the community, and the environment. This educational outreach helps minimize risks to research personnel, the broader community, and the environment, thereby enhancing overall institutional safety and compliance.

The IBC also plays a coordinating role in reviewing and approving research projects that overlap with other institutional oversight bodies, such as **Export Controls**, **Conflicts of Interest**, the **Institutional Animal Care and Use Committee (IACUC)**, and the **Institutional Review Board (IRB)**. This collaborative approach ensures that research involving biohazardous materials is conducted with the highest level of integrity, safety, and ethical responsibility.

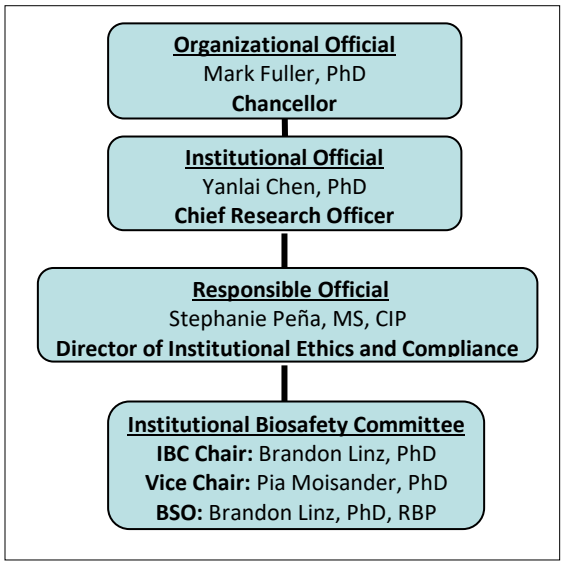
Designations:

Organization:	University of Massachusetts, Dartmouth [UMassD]
Organizational Official (OO):	Chancellor
Institutional Official (IO):	Chief Research Officer
Responsible Official (RO):	Director of Institutional Ethics & Compliance [DIEC]
BioSafety Officer (BSO):	Director of Environmental Health & Safety [DEHS]
Interim BioSafety Officer (iBSO):	Triumvirate Environmental Consultant Biosafety Officer

Committee Composition:

Chair, Scientific Member, rDNA Expert	Christopher Brigham, PhD
Vice Chair, Scientific Member:	Pia Moisander, PhD
Scientific Member, Plant Protein Expert	
Scientific Member, Human Gene Expert:	Lamya Karim, PhD
Scientific Member, Animal Expert	Amy Hancock-Ronemus, VMD
Scientific Member	Mark Silby, PhD
Scientific Member	Shuowei Cai, PhD
Scientific Member	Xioafei Jia, PhD
Responsible Official (RO), Non-Scientific Member:	Stephanie Pena, MS, CIP
Non-Affiliated Community Member:	Luke Gelinas, PhD
Non-Affiliated Community Member:	Peter Bangs, PhD
University BioSafety Officer, Ex-Officio Member:	Brandon Linz, PhD, RBP.
Total Number of Voting Committee Members = 11	Quorum = 7
Consultants:	
Scientific Consultant, Nano/Microparticles	Wei-Shun Chang, PhD

IBC Organizational Chart:



Section 2: Roles and Responsibilities

Organizational Official
Institutional Official
Responsible Official
IBC Chairs
IBC Membership
IBC Meeting Chair
IBC Members
Biosafety Officer
EHS
Principal Investigators
Faculty Sponsors
Lab Personnel

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.

Organizational Official

The Organizational Official (OO) is the leader of the Biosafety Program, and their responsibilities include:

- Ensure the allocation of sufficient resources for IBC oversight and periodically review these resources to support thorough and timely reviews, based on the volume and type of research conducted.
- Foster a culture of compliance with IBC requirements.
- Ensure complaints and allegations concerning the IBC are handled appropriately.
- Investigate and correct systemic issues within the IBC.

Institutional Official

Appoint by the OO, the Institutional Official (IO) responsibilities include:

- Appointing an individual to serve as an Institutional Responsible Official (RO) on the IBC, typically the [DIEC].
- Appointing a BSO if research involves a BSL-3 or BSL-4 agent or large-scale research [any single culture exceeding 10 liters in volume].
- In consultation with the RO, appoint, evaluate, and remove IBC members to ensure the IBC is composed of individuals with appropriate expertise and commitment.
- Reviewing all major IBC actions, including initial registration, maintenance, annual renewal, and inactivation, as prepared by the RO.
- Limiting, disapproving, suspending, or terminating biological research subject to IBC oversight.
- Determining if incidents represent General Noncompliance, Serious Noncompliance, Continuing Noncompliance, or if they warrant Suspension or Termination of IBC approval, and taking appropriate action against employees in cases of Serious or Continuing Noncompliance. Ensuring the independence of the review process and address complaints and allegations concerning the IBC appropriately. Investigating and rectifying any allegations and findings of undue influence on the biological research review process.
- Annually evaluate allocation of resources to the IBC and make recommendations for adjusts as necessary.
- Providing and maintaining adequate facilities for biohazardous research.
- 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.

The IO cannot approve research that the IBC has not approved.

Responsible Official

Appointed by the IO, the RO oversees the IBC's functioning and works closely with the IBC Chair(s), BSO, DEHS/EHS, IBC members, and researchers to ensure that research involving biohazardous materials is conducted in compliance with all applicable local, state, and federal regulations. The RO responsibilities include:

- Filing IBC registrations, biographical sketches, and if necessary, the annual report with NIH/OSP.
- Managing the registration intake, review process, and coordinating IBC registration reviews.
- Drafting, developing, and distribution of IBC agenda, minutes, discussion items, and determinations/approvals.
- Maintaining up to date records of registrations submitted, documentation provided for review, and actions taken.
- Notifying PIs of the outcome of a registration review.
- Providing administrative support to the IBC Members, IBC Chair, IBC Vice Chair, and BSO.
- Reporting oversight activity to the IBC when the activity does NOT require IBC oversight.
- Interfacing relevant information between the IBC, IRB, and IACUC (attends meetings of all three committees).
- Serving as a point of contact for regulatory agencies.
- Evaluating IBC membership to maintain a composition of individuals with appropriate expertise and commitment.
- Determining if IBC registrations at the University may rely on another institution for oversight.
- Providing training materials for PIs, IBC members, students, and staff in coordination with EHS or BSO, as necessary. Ensuring appropriate approved training is provided for IBC members, PIs, and laboratory staff.

- Reviewing all guidelines outlined in this charter at least once a year to allow for continued evaluation of the biosafety guidelines and ensure all regulatory requirements and community needs are met. Periodically reviewing existing policies and procedures to ensure compliance with local, state, and federal regulations. 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 review, discussion, and action. The University of Massachusetts System General Counsel may revise policies and procedures as necessary to comply with new statutory or regulatory requirements.

IBC

The OO and the IO charge the IBC to review, approve, and provide oversight and guidance to those research personnel who seek to use rDNA, biohazardous materials, agents, and toxins in experiments or teaching.

The IBC has the responsibility to:

- Advise the RO, IO, and OO on policies, procedures, adequacy of the facilities, SOPs, and safety practices & training associated to the use of biohazardous materials in academic or clinical setting which may involve human subjects or animal care research activities.
- Conduct independent review of individual research registrations involving the use of biohazardous materials. At initial review, continuing review, and modification, the IBC reviews registrations to assess the facilities, study procedures, safety practices, containment practices, and training/expertise of personnel involved for the proposed research. Consult the available resources for current best practices and safe conduct of research. Review IBC registrations for compliance with the NIH Guidelines, institutional practices, surveillance, data reporting, and adverse event reporting. Notify the PI of the results of the review.
- Report any significant problems with or violations of the NIH Guidelines, and any significant research-related accidents or illnesses to the IO and NIH/OSP within 30 days, as applicable.
- Communicate and coordinate review and approval with [DIEC] of research projects with the Institutional Animal Care and Use Committee (IACUC), Institutional Review Board (IRB), or export-controlled work.
- Provide recommendations for education and training related to biosafety for all UMassD faculty, staff, and students that may be involved in the use of such materials.
- Review policies, programs, and directives regarding the use of biohazardous materials in academic, research, clinical, and animal use/care activities for compliance with NIH Guidelines, and other applicable federal, state, and local laws/regulations.

The IBC has the authority to:

- Determine the level of review the research requires, biological safety containment level, and adequacy of containment practices, proposed facilities and Principal Investigator qualifications for individual research proposals.
- To approve, require modifications to secure approval, and disapprove all research activities overseen by the University.
- To Suspend or withdraw approval of research not being conducted in accordance with IBC requirements or that had been associated with unexpected serious harm to participants.

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.

IBC Membership

Composition:
The IBC must be composed of at least 5 members, two who are not affiliated with the institution in any way other than serving on the IBC to represent the interest of the surrounding community with respect to health and protection of the environment. 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.

Required Membership:

- 2 Unaffiliated Community Members
- Biosafety Officer (required if the IBC oversees a BSL3 facility or large-scale research is conducted)
- rDNA Technology Expert
- Plant, Plant Pathogen, Plant Pest Containment Expert
- Animal Containment Expert
- Human Gene Expert

Recommended Membership:

- Experts in biosafety and physical containment
- Responsible official for institutional policies and applicable laws
- Laboratory technical staff

IBC Leadership (Chair & Vice Chair)

The IBC Chair(s) are appointed by the IO to provide leadership to the IBC. In lieu of appointing a chair, the IO may delegate appointment of the chair to the IBC. Acting under such delegation, the IBC may elect a chair. The IBC chair serves a one-year term.

The Chair(s) have the responsibility to:

- In consultation with the RO, determine which registrations are exempt from convened meeting review.
- Develop meeting agendas and topics of discussion.
- Provide orientation and training of new members. Ensure all IBC members are properly trained. Help IBC members meet their expectations. Mentor and guide IBC members to use the criteria for approval.

- Assign designated reviewers to review an issue prior to official committee decisions made at the convened meeting.
- Lead the IBC convened meetings, ensure all IBC members participate actively and equally in discussions.
- Liaison between research personnel and IBC.
- Assess any reported or suspected biosafety misconduct, investigating any biosafety violations, and determining and recommending subsequent actions.
- Serve as one of three points of contact for regulatory agencies.
- Authorized to suspend or terminate research.

IBC Members

IBC members are appointed by the IO to participate in the review of IBC registrations, program policies, and procedures.

General Responsibilities:

- Undergo initial member training and participate in continuing education activities via citiprogram.org at least every 4 years.
- Treat all oral and written information obtained as part of the review process as confidential, and do not disclose or use confidential information without prior authorization.
- For each review consider if there is a Conflicting Interest. Members are expected to know the definition of Conflicting Interest and self-identify their Conflicting Interests. A conflicted member should not participate in that review (including discussion or voting), except to provide information requested by the IBC.
- Attend meetings and notify IBC Chair and RO of scheduling conflicts.
- In advance of the meeting, review materials provided as directed. Additional Review Considerations:
    - If one or more criteria are not met, consider what specific and directive changes would make the protocol approvable.
    - Notify the IBC Chair and RO if additional information is necessary to answer questions about the submitted materials, previous minutes, or other IBC documents.

Members assigned Primary Reviewer and Designated Reviewer are to:

- Conduct a biosafety review and risk assessment with preliminary judgments as to whether each criterion is met and provide preliminary study-specific findings.
- Review all submitted materials for accuracy and consistency.
- If committee review is required, prepare to lead the discussion regarding assignment at the meeting.

At meetings, Members are to:

- Members are expected to offer and accept constructive feedback, actively contribute to meetings, and uphold the integrity of the biosafety program.
- Ask questions and provide information which has not been discussed.
- Think critically and use the criteria for approval to decide whether to approve research and which are not met. Identify concerns, problems, or recommended change based on the criteria for approval.
- Make decisions by majority rule, not consensus.
    - Listen and learn from the group but think and vote independently.
    - Know that dissent is healthy and expected.
- Report Allegations of Undue Influence related to the Biosafety Program to IO.
- Report Allegations of Noncompliance or Findings of Noncompliance to IBC Chair and RO.

Biosafety Officer

A Biological Safety Officer (BSO) is appointed by the IO if the institution plans to engage 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 IO and DEHS has responsibility for oversight of research and other activities involving the use of biological materials at the institution. In the absence of a BSO, staff from the Environmental Health and Safety Office will fulfill this role. The BSO plays a vital role in maintaining biosafety standards across UMassD's research programs, offering expertise, oversight, and training to ensure the safe handling of biological materials.

The BSO responsibilities include:

- Advise and train the IBC members, faculty, and staff (as necessary) in safe use and practices for working with potentially biohazardous materials.
- Pre-review registrations for the IBC and make recommendations to ensure safe practices are followed. Determine containment levels in accordance with the NIH Guidelines and Center for Disease Control and Prevention. Determine the necessity for health surveillance of personnel involved in projects that involve biohazardous substances.
- Annually inspect facilities and report to the IBC results regarding all UMassD biosafety facilities (including laboratories and satellite facilities). Review and inspect activities involving biohazardous materials in coordination with EHS personnel, the Office of Research Services Facility Manager, and the [DIEC].
- Report concerns, research-related accidents or illnesses, and violations of the NIH Guidelines and UMassD SOP to the IBC and RO. If a biosafety violation occurs, then an investigation will be initiated by the IBC Chair with assistance from the RO, BSO, and EHS staff.
- Help investigators develop protocols, biosafety hazardous management plans, and emergency response plans which address containment, handling accidental spills, and personnel contamination. Provide technical advice to PIs on laboratory containment facilities, safety equipment, security, and safety procedures. Provide training for staff and students in safe handling and accidental exposure procedures for their specific research-related activities.
- Provide assistance, input, and support required during an emergency response.
- Provide training on safe practices and handling of biohazardous materials, ensuring the entire institution understands the best practices for working with these substances.

Environmental Health and Safety (EHS) Office

The EHS Office ensures the safe conduct of research and laboratory activities by offering oversight, consultation, training, and technical assistance. It plays a central role in maintaining compliance with safety standards and protecting the health of personnel.

EHS responsibilities include:

- Regularly inspect laboratories to ensure compliance with safety and health guidelines and applicable regulations and to assist laboratories with remediating identified safety issues.
- Investigate laboratory incidents and accidents, recommending corrective actions to prevent recurrence and reduce safety risks.
- Coordinate and manage clean-up operations in the event of biohazardous spills, contamination, or other laboratory accidents.
- Develop and deliver training on laboratory and biological safety, ensuring personnel are knowledgeable about the safe handling of materials and emergency procedures.
- Ensure that the training covers the key policies and procedures outlined in the University's safety guidelines.
- Collaborate with federal, state, and local officials to ensure adherence to applicable safety codes and enforcement regulations.
- Assist laboratory personnel in identifying, evaluating, preventing, and controlling potential hazards in the research environment.
- Provide expert advice to ensure the safe conduct of experiments and the proper use of equipment and materials.
- Oversee the implementation and adherence to all University health and safety policies, ensuring they are updated to reflect new safety guidelines and practices.
- Maintain and regularly update the University's Biological Safety Manual, ensuring it reflects current safety protocols and regulatory requirements.
- Post and maintain biohazard warning cards for laboratories that store or use biohazardous materials to clearly identify risks and provide essential information for emergencies.

Principal Investigator

Principal Investigators (PIs) are responsible for ensuring compliance with the NIH Guidelines and the UMassD Institutional Biosafety Committee (IBC) Standard Operating Procedure (SOP) in all research involving biohazardous materials. PIs are expected to lead by example, enforcing regulations, providing clear directives, and ensuring the safety of their research teams.

The PI responsibilities include:

- Identify biohazardous and/or potentially infectious materials proposed for use.
- Notify the Office Research Administration (ORA) of any proposed activity using biohazards by indicating so on the Proposal Routing Form (PRF) accompanying a grant proposal. Ensure approval letters are forwarded to the funding agency or sponsor and fulfill all reporting requirements.
- Submit research registration form(s) to the IBC for review before commencing with any research activities using biohazardous substances or purchasing biohazardous substances. For legacy studies which now qualify for review under UMassD Other biohazardous materials, submit registration as soon as possible, while work continues. For BSL2 and category iii-D or greater await IBC approval before commencing research.
- To not make modifications to the research without prior IBC review and approval unless necessary to eliminate apparent immediate hazards Modifications to research which may alter the risk assessment, addition of new agents or vector systems, or modifications which alter the approval category require review and approval. Submit revisions to registration to the IBC for review and approval before implementing changes to activities involving the use of rDNA, synthetic nucleic acid molecules, or biohazardous materials and any other committee approvals have been obtained, as necessary.
- Oversee co-investigators, student investigators, staff, students, and co-occupants of shared spaces, ensuring they are aware of potential hazards, safety practices, and procedures for dealing with accidents. Ensure all personnel are equipped with necessary protocols that outline biohazards and safety precautions. Train staff (and co-occupants of shared spaces) in: (i) the potential hazards of the materials they are working with; (ii) the practices and techniques required to ensure safety, (iii) the procedures for dealing with accidents and safety, (iv) and the reasons and provisions for any precautionary medical practices advised or requested (e.g., vaccinations or serum collections).
- Ensure adequate resources (time, space, staff expertise, equipment) are available to conduct the research safely. This includes, but is not limited to, sufficient investigator time, appropriately qualified research team members, equipment, space, training, expertise, credentials, protocol requirements, and when relevant privileges. Develop biosafety protocols for staff and students in safe handling and accidental exposure procedures for their specific research-related activities.
- Conduct research in accordance with relevant current activities approved by the IBC. Ensure compliance with the regulations, UMassD IBC determinations, and provide directives and guidelines for the work they supervise.
- Submit continuing reviews 60 days prior to approval expiration, typically 3 years after initial approval. If research approval expires, stop all research activities, and immediately contact the IBC Chair(s) and RO.
- Maintain up to date study records; including: copies of registrations, training certificates, cabinet/fume hood certifications, safety sheets, shipping documents, and approval letters are stored chronologically and are available for audit review.
- If proposing to ship biohazardous materials, coordinate with EHS for proper handling and compliance with shipping requirements for biological materials, following EHS policies.
- Assist in any decontamination, follow-up investigation, or reporting that may be required.
- Personally conduct the activities to:
    - Supervise the laboratory staff and ensure the implementation of safety practices, maintain containment integrity (biological and physical), and correct any errors that could lead to biohazardous exposure.
    - Implement necessary specific control procedures within their own laboratories and ensure students and co-occupant staff working there receive proper instruction in the potential hazards of the materials they are working with.
    - Ensure the integrity of physical containment (e.g., biological safety cabinets) and the biological containment (e.g. purity and genotypic and phenotypical characteristics).
    - Correct work errors and conditions that may result in the release of biohazardous materials in the surrounding area or environment.

- Investigate and report any significant problems or incidents pertaining to the operation, containment practices, and/or study procedures in writing to IBC and RO. Report the following to the IBC within 5 days:
    - Significant problems or research-related accidents and illnesses.
    - Significant deviations from IBC approved practices or deviation due to the action or inaction of the investigator or research staff.
    - Allegations of Noncompliance or Findings of Noncompliance with the NIH guidelines or UMassD SOP.
    - Protocol deviation made without prior IBC approval to eliminate an immediate hazard.
    - Audit, inspection, or inquiry by a federal agency.
    - State medical board or hospital medical staff actions.
    - Suspension or premature termination by the sponsor, investigator, or institution.
    - New or increased risk.
    - Loss of containment.

Faculty Sponsor

The faculty sponsor is selected by a student investigator and is responsible for overseeing the research activities of students and staff involved in biosafety-related research. They are responsible for guiding students through the IBC registration process, ensuring compliance with biosafety policies, federal regulations, and ethical standards. The faculty sponsor acts as a mentor and liaison between the students and the IBC, helping to facilitate the development of the IBC registration application, ensuring that all aspects of the research protocol are thoroughly articulated. Their responsibilities include:

- Ensuring all students and staff involved in the research have completed the required biosafety training and verifying all personnel are adequately educated on safe handling practices for biohazardous materials.
- Actively monitor ongoing research activities to ensure compliance and be vigilant for any changes in research practices that may require amendments to the IBC registration and promptly report any deviations or incidents.
- Submitting necessary documentation, responding to IBC inquiries, and ensuring that all required reports and renewals are completed on time.
- Conducting continuous risk assessments and evaluating potential hazards associated with biohazardous materials to ensure the appropriate containment and decontamination procedures are in place.
- Maintaining accurate records of training certifications, safety inspections, and any incidents related to biosafety.

Lab Personnel

Lab personnel are appointed by PIs and are responsible for adhering to safety protocols, completing mandatory training, and promptly reporting any incidents involving biohazardous materials. Their role is vital in maintaining a safe laboratory environment through continuous awareness, risk assessment, and thoughtful experimental planning. Responsibilities of lab personnel include:

- Following all specified safety procedures and protocols as outlined by the PI and the Institutional Biosafety Committee (IBC).
- Completing all required safety training relevant to working with biohazardous materials.
- Maintaining constant awareness of surroundings and actively assess risks in the lab.
- Incorporating safety considerations into all experimental designs and activities.
- Informing supervisors of any health conditions that may increase risks when working with or being exposed to biohazardous substances.
- Promptly reporting any safety incidents, accidents, or hazardous situations to the PI and appropriate personnel.
- Engaging with PIs in safety discussions, particularly during experimental planning.
- Continuously address and integrate safety measures throughout the research process.

Departments should provide PIs the necessary support to encourage attention to important safety considerations. PIs are encouraged to engage their laboratory personnel in the discussion of safety consideration, when appropriate everyone is committed to safety, a strong sense of community identity invested in safety will emerge and benefit all.

Section 3: IBC Oversight

IBC Oversight

The IBC oversight applies to all activities involving biohazardous materials at or supported by the UMassD regardless of funding.

The biohazardous materials which the IBC currently oversees include:

1. **Large-scale cultures and whole organisms:**
   - Large-scale cultures or volumes exceeding 10 liters of culture.
   - Whole animals or whole plants, including transgenic varieties.
   - Organisms, which if released, could have a significant impact on the environment (i.e., exotic plants, non-indigenous plant pathogens or regulated insects) or are export controlled.
2. **Biohazardous materials and biological samples:**
   - Biohazardous materials, nanomaterials, biological agents (infectious, parasitic, pathogenic, or of unknown pathogenicity), or genetically engineered/modified microorganisms (bacteria, viruses, fungi, protozoa, yeast, algae, etc.); including: storage or concentration of any materials which pose zoonotic disease concerns.
   - Biological specimens (blood or blood components, cellular lines/materials, tissues, feces, saliva, urine, or byproduct) known or suspected to be contaminated with an infectious or biohazardous agent.
   - Biological toxins, synthesized toxins, bioactive derivatives, or subunits of toxins and Federal Select Agents and Toxins.
3. **Genetic manipulation and host-vector systems:**
   - Nucleic acid molecules (DNA, synthetic DNA [sDNA], recombinant DNA [rDNA], RNA, or synthetic RNA [sRNA]) and prions or prion-like proteins.
   - Manipulation of genetic material via cloning, editing, synthesis, transformation, recombination, or mutagenesis.
   - Host-vector systems, including non-pathogenic prokaryotes or lower eukaryotic hosts, employing Risk Group 2, 3, 4, or other restricted agents.
   - Xenotransplantation or transfer of genetic material into humans, whole animals, or plants, or microorganisms.
4. **Other:**
   - Soil seed, spores, plant pathogens (bacteria, viruses, fungi, or parasite), or any other material received under an agreement or permit.
   - Necropsy of animals not under the care of the University Veterinarian, necropsy of animals with unknown health status and/or animals reasonably suspected or known to be infectious.
   - Except for general surveillance, arthropods that serve as vectors of disease to humans, animals, or plants and arthropods considered an environmental hazard.
   - Studies which pose a Dual Use Research of Concern.
   - Export controlled biological agents and biopharmaceuticals.
   - Other work as deemed necessary for review by the Biological Safety Officer, IBC, or sponsor.

From this point forward, the term "biohazardous materials" refers to the agents and substances listed above.
For more information, email ibc.research@umassd.edu.

Classifications

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. 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. Laboratory containment classification and risk assessment are fundamental aspects of biosafety practices aimed at ensuring the safe handling of biological materials. This section provides an overview of biosafety levels (BL), risk group (RG) classification, and additional considerations for effective biosafety management (Appendix ##).

Biosafety Levels (BL) Classification:

Biosafety levels categorize laboratory activities and facilities based on the level of risk posed by biological agents. These levels help in establishing appropriate containment measures to minimize the risk of exposure to laboratory personnel, the community, and the environment. There are four biosafety levels, each characterized by specific combinations of laboratory practices, safety equipment, and facilities tailored to the potential hazards posed by the agents being handled. These levels range from BL1 (minimal risk) to BL4 (highest containment), with each level imposing progressively stringent requirements for specific laboratory practices, safety equipment, and facilities. For example, BL1 facilities typically handle well-characterized agents not known to cause disease in healthy adults, while BL4 facilities are designed to handle dangerous pathogens requiring maximum containment measures.

Biosafety Level 1 (BL1):

BL1 facilities are suitable for handling agents that pose minimal risk to personnel and the environment. Agents are well-characterized, not known to cause disease in immunocompetent adult humans, and present minimal potential hazard to laboratory personnel and the environment. BSL-1 laboratories are not necessarily separated from the general traffic patterns in the building. Work is typically conducted on open benchtops using standard microbiological practices. Special containment equipment or facility design is not generally required but may be used as determined by appropriate risk assessment. Laboratory personnel receive specific training in the procedures conducted in the laboratory and are supervised by a scientist with training in microbiology or a related science.

Biosafety Level 2 (BL2):

BL2 facilities are designed for handling agents associated with human disease and pose moderate hazards to personnel and the environment. These facilities incorporate additional safety measures such as controlled access, biological safety cabinets (BSCs) for working with aerosols, and enhanced waste management procedures. BSL-2 differs from BSL-1 primarily because: 1) laboratory personnel receive specific training in handling agents and are supervised by scientists competent in handling agents and associated procedures; 2) access to the laboratory is restricted when work is being conducted; and 3) all procedures in which infectious aerosols or splashes may be created are conducted in BSCs or other physical containment equipment.

UMassD works only with materials/agents classified as BSL2 or lower.

Biosafety Level 3 (BL3):

BL3 facilities are required for handling agents that may cause serious or potentially lethal diseases through inhalation route of exposure. These facilities feature specialized engineering controls such as negative pressure rooms, double-door access systems, and dedicated exhaust systems to prevent the release of infectious aerosols. 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 receive specialized training in handling agents, adhere to strict decontamination procedures, 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 PPE.

Biosafety Level 4 (BL4):

BL4 facilities represent the highest level of containment and are reserved for handling dangerous and exotic agents that pose a high risk aerosol-transmitted laboratory infections and life-threatening diseases that are frequently fatal, agents for which there are no vaccines or treatments, or work with a related agent with unknown risk of transmission. Agents with a close or identical antigenic relationship to agents requiring BSL-4 containment are handled at this level until sufficient data are obtained to re-designate the level. Laboratory staff receive specific and thorough training in handling extremely hazardous infectious agents. Laboratory staff understand the primary and secondary containment functions of standard and special practices, containment equipment, and laboratory design characteristics. All laboratory staff and supervisors are competent in handling agents and procedures requiring BSL-4 containment. The laboratory supervisor controls access to the laboratory in accordance with institutional policies. These facilities employ the most stringent containment measures, including complete personal protective equipment (PPE) suits with supplied air, stringent entry and exit procedures, and highly controlled laboratory environments to prevent any possibility of escape of infectious agents. Only authorized persons are allowed to enter and work in the area and must follow stringent guidelines for safety.

Risk Group (RG) Classifications:

Understanding the potential hazards posed by biological agents, the characteristics, and classifications of risk groups is crucial for implementing appropriate containment measures and ensuring the safety of laboratory personnel and the surrounding environment. Biological agents are categorized into four risk groups (RG) based on their pathogenicity to a healthy human adult. These risk groups provide a framework for assessing the potential risks associated with handling biological materials. Assessments are based on the Risk Group (RG) of an agent, which determines the precautions needed to handle it safely.

Risk Group 1 (RG1):

RG1 agents pose minimal risk to laboratory personnel and the environment and are not associated with disease in healthy adult humans. They are unlikely to cause disease in healthy individuals and typically include well-characterized microorganisms with low pathogenicity. Examples of RG1 agents may include non-pathogenic bacteria and viruses commonly found in laboratory settings.

Risk Group 2 (RG2):
RG2 agents pose a moderate risk to laboratory personnel and the environment. They may cause mild to moderate disease in humans but are unlikely to spread rapidly or cause significant outbreaks. RG2 agents are associated with human disease, which is rarely serious and for which preventative or therapeutic interventions are often available. RG2 agents require appropriate containment measures and safety precautions, including personal protective equipment (PPE) and facility controls. Examples of RG2 agents may include certain bacteria, viruses, and fungi known to cause human disease, such as influenza viruses and Salmonella spp.

Risk Group 3 (RG3):
RG3 agents pose a significant risk to laboratory personnel and the environment. They may cause severe or potentially lethal disease in humans and have the potential for spread within the community and for which preventative or therapeutic interventions may be available (high individual risk but low community risk). RG3 agents require stringent containment measures, including specialized facilities with controlled access, containment equipment, and enhanced biosafety practices. Examples of RG3 agents may include highly pathogenic bacteria, viruses, and parasites, such as Mycobacterium tuberculosis and Ebola virus.

Risk Group 4 (RG4):
RG4 agents pose the highest risk to laboratory personnel and the environment. They may cause severe or life-threatening disease in humans and have the potential for widespread transmission and significant public health impact and for which preventative or therapeutic interventions are not usually available (high individual risk and high community risk). RG4 agents require maximum containment measures, including high-level biosafety laboratories (BSL-4) with strict access controls, specialized engineering controls, and rigorous safety protocols. Examples of RG4 agents may include highly virulent viruses such as Ebola virus and Marburg virus.

Hazard Classification of Human Etiologic Agents

Appendix B: Classification of Human Etiologic Agents on the Basis of Hazard

Human etiologic agents, also known as pathogens, are classified into various hazard groups based on their potential risk to human health and safety. This classification system provides a framework for assessing the level of risk posed by different agents and implementing appropriate containment measures to mitigate potential hazards. The following is a summary of the hazard groups commonly used in biosafety and biosecurity practices:

Hazard Group 1 (HG1): HG1 Agents pose minimal risk to human health. They are unlikely to cause disease in healthy individuals and do not typically spread from person to person.

Hazard Group 2 (HG2): HG2 Agents pose a moderate risk to human health. They may cause mild to moderate disease in humans, but the risk of transmission is limited. Proper handling and containment measures are required to prevent accidental exposure.

Hazard Group 3 (HG3): HG3 Agents pose a significant risk to human health. They may cause severe or potentially lethal disease in humans and have the potential for spread within the community. Enhanced containment measures are necessary to prevent exposure and minimize the risk of transmission.

Hazard Group 4 (HG4): HG4 Agents pose the highest risk to human health. They may cause severe or life-threatening disease in humans and have the potential for widespread transmission and significant public health impact. Maximum containment measures are required to prevent accidental exposure and contain outbreaks.

Definitions

Biohazardous Material: Biohazardous materials or agents present have the potential to place the health of humans or animals at risk, either directly through infection or indirectly through damage to the environment.

Biohazardous Management Standard Operating Procedures (BHMSOPs): Detailed instructions outlining the specific steps and safety precautions to be followed when handling biohazardous materials or performing laboratory procedures. It addresses the systematic identification, assessment, and management of risks associated with the handling, storage, transportation, and disposal of biohazardous materials to minimize the potential for adverse outcomes, including exposures, infections, and environmental contamination.

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.

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 Review: Review of administrative and regulatory issues unrelated to the criteria for approval that under the NIH guidelines must be determined by a convened IBC.

Biosafety Reviewer: Individual who conducts the Biosafety Review.

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

- **Allegation of Noncompliance:** An unproven assertion of Noncompliance.
- **Noncompliance:** Failure to follow the NIH guidelines, local requirements, or determinations of the IBC.
- **General Noncompliance:** Deviation from the approved research protocol or practices commonly accepted by the scientific community.
- **Continuing Noncompliance:** A pattern of noncompliance that is likely to continue without intervention or failure to work with the IBC to resolve noncompliance.
- **Corrective Action Plan (CAP):** an outline of specific steps to be taken to remedy the cause of Noncompliance.
- **Serious Noncompliance:** Noncompliance violations which deviate from the approved research protocol and practices commonly accepted by the scientific community; negatively affect the integrity of the study, the rights and welfare of researchers, the general public, subjects and the environment; require revision to the approved protocol; and had the potential to result in an adverse biosafety event. The actions of the investigator pose a substantive harm to the health and/or safety of personnel, students, the institution, and/or the public environment.
- **Need to Know Individuals**: For Research Noncompliance: PI, IBC Chair, Chair of the Respondent's department, applicable IO, DIEC, Office of the General Counsel, and Provost (if externally funded). For IBC Noncompliance: DIEC.

Biosecurity: Protection of high-consequence microbial agents and toxins, or critical relevant information, against theft or diversion by those who intend to pursue intentional misuse.

Biologic Terrorism: Use of biologic agents or toxins (e.g., pathogenic organisms that affect humans, animals, or plants) for terrorist purposes.

Biological Safety Officer (BSO): The 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 section s IV-B-3 of the *NIH Guidelines*.

Biological Specimens: Samples of biological material, such as tissues, cells, blood, urine, saliva, feces or other bodily fluids, collected from humans, animals, plants, or microorganisms for research, diagnostic, or therapeutic purposes. Biological specimens are used to study physiological processes, identify disease biomarkers, develop diagnostic tests, and investigate the effects of environmental exposures.

Bloodborne Pathogens: Pathogenic microorganisms present in human blood that can cause diseases in humans, such as hepatitis B virus (HBV), hepatitis C virus (HCV), human immunodeficiency virus (HIV), syphilis, malaria, brucellosis, leptospirosis, Ebola, and Marburg viruses.

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 UMassD officials with the responsibility for ordering Select Agents.

Chain of Custody: The serial holders of a pathogen, each of whom is responsible for securing the pathogen and are accountable for its documentation.

Committee Review: All review processes which requires a convened IBC.

Conditional Approval: When a registration submission requires administrative revisions for the registration to be granted approval.

Conflicting Interest: Any situation in which an individual (or the individual's spouse, domestic partner, children, and/or dependents) is involved in research has a personal, professional, financial, or other interest that could potentially influence their objectivity, judgment, or decision-making regarding the review, approval, or oversight of research protocols. Conflicts related to research may involve the sponsor, product or service being tested, or competitor of the sponsor held by the individual or the individual's immediate family, including:

- Involvement in the design, conduct, or reporting of the research.
- Financial interests related to equity holdings, exclusive of interests through mutual funds, compensation related to the research in the preceding 12 months, or proprietary interests (patent, trademark, copyright or licensing agreement).
- Ownership interest, stock options, or other ownership interest of any value exclusive of interests in publicly-traded, diversified mutual funds.
- Compensation of any amount in the past year or of any amount expected in the next year, excluding compensation for costs directly related to conducting research.
- Board or executive relationship, regardless of compensation.
- Reimbursed or sponsored travel by an entity other than a federal, state, or local government agency, higher education institution or affiliated research institute, academic teaching hospital, or medical center.
- Affiliation with organizations, companies, or ventures related to the research that could result in a direct financial benefit.
- Personal or professional relationships with the researchers or sponsors or investigators of the research which could create bias or the appearance of bias.
- Any other circumstance that could reasonably be perceived as affecting the impartiality or integrity of the review process.

Disclosure of conflicts deemed related to research is essential for maintaining transparency, integrity, and public trust in the review and oversight of biohazardous material research conducted. Conflicts must be identified and managed appropriately to ensure that decisions are made in the best interests of safety, compliance, and ethical conduct. Conflict of interest must be disclosed at the beginning of review of any documents and meeting attendance.

Containment: The strategies and procedures implemented to prevent the unintentional release of biohazardous materials into the environment or exposure to laboratory workers and the public. Containment involves the continuous monitoring and evaluation of laboratory practices are necessary to identify areas for improvement and ensure compliance with biosafety standards. This includes regular inspections, audits, and reviews of containment facilities, procedures, and training programs.

Collaborative Efforts: Effective biosafety management requires collaboration among researchers, biosafety officers, and the IBC. Regular communication and coordination are essential for implementing and maintaining biosafety protocols, conducting risk assessments, and addressing emerging challenges.

Decontamination: The process of removing or neutralizing biohazardous materials from surfaces, equipment, or other items to reduce the risk of contamination and potential exposure.

Designated Reviewer: An Experienced IBC member designated by the Chair, BSO, or RO to conduct a Non-Committee review.

Engineering Controls: Physical barriers, equipment, and design features implemented to minimize the risk of exposure to biohazardous materials, such as biological safety cabinets, fume hoods, and ventilation systems.

Environmental Monitoring: The systematic surveillance and assessment of laboratory environments for the presence of biohazardous materials, contaminants, and hazardous conditions to ensure the safety of personnel, facilities, and the surrounding community.

Experienced IBC Member: An IBC member who based on professional competence has sufficient knowledge and skill in conducting IBC reviews to serve as Designated Reviewer.

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

Gene Cloning: The process of isolating and copying a specific gene or DNA fragment from one organism and inserting it into another organism or vector to produce multiple copies of the gene for further study or manipulation. Gene cloning is a fundamental technique in molecular biology and genetic engineering.

Gene Editing: The precise modification of DNA sequences within the genome of an organism using engineered nucleases or other molecular tools to insert, delete, or replace specific DNA sequences. Gene editing technologies, such as CRISPR-Cas9, allow targeted modifications to be made to the genome with unprecedented accuracy and efficiency.

Genetic Engineering: The manipulation of an organism's genetic material using recombinant DNA technology to introduce new genetic material or alter existing genetic sequences. Genetic engineering techniques enable the creation of genetically modified organisms (GMOs) with desired traits for agricultural, medical, industrial, or research purposes.

Genetic Manipulation: The deliberate alteration or modification of the genetic material of an organism, typically using molecular biology techniques such as gene cloning, gene editing, or genetic engineering. Genetic manipulation allows scientists to study gene function, modify traits, produce genetically modified organisms (GMOs), and develop new biotechnological products and applications.

Hazard Group (HG): Hazard groups categorize biological agents based on their inherent hazard to human health and the environment. Hazard groups are typically used in biosafety and biosecurity practices to assess the potential risk associated with handling specific biological agents. Hazard groups consider factors such as the pathogenicity, virulence, mode of transmission, and potential for causing harm to humans and the environment.

Hazardous Waste: Any waste material that poses a potential threat to human health or the environment due to its chemical, biological, radiological, or physical properties.

Human Gene Transfer Research: The deliberate transfer of recombinant or synthetic nucleic acid molecules, or DNA or RNA derived from recombinant or synthetic nucleic acid molecules, into human research participants.

Human Embryonic Stem Cells (HESC): Pluripotent cells derived from the inner cell mass of early-stage embryos. These cells have the remarkable ability to self-renew indefinitely and to differentiate into various specialized cell types representing all three germ layers of the human body: ectoderm,

mesoderm, and endoderm. Due to their unique characteristics, HESC hold significant potential for regenerative medicine, drug discovery, and disease modeling. However, their use is subject to strict ethical and regulatory guidelines to ensure responsible and ethical research practices.

Health and Human Services (HHS): The United States Department of Health and Human Services (HHS) is a cabinet-level department of the federal government responsible for protecting the health of all Americans and providing essential human services. HHS oversees a wide range of agencies and programs, including the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), the National Institutes of Health (NIH), and the Centers for Medicare & Medicaid Services (CMS), among others. Its mission encompasses public health, biomedical research, disease prevention, healthcare delivery, and social services, with the goal of promoting the well-being and health security of individuals and communities across the nation.

Inactivation: The process of rendering biohazardous materials non-infectious or non-viable through physical or chemical means, such as autoclaving, disinfection, or sterilization.

Incident Response Plan: A documented plan outlining the strategies and procedures to be followed in the event of an emergency or biosafety incident, such as spills, exposures, or accidents, security breaches, and include notification protocols and emergency response actions. Effective plans are critical for mitigating risks and minimizing harm in the event of accidents or incidents. Laboratories should have clear protocols in place for handling spills, exposures, or breaches in containment, including procedures for decontamination and medical response.

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 committee responsible for overseeing all animal care and use at UMassD and has adopted policies and procedures that apply to all vertebrate animals used for research and teaching.

Institutional Biosafety Committee (IBC): A committee responsible for the 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.

Institutional Review Board (IRB): The committee 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.”

Laboratory Audit: A comprehensive review and evaluation of laboratory facilities, operations, procedures, and practices conducted by internal or external auditors to assess compliance with regulatory requirements, institutional policies, and industry standards in biosafety and biosecurity.

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

Meeting Chair: The IBC member running a convened IBC meeting. The Meeting Chair may be an IBC Chair, Vice Chair, or an IBC member temporarily designated by a Chair.

Minimal Risk: The probability and magnitude of harm or discomfort anticipated in the research that are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

National Institutes of Health (NIH): The government body is comprised of 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 in1976). 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, bacteria, viruses, and animals, and for the safe conduct of human gene transfer research. The document keeps pace with the changing state of science.

Nanomaterials/Microparticles: Substances or particles with dimensions at the nanometer or micrometer scale, respectively, typically engineered or manufactured for specific applications in materials science, engineering, medicine, or biotechnology. Nanomaterials and microparticles exhibit unique physical, chemical, and biological properties due to their small size and high surface-to-volume ratio.

Necropsy: Also known as an autopsy or post-mortem examination, a necropsy is a thorough examination performed on the body of a deceased organism, typically an animal, to determine the cause of death, identify underlying diseases or injuries, and gather diagnostic information. Necropsies are commonly conducted in veterinary medicine, pathology, and research settings to study disease processes, assess treatment efficacy, and investigate unexpected deaths. The procedure involves the systematic examination of organs, tissues, and bodily fluids, often including gross observation, histological analysis, and microbiological testing. Necropsies play a crucial role in understanding disease pathogenesis, monitoring animal health, and informing clinical and research practices.

New or Increased Biosafety Risk: Information that:
- Is unexpected (inconsistent with the information previously reviewed by the IBC); and
- Indicates that researchers or others are at increased risk of harm because of the research study.

Non-Committee Review: All review processes that do not require a convened IBC: non-biological research determinations, non-engagement determinations, exemption determinations, and expedited review.

Occupational Exposure: Any reasonably anticipated skin, eye, mucous membrane, or parenteral contact with biohazardous materials that may result from the performance of an employee's duties.

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

Other Potentially Infectious Materials (OPIM): Including the following human body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, body fluid that is visibly contaminated with blood and all body fluids where it is difficult or impossible to differentiate between body fluids; any unfixed tissue from human and HIV/HBV containing culture medium.

Parenteral: Entry into the body by other means than through the digestive tract such as by piercing mucous membranes or the skin by needle sticks, human bites, cuts, and abrasions.

Personal Protective Equipment (PPE): Clothing, gloves, goggles, face shields, respirators, or other equipment worn by laboratory personnel to protect against exposure to biohazardous materials.

Plant Pathogens: Microorganisms, including bacteria, fungi, viruses, nematodes, and phytoplasmas, that cause diseases in plants, leading to crop losses, reduced yield, and economic damage in agriculture and horticulture. Plant pathogens can infect various parts of plants, including leaves, stems, roots, and fruits, and may spread through vectors, soil, water, or air.

Principal Investigator: Any UMassD 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.

Prions or Prion-Like Proteins: Abnormal, misfolded proteins that can induce the misfolding of normal proteins and cause a variety of neurodegenerative diseases, including Creutzfeldt-Jakob disease (CJD), variant CJD, and kuru, in humans and other animals. Prions are unique infectious agents that lack nucleic acids and are resistant to conventional sterilization methods.

Quality Assurance (QA): A system of procedures and activities implemented to ensure that biosafety practices and protocols are effectively implemented, monitored, and continuously improved to meet established standards and regulatory requirements.

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 (rDNA) 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.

Responsible Official: A facility official who has been designated the responsibility and authority to ensure that the requirements of 42CFR73, 9CFR121, and 7CFR331 are met, as appropriate, for the pathogen/toxin in use.

rDNA Research: Research involving the manipulation of DNA molecules to create new combinations of genetic material not found in nature. Recombinant DNA techniques allow scientists to insert, delete, or modify genes from different organisms to study gene function, produce recombinant proteins, develop genetically modified organisms, and advance biotechnological applications.

Responsible Conduct: The adherence to ethical principles, professional standards, and regulatory requirements in the planning, conduct, and reporting of biohazardous material research. Responsible conduct encompasses integrity, honesty, transparency, and accountability in all aspects of research activities, including experimental design, data collection and analysis, interpretation of results, authorship and publication practices, and adherence to relevant laws, regulations, and institutional policies. Researchers and institutional officials are expected to demonstrate responsible conduct to ensure the integrity and credibility of scientific research, protect the welfare of human subjects and animals, safeguard the environment, and maintain public trust in the research enterprise.

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

Returned: When the initial, continuing, or modification registration submission does not meet the criteria for approval and the IBC considers the research to have extensive deficiencies to the protocol which must be addressed.

Risk Assessment: The systematic evaluation of potential hazards, exposures, and risks associated with specific activities, materials, or processes to determine appropriate control measures and mitigate potential risks to personnel, the environment, and public health.

Risk Mitigation: The implementation of measures and controls to reduce or eliminate the likelihood and severity of potential risks associated with biohazardous materials research, laboratory activities, and operations.

Scientific Integrity: Steadfast adherence to ethical principles and professional standards in all facets of scientific inquiry, encompassing honesty, accuracy, objectivity, and transparency from hypothesis formulation to the dissemination of findings. It entails upholding the highest standards of conduct, including responsible research practices, appropriate attribution of credit, and avoidance of conflicts of interest, to foster trust, credibility, and reliability in the scientific community and society at large.

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. Specifically, regulated pathogens and toxins as defined in Title 42, CFR, Part 73, including pathogens and toxins regulated by both DHHS and USDA (i.e., overlapping agents or toxins) and plant pathogens regulated by USDA alone. In this document, "*Select Agents (SA) pathogens*" and "*SA pathogens*" refer to both select agent pathogens and toxins for all biosecurity purposes.

Select Agent Access: The ability to take physical possession of select agents/toxins. Such access includes areas where unlocked freezers, small unsecured, yet locked, containers, and cabinets contain select agents/toxins.

Select Agent Area: An area where select agents/toxins are used or stored, regardless of whether they are in locked containers. Such an area would be a laboratory room or connecting rooms where select agents are used or stored. Corridors outside the laboratory room where select agents are used or stored may or may not be declared a select agent area, depending upon the biosecurity plan approved by the RO.

Suspension of IBC Approval: Temporary or permanent withdrawal of IBC approval for some or all research procedures.

Synthetic Nucleic Acids: Artificially synthesized DNA or RNA molecules created using chemical synthesis techniques rather than being derived from living organisms. Synthetic nucleic acids can be designed to have specific sequences and properties for use in research, diagnostics, therapeutics, and biotechnology applications.

Tabled: When a Committee Review determines further information is necessary to supplement the initial, continuing, or modification registration submission as its status does not meet the criteria for approval. Additionally, when registration submissions may be tabled when quorum is lost at Committee Review.

Termination of IBC Approval: Withdrawal of IBC approval for all research procedures where the IBC does not anticipate re-opening the study.

Training and Education: Formal instruction and ongoing training programs provided to personnel to ensure they have the knowledge, skills, and competencies required to safely handle hazardous materials, operate equipment, and follow biosafety protocols.

Unanticipated Problem Involving Risks: An unexpected event that indicates an increased risk of harm due to the research study.

United States Department of Agriculture (USDA): The USDA is a federal executive department responsible for developing and executing policies related to farming, agriculture, forestry, and food. The USDA's mission includes promoting agricultural trade, ensuring food safety, conserving natural resources, supporting rural communities, and providing nutrition assistance programs. The department oversees various agencies, including the Food Safety and Inspection Service (FSIS), the Agricultural Marketing Service (AMS), the Natural Resources Conservation Service (NRCS), and the Animal and Plant Health Inspection Service (APHIS), among others. Through its diverse programs and initiatives, the USDA plays a crucial role in enhancing the sustainability, productivity, and resilience of America's agricultural and food systems.

Vector Maps: Diagrams or representations of recombinant DNA vectors used in molecular biology to illustrate the structure, organization, and key features of the vector, including the DNA sequences, restriction sites, selectable markers, and other genetic elements incorporated into the vector for cloning or gene expression purposes.

Waste Management: The proper handling, storage, and disposal of biohazardous waste generated during laboratory activities, in accordance with regulatory requirements and institutional policies.

Xenotransplantation: The transplantation of living cells, tissues, or organs from one species (the donor) to another species (the recipient), typically involving the use of animal-derived tissues or organs in human patients. Xenotransplantation holds promise for addressing organ shortages and treating certain medical conditions but raises concerns about the risk of transmitting zoonotic diseases and immune rejection.

Zoonotic Disease: Infectious diseases caused by pathogens that can be transmitted between animals and humans, posing risks to both animal handlers and the general public.

IBC Levels of Review

The IBC levels of review correspond to the risk classification, containment level, and nature of the research involving biohazards, recombinant or synthetic nucleic acid molecules, infectious agents, or other biological materials. These reviews ensure adherence to institutional, federal, and NIH Guidelines for biosafety, while minimizing risks to researchers, the public, and the environment. These levels generally fall into the following categories:

Exempt Review

Involves research that presents minimal risk and does not fall under NIH Guidelines requiring higher levels of review. The risks are well-understood, and the materials used are generally considered safe for humans and the environment. Includes certain types of research using exempt quantities of recombinant DNA, non-hazardous biological agents, or materials that pose no significant risk to humans, animals, or the environment.

Examples:

- **Recombinant DNA**: Use of non-replicating recombinant DNA in E. coli K12 or other organisms recognized as safe (e.g., use of cloning vectors in strains of E. coli that are non-pathogenic).
- **Bacterial cultures**: Working with non-pathogenic bacterial strains (e.g., *Lactobacillus acidophilus*) for fermentation or probiotic research.
- **Yeast or fungi**: Experiments involving Saccharomyces cerevisiae (common yeast) in food science studies that are not intended to pose a biohazard risk.
- **Environmental samples**: Studies analyzing environmental samples (e.g., soil or water) that do not contain harmful biological agents and pose no risk of contamination.

Review Process: Exempt submissions are reviewed via Non-Committee Review by the IBC Chair, RO, and BSO. The IBC Chair may assign a designated reviewer to participate in the review if necessary. There is no requirement for a full committee review, once the reviewers agree the criteria of approval are met, and approval letter is issued.

Expedited Review

Involves research that presents moderate-risk biohazardous materials or agents where the risks are well understood and manageable. Typically involves **BSL-1** research, where proper containment and handling can mitigate risk.

Examples:

- **BSL-1 organisms:** Work with Risk Group 1 organisms such as *Bacillus subtilis* or *Escherichia coli K12*, which are known to be non-pathogenic under standard lab conditions.
- **Inactivated viral vectors:** Use of replication-incompetent viral vectors, such as adenovirus or lentivirus in cells, provided they don't express harmful genes.
- **Plasmid work:** Work with plasmids expressing genes that are non-toxic or non-infectious in bacterial systems like E. coli or yeast.
- **Human cell lines:** Non-viral transfection of human cell lines (e.g., HEK293 cells) that are non-cancerous and do not pose a risk of human infection.
- **Synthetic nucleic acids:** Work with synthetic RNA that does not replicate or code for infectious agents or toxins.
- **Minor amendments**: Changes to the protocol that do not increase the risk level, such as adding new personnel, small changes to lab procedures or timeline, modifying non-biohazardous reagents. Minor amendments do not apply to changes in biosafety levels, biohazard management, or biocontainment measures. 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.
- **Annual Continuing Review**: Ongoing research projects involving biohazards must undergo periodic review to ensure that safety protocols are still being followed and that there have been no significant changes. The PI must report the study's status annually to the IBC, confirming:
  - No incidents or noncompliance have occurred.
  - No new amendments or changes to the protocol are required.
  - Whether the study remains active or if closure is planned.

Review Process: The review is based on a predefined risk assessment and containment strategies, following NIH Guidelines and institutional biosafety policies. Expedited submissions are reviewed via Non-Committee Review by the IBC Chair, RO, and BSO. The IBC Chair may assign a designated reviewer to participate in the review if necessary. There is no requirement for a full committee review, once the reviewers agree the criteria of approval are met, and approval letter is issued.

Full Committee Review

Full committee review is required for research that poses significant risks, involving hazardous biological agents, infectious organisms, recombinant DNA, or synthetic nucleic acid molecules which pose a potential for significant risks to human health, the environment, or safety concerns requiring stricter oversight. The research is typically conducted in **BSL-2** containment environments.

Examples:

- **Risk Group 2 organisms**: Research involving pathogens like Salmonella typhimurium, Staphylococcus aureus, or Herpes simplex virus, which can cause disease in humans.

- **BSL-2 containment**: Studies involving adenovirus or lentivirus for gene expression in human cells, where the vectors pose moderate risks but are unlikely to cause widespread harm.
- **Animal research with rDNA**: Experiments that involve generating or using transgenic animals or modifying the genome of animals using recombinant DNA or CRISPR techniques.
- **In vivo studies with recombinant DNA**: Animal studies where mice or rats are injected with recombinant adenovirus to study gene function or disease models, with a moderate risk of exposure to lab personnel.
- **Human-derived materials**: Experiments involving human blood, tissues, or primary cell cultures, which may potentially carry bloodborne pathogens such as hepatitis B (HBV) or HIV.
- **Human gene therapy**: Trials involving gene editing technologies such as CRISPR or viral vector delivery in human subjects, including treatments for genetic disorders (e.g., research on adeno-associated viruses (AAV) for gene delivery).
- **Dual-use research**: Projects involving organisms or toxins that could potentially be weaponized, such as anthrax (Bacillus anthracis) or the H5N1 influenza virus.
- **CRISPR gene editing**: Research involving CRISPR/Cas9 techniques to modify genes in human cell lines, which carries risks related to the potential off-target effects or unintended mutations.
- **Major amendments**: Significant changes to the protocol that increase risk, such as changing the organism used in research, increasing the biosafety level/containment, introducing new hazardous materials, or for changes in any of the approved: management of biohazards, accidental exposure plans, or work location.

Review Process: The review is based on a predefined risk assessment and containment strategies, following NIH Guidelines and institutional biosafety policies. The protocol must be reviewed via Committee Review at a convened IBC meeting. The full committee assesses risks, containment levels, adequacy of safety measures, training of personnel, and emergency response plans for accidental exposures. The IBC may request additional information or modifications before approval to ensure regulatory compliance.

Dual Use Research of Concern (DURC) Review

Research that has the potential to be misused in a way that poses significant risks to public health, agriculture, the environment, or national security. DURC typically involves experiments that could be used for harmful purposes beyond the scope of their intended research.

Examples:

- **Pathogen enhancement**: Experiments involving gain-of-function mutations in viruses like H5N1 (avian flu) or SARS-CoV-2 that could increase transmissibility or virulence.
- **Toxin production**: Research that enhances the production of botulinum toxin, or other select agents that could be misused for biological warfare or terrorism.
- **Resistance mechanisms**: Studies that involve engineering organisms with resistance to **antibiotics** or **antiviral drugs** in a manner that could be exploited to undermine public health.

Review Process: This is a specialized review that requires a higher level of scrutiny and may involve both the IBC and additional oversight from institutional or federal bodies. DURC protocols are reviewed with the potential for misuse in mind to ensure risk mitigation strategies, such as limiting dissemination of findings, are in place. Federal guidance and additional reporting to agencies like the NIH or CDC may be required. The protocol must be reviewed via Committee Review at a convened IBC meeting.

Post Approval Processes for IBC Protocols:

Amendments: Prior to implementing any changes or modifications that impact the approval category, risk, population, study funding, or Principal Investigator (PI), the PI must obtain IBC approval for the amendments.

Minor Amendments:

Minor amendments do not apply to changes in biosafety levels, biohazard management, or biocontainment measures and do not increase the risk to personnel, the public, or the environment. Examples include:

- Adding trained personnel to an approved project.
- Minor procedural changes that do not alter the risk profile.
- Addition of agents, vectors, or cell lines that require the same or lower biosafety levels.
- Adjustments in the experimental timeline.

Note: A minor amendment form must be submitted for small changes to an already approved registration before any changes can be made. The designated reviewer assesses the changes, and if there are no objections from other IBC members, the amendment is approved. Documentation of the expedited review is recorded in the meeting minutes.

Major Amendments:

Major amendments involve significant changes to an approved protocol that may increase biosafety risks or require a higher level of containment and require a full committee review for the:

- Introduction of new biohazardous agents or recombinant DNA materials.
- Increase of the risk group classification of the biological agents.
- Substantial changes to the scope or design of the research that affect biosafety.

- Addition of a new facility that requires reevaluation of containment measures.

Note: The process for major amendments follows the full committee review procedure. These amendments require review during a convened meeting, with discussion focused on ensuring appropriate risk containment and compliance with biosafety standards.

Annual Continuation Reporting:

Annually, the PI is required to report to the IBC the study status; to confirm the research is still in compliance with biosafety standards, no new incidents, deviations, or noncompliance have occurred, no changes are required, and whether the study remains active, or study closure is planned. The IBC notifies the PI 60 days prior to the annual check-in deadline to ensure timely submission of the status report.

Continuation Post Expiration:

IBC registrations are approved for three years; the expiration date is included in the approval letters. PI's are notified 60 days prior of the upcoming expiration date. PIs who wish to continue their research projects beyond the three-year term should plan to submit a new registration for review before the expiration date. Any active protocol approved by Committee Review must be reviewed via Committee Review to obtain approval for its continuation. In certain cases, a protocol that previously received approval via Committee Review can go through an Expedited Review if it meets one of the following conditions:

- All research-related activities involving biohazardous materials have been completed.
- The research remains active only for long-term data analysis without additional risks identified.

New Information, Unanticipated Problems, Incident Reports, and Risk Safety Assessments:

PIs must promptly report any new information, incident, risk/safety assessment, or unanticipated problems that may affect the risk to personnel or the environment to the IBC. This includes any findings that may impact ongoing research, or the welfare of personnel involved. The PI must submit a report detailing the nature of the new information or unanticipated problem, the potential impact on the research, and any proposed changes to the protocol. Provide a detailed account of the event should be included, documenting the date, time, location, individuals involved, and an evaluation of the associated risks and potential impacts on personnel, the environment, and ongoing research. This should assess whether the incident was accidental, anticipated, unanticipated, related to the research, or unrelated to the research. Documentation of how information about the incident was communicated to relevant stakeholders, including staff, the institutional biosafety committee, and Environmental Health and Safety (EHS), should also be provided. If noncompliance is reported, justification for why it was necessary for safety reasons, including any protocol deviations required to prevent harm or ensure safety, should be included. Outline the measures taken or proposed to address the incident, prevent recurrence, and ensure safety, along with plans for ongoing monitoring and assessment of the effectiveness of these actions. This section should also include documentation of any follow-up investigations or evaluations conducted after the incident to ensure compliance and safety.

Note: All submissions should include relevant documentation, outline revisions and/or new information within submission documents, include new vector maps, MSDS, reference publications, reports, etc.

Post Approval Required Reporting and IBC Reviews:

Please report the following items to the IBC within 5 business days of discovery. If unsure, contact the IBC.

1. **New Funding and Financial Conflicts of Interest**
    - **Types of Reports**: New financial conflicts of interest or changes in funding affecting the study's integrity.
    - **IBC Review Process**: Expedited or Committee Review to evaluate potential impacts on research objectivity and safety.
2. **New or Increased Risk/Safety Issues and Protocol Deviations**
    - **Types of Reports**: New information indicating increased or new risks, protocol violations or deviations that harm personnel or increase their risk, and participant complaints indicating new risks. Any changes significantly increasing the risk to personnel and affecting the research conduct, including deviations from the approved protocol.
    - **IBC Review Process**: Full Committee Review to evaluate the severity and impact of the risk or deviation on safety and study conduct.
3. **Unexpected Harm Related to Research**
    - **Types of Reports**: Harm that is unexpected based on previously reviewed risk information. This includes serious adverse effects on health or safety, life-threatening problems, or death associated with a procedure not previously identified.
    - **IBC Review Process**: Full Committee Review to evaluate the severity and relevance of the harm.
4. **Compliance and Data Integrity Issues**
    - **Types of Reports**: Noncompliance with federal regulations or IBC requirements, inspection audit reports, issues affecting the integrity or validity of research data, including potential falsification or manipulation.
    - **IBC Review Process**: Full Committee Review to evaluate the nature, severity, and impact of the compliance and data integrity issues.
5. **External Reports**
    - **Types of Reports**: Early suspension or termination of the study by the sponsor, investigator, or institution, findings from additional regulatory bodies, significant participant complaints related to study procedures or safety.

- **IBC Review Process**: Full Committee Review to evaluate the circumstances, address additional regulatory findings, and assess the impact on participants.

Noncompliance with IBC Policies, Procedures, or Decisions:

The IBC cannot retrospectively approve research. Please do not begin non-exempt research without IBC approval. Approved IBC protocols that deviate from the policies, procedures, or stipulations of the IBC are subject to further inquiry by the IBC. The IBC may send a notice requesting the suspension of all research activities while the issue of noncompliance is reviewed, consistent with federal mandates. This initial notice will also include a rationale for the IBC's action. The IBC will investigate allegations of noncompliance.

Areas of Noncompliance IBC Inquiry Review:

- **Category of Review**: Determine if the study was approved via Exempt Review or Full Committee Review.
- **Type and Nature**: Identify whether the noncompliance is general, serious, or continuing.
- **History of Noncompliance**: Review the noncompliance history of the PI and any collaborators.
- **Deviation and Implications**: Assess specific deviations observed and evaluate how investigators deviated from the approved protocol or failed to adhere to IBC procedures. Consider the context of these deviations and their impact on research integrity.
- **Reporting**: Evaluate how and when the event was reported to the IBC, including the submission of final reports and corrective action plans.
- **Corrective Actions**: Assess actions taken to address and mitigate noncompliance, including necessary revisions to the protocol. Evaluate plans for training or re-training research staff on procedures and practices to prevent recurrence.
- **Preventive Actions**: Examine changes made to processes or systems designed to prevent similar issues in the future, including how feedback will be collected and addressed.

Noncompliance Process:

Allegation:

1. Concerns about possible Noncompliance can be raised by RO, BSO, IBC Chairs, IBC members, investigators, subjects, or others. Concerns not raised by a DIEC should be forwarded to a DIEC for initial determination.
2. The RO may determine if the concern constitutes General Noncompliance or warrants further inquiry. Concerns determined to be greater than General Noncompliance are considered allegations and are forwarded to the Chair for review.

Allegations prompt investigations led by the IBC Chair, RO, BSO, and/or an EHS representative to gather information through:

- Unannounced visits to the laboratory or facility.
- Review of laboratory procedures, IBC registrations documents, and all other relevant lab/facility documents (including records pertaining to material purchases and research records);
- Interviews with the Principal Investigator (PI), laboratory personnel, and any other individual who might provide information.
- Consultation with experts in the area of research to make definitive, unbiased, and educated decisions regarding a potential violation.
- Assistance from other IBC members in collection of information.

Investigation:

1. RO and BSO conduct the Investigation, contacting relevant individuals for verification of facts.
2. Once sufficient information is available regarding the allegation, a report is prepared for committee review.
3. The Chair or convened IBC may accept, reject, or modify DIEC's findings and recommendations report. Corrective actions may include changes to the research protocol, required training, research restrictions, subject notification, data destruction, publication disallowance, oversight monitoring, or protocol suspension/termination.
4. The Convened IBC, Chair, or RO can make a final determination, including severity and corrective actions, will be documented in the IBC meeting minutes.
5. A Final Report reflecting the IBC's final determinations is sent to the IO. If Noncompliance is found, the Report is sent to Need to Know Individuals; if not, it is provided only to the Respondent.

Outcome:

1. If the Respondent disagrees with the Final Report, they may notify the IO, RO, and IBC Chair, to request an appeal citing reasons for disagreement within 30 days. The IBC Chair or RO can make the final decision, in consultation with the IO, as necessary.
2. If the PI agrees with the Final Report or after the IBC's final decision, the DIEC or IBC Chair ensures the corrective and preventive action plan is implemented. If necessary, a notice of closure is sent to Need to Know Individuals. 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.

Not for Cause Audits:

1. If Noncompliance is identified during a RO audit, RO determines the type of Noncompliance.
2. If not General Noncompliance, RO follows the same steps for investigation, reporting, and corrective actions as detailed above.

Notification to Regulatory Agencies or Sponsors:

The RO reports Serious or Continuing Noncompliance to the appropriate regulatory agencies and sponsors as required. This includes OSP and other relevant parties at the RO's discretion.

Note: The IBC has the authority to address findings of serious or continuing noncompliance with the NIH Guidelines, the BMBL, University policies and procedures and other legal requirements via one or more of the following actions:

- Suspension or Termination of approval for use biohazardous material.
- Confiscation or Destruction of the biohazardous materials.
- Any other action necessary to protect the public and/or University, including restricting access to the laboratory in order to suspend activities.

Lapse in Approval:

If IBC approval of a project expires, no activities involving the use of biological materials may occur. The Principal Investigator (PI) must report the lapse to the IBC and include:

1. An explanation of how and why the lapse occurred.
2. A corrective action plan to avoid future lapses.
3. Confirmation that no research activities took place during the lapse.
4. The timeline for when the lapse will be resolved, either through a Continuing Review application or Study Closure.
5. Confirmation that there are no pending issues/modifications, participant complaints/concerns, etc.
6. A statement about whether there have been prior lapses for this project.
7. Verification the lapse has been communicated to the sponsor, local site/IRB, DSMB, etc., if/when applicable.

Transfer of Research when PI is Leaving the University:

If the PI of an IBC-approved study plans to leave the university, consider the following options:

1. **Transfer to Another Institution**: Submit a modification describing plans for transfer.
2. **Change of PI at Current Institution**: Identify a qualified individual to serve as PI at UMassD and submit a modification.
3. **Data or Material Transfer**: Execute an appropriate agreement before transferring any data or materials.

Study Closure:

Regardless of how a study was approved (committee review or exempt review), closure is required in any of the following situations:

- The study was not initiated and will not be.
- The study was discontinued before completion.
- The IBC-approved time period has ended.
- All research-related activities are complete.
- The PI will no longer be affiliated with UMassD and does not plan to transfer the protocol.

The IBC may close a study without the principal investigator's permission if:

- The principal investigator is no longer affiliated with UMassD, and no protocol transfer was arranged.
- The protocol has lapsed, and no extension or closure request was made.
- The IBC determines the protocol should be terminated due to issues like misrepresentation or ethical concerns.

Closing Process

Submit a closure report upon completion of the study before the study expiration date.

What to Do After Closing a Study

After closing a study, the research team must cease data collection and analysis of data. For additional data collection post-closure, submit a new registration to the IBC.

Section 4: Submission Information

Materials that Require Registration

The IBC oversight applies to all activities involving biohazardous materials at or supported by the UMassD regardless of funding.

The biohazardous materials which the IBC currently oversees include:

1. **Large-scale cultures and whole organisms:**
   - Large-scale cultures or volumes exceeding 10 liters of culture.
   - Whole animals or whole plants, including transgenic varieties.
   - Organisms, which if released, could have a significant impact on the environment (i.e., exotic plants, non-indigenous plant pathogens or regulated insects) or are export controlled.
2. **Biohazardous materials and biological samples:**
   - Biohazardous materials, nanomaterials, biological agents (infectious, parasitic, pathogenic, or of unknown pathogenicity), or genetically engineered/modified microorganisms (bacteria, viruses, fungi, protozoa, yeast, algae, etc.); including: storage or concentration of any materials which pose zoonotic disease concerns.
   - Biological specimens (blood or blood components, cellular lines/materials, tissues, feces, saliva, urine, or byproduct) known or suspected to be contaminated with an infectious or biohazardous agent.
   - Biological toxins, synthesized toxins, bioactive derivatives, or subunits of toxins and Federal Select Agents and Toxins.
3. **Genetic manipulation and host-vector systems:**
   - Nucleic acid molecules (DNA, synthetic DNA [sDNA], recombinant DNA [rDNA], RNA, or synthetic RNA [sRNA]) and prions or prion-like proteins.
   - Manipulation of genetic material via cloning, editing, synthesis, transformation, recombination, or mutagenesis.
   - Host-vector systems, including non-pathogenic prokaryotes or lower eukaryotic hosts, employing Risk Group 2, 3, 4, or other restricted agents.
   - Xenotransplantation or transfer of genetic material into humans, whole animals, or plants, or microorganisms.
4. **Other:**
   - Soil seed, spores, plant pathogens (bacteria, viruses, fungi, or parasite), or any other material received under an agreement or permit.
   - Necropsy of animals not under the care of the University Veterinarian, necropsy of animals with unknown health status and/or animals reasonably suspected or known to be infectious.
   - Except for general surveillance, arthropods that serve as vectors of disease to humans, animals, or plants and arthropods considered an environmental hazard.
   - Studies which pose a Dual Use Research of Concern.
   - Export controlled biological agents and biopharmaceuticals.
   - Other work as deemed necessary for review by the Biological Safety Officer, IBC, or sponsor.

From this point forward, the term "biohazardous materials" refers to the agents and substances listed above.
For more information, email ibc.research@umassd.edu.

Completing the IBC Registration Form: A Step-by-Step Guide

Part A – Basic Information

Principal Investigator (PI) Information: Full Name, Department, and Contact Information (Phone and Email).
Project Title: Concise and descriptive title of the research or multiple projects covered.
Sponsorship Information: Funding Sources and Grant or Contract Numbers
PI Assurance Statement: Signature and date confirming adherence to biosafety standards.

Part B – Classification and Confirmations

Establish Level of Oversight per NIH and UMass Dartmouth local oversight.
Assess and confirm whether the research qualifies for exemption review.
Assess and confirm whether the research presents dual-use concerns.

Part C – Material Information

Biohazardous Material(s): Identify the biohazardous material(s) being used, specify the corresponding biosafety level (BSL) and risk group (RG), and provide product safety sheets (SDS) to confirm the assigned BSL and risk group for the materials being used.
Source of Material: Identify the source of the materials and any associated agreements (e.g., Material Transfer Agreements).
Material Characteristics: Describe any unique characteristics of the materials (e.g., cell lines, vectors, phages, genes) and indicate whether these characteristics impact the assigned biosafety level.
Publication Support: Provide relevant publications for reference that support the proposed research and use of the biohazardous materials.

Part D – Protocol Information

Host and Vector Information ***[Attach corresponding detailed vector maps that illustrate the constructs being utilized]***

- Identify the bacteria (e.g., E. coli K12) and/or mammalian cell lines (e.g., HeLa cells) that will serve as hosts for the recombinant DNA.
- Specify the cells used for amplification of recombinant DNA and their source.

Background, Study Design, & Intended Use of Material(s)

- Clearly articulate the overarching goal of the research and outline the central research question being addressed.
- Explain the significance of the study and the reasons for using the proposed biohazardous materials.
- Describe the methodology in lay terms, include a flowchart or schematic diagram illustrating the experimental design if necessary.
- Specify any control groups included to validate results.
- Assess any potential environmental impacts associated with the use of biohazardous materials.
- Outline how the research will be monitored for safety and provide a detailed emergency response plan for accidents or exposures.
- Mention any collaborations or external support related to the study.
- Discuss any long-term plans for monitoring or follow-up studies.

Material and Methods

- If using recombinant DNA molecules or manipulations, provide vector maps as necessary. Include details about the recombinant DNA constructs, such as: the origin of the vector, key features (promoters, resistance genes, etc.), and any modifications made to the vector.
- Outline procedures and techniques to be performed (e.g., cloning, DNA or RNA synthesis, expression, cell culture, etc.).
- Include any recombinant DNA gene manipulations/gene editing, identifying the gene product (protein) you wish to express.
- If using viruses, identify the viral vector(s), marker genes, and foreign insert genes. Clarify replication features and whether they are replication-deficient or replication-competent.

Risks

- Assess potential risks associated with the use of and exposure to biohazardous materials.
- Address the potential for accidental exposure and specify how such exposure might occur.
- Explain potential repercussions of human exposure and available treatment options.
- For studies using a BSL2 agent, provide a separate Biological Hazards Material Standard Operating Protocols (BHMSOP).

Management of Biohazards

- Describe the equipment and locations where biohazardous materials will be handled.
- Outline the training the PI will implement to protect staff from hazards.
- Detail the response plan for handling accidental exposures.
- Describe biosecurity measures in place to minimize access to the lab facility.
- Describe methods for storage, transport, decontamination, and disposal of biohazardous materials.

Indicate the Highest Risk Group Level
Indicate the Highest Biosafety Containment Level
Personal Protective Equipment (PPE) List all PPE required for personnel.
Engineering Controls and Laboratory Equipment List location(s) of all device and locations used.

Part E - Appendices

Appendix for Animal Use *[Attach required IACUC Approval]*

Identification of Animal Models:

- Provide details about the animal models being used, including species and source.
- Specify the type of materials involved in the study and the biosafety level required for the animal models used.
- Clarify whether the agent occurs naturally in the species being used.
- State the number of experimental animals to be used and number of experiments to be conducted in the study.
- Clarify whether any cells will be purposely infected with human or animal pathogens?
- Describe procedures to minimize risks during the infection process, including:
    - Use of appropriate personal protective equipment (PPE) such as gloves, gowns, masks, and face shields.
    - Implementation of biosafety cabinets or containment facilities during inoculation.
    - Training for staff on handling biohazardous materials and emergency response protocols.
- Describe how materials will be handled to minimize the risks of accidental exposure to pathogens. Include:
    - Testing for pathogen-free status; if not tested, specify the need for bloodborne pathogen screening.
    - Procedures for managing any accidental exposures or spills.
- Outline how staff and occupants will be informed about infection procedures and associated risks:
    - Regular safety briefings and training sessions.
    - Posting clear signage indicating areas of biohazard risk and access restrictions.
    - Providing written protocols and contact information for the biosafety officer or designated safety personnel.
- Provide estimates of when after inoculation the animal may begin shedding the agent, typically ranging from a few days to weeks.
    - Discuss potential hazards to human health associated with shedding: routes of transmission (e.g., aerosol, direct contact).
    - Symptoms to monitor in staff who may encounter infected animals
    - Containment measures to be enacted during the shedding period.

Appendix for Human Subject Use *[Attach required IRB Approval]*

- Identify the source of human materials used in the study (e.g., whole human, cell lines, body fluids).
- Specify the type of human materials involved in the study.
- Clarify if any known pathogens exist in the materials and how they will be disposed of.
- Clarify if human cells will be purposely infected with human pathogens.
- Describe precautions to minimize risks associated with infection.

Appendix for Select Agent Use

- Identify each agent being used, including the source and biosafety level (BSL).
- Provide relevant permit numbers and dates obtained for the select agents.
- Clarify storage conditions and security measures in place for the select agents.
- Outline plans for notification in case of accidental exposure.

Appendix for Toxin Use

- Identify the toxin being used, including the source and biosafety level (BSL).
- Specify the LD50 for the toxin.
- Identify symptoms associated with exposure to the toxin.
- Clarify how personnel will be monitored post-handling of the toxin.
- Outline the procedures to be used for inactivating the toxin, including:
    - Specific methods (e.g., chemical agents, heat treatment, enzymatic degradation).
    - Duration and conditions (temperature, pH, etc.) necessary for effective inactivation.
- Describe in detail the methods used to verify the efficacy of inactivation, including:
    - Analytical techniques (e.g., bioassays, toxicity assays) to confirm the absence of active toxin.
    - Environmental monitoring procedures to assess any residual toxicity in the work area.
    - Record-keeping practices to document inactivation results and any corrective actions taken if inactivation fails.

Documentation the Investigator Provides to the IBC

For new submissions, include:

- **Reference Publications:** Scholarly articles or studies that support the proposed research and use of biohazardous materials.
- **Product Safety Sheets:** Safety data sheets (SDS) that provide information on the properties, hazards, and safe handling practices for the biohazardous materials used.
- **Training Records:** Documentation of completed training sessions for all personnel involved in handling biohazardous materials, including dates and topics covered.

Include the following as applicable:

- **Grant Awards:** Documentation of funding sources that support the research project, including grant numbers and details about the funding organization.
- **Material Transfer Agreements:** Legal documents outlining the terms and conditions for transferring biohazardous materials between institutions or parties.
- **End User Agreements:** Contracts that specify the responsibilities of the end user regarding the handling and use of biohazardous materials.
- **Vector Maps:** Diagrams detailing the genetic constructs used in the research, including information about the origin of the vector and key features.
- **IACUC Approval Documents**: Approval letters or protocols from the Institutional Animal Care and Use Committee, confirming compliance with animal research regulations.
- **IRB Approval Documents:** Approval letters or protocols from the Institutional Review Board, confirming compliance with regulations for research involving human subjects.
- **Biosafety Permits:** Regulatory approvals necessary for the use of certain biohazardous materials, including permits for select agents or toxins.

For all revisions, include as appropriate:

- **Revised Protocols**: Updated research protocols or standard operating procedures reflecting any changes made in response to the incident should be provided. Relevant documentation relating to the revision of study design or changes in materials used (reference publications, vector maps, MSDS, etc.) must be included.
- **Training Records**: Evidence of additional training provided to personnel following the incident, ensuring understanding of new procedures or safety measures, should be documented.

Criteria for Approval

To meet the criteria for approval, the Institutional Biosafety Committee (IBC) must ensure the following conditions are satisfied:

1. **Appropriate Expertise**: The IBC members and any external consultants involved in the review must have the necessary expertise to understand and evaluate the scientific, biosafety, and ethical aspects of the research. This includes, but is not limited to, knowledge in characteristics of biological agents (e.g., virulence, pathogenicity, environmental stability), genetic manipulations involved in the study, source, nature, and function of inserted genetic material, host/vector systems, biosafety containment measures appropriate for the risk group, occupational health and environmental safety concerns, NIH Guidelines, relevant biosafety protocols, and containment methodologies for animals and plants. If the IBC lacks the necessary expertise for a specific protocol, it may seek input from external experts, ensuring there is no conflict of interest.
2. **Appropriate Biosafety Containment and Risk Assessment**: The containment level for the research must be appropriate for the risk group of the study agents. A thorough risk assessment must be conducted to ensure that risks to personnel, co-occupants, and the public environment are reasonable, including consideration of the nature of the study agent, the risk group, and any genetic modifications introduced. Risk to personnel, students or visitors, and environment is reasonable in relation to the threats and hazards associated with use of the materials.
3. **Effective Safety Procedures**: Safety procedures are developed and monitored for hazards and risks associated with the project or activity. Safety procedures must be developed in collaboration with Environmental Health and Safety (EHS) staff and the BSO to address associated hazards and risks. The BSO is available to assist Principal Investigators (PIs) in the development of individual BioHazardous Material Standard Operating Procedures (BHMSOPs) tailored to each study and lab. Risks to personnel, students, or visitors must be reasonable compared to the threats posed by the materials. Additionally, risks to community health and the environment must be adequately mitigated, and necessary medical measures, such as occupational health consultations, must be in place to minimize risks. EHS staff may conduct routine monitoring of facilities to ensure compliance. Where appropriate, preventative medical measures are taken to minimize risks associated with breeches in safety procedures (including any required occupational health consultations).
4. **Adequate Emergency Response Plans and Facilities**: Adequate emergency plans must be in place to handle accidental spills, exposures, or other unforeseen incidents, including protocols for responding to researcher or personnel contamination. The research facilities and operational procedures are sufficient to protect against the risks posed by the research, including proper use of containment equipment, safety protocols, and regular safety training programs.
5. **Compliance with Guidelines**: The proposed research must comply with the NIH Guidelines, the Biosafety in Microbiological and Biomedical Laboratories (BMBL) manual, and any other applicable institutional or federal biosafety regulations.

6. **Completion and Consistency of Registration Materials**: All registration documents must be complete, consistent, and compliant with the NIH Guidelines, the BMBL, and the IBC's Charter. Incomplete or inconsistent applications may result in the delay or denial of approval. All necessary documents have been provided with review (reference publications, Material Data Safety Sheets, vector maps, training certificates, and external agreements and permits, etc).
7. **Proper Assessment and Monitoring of Risks and Noncompliance**: Any previous instances of unanticipated risks, noncompliance, or new information must be considered during the review process. Ongoing monitoring of the research process must be conducted to identify any emerging risks or issues, with clear requirements for reporting to the IBC. If required, modifications to protocols, corrective action plans, or enhanced monitoring may be mandated.

These criteria ensure that the research is conducted safely, ethically, and in compliance with all relevant regulations, while also addressing potential gaps in expertise and preparedness.

Training Requirements

CITI Online Training Requirement

All personnel involved in the use of biohazardous materials in research activities or in the academic laboratory training of students are required to complete the online Collaborative Institutional Training Initiative (CITI) at www.citiprogram.org. This training is crucial for ensuring that all researchers are equipped with the knowledge to safely handle biological materials, understand regulatory requirements, and mitigate risks associated with biohazards.

Training Certification Submission: Participants must submit copies of their training certification(s) for all personnel listed on the registration forms. CITI training is offered free of charge, allowing users to select and customize modules according to their specific research needs and responsibilities. Certificates of Completion should be submitted via email to ibc.research@umassd.edu.

General concepts covered in CITI biosafety training include:

- **Introduction to Biosafety Concepts:** Overview of biosafety principles, practices, and the importance of a biosafety culture in research settings.
- **Regulations and Guidelines Overview:** An introduction to the regulatory framework governing biosafety, including federal, state, and institutional policies.
- **OSHA Bloodborne Pathogens Standard:** Training on the identification and management of bloodborne pathogens, including exposure prevention and post-exposure procedures.
- **Laboratory-Acquired Infections:** Insight into the risks of laboratory-acquired infections and the practices necessary to prevent them.
- **Risk Management:** Strategies for identifying, assessing, and mitigating risks associated with biological materials.
- **Select Agents:** Overview of select agents and toxins that pose a significant threat to public health and safety.
- **Packaging and Shipping:** Guidelines for the safe packaging and transport of biohazardous materials, in compliance with federal regulations.
- **Animal Biosafety:** Best practices for handling animals in research and the associated biosafety considerations.

The following courses are offered via CITI and are required as applicable:

- **Biosafety Complete Training:** Mandatory for all researchers utilizing biohazardous materials. This training provides comprehensive coverage of safety practices, including risk assessment, personal protective equipment (PPE) usage, and emergency procedures specific to handling biohazards.
- **OSHA Bloodborne Pathogens Training:** Required for researchers handling human samples. This training ensures participants are knowledgeable about Occupational Safety and Health Administration (OSHA) regulations and the procedures for minimizing exposure risks to bloodborne pathogens.
- **Shipping and Transport of Regulated Biological Materials Training:** Mandatory for all researchers who need to ship biological samples. This training covers critical regulatory requirements, best practices for packaging, and safety protocols to ensure compliance with federal and state shipping regulations.
- **Good Laboratory Practice (GLP):** Recommended for all laboratory personnel. This training emphasizes principles that promote quality and consistency in laboratory research, helping ensure reliability and accuracy in experimental results.
- **Laboratory Chemical Safety Training:** Required for all laboratory personnel using chemicals. This training provides essential information on the safe handling, storage, and disposal of hazardous chemicals, as well as understanding safety data sheets (SDS).
- **Radiation Safety Training:** Mandatory for all personnel using radioactive materials or devices. This training focuses on safe practices for handling radioactive substances, understanding radiation exposure limits, and emergency response procedures.
- **Laser Safety Training:** Required for all personnel using lasers. This training covers the safe operation of lasers, the potential hazards associated with laser use, and the necessary protective measures to ensure safety in the laboratory environment.

EHS Laboratory Safety Training

All faculty, staff, graduate students, teaching assistants, and researchers who use chemicals or biological materials (including those with potential bloodborne pathogens), generate hazardous or biohazardous waste, or conduct work beyond classroom activities in laboratories are required to attend EHS Laboratory Safety Training on an annual basis.
Training Content: This comprehensive training provides essential information about:

- **EHS Staff and Responsibilities:** Understanding the roles of Environmental Health and Safety (EHS) staff in maintaining a safe laboratory environment.
- **Right-to-Know Law:** Educating participants on their rights regarding hazardous materials in the workplace.
- **Emergency Spill Response Notification**: Procedures for reporting and managing spills of hazardous substances.
- **Bloodborne Pathogens and Biohazards:** Information on identifying and managing risks associated with bloodborne pathogens and other biohazardous materials.
- **Personal Protective Equipment (PPE):** Proper use and selection of PPE to minimize exposure risks.
- **Hazardous Waste Management:** Guidelines for the safe disposal of hazardous and biohazardous waste in compliance with regulatory requirements.
- **Fire Response Procedures:** Essential practices for responding to fire emergencies in the laboratory setting.
- **Laboratory Practices and Policies:** Overview of best practices and institutional policies that govern laboratory work.

Responsibility of Oversight: It is the responsibility of the PI or laboratory manager overseeing the laboratory to ensure all workers have completed the EHS Laboratory Safety Training and are certified. Training certificates are kept on file at the EHS Office.

Training for Students

Students enrolled in courses that include laboratory activities requiring registration with the IBC must complete the necessary training certification via CITI. The faculty member responsible for the course is tasked with monitoring and tracking the training certifications of students enrolled at UMassD.

Immunization Requirements: Faculty should also be aware that all students admitted to UMassD are required to have certain immunizations as mandated by state law, including but not limited to Hepatitis B, which is particularly relevant for students engaged in research involving blood or other potentially infectious materials.

Free Training Resources for Students
Students participating in IBC-regulated research, especially those working with recombinant DNA, biohazards, or infectious agents, are encouraged to complete biosafety training early in their research careers. The following free training resources are available to support their learning:

1. **NIH Office of Science Policy (OSP):** The NIH provides a wealth of online resources and guidelines for safe research practices involving recombinant or synthetic nucleic acids. Their website features training modules and video tutorials on essential biosafety practices that help students understand the regulatory landscape.
    - Link: **NIH Office of Science Policy Training**
2. **Centers for Disease Control and Prevention (CDC) Biosafety Resources:** The CDC offers a range of free training materials focused on laboratory biosafety, including comprehensive guides for the safe handling of pathogens and materials. These resources are particularly beneficial for students involved in BSL-1 and BSL-2 level research, ensuring they are aware of safety protocols.
    - Link: **CDC Safe Labs Biosafety Resources and Tools**
3. **American Biological Safety Association (ABSA International):** ABSA provides numerous free resources, including webinars and online training materials focused on biosafety. Their offerings include videos on risk assessment, lab safety, and best practices for working with biological materials.
    - Link: **ABSA Training Tools & Resources**

Research-Specific Training

Faculty members are responsible for developing protocols and providing specialized training for staff and students in safe handling practices and procedures for accidental exposure relevant to their specific research activities. This includes:

- Conducting hands-on training sessions.
- Offering guidance on emergency procedures tailored to the specific hazards present in their research.
- Ensuring that all personnel are familiar with the specific risks associated with their research and the best practices for minimizing those risks.

Timeline.

Section 5: Elements for Consideration:

Elements of Consideration

The IBC considers the following key elements to ensure safety, compliance, and ethical integrity. This guidance aims to help Principal Investigators (PIs) develop their protocols responsibly, emphasizing best practices and ethical considerations throughout the research lifecycle.

Experimental Design

The experimental design of the research should be scientifically sound and justifiable. PIs must clearly define the research objectives and articulate why the use of biohazardous materials is essential for achieving these goals. Defining specific research questions and hypotheses serves to justify the proposed use of these materials to the IBC. Conduct preliminary studies to test hypotheses or methodologies before committing to larger-scale research to enhance the validity of the findings and help identify potential issues early in the process. Evaluate the feasibility of replicating studies to ensure robustness and reliability in the experimental design and consider the availability of resources, personnel, funding, equipment, expertise, and time necessary for successful replication. Perform a thorough risk-benefit analysis to ensure that the potential benefits of the research outweigh the associated risks. The analysis should encompass risks to researchers and subjects, as well as broader implications for public health and safety, and must be documented for the IBC's review. PIs should address the ethical justification for using specific biohazardous materials, highlighting how the research contributes to scientific knowledge or public health. Request feedback from colleagues, mentors, or biosafety professionals to strengthen the experimental design. Constructive input can help identify potential weaknesses or overlooked considerations in the research proposal and/or help identify potential weaknesses or overlooked considerations within the research proposal. Provide any relevant feedback as references for the IBC to review, this transparency aids in the review process.

Risk Assessment

Laboratory directors, laboratory supervisors, and PIs share the responsibility of providing a comprehensive initial risk assessment to determine the risk levels associated with proposed research activities. PIs must identify potential hazards linked to the biological agents they intend to use, taking into account factors such as pathogenicity, virulence, transmission routes, and the agents' effects on human health and the environment. Examine existing literature or historical data on similar research to gain insights into potential risks, including analyzing past incidents or outcomes related to the biological agents under study, as this information can inform risk mitigation strategies. Collaborate with stakeholders, such as facility managers, safety personnel, BSO, and EHS, to gather insights on risk mitigation strategies and unique risks related to the specific laboratory environment and procedures. A dynamic risk assessment system should be implemented to adapt throughout the research lifecycle, allowing for adjustments based on evolving conditions, new information, or emerging risks, ensuring that safety measures remain effective and relevant. PIs are encouraged to document their risk assessment processes and decisions and provide any relevant publications or data as references to facilitate and inform the IBC review.

Biosecurity

Ensuring biosecurity is a shared responsibility, which is accomplished only by having protocols to regularly review and update security measures based on evolving risks and emerging threats. PIs should assess the risk associated with each biological material (e.g., low, medium, or high) and conduct a vulnerability assessment to identify security gaps in the use, storage, and handling of the material. The security measures should be proportional to the assessed risk level and involve a vigilant staff which restricts access to biological materials to authorized personnel to prevent potential misuse. Key biosecurity considerations include:

- **Physical Security**: Additional locks, such as padlocks or electronic access cards, should be installed on laboratories, freezers, and other storage locations where biological agents are housed. Controlled access areas should be clearly designated, with enhanced security for high-risk materials.
- **Chain-of-Custody**: Use of chain-of-custody forms within the laboratory to track the movement, transfer, and usage of biological materials to reduce the possibility of mishandling.

- **Inventory Management**: A complete and up-to-date inventory of biological materials should be maintained. Inventories should track not only the presence of the material but also any usage or transfer, ensuring clear oversight.
- **Access Logs**: Maintain logs of all individuals who have accessed laboratories or storage areas containing biological materials to track access and identify any unauthorized entry.
- **Threat and Vulnerability Assessment**: Conduct a formal assessment of potential threats or vulnerabilities related to the use and storage of biological materials to inform security enhancements, personnel access, and emergency response planning.

Containment and Safety Measures

PIs are responsible for ensuring their protocols reflect an understanding of the appropriate biosafety level (BSL) required for their research. Clearly detail the use of personal protective equipment (PPE), safety cabinets, and sterilization procedures in the protocol. Work with the BSO to develop biohazardous management standard operating procedures (BHMSOPs) for the handling, storage, and disposal of biohazardous materials tailored to the lab environment and outline both routine procedures and protocols for emergency situations. Schedule regular inspections of containment facilities to ensure compliance with biosafety standards and to promptly address any deficiencies. Document inspection findings and follow up on corrective actions to maintain a safe research environment. Ensure all emergency equipment (e.g., eyewash stations, safety showers) is easily accessible and regularly tested. Maintain records of inspections and any maintenance performed on emergency equipment.

Personal Protective Equipment

The PI is responsible for implementing a comprehensive Personal Protective Equipment (PPE) program tailored to the specific hazards associated with the research being conducted and aligns with UMassD biosafety policies and relevant regulations. The PI should establish protocols for the proper maintenance, regular inspections of PPE to identify wear and tear, procedures for cleaning and decontaminating reusable PPE, and safe disposal methods for single-use or contaminated PPE. The PI must ensure all laboratory personnel receive thorough training on the proper selection, use, and maintenance of PPE for different tasks and understand its importance in minimizing exposure risks. Regular audits and inspections should be conducted to ensure compliance with PPE requirement to be readily available and accessible in the laboratory. The PI should conduct a risk assessment to determine the appropriate PPE based on the type of biological, chemical, or radiological agents being used, the nature of the procedures involved (e.g., handling, mixing, transporting materials), and the potential routes of exposure (inhalation, dermal contact, ingestion). The PI should regularly replenish PPE supplies to ensure that all personnel always have access to appropriate protective gear. Noncompliance must be addressed promptly through retraining or disciplinary measures as necessary.

Refer to the UMassD Biosafety Manual, for detailed guidelines and best practices for PPE in laboratory settings.

Decontamination and Disposal Practices

Effective decontamination and disposal practices are essential for maintaining a safe laboratory environment, particularly when working with biohazardous materials. Develop proper decontamination protocols to mitigate risks associated with these materials, ensuring compliance with institutional and federal regulations. Begin with a thorough assessment of all hazardous materials involved in the research project, considering the nature and classification of these materials, including their biological, chemical, and radiological properties. Understand the characteristics of the agents being used to evaluate the specific risks associated with each material and inform the selection of appropriate and effective decontamination methods and agents. Choose agents based on the types of contaminants present, ensuring they are capable of inactivating or removing the specific pathogens or hazardous materials involved. Common options include chemical disinfectants, such as bleach solutions, ethanol, and hydrogen peroxide, as well as sterilization methods like autoclaving. It is essential to verify the selected agents are compatible with the surfaces, equipment, and materials found within the laboratory setting to avoid damage or adverse reactions. Develop clear and comprehensive procedures for decontaminating laboratory surfaces, equipment, and PPE after use. Ensure procedures include step-by-step instructions for cleaning and disinfecting work surfaces, instruments, and personal items, such as lab coats. Additionally, procedures should outline specific guidelines for handling and disposing of contaminated materials safely, including biohazard waste disposal protocols. Train all laboratory personnel on proper decontamination practices is critical to ensuring consistency and safety across the research team. The PI should emphasize the importance of adhering to these practices to prevent contamination and exposure, conducting practical demonstrations to enhance understanding and compliance. To ensure decontamination activities are effective, a systematic monitoring program should be implemented to include regular checks to verify adherence to decontamination procedures and identify any areas for improvement. Personnel should be encouraged to document their decontamination activities, noting any incidents, challenges, or deviations from established protocols, which can be critical for continuous improvement. In the event of spills or exposure incidents, clear and well-documented response protocols must be established to outline immediate decontamination steps, such as isolating the affected area and using appropriate agents, as well as procedures for notifying the necessary authorities, including the EHS Office. All personnel should be trained to recognize situations requiring immediate action and be familiar with the procedures to follow in such events.

Emergency Procedures

PIs must create comprehensive emergency response plans that address specific scenarios, including spills, exposure incidents, and equipment failures. Each plan must detail the precise actions to be taken in response to these situations, providing a clear roadmap for all personnel. Establish protocols for notifying relevant authorities and stakeholders, ensuring that every team member knows these procedures and their specific roles during an emergency. Regular training drills help reinforce these protocols and ensure that team members can act swiftly and confidently in a crisis. Implement an incident reporting system that promotes reporting to facilitate incident documentation, incident analysis, and improve future emergency responses.

Long-Term Management of Biohazardous Materials

Implement an inventory management system to document and track the receipt, storage, handling, use, and disposal biohazardous materials throughout their lifecycle. Schedule periodic reviews to assess storage conditions and establish whether materials are stored securely and whether the storage

environment meets biosafety requirements to ensure compliance with regulations regarding long-term storage. Documentation should be readily accessible for inspections and audits to demonstrate adherence to biosafety protocols.

Biohazardous Management Standard Operating Procedure (BHMSOP)

While only required for studies employing BSL-2 materials, all PIs are encouraged develop a comprehensive lab-specific biohazardous management plan. This plan should address all aspects of handling, storage, and disposal of biohazardous agents in compliance with regulatory requirements and institutional policies. Below are key components that should be included in the management plan:

1. **Identification of Biohazardous Materials:** Clearly identify all materials to be used in the laboratory. This includes cataloging the specific agents, their characteristics, and potential risks. It is crucial to maintain an updated inventory that outlines the biological agents' names, strains, and quantities being handled.
2. **Laboratory Design and Access Control:** Ensure the laboratory is designed and equipped to meet required BSL standards. This includes having a restricted access area to prevent unauthorized entry, ensuring all laboratory doors are self-closing, and installing handwashing facilities. Signage indicating the biohazard status of the lab should be prominently displayed.
3. **Personal Protective Equipment (PPE):** Establish specific PPE requirements for all personnel working with materials. This typically includes gloves, lab coats, face shields or goggles, and respiratory protection when necessary. PIs should ensure that all personnel are trained in the correct use of PPE and that appropriate PPE is available and maintained.
4. **Work Practices:** Develop step by step work practices for handling the materials. These SOPs should include instructions for safe handling, decontamination procedures, and emergency protocols for spills and exposures. Regularly review and update SOPs to incorporate the latest safety guidelines and best practices.
5. **Decontamination Procedures:** Outline effective decontamination procedures for surfaces, equipment, and waste generated during the research process. This should include the use of appropriate disinfectants for the specific agents being handled, as well as the proper methods for cleaning and disinfecting work areas. Establish a routine schedule for decontamination to ensure ongoing safety.
6. **Waste Management:** Develop a comprehensive waste management plan for disposing of biohazardous waste generated during research. This plan should outline procedures for segregating, collecting, and disposing of waste in accordance with local, state, and federal regulations. Ensure that biohazardous waste is labeled appropriately and stored in designated containers until it is treated or disposed of.
7. **Emergency Response Plan:** Create a detailed emergency response plan specific to the laboratory. This plan should outline procedures for responding to spills, exposures, and accidents involving the materials. It should also include contact information for emergency response teams and the BSO. Regular training drills should be conducted to ensure that all personnel are familiar with the emergency procedures.
8. **Training and Recordkeeping:** Document training sessions for all personnel working with the materials. Training should cover safe work practices, emergency procedures, and the proper use of PPE. Maintain records of training completion, as well as any incidents or accidents that occur in the lab, to identify areas for improvement and enhance safety culture.
9. **Incident Reporting and Review:** Establish procedures for reporting and reviewing incidents involving materials. Encourage a culture of transparency where all personnel feel comfortable reporting near misses, spills, or exposure incidents without fear of reprisal. Conduct regular reviews of reported incidents to identify trends and implement corrective actions.
10. **Regular Review and Updates**: The biohazardous management plan should be reviewed and updated regularly to reflect changes in research protocols, personnel, and regulations. PIs should seek feedback from the IBC and incorporate new safety measures and best practices as they become available.

Please contact the IBC for template BHMSOP.

External Collaborators

Involvement of external collaborators requires careful consideration and planning. Identify and address any potential conflicts of interest that may arise from the collaboration. Establish clear guidelines for transparency in decision-making processes. Ensure external collaborators receive proper orientation regarding institutional policies, safety protocols, and specific procedures related to biohazardous materials. Engage external collaborators in the risk assessment process to identify and evaluate potential hazards associated with the research. Establish mechanisms for evaluating the contributions of external collaborators, including assessing their performance and the impact of their work on the overall project objectives. Maintain open lines of communication among all collaborators to facilitate information sharing, progress updates, and collaborative problem-solving. PIs should develop clear agreements to outline role, responsibilities, and expectations among collaborators to prevent overlaps or gaps in accountability and address any potential conflicts of interest and transparency in decision-making processes. Appliable agreements include:

- **Memorandums of Understanding (MOUs)**: Develop clear MOUs to outline the goals, responsibilities, and expectations of all parties involved in the research project. This document serves as a foundation for collaboration and clarifies each collaborator's roles.
- **Material Transfer Agreements (MTAs)**: MTAs govern the transfer of biohazardous materials between institutions, ensuring compliance with regulations regarding the handling and use of these materials.
- **Statements of Work (SOWs)**: SOWs detail the specific tasks, deliverables, timelines, and responsibilities of each collaborator. This helps establish accountability and aligns expectations.
- **Nondisclosure Agreements (NDAs)**: Implement NDAs to protect sensitive information and intellectual property shared between collaborators. This agreement ensures confidentiality regarding proprietary information.
- **Collaborative Research Agreement (CRA)**: Implement a CRA to formalize terms of collaboration, including funding, intellectual property rights, and data management.
- **Data Use Agreement (DUA) or Data Transfer Agreement (DTA)**: Implement a DUA/DTA to outline terms for using shared data, particularly for sensitive information.

Dual Use Research

PIs should carefully assess whether the research has the potential for dual-use concerns, meaning the knowledge, tools, or techniques developed could be misused for harmful purposes, such as bioweapons or other malicious applications. In the protocol background ensure to address the following:

- **Intent and Application:** Clearly define the intended purpose of the research and identify any potential misuse scenarios. Evaluate how the results could be applied outside of the original research context and whether those applications could pose risks to public safety or national security.
- **Oversight and Review:** Implement appropriate oversight mechanisms, such as internal and external ethical reviews, to ensure that dual-use concerns are systematically identified and addressed. PIs may benefit from consulting with ethics or legal advisors specializing in dual-use research.
- **Public Communication:** Consider how to communicate the findings of the research to the public and other stakeholders. PIs should be prepared to discuss the benefits of the research while addressing potential concerns about misuse.
- **Education and Training:** Incorporate training for all research team members on the ethical implications of dual-use research. This includes developing a clear understanding of the ethical responsibilities associated with the research and the importance of considering potential misuse during all stages of the research process.

Biological Toxins and Select Agents

Biological toxins include naturally occurring or synthetic substances that can cause harm to living organisms. PIs must identify the biological toxins to be used in research and understand the specific hazards associated with each toxin, including toxicity levels, routes of exposure, and potential health effects. Before initiating any work with biological toxins, PIs must obtain the necessary approvals and permits. When conducting experiments with biological toxins, PIs should implement appropriate containment measures which designated biosafety cabinets, secure storage areas, and restricted access to laboratories where toxins are handled. Ensure all workspaces are properly labeled and equipped with necessary safety equipment, such as eyewash stations and emergency showers. Develop a waste management plan that outlines the appropriate methods for disposing of toxin contaminated materials.

For Select Agents registration, the EHS staff and BSO collaborates with the PI to ensure compliance with UMassD policies and federal regulations, including CDC, Homeland Security, the Patriot Act, and others. The registration process involves:

- Determining whether the Select Agents require registration with the CDC or are exempt.
- Justifying the scientific need for using the biological agent, toxin, or delivery system.
- Conducting detailed risk assessments for the agent, procedures, and environment.
- Registering Select Agent(s) with the appropriate federal, state, or municipal agencies.
- Identifying and securing the storage and usage locations for Select Agents.
- Developing security protocols for control of the Select Agents when not in use.
- Ensuring only authorized personnel have access to the Select Agents.
- Defining methods for disinfection, decontamination, and disposal.
- Establishing comprehensive emergency response procedures.
- Providing training recommendations and oversight for PI and research personnel.

Considerations for Toxin and Select Agents Protocol

- Conduct an initial risk assessment to determine the appropriate biosafety level (BSL) for handling the toxin or Select Agent, including toxicity, routes of exposure, risks of transmission, environmental contamination, and unauthorized access.
- Collaborate with the BSO to develop a Biohazardous Management Standard Operating Procedure (BHMSOP), specifically addressing:
  - Physical and personnel security plans.
  - Control measures to prevent unauthorized access to Select Agents.
  - Guidelines on handling, transport, and storage of Select Agents.
  - Emergency response protocols and incident reporting mechanisms.
- Ensure all necessary documents are prepared and submitted with the permit application, including:
  - Justification for the Select Agent use.
  - Security measures as outlined in the BHMSOP.
  - Risk assessments, training plans, and biosafety protocols.
- The PI should apply for necessary permits (e.g., CDC, USDA, or DHS) **6-12 months** before initiating the research to accommodate long processing times and required agency approvals. This includes:
  - CDC Select Agent Program registration.
  - USDA APHIS permits, if applicable.
  - Any required state or local permits.

Note: All required approvals must be in place before starting any work with a toxin or Select Agent.

Transgenic Animals

The creation, generation, breeding, and propagation of transgenic animals are covered under Section III-D-4 of the NIH Guidelines. These activities are not exempt from the NIH Guidelines and must be reviewed by the IBC. This includes models that involve the introduction of DNA into the germ line. Knock-out (gene silencing, gene ablation, etc.) models may be exempt from IBC review if the method used to generate the model does not leave any "new" genetic material or any markers in the animal. If the recombinant or synthetic nucleic acid molecules used to create the knock-out are permanently inserted into the genome, the experiment must be reviewed by the IBC. Models that have mutations or genetic modifications resulting

from natural variation, chemical mutagenesis, or radiation exposure, but have not undergone molecular manipulation, are also reviewed by the IBC. Experiments involving the generation of transgenic animals that require BL1 containment are described under Section III-E-3 of the Guidelines, Experiments Involving Transgenic Animals, and thus require IBC Committee notification simultaneously with initiation. Transgenic and knockout animals produced in core facilities must also be registered.

Experiments involving the breeding of certain BL1 transgenic animals are exempt if the requirements described in Appendix C-VIII of the NIH Guidelines are met. The breeding of two different transgenic animals or the breeding of a transgenic animal and a non-transgenic animal with the intent of creating a new strain of transgenic animal that can be housed at BL1 containment are exempt if: (1) Both parental animals can be housed under BL1 containment; and (2) Neither parental transgenic animal contains the following genetic modifications: (i) incorporation of more than one-half of the genome of an exogenous eukaryotic virus from a single family of viruses; or (ii) incorporation of a transgene that is under the control of a gamma-retroviral long terminal repeat (LTR); and (3) The transgenic animal resulting from this breeding is not expected to contain more than one-half of an exogenous viral genome from a single family of viruses.

Transportation of Biological Materials

PIs should assess the biological materials being transported and classify them according to the applicable regulations, including those from the Centers for Disease Control and Prevention (CDC), the Department of Transportation (DOT), and the International Air Transport Association (IATA). Contact the BSO and EHS to ensure the proper classification and determine the required packaging, labeling, and documentation. Develop an emergency response plan in case there is a spill or incident during transportation, outlining the steps to take, containment measures, and reporting procedures. When preparing biological materials for transportation, ensure all materials are securely packaged according to the regulations. Packaging must be designed to prevent leakage or contamination during transport. The outer package should be clearly labeled with the appropriate hazard symbols and handling instructions. Additionally, PIs must provide complete and accurate documentation accompanying the shipment, which includes a description of the biological material, its classification, and any necessary permits or approvals. Documentation should also include emergency contact information in case of an incident during transportation. PIs should be aware of the specific transportation requirements for different modes of transport (ground, air, or sea) and comply with the respective regulations. Consider the destination's regulations as well, as they may impose additional restrictions or requirements for receiving biological materials.

Monitoring and Reporting of Adverse Events

Establish a system for monitoring and reporting adverse events incident during biohazardous research. PIs should consider:

- **Incident Definition:** Clearly define what constitutes an adverse event in the context of the research. This includes not only spills or exposures but also any unexpected outcomes related to biohazardous materials, such as adverse reactions in a human or animal.
- **Documentation Protocol:** Develop detailed procedures for documenting adverse events, ensuring all incidents are recorded accurately and promptly. This documentation should include the nature of the event, contributing factors, immediate responses taken, and any follow-up actions required.
- **Reporting Channels:** Outline clear reporting channels for adverse events, specifying who should be notified, including BSO, IBC, RO, and any potentially affected parties. PIs must ensure all research personnel are aware of these channels and understand their responsibility to report incidents immediately.
- **Follow-up and Mitigation:** Create a plan for assessing the impact of adverse events and determining necessary corrective actions. This includes analyzing root causes, implementing changes to protocols to prevent recurrence, and ensuring all team members are informed of any modifications to safety procedures.
- **Regular Reviews and Drills:** Incorporate regular reviews of adverse event reports and conduct drills to ensure all personnel are familiar with the reporting process.

Impact on Human and Animal Subjects

Conduct a thorough risk-benefit analysis to ensure the potential benefits of the research outweigh the risks to human and animal subjects. For human subject's research, the informed consent process should inform participants of potential risks and benefits associated with their participation. Outline any measures taken to minimize risks, such as monitoring protocols and post-exposure follow-ups. Measures should aim to protect participants and address any concerns related to their safety. Projects requiring the use of biohazardous materials must undergo dual committee review, involving both the IRB for human subjects and the IACUC for animal subjects. The Director of Institutional & Compliance (DIEC) serves on each oversight committee to coordinate projects that require oversight from more than one committee. For research involving human subjects, an IRB application must be completed and submitted for review. Similarly, for projects involving vertebrate animals, 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 obtained prior to the review of the IRB application, the proposal approval will be contingent upon the approval of the dual committee review. For projects that involve the use of human and nonhuman primate source materials, the PI must comply with the UMassD Bloodborne Pathogen Program and Exposure Control Plan. The transfer of these types of materials between institutions must also follow specific packaging and shipping requirements.

Environmental Impact

Evaluate the risks of an accidental release or contamination of biohazardous materials, considering both immediate and long-term effects on local ecosystems and public health. Conduct assessments of local ecosystems to comprehend the potential impacts of the research on wildlife, natural resources, and identify vulnerable species and habitats that may be affected. Develop strategies to mitigate environmental risks, including containment measures and protocols for responding to spills to prevent environmental contamination. Engage with the BSO during the protocol development phase can provide additional insights into minimizing ecological risks.

Identification of Conflict of Interest

A conflict of interest must be disclosed at the beginning of any meeting or before the review of any documents to the Committee Chair or to the Responsible Official (RO). This ensures the following:

- The responsible conduct and integrity of decisions made by the Committee.
- Protection of the Committee membership and the University from unnecessary and avoidable litigation.
- Compliance 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 defined as any situation in which a committee member has any of the following:

- An affiliation with any organization, company, venture, or other entity that involves a direct financial interest or benefit, either directly or through relatives by blood or marriage, in the subject matter or materials of a protocol or registration under review by the committee.
- Direct involvement in the research subject matter being reviewed by the committee.
- A familial relationship, by blood or marriage, or a business partnership with a researcher undertaking a protocol or registration considered by the committee.
- Being a research competitor or having a personal conflict with the project or the investigators, which could lead to a perceived bias.

The meeting agenda will include the item "Identification of Conflicts of Interest." Each committee member is obliged to disclose any conflict of interest or potential conflict of interest as soon as it comes to their attention. If a committee member is unaware of any conflict of interest at the time they attend a meeting and later discovers that they are in a conflict situation, they should immediately inform the Chair of the Committee or the Responsible Official (RO) once the conflict becomes apparent.

Members assigned to review a registration for which they are conflicted will be reassigned. Members are to notify the IBC Chair and the RO of any potential conflict for reassignment.

If a committee member has any doubt about whether they are in a potential conflict situation, they must raise this concern with the committee members at the commencement of the meeting. Faculty members residing in the same Department may review protocols and registrations originating from that 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 during the discussion to answer questions but must recuse themselves from the discussion related to voting and approval. Members with a declared conflict of interest cannot be present during the IBC vote on the conflicted item.

Environmental Health and Safety

The Environmental Health and Safety (EHS) Department is responsible for overseeing the procurement, use, and inventory of hazardous materials, as well as providing various safety training programs related to the handling of these materials. EHS has its own set of policies that can be accessed at UMassD EHS Policies. The IBC reviews proposed experiments, evaluates facility capabilities, and assesses institutional procedures, as well as PI training and expertise, to ensure that projects involving biohazardous materials are conducted safely and in compliance with NIH guidelines. While the IBC focuses on research proposals, the EHS staff oversee facility operations and the safe use of materials within each research environment. If the project is to be conducted in a UMassD laboratory, EHS staff (or BSO) may inspect the site(s) where the research will be conducted. Access to hazardous agents shall be limited to authorized personnel, in accordance with the safe handling, storage, and disposal practices established by UMassD. The use of appropriate ventilation systems, such as chemical fume hoods or biological safety cabinets, is mandatory to minimize exposure risks and ensure the safety of personnel working with hazardous agents. Hazardous agents include biological, radiological, and chemical materials that may be utilized during research projects. Facilities used for animal experimentation involving hazardous agents must be physically separated from animal housing and support areas to prevent cross-contamination and ensure the safety of both personnel and animals.

All biohazardous materials must be purchased and inventoried through the UMassD EHS Hazardous Materials PeopleSoft purchasing program. All Material Safety Data Sheets (MSDS) and product safety information sheets are accessible through the EHS Office. The disposal of hazardous materials—including biological, chemical, and physical agents—will be conducted in accordance with the UMassD EHS Office program and applicable federal, state, and municipal regulations.

In the event of accidents, injuries (including animal bites and needle sticks), or exposure incidents, immediate reporting to the supervisor, the Environmental Health and Safety Office, and the Human Resources Office is mandatory. For immediate medical emergencies, an emergency phone (ext. 9191) has been established and is staffed 24 hours a day by the UMassD Public Safety Office. All exposure incidents must be reported, investigated, and documented using an Incident Report Form.

Biosafety Violations and Reporting Procedures

Deviations from the policies and procedures, or biosafety/biosecurity-related incidents, must be reported the BSO, RO, and IBC Chair to be communicated to the IBC members. Individuals with biosafety and/or biosecurity-related concerns can contact the RO directly via email or phone. The IBC is responsible for reviewing and investigating concerns involving biohazardous materials. While all complaints will be reviewed, not every complaint may require a formal investigation.

When registration violations are identified, the IBC will work to ensure compliance or take immediate action to halt or suspend research activities posing a hazard to personnel. The IBC Chair (or BSO) has the authority to suspend any research or teaching activity if

- Violations pose substantive threat or harm to the health or safety of personnel, students, the public, or the environment;

- Action deviates from the approved research protocol or from the practices that are commonly accepted by the scientific community or could result in an adverse biosafety event; or
- A PI demonstrates misconduct or other serious or continued noncompliance with federal, state, or local laws, regulations or policies.

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.

Misconduct

If a PI continues research activities after notice of suspension by the IBC, or if PI conducts research without proper registration, such actions will be considered noncompliance and may also be considered Research Misconduct per UMassD Policy. The misconduct will be forwarded to the Director of Institutional Ethics and Compliance and the IO for administrative review. Such violations

Reporting Requirements

PI Reporting

The PI and study personnel must report any significant incident, violation of the NIH Guidelines, or any significant, research-related accidents and illnesses immediately by contacting the BSO. Examples of incidents and violations include:

- Overt exposures are defined as exposures that result in direct personnel exposure to biohazardous materials such as injection, spills, splashes or aerosol inhalation.
- Potential exposures are defined as exposures that have a high risk of exposing personnel to biohazardous materials such as spills, containment failure while working with the agent or equipment failure that may produce aerosols.
- Any exposure (overt or potential) in a BSL-3 lab.
- Overt exposure in BSL-1 or BSL-2 labs
- Any illness that may be caused by the agents used in the laboratory incidents involving the improper disposal of recombinant or synthetic nucleic acid molecules.

PIs must report other information to the IBC as soon as they become aware of the information (must also be reported to OSP):

- Information to support a new host-vector system.
- Petitions for proposed exemptions to the NIH Guidelines.
- Petitions for approval to conduct experiments specified in Sections III-A-1 and III-B.
- Petition for determination of containment for experiments not covered by the NIH Guidelines.

BSO Reporting

The BSO is required, by the NIH Guidelines, to report to the IBC:

- All violations of the NIH Guidelines and significant incidents.
- Any significant research-related accidents or illnesses.

IBC Reporting

The IBC, through the IO, will file an annual report with OSP that includes:

- A roster of all IBC members clearly indicating the Chair, contact person, BSO, plant expert, and animal expert.
- Biographical sketches of all IBC members.

The IBC is required, by the *NIH Guidelines*, to report to the appropriate University official and to the NIH/OSP within 30 days any significant incidents, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses. The IBC will be responsible to determine what actions, if any, are necessary. For example, the IBC may choose to change the frequency of lab inspections, or change the Biosafety Level of the protocol, based on results of the incident. The IBC is required to complete a final copy of the Biological Incident Reporting Form which it will be signed and dated by the IO, IBC Chair and the BSO.

Other IBC reporting requirements (to OSP and other agencies) include but are not limited to:

- Research involving recombinant or synthetic nucleic acid molecules and biohazardous materials, agents and toxins without prior IBC approval.
- Lax security, unsafe procedures used in a laboratory setting, improper disposal of recombinant waste.
- Significant changes to proposed research risk without prior notification and approval by IBC.

Certain types of incidents must be reported to OSP on an expedited basis. Spills or accidents in BL2 laboratories (involving recombinant or synthetic nucleic acid molecules) resulting in an overt exposure must be immediately reported to OSP. In addition, spills or accidents involving recombinant or synthetic nucleic acid molecules occurring in high containment (BL3 or higher) laboratories resulting in an overt or potential exposure must be immediately reported to OSP. The IBC will report to the appropriate institutional official, who, in turn will report to OSP, any of the above-described incidents.

Institutional violations that will be reported to the appropriate College or department head may include but are not limited to:

- Lapses in protocol approval.
- Failure to comply with institutional and federal regulations, guidelines, and policies.

As per Section IV-B-2-a-(7) of the *NIH Guidelines*, if public comments are made on IBC actions, the IBC, through the IO, will forward both the public comments and the IBC's response to the Office of Science Policy.

RO Reporting

Upon receiving a report from the IBC, the RO will report:

- In writing any problems with or violations (noncompliance) of the NIH Guidelines any significant incident, accidents, or illnesses related to recombinant or synthetic nucleic acid molecules to the NIH/OSP within 30 days or immediately for overt exposure to a BSL-2 agent or potential/overt exposure to a BSL-3 agent.
- For incidents involving Select Agents and/or Select Toxins the RO must notify the CDC/USDA.
- Any significant research-related illness or accident that may be hazardous to the public health and cooperate with state and local public health departments.

Reporting for External Requests of Information

Minutes are not for general distribution or public access but may, upon request, the institution will make available to the public all IBC meeting minutes and any documents submitted to or received from funding agencies which the latter are required to make available to the public. Information released to the public must be balanced with the need for security. Information vital to institutional or national security, or personnel or employee protection, may be redacted from IBC minutes. Redaction of proprietary and private information is allowed but "must be done so judiciously and consistently for all requested documents." Information about the location of Select Agents and Toxins may not be released. Reasonable charges for photocopying of documents may be passed on to the organization or person requesting such information.

Reporting Undue Influence and Coercion

In cases where an IBC member or OIEC staff person experiences undue influence or coercion, they should document the issues in writing to both the RO and the IO to initiate a formal report. The IO will review the information and may convene a meeting or gather additional information as necessary. The findings will then be communicated to the IBC, which, alongside the IO, has the authority to take corrective actions as needed.

Reporting a Complaint or Request a Dispute Resolution

Individuals wishing to file a complaint regarding IBC activities or dispute resolution should provide a detailed description of the issue, including:

- The name of the study.
- The Principal Investigator (PI).
- A clear account of the complaint or dispute, including any specific deviations from approved protocols or IBC policies.
- Any relevant documents supporting the complaint.

Review and Evaluation

Upon receipt of a complaint or dispute, the IBC will:

- Acknowledge receipt within [specific time frame, e.g., 5 business days].
- Review the complaint or dispute to assess its validity and relevance.
- Gather additional information if necessary to understand the context and impact.

Compliant Resolution

The IBC will determine appropriate actions based on the complaint review, which may include:

- Discussing the issue with the PI and/or relevant parties.
- Requesting corrective actions or modifications to the research protocol.
- Implementing additional monitoring or oversight measures.
- If the complaint involves serious violations/concerns or remains unresolved at the IBC level, it will be escalated to the IO for further review and action.

Dispute Resolution

For disputes regarding IBC decisions, the Chief Research Officer and the IBC Chair may be petitioned for reconsideration if the PI disagrees with the IBC's findings. At the time of submission, the petitioner may request full committee review. All disapproval decisions of the IBC are final and cannot be overridden by the IO. However, other decisions may be appealed to the IO. Requests for reconsideration must be submitted in writing within 30 days of receipt of the IBC's decision and must include relevant materials and new evidence, if applicable.

Follow-Up

The IBC will document all complaints, disputes, and actions taken to resolve each.

Notice:
UMassD takes steps to protect employees and agents who report in good faith from retaliation and harassment. Every effort will be made to protect the complainant's confidentiality, but UMassD is an agency of the Commonwealth of Massachusetts and is therefore subject to the Massachusetts Public Records law, G.L. c.66, § 10; 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 UMassD Policy on Misconduct in Science.

Section 6: IBC Procedures

- Submission of IBC Registration
- Biosafety Review
- Non-Convened Review
- Committee Review Full Committee Review
    - Meeting Preparation
    - Meeting Review Procedures
    - Meeting Vote
- Administrative Process
    - Schedule and Distribution:
    - Agenda:
    - Minutes
    - Correspondence
    - Education and Training
    - Documentation and Record-Keeping
    - Monitoring Compliance and Audits
    - Review of Policies and Procedures
    - Post Review
    - IBC Follow Up
    - Consultant Review
    - IBC Record Requirements
    - Annual Reviews & OSP Reports

IBC Review Procedures

The IBC oversees the safe conduct of research involving biohazards, ensuring compliance with safety standards and regulations. The IBC review process is categorized into the following key areas:

Submission of IBC Registration

- **Protocol Submission**: Researchers must submit protocols to the IBC for review before starting any research involving biological materials. Submissions should include a completed IBC application form, a detailed research description, risk assessments, and relevant supporting documents.
- **Submission Deadline**: Protocols requiring Committee Review must be submitted at least 2 weeks before the scheduled IBC meeting to allow adequate time for review.

Review Procedures

Biosafety Review (Pre-Review)

This review procedure begins when the RO and Chair receive a notification of new or revised registration. The Chair, BSO, and RO make a Biosafety Risk Assessment to:

- Assess submission completion by ensuring no materials are missing from the registration.
- Assess the risk group of agents, biosafety level, and investigator's qualifications/training/experience.
- Identify any other concerns that will limit approval.
- Identify determinations for the IBC to review before the approval of the research.
- Determine if registration requires review by Non-Committee Review or Committee Review.

Non-Committee Review

The Non-Committee Review procedure begins when the BSO or RO determine a registration, or minor revision presents may be reviewed and approved via a Non-Committee Review. The Non-Committee Review process applies to both the exempt review and expedited review processes. The expedited review process is reserved for non-rDNA BSL 1 biohazardous materials and minor amendments which do not apply to changes in biosafety levels, biohazard management, or biocontainment measures. After the BSO confirms the appropriateness of the Non-Committee Review designation and notifies the RO, the Chair or RO will assign the Non-Committee Review assignment to a Designated Reviewer to:

- Confirm there is no Conflict of Interest (COI). If a COI is identified, the Designated Reviewer must notify the Chair and RO to establish reassignment.
- Confirm sufficient review expertise or request reassignment from the Chair and RO if lacking:
    - Scientific or scholarly expertise.
    - Knowledge of biosafety practices.
    - Knowledge of NIH Guidelines.
    - Knowledge of institutional requirements.
- Confirm the Biosafety Risk Assessment is complete and accurate. If additional documents or information are necessary, the Designated Reviewer should notify the Chair and RO. The Designated Reviewer, Chair, BSO, or RO may reach out to the Principal Investigator and/or study team to obtain clarifications/documentation, may make recommendations to clarify processes or suggest improved handling procedures, and update Biosafety Risk Assessment if any additional information and documentation provided after the initial review.
- If no further information is required, the Designated Reviewer notifies the Chair, BSO, and RO of the review recommendation:
    - **Approval**: The submission meets the Criteria for Approval.
    - **Conditional Approval**: The submission requires minor to moderate changes before being granted approval. The Designated Reviewer provides the Chair, BSO, and RO with a list of concerns that require modifications and/or justification to be addressed before approval can be issued. Conditional Approval requires the resubmission to be re-reviewed by the assigned Designated Reviewer, RO, BSO, or Chair.
    - **Return/Deny**: The initial, continuing, modification, or report submission does not meet the criteria for approval and is found to have extensive deficiencies. The Designated Reviewer provides the Chair, BSO, and RO with a list of concerns that require modifications and/or justification to be addressed.
    - **Rescind Approval**: A prior approval of a document, site, investigator, procedure, use of a biologic agent, etc., was incorrectly provided, and therefore approval is rescinded. The research may not continue once approval is rescinded. The Designated Reviewer provides the Chair, BSO, and RO with a list of concerns that must be addressed before approval can be reissued.
    - **Committee Review**: The submission warrants review by the full board.

Documentation of the Non-Committee Review approval are recorded in the meeting minutes.

Committee Review

This review procedure begins when the Chair, BSO, RO, or Designated Reviewer determines a registration requires review via a Committee Review. New registrations that present hazards (to humans, animals, the environment), include BSL2 containment, involve the release of genetically modified organisms, or are deemed by the NIH to require convened review require Committee Review. Or a revised registration which includes a major amendment. **Major Amendments** involve significant changes to an approved protocol that may increase biosafety risks or require a higher level of containment. Major amendments require Committee Review and a discussion focused on ensuring appropriate risk containment and compliance with biosafety standards. Examples include:

- Introducing new biohazardous agents or recombinant DNA materials.
- Increasing the risk group classification of the biological agents.

- Substantial changes to the scope or design of the research that affect biosafety.
- Moving research to a new facility that requires reevaluation of containment measures.

Official IBC business is reserved to occur at Committee Review meetings and must include a quorum of members for the meeting to be held (Quorum is established by the presence of at least 5 voting members). The Chair and RO determine the maximum number of items on the agenda to ensure reasonable workloads; limits are based on the complexity of agenda items, the time available to meet, and urgency of approval requirements. Limits are adjusted as needed by the RO. Full committee reviews occur during regularly scheduled IBC meetings. PIs are encouraged to attend these meetings to address any questions. PIs should allow 10-15 working days for the full review and approval process. All concerns raised by the IBC must be addressed before final approval.

Meeting Preparation

The RO prepares the IBC for a convened meeting by ensuring to:

- Confirm IBC members (regular, alternate, IBC chairs) availability to be present at the meeting. Ensure the meeting quorum will be appropriately met. If the meeting will not meet the quorum requirements, make arrangements to meet quorum requirements.
- Prepare an agenda.
- Assign IBC member(s) to present each agenda item.
- Ensure that the IBC has appropriate expertise to review registrations listed on the agenda. If the IBC does not have the relevant expertise available, a consultation may be requested from university employees or external consultants. If a consultant is requested, the RO will ensure there is no Conflict of Interest and document the agreement of the consultant to maintain confidentiality of information provided prior to Committee Review invitation. If the consultant provides a written report, the RO will provide the report to the IBC members for review.
- Ensure that all attendees are provided or have access to the materials at least one week before meetings.

Meeting Conduct

The Meeting Chair is responsible for oversight of meeting conduct at the IBC meeting and is expected to:

- Help IBC members meet their expectations and responsibility.
- Encourage IBC members to:
    - Ask questions.
    - Speak their minds at every protocol review.
    - Share information that has not been discussed.
    - Listen and learn from the group.
    - Respect dissenting opinions.
    - Think and vote independently.
- Mentor and guide IBC members to use the criteria for approval by:
    - Facilitating IBC members' understanding of the research to apply the criteria for approval.
    - Having IBC members base concerns and recommended changes on the criteria for approval.
    - Framing difficult or controversial issues in terms of the criterion that is the basis of the controversy.
    - Taking votes on the criterion for approval that is the basis for a controversy if, after sufficient discussion, a controverted issue remains unresolved. Reminding IBC members who believe that one or more criteria for approval voted are not met that they should not vote for approval.
    - Removing issues from consideration when the Meeting Chair and IBC members determine they do not affect the criteria for approval.
    - Supporting and rewarding dissent based on the criteria for approval.
    - Obtaining assistance from the RO or BSO when IBC members are uncertain whether an issue affects the criteria for approval.
- Encourage IBC member engagement by:
    - Reinforcing IBC member expectations.
    - Encouraging IBC members to use their unique perspective to contribute to IBC deliberations.
    - Providing recognition and praise to IBC members.
    - Encouraging IBC members to develop their review skills.
    - Ensuring opinions of IBC members count.
- Ensure IBC members know the definition of and self-identify their Conflicting Interests. If there are individuals (either IBC members or consultants) with a Conflicting Interest related to an agenda item, neither should participate in the review (including discussion or voting), except to provide information requested by the IBC. Conflicted members may be present for discussion and to answer questions but will be asked to recuse themselves from the vote. If a committee member is unaware of any conflict of interest or potential conflict of interest at the time they sit in a meeting and later discovers the Conflict of Interest, the member should inform the Meeting Chair and RO immediately. 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.
- Ensure all IBC members who are part of quorum vote, noting that consultants and guests may not vote. If quorum is lost, ensure no further action is taken until quorum is restored.
- Ensure notes and/or concerns provided by absent IBC members are included in the discussion. Absent IBC members may not vote.
- If alternate members are present, determine the voting status of the alternate IBC members by ensuring:
    - The number of IBC members with voting status is not greater than the number of regular IBC members on the IBC roster.
    - Notify the RO at the meeting of any change in IBC members' voting status.
- If a guest/observer attends, ensure that they are aware that they may not participate in the deliberations unless invited to do so by the Meeting Chair. Neither can participate in the vote and must agree to main confidentiality of the IBC proceedings.

- If the study is eligible for Non-Committee Review, the Meeting Chair can make a motion for members to vote on taking no action and have the item reviewed via Non-Committee Review.

- After sufficient discussion of each agenda item, call for a vote from IBC members present at Committee Review as "For," "Against," or "Abstaining" in the motion for:
  - **"Approval":** When the IBC determines that the research meets or still meets the criteria for approval and more that 50% of the quorum votes in favor or protocol approval. For initial and continuing review, include in the motion, the level of risk (minimal risk or greater than minimal risk), and either that continuing review is not required, or the period of continuing review.
  - **"Conditional Approval":** When the IBC determines that the research will meet the criteria for approval with minor prescriptive changes or requirements that can be verified without considering the criteria for approval. Summarize the IBC required modifications and reasons. For initial and continuing review, include in the motion, the level of risk (minimal risk or greater than minimal risk), and either that continuing review is not required, or the period of continuing review. If after discussion the IBC members determine the protocol is ambiguous, resolve ambiguity by informing RO of request to obtain written information from the sponsor or investigator as an alternative to Conditional Approval. Alternative must be discussed and review by IBC members before the vote.
  - **"Table":** When the Committee Review determine further information is necessary to supplement the initial, continuing, or modification registration submission as its status does not meet the criteria for approval and require re-review by the Committee Review. Summarize the IBC reasons for motion and detail information necessary. Review of registrations may also be tabled when quorum is lost. A tie votes for and against "Approval" / "Conditional Approval" also results in the tabling of a registration review.
  - **"Return/Deny":** When the initial, continuing, or modification submission does not meet the criteria for approval and the IBC considers the research to have extensive deficiencies. Summarize the IBC reasons for motion and detail all information required to meet criteria.
  - **"Suspend":** When the IBC determines that based on new information the previously approved research no longer meets the criteria for approval or when only some research activities meet the criteria for approval or when the IBC has revision recommendations to make the research meet the criteria for approval. Summarize the IBC reasons and/or recommendation for the motion, include which research activities must stop or be modified, and detail all information required to meet criteria. The IBC may lift suspension when resubmission addresses concerns and meets criteria of approval via Non-Committee Review.
  - **"Terminate":** When the IBC determines that based on new information the previously approved research no longer meets the criteria for approval and the IBC has no recommendations to make the research approvable. Summarize the IBC reasons for the motion.

Meeting Review Process

The review of any registration at a Committee Review involves a discussion led by the Primary Reviewer (typically the Designated Reviewer) in collaboration with the Meeting Chair and IBC members who collectively share the responsibility of:

- Having the appropriate expertise to discuss scientific/scholarly review of:
  - Agent or Material's 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.
  - Containment conditions to be implemented.
  - Animal or plant containment methodologies and practices
  - Occupational health concerns
  - Whether expression of a foreign gene will be attempted, and if so, the protein that will be produced.
  - The NIH Guidelines (e.g., Section II-D-1. Section III-E-1, etc.).
- Review all submitted materials for consistency. Then review the findings/concerns identified via the Biosafety Review. Identify any additional findings/concerns. Notify the Meeting Chair, BSO, and RO if additional information is necessary to answer questions about the submitted materials.
- Assess if the criteria of approval are met, if one or more criteria are not met, consider what specific and directive changes would make the protocol approvable.
- For a reviews related to an Unanticipated Problem Involving Risks to Researchers or Others, General Noncompliance, Serious Noncompliance, Continuing Noncompliance, Suspension of IBC Approval, Termination of IBC Approval or new information is provided determine whether additional information is necessary, or if the registration, approval interval, biosafety SOP, corrective action plan, or monitoring plan requires modification.
- The Designated Reviewer and Meeting Chair summarize the IBC's consensus and provide notes to the RO for the generation of minutes and correspondence.

Administrative Processes

The RO is responsible for administrative oversight of the IBC review process. The RO schedules meetings, creates the meeting agenda, disseminates registration forms and relevant meeting materials electronically, records minutes, and then distributes the minutes for IBC members to review.

Schedule and Distribution

The IBC meets on the first Thursday of every month. If there are no registrations requiring Committee Review, the meeting is canceled by the Chair or RO. If there is a time-sensitive matter requiring Committee Review, such as registrations with specific funding timelines, noncompliance, or serious and/or unexpected events, an emergency ad hoc meeting can be called by the Chair or RO as necessary. Meetings may be conducted by

teleconferencing, and a written record of the meeting is created by the RO to document committee actions and requirements. Email is used to distribute registrations, conduct designated reviews, pre-meeting discussions, and to poll members as necessary.

Agenda

The agenda is provided to IBC members with sufficient time in advance to review and includes:

- New registration applications.
- Identification of conflicts of interest.
- Listings of registrations approved, conditionally approved, and withdrawn via Non-Committee Review since the last meeting.
- Previous committee review meeting minutes for review and approval.
- Administrative updates relating to IBC announcements and/or educational materials.

Minutes

Meeting minutes are drafted and distributed to all IBC members by the RO before the next meeting for review and approval. Committee Review minutes include the meeting date, time of start and finish, attendance, conflicts of interest, and discussion of agenda items. The minutes section of each registration includes:

- **Registration Information:** Lists the IBC Number, Project Title, PI, Sponsor Name, Grant Number, NIH Category (e.g., III-D vs III-E), and whether IRB/IACUC committee approvals are required/available.
- **Material Information:** Lists the Material, Agents, Hosts, Vectors, Methodology, Risk Group, and Biosafety Containment Level.
- **Discussion Summary:** Includes a brief summary of previous actions, consultation reports, and identified issues or concerns regarding agent/host/vector characteristics, types of manipulations, and the nature or source of materials, along with proposed resolutions. This section also mentions controverted issues—topics where committee members have differing opinions or unresolved disagreements, such as ethical dilemmas related to specific materials or methods, differing interpretations of regulatory guidelines, or debates on risk assessment thresholds.
- **Motion:** Each motion requires specific information to be captured:
    - For a motion of “Approval,” no other information needs to be recorded.
    - For a motion of “Conditional Approval,” the reasons and required modifications must be recorded.
    - For a motion of “Table” and “Return/Deny,” the IBC’s reasons and recommendations must be documented.
    - For a motion of “Suspend,” the specific activities suspended, reason for suspension, and the IBC’s recommendations must be noted.
    - For a motion of “Lift Suspension,” no other information needs to be recorded.
    - For a motion of “Terminate,” the IBC’s reasons must be documented.
- **Vote:** Each vote must be captured for each voting member’s vote as:
    - “For”: Voting for the motion.
    - “Against”: Voting against the motion.
    - “Abstain”: Present for the vote but not voting “For” or “Against.”
    - “Absent”: Present for the meeting but not present for the vote.
    - “Recused”: Present for the meeting but not present for discussion and vote due to a conflict of interest.

Correspondence

The RO is responsible for drafting all IBC correspondence (determination letters, notices, and memos) for review and approval by the Chair prior to distribution.

Education and Training

The RO is responsible for educating IBC members and faculty on IBC procedures, training requirements, and conflict of interest policies. Training is available through citiprogram.org.

Documentation and Record-Keeping

The RO is responsible for maintaining up-to-date records of all official IBC business. This includes:

- **Meeting Minutes:** Detailed records of IBC meetings, including attendance, discussions, motions, and voting outcomes.
- **Registration Forms:** Copies of all submitted registration forms for research projects, including new registrations, amendments, and renewals.
- **Approval Correspondence:** Documentation of all correspondence related to approvals, conditional approvals, and disapprovals, including determination letters and notices sent to PIs.
- **Conflict of Interest Disclosures:** Records of any disclosed conflicts of interest by IBC members, along with the management plan for such conflicts.
- **Educational Materials:** Copies of training materials and resources provided to IBC members and faculty regarding biosafety practices, IBC procedures, and ethical considerations.
- **Audit Reports:** Documentation of lab audits conducted by the BSO, including findings, recommendations, and follow-up actions taken in response to audit results.
- **Policy Documents:** Up-to-date versions of IBC policies and procedures, including any revisions or amendments made over time.
- **Compliance Documentation:** Records of compliance-related activities, including reports of noncompliance, corrective actions taken, and communications with PIs regarding compliance issues.
- **Historical Records:** Archived records of past IBC activities, decisions, and correspondence to ensure transparency and continuity in governance.

The RO must ensure all records are securely stored in an electronic system with appropriate data backup procedures and are easily accessible for review by IBC members, regulatory agencies, and institutional officials as needed. Regular audits of documentation practices may also be conducted to ensure compliance with institutional and regulatory requirements.

Monitoring Compliance and Audits

The BSO conducts regular lab audits to monitor compliance with approved protocols and ensure adherence to biosafety standards. The BSO reports lab audit results to the RO for IBC review and consideration, establishing if any additional registrations are required or if existing registrations require revision through an amendment. The frequency of audits and criteria for selecting which labs to audit will be specified, along with how findings are communicated to PIs and any follow-up actions that are required.

Review of Policies and Procedures

The RO conducts regular audits of existing policies and procedures to determine which require revisions. Noncompliance and lab audit reports are taken into account when deciding whether new policies or procedures must be established or if new educational guidance is necessary.

Approval Criteria

To meet the criteria for approval, the Institutional Biosafety Committee (IBC) must ensure the following conditions are satisfied:

1. **Appropriate Expertise**: The IBC members and any external consultants involved in the review must have the necessary expertise to understand and evaluate the scientific, biosafety, and ethical aspects of the research. This includes, but is not limited to, knowledge in characteristics of biological agents (e.g., virulence, pathogenicity, environmental stability), genetic manipulations involved in the study, source, nature, and function of inserted genetic material, host/vector systems, biosafety containment measures appropriate for the risk group, occupational health and environmental safety concerns, NIH Guidelines, relevant biosafety protocols, and containment methodologies for animals and plants. If the IBC lacks the necessary expertise for a specific protocol, it may seek input from external experts, ensuring there is no conflict of interest.
2. **Appropriate Biosafety Containment and Risk Assessment**: The containment level for the research must be appropriate for the risk group of the study agents. A thorough risk assessment must be conducted to ensure that risks to personnel, co-occupants, and the public environment are reasonable, including consideration of the nature of the study agent, the risk group, and any genetic modifications introduced. Risk to personnel, students or visitors, and environment is reasonable in relation to the threats and hazards associated with use of the materials.
3. **Effective Safety Procedures**: Safety procedures are developed and monitored for hazards and risks associated with the project or activity. Safety procedures must be developed in collaboration with Environmental Health and Safety (EHS) staff and the BSO to address associated hazards and risks. The BSO is available to assist Principal Investigators (PIs) in the development of individual BioHazardous Material Standard Operating Procedures (BHMSOPs) tailored to each study and lab. Risks to personnel, students, or visitors must be reasonable compared to the threats posed by the materials. Additionally, risks to community health and the environment must be adequately mitigated, and necessary medical measures, such as occupational health consultations, must be in place to minimize risks. EHS staff may conduct routine monitoring of facilities to ensure compliance. Where appropriate, preventative medical measures are taken to minimize risks associated with breeches in safety procedures (including any required occupational health consultations).
4. **Adequate Emergency Response Plans and Facilities**: Adequate emergency plans must be in place to handle accidental spills, exposures, or other unforeseen incidents, including protocols for responding to researcher or personnel contamination. The research facilities and operational procedures are sufficient to protect against the risks posed by the research, including proper use of containment equipment, safety protocols, and regular safety training programs.
5. **Compliance with Guidelines**: The proposed research must comply with the NIH Guidelines, the Biosafety in Microbiological and Biomedical Laboratories (BMBL) manual, and any other applicable institutional or federal biosafety regulations.
6. **Completion and Consistency of Registration Materials**: All registration documents must be complete, consistent, and compliant with the NIH Guidelines, the BMBL, and the IBC's Charter. Incomplete or inconsistent applications may result in the delay or denial of approval. All necessary documents have been provided with review (reference publications, Material Data Safety Sheets, vector maps, training certificates, and external agreements and permits, etc).
7. **Proper Assessment and Monitoring of Risks and Noncompliance**: Any previous instances of unanticipated risks, noncompliance, or new information must be considered during the review process. Ongoing monitoring of the research process must be conducted to identify any emerging risks or issues, with clear requirements for reporting to the IBC. If required, modifications to protocols, corrective action plans, or enhanced monitoring may be mandated.

These criteria ensure that the research is conducted safely, ethically, and in compliance with all relevant regulations, while also addressing potential gaps in expertise and preparedness.

IBC PROCEDURES

The IBC receives an annual report from the BSO regarding the annual inspections of all UMassD biosafety facilities (including laboratories and satellite facilities). The BSO may delegate this function to an appropriate Biosafety official.

In order to approve proposed activities or changes in ongoing biohazardous activities, the IBC reviews components related to biosafety and may make recommendations to clarify processes or suggest improved handling procedures.

Meetings

Minority views are recorded in the minutes.
The vote will show the total number of members present, the total votes (yes and no), and one member 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.
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.

Meeting schedules are typically set six months in advance and posted on the IBC website.

All registrations (exempt, expedited, and approved) are recorded in meeting minutes.

Meeting Protocol

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.

Meeting Documentation

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. 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.

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

Every effort will be made to determine exemption status within 3 business days of receipt of the completed application. Projects that are exempt from full committee review will be reported to the full IBC at regularly scheduled meetings.

Approval Information

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.

Post Review:

The post-review process begins when a Designated Reviewer or Committee Review determines whether a submission requires revision to secure approval or cannot be approved.

Communication of Findings and Actions:

- The IBC communicates its findings and actions to the investigator.
- The IBC reports its findings and actions to the institution, the NIH Office of Science Policy, or other relevant agencies as required under the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, OSHA, or local/state biosafety regulations.
- When the IBC disapproves research, it provides the investigator with a statement of the reasons for the decision and offers the opportunity to respond in person or in writing.

Timeliness of Communications:

- Communication of review results to investigators is completed within 7 business days of the IBC meeting or receipt of completed review.
- Reporting of noncompliance, containment breaches, termination of IBC approval, and incidents related to the use of biohazardous materials to outside agencies, as applicable, must occur within 30 days of the determination of a reportable event.

Appeal of IBC Decisions:

- If an investigator disagrees with an IBC decision, they may submit a written appeal to the IBC Chair or the Office of Institutional Ethics and Compliance (OIEC) within 30 days of receiving notification of the decision.
    - The appeal should include information supporting the disagreement.
    - For appeals involving research reviewed by a Designated Reviewer, the appeal is reviewed by the Designated Reviewer, IBC Chair, and OIEC.
    - For appeals involving research reviewed by the convened board, the appeal is reviewed by the convened board. The investigator may request to address the board to provide clarification or additional information.
    - The investigator will be notified in writing of the decision.
- The Institutional Official (IO) may override the IBC's decision to approve research; however, the IO or institution cannot approve research that has not been approved by the IBC or overrule other IBC decisions.

IBC Follow-Up:

- Check in with investigators who have not resubmitted within 14 days of a request for revisions.
- Remind investigators whose study involves biohazardous agents within 30 days of the anniversary of approval that their study will continue to be considered open unless a closure report is submitted.
- Notify investigators whose approval has lapsed due to lack of continuing review.
    - When possible, contact the investigator to determine if enrolled subjects or ongoing experiments should continue in the research because it is in their best interest or in compliance with containment standards.
    - Inform the investigator:
        - Which research procedures may continue
        - The continuing review progress report must be submitted as soon as possible.

Consultant Review:

The IBC utilizes consultants to enhance IBC reviews when a project requires specialized expertise beyond the scope of IBC membership. Consultants may be needed for:

- Expertise related to a particular biohazardous agent, intervention, or containment practice.
- Understanding of biosafety levels (BSL1-4) and the necessary laboratory containment practices.
- Knowledge of risk assessments related to Dual Use Research of Concern (DURC) or biohazardous materials that may present significant risks to public health or safety.

- Experience with the research population, including considerations of community safety or exposure.
- Knowledge of environmental impact and safety requirements for research involving genetically modified organisms (GMOs) or other materials with ecological risks.
- Expertise related to protecting participants, including informed consent, privacy, and data confidentiality, especially in research involving human subjects and biospecimen collection.

During the initial review of a submission, if the Designated Reviewer identifies the need for additional expertise, they must notify the OIEC or IBC Chair. Once identified, the OIEC, IBC Chair, or IO will consult with IBC members, University, or affiliate administrators and faculty to identify suitable experts.

The convened IBC may also determine that additional expertise is required:

- If the IBC decides that additional expertise is necessary before approval, the review and approval are deferred until the consultant's review is completed and presented at a subsequent meeting.
- If the IBC approves the submission with conditions but deems consultation necessary for finalizing changes, the consultant will work with the Designated Reviewer and OIEC to confirm the necessary information from the PI.

Consultants are not appointed members of the IBC and do not have voting rights. Their role is limited to providing expertise for specific submissions. Once an appropriate consultant is identified, the OIEC ensures:

- The consultant has no conflicts of interest that might affect the review before engaging in the review process. Consultants with conflicts may only participate under these conditions:
    - They restrict their input to the information requested by the IBC, or
    - They disclose their conflict to the IBC before presenting their comments if no alternative expert is available.
- Consultants receive relevant materials and must provide written comments and recommendations. These documents are attached to the agenda.
- Consultant reviews, which summarize findings, considerations, and recommendations, are presented to the Designated Reviewer via email or at the IBC meeting by the consultant or IBC Chair.

IBC Record Requirements:

The IBC prepares and maintains adequate documentation of IBC activities within the Office of Sponsored Programs, including the following:

1. Research Proposals and Biosafety Protocols:
    - Copies of all research proposals and registrations reviewed and approved.
    - Reports submitted by investigators, including lab inspections and safety audits.
2. Minutes of IBC Meetings:
    - Members present (any consultants/guests/others shown separately).
    - Results of discussions on biosafety concerns and record of IBC decisions.
    - Record of voting (showing votes for, against, and abstentions).
3. Continuing Review Activities:
    - Records of continuing review activities.
    - Updated biosafety protocols and summaries of ongoing project activities.
4. Correspondence:
    - Copies of all correspondence between the IBC and the investigators, including communication with the Environmental Health and Safety (EHS) Office regarding lab inspections or containment audits.
    - Copies of all correspondence between federal agencies and the IBC.
5. Incident Reports and Safety Concerns:
    - Any statements of significant findings (e.g., unanticipated risks, adverse reactions, or containment breaches) were provided to the investigator and IBC.
6. Adverse Event Reports:
    - Adverse event reports and documentation that the IBC reviews such reports.
7. Emergency Use Reports:
    - Emergency use reports of biohazardous agents or containment breaches.
8. General Project Information:
    - General project information provided to subjects or personnel (e.g., biosafety manuals, training requirements).

These documents and records shall be retained for at least three (3) years after the research is completed. The records shall be accessible for inspection and copying by authorized representatives of the NIH Office of Science Policy, the Centers for Disease Control (CDC), and other federal regulatory agencies at reasonable times and in a reasonable manner.

Annual Review and OSP Reports

IBC SOP 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 audit and review of facilities report assesses the overall biosafety at UMassD, ensures ongoing projects meet all regulatory requirements, and identifies areas of deficit and noncompliance.

Committee composition documentation is compiled by the Office of Institutional Ethics & Compliance and submitted to the National Institutes of Health, Office of Science & Policy. Annual reports must include a committee roster indicating the role and a biosketch of each member with a cover letter should indicate the information submitted is for the annual report.

Section 7: Appendices

Appendix A – Guide for Effective Safety

When determining the biosafety level and risk group classification, use the following considerations to help determine the appropriate classification and guide the implementation of effective safety measures:

1. **Characteristics:**
   - **Ease of Handling:** How easily can the agent be manipulated or cultured in laboratory settings?
   - **Severity of Disease and Symptoms:** How severe or harmful are the effects of the agent on humans, animals, or plants? What are the typical symptoms and signs of infection with the agent? What is the progression and outcome of infections caused by the agent?
   - **Host Specificity, Susceptibility, and Infectious Dose:** Does the agent have a narrow or broad range of hosts (e.g., specific to humans, animals, plants) and how susceptible are they to infection? What quantity of organisms is required to cause infection or disease?
   - **Environmental Stability:** How long does the agent remain viable in various environmental conditions? Can the agent persist in environmental reservoirs (e.g., soil, water) and contribute to ongoing transmission?
   - **Communicability and Route of Transmission:** How easily can the agent be transmitted from one individual to another? Through what means does the agent typically spread from one host to another (e.g., through direct contact, aerosols, ingestion, droplets, etc.)?
   - **Incidence and Prevalence:** How common are infections caused by the agent in the population? What are the rates of illness and death associated with infections caused by the agent? Is it capable of causing outbreaks or epidemics?
   - **Availability of Treatment:** Are vaccines, treatments, or preventive measures available to protect against infection or mitigate disease severity?
2. **Laboratory Operations:**
   - **Quantity and Availability:** How much of the agent is being handled, and how frequently?
   - **Type of Work:** What is the purpose of activities involving the agent (i.e.: diagnostic, research, clinical, or production-related)?
   - **Potential Hazards and Risks:** What are the potential hazards or risks associated with the agents and the procedures performed? What is the risk of accidental exposure or infection among laboratory personnel?
3. **Facility and Equipment:**
   - **Physical Containment:** Are there appropriate physical barriers and containment measures in place to prevent accidental exposure?
   - **Safety Equipment:** What safety equipment is necessary to protect personnel from exposure (e.g., personal protective equipment (PPE), biological safety cabinets)?
   - **Engineering Controls and Effectiveness:** Are there specialized engineering controls to minimize the risk of transmission or environmental release and how effective are these control measures in preventing transmission or reducing the impact of infections (e.g., vaccines, PPE, hygiene practices)?
4. **Emergency Response and Contingency Plans:**
   - **Emergency Procedures:** Are there established procedures for responding to accidents, spills, or exposures? Is there a clear communication plan in place to notify relevant personnel and authorities in the event of an emergency?
   - **Equipment Maintenance and Inspection:** Are emergency response equipment, such as spill kits, eyewash stations, and emergency showers, regularly inspected, maintained, and kept in working condition?
   - **Decontamination Protocols:** How are spills or contamination incidents addressed, and what decontamination procedures are in place?
5. **Personnel Training and Expertise:**
   - **Training Requirements:** What level of training and expertise do personnel need to safely handle the agent? Are laboratory personnel trained in emergency response procedures, and are regular drills conducted to ensure preparedness?
   - **Supervision and Oversight:** How experienced are the individuals working with the agent, and who is overseeing their activities?
6. **Additional Requirements:**
   - **Permitting and Licensing:** Are there specific permits or licenses required for working with certain agents?

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.

Table 1: Federal, State, and Local Regulations:

All individuals involved in the use of biohazardous materials at UMassD will follow the following regulatory guidelines:

Federal Regulations:

1. **Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH): Biosafety in Microbiological and Biomedical Laboratories (BMBL):** Guidelines for microbiological practices, safety equipment, and facilities constituting the four biosafety levels.
2. **The NIH Guidelines for Research Involving Recombinant DNA Molecules:** Provides guidelines for constructing and handling recombinant DNA molecules and organisms containing rDNA.
3. **Federal Select Agent Program (FSAP):** Managed jointly by the Centers for Disease Control and Prevention (CDC) and the Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture (USDA) it oversees the possession, use, and transfer of select agents and toxins.
4. **APHIS**: Regulates the import and export of plants, plant products, animals and animal-derived materials, and certain biological materials to prevent the spread of pests and diseases that could harm agriculture. Regulate the importation to ensure exotic animal and poultry diseases are not introduced into the United States. Generally, a USDA veterinary permit is needed for materials derived from animals or exposed to animal-source materials.
5. **Occupational Safety and Health Administration (OSHA): Bloodborne Pathogens Standard:** OSHA sets standards for workplace safety, encompassing the handling of biohazardous materials and the use of personal protective equipment. These standards cover occupational exposure to human blood and other potentially infectious materials, specifying controls and training to reduce infection risks. Personnel potentially exposed to such materials must be offered immunization against hepatitis B and receive annual training. Additionally, those working with HIV or hepatitis B in a research laboratory must undergo additional training and demonstrate proficiency in handling human pathogens.
6. **OSHA Hazard Communication:** Ensures that chemical hazards in the workplace are identified and communicated to workers through safety data sheets and labels.
7. **U.S. Department of Commerce (DOC):** The Bureau of Industry and Security (BIS) within the DOC administers and enforces the Export Administration Regulations (EAR). These regulations control the export, re-export, and transfer of certain commercial items, software, and technology, including biological materials that have dual-use applications.
8. **U.S. Department of State (DOS):** The Directorate of Defense Trade Controls (DDTC) within the DOS regulates the export of defense articles and defense services which includes certain biohazardous materials that have military or defense applications.
9. **U.S. Food and Drug Administration (FDA):** The FDA regulates certain materials with hazards, including human and animal specimens, blood, tissues, and cells, to ensure compliance with safety and quality standards. 21 CFR Part 1271 - e-CFR: Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps); 21 CFR Part 607 - e-CFR: Establishment Registration and Blood Product Listing for Manufacturers of Human Blood and Blood Products; 21 CFR Part 507 - Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals;
10. **U.S. Department of Transportation and International Air Transportation Authority:** Regulations for Shipment and Transportation of Hazardous Materials, including biological agents. Chapter 11 provides information on shipping regulations.
11. **CDC: Interstate Shipment of Etiologic Agents.** Regulations for Importation or Transportation of Etiologic Agents, which include a permit application that must be submitted and approved prior to any such importations.

State and Local Regulations:

1. **Massachusetts Department of Public Health:** Regulates storage, handling, disposal, labeling, and record-keeping of infectious materials. The MADPH regulates the management of biological wastes in the state (105 CMR 480) and also inspects BSL3 laboratory spaces on a regular basis.
2. **Massachusetts Department of Environmental Protection (MassDEP):** Tasked with ensuring the cleanup of oil and hazardous material releases and with protecting health, safety, public welfare, and the environment from oil and/or hazardous material releases.
3. **Dartmouth Board of Health:** Tasked with the protection of the community from environmental hazards, prevent the spread of disease, to assure safe water, a safe and healthy food supply, clean air, and acceptable housing.

Other Relevant Policies and Guidelines:

UMassD Environmental Health and Safety Office Policies and Procedures
All other relevant policies of the University of Massachusetts.

Table 2. Materials and Activities Requiring Additional Permits or Approvals

Certain biological materials and activities require federal, state, or local permits to ensure compliance with regulatory standards. Before initiating any research that involves these materials or activities, researchers must obtain the necessary approvals and register the materials with the IBC. Copies of all required permits must accompany the registration. The following list details the key federal and state permits that may be required:

Federal Permits Requiring the Institutional Official's Signature

The Institutional Official (IO) or their designee must sign federal permits in the following areas:

a. Animal and Plant Health Inspection Service (APHIS) Permits

APHIS, a division of the USDA, issues permits for the import, export, interstate movement, and environmental release of regulated biological materials, including genetically modified organisms (GMOs) and biological agents affecting agriculture. Research involving transgenic plants, animals, or microorganisms that impact agriculture may require an APHIS permit. Field trials involving GMOs require a permit from APHIS. Research involving genetically modified organisms, particularly transgenic plants, must comply with USDA guidelines, particularly when the plants are designed for pharmaceutical or industrial applications ("bio-pharming"). The IO must sign these permits for field testing. Specific guidelines can be found in the USDA's "Field Testing of Plants Engineered to Produce Pharmaceutical and Industrial Compounds" (7 CFR Part 340). More information is available on the APHIS Regulated Organism and Soli Permits website.

b. Centers for Disease Control and Prevention (CDC), Permits

The CDC regulates the importation of infectious biological materials that could cause disease in humans. The CDC Import Permit Program (IPP) ensures these agents are monitored to prevent their introduction and spread into the U.S. Facilities receiving these permits must demonstrate appropriate biosafety measures to work safely with imported agents. The program applies to a wide range of materials, including pathogens, biological toxins, and diagnostic specimens that could present a risk to public health. More information is available on the CDC Import Permit Program (IPP) website.

c. Food and Drug Administration (FDA)Permits

The FDA regulates research involving investigational new drugs (INDs), biologics, or medical devices. Research involving human drugs, biological materials, or food-related studies may require FDA approval or notification.
Visit the FDA website for more details.

d. Environmental Protection Agency (EPA) Permits

The Environmental Protection Agency (EPA) oversees permits related to environmental safety, including those involving GMOs or the use of biological materials that may impact the environment. Research that potentially releases biological materials into the environment requires EPA approval. More Information is available on the EPA Permit Programs website.

e. American Type Culture Collection (ATCC)

Researchers ordering biological materials from the American Type Culture Collection (ATCC) may be required to complete a new account application, which typically needs the signature of the Institutional Official (IO) or Biological Safety Officer (BSO). For more information, visit the ATCC website.

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
*Approval required before initiation. ** Notify IBC at project initiation, approval still required.

Level	Approval/Review Required	Experiments Covered
III-A	**Experiments that Require IBC Approval, and NIH Director Approval Before Initiation***	1. Major Actions under the NIH Guidelines (see Section IV-C-1-b-(1)). 1a. Deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally, if such acquisition could compromise the ability to control disease agents in humans, veterinary medicine or agriculture.
III-B	**Experiments that Require NIH OSP and IBC Approval Before Initiation***	1. Involves the Cloning of Toxin Molecules with LD50 of Less than 100 Nanograms Per Kilogram Body Weight. 2. Experiments Approved (under Section III-A-1-a) as Major Actions.
III-C	**Experiments Involving Human Gene Transfer Require NIH OSP, IRB, and IBC Approval Before Initiation ***	Proposals involving the deliberate transfer of rDNA, or DNA or RNA derived from rDNA, into human subjects (human gene transfer).
III-D	**Experiments that Require IBC Approval Before Initiation***	1. Use of Risk Group 2, Risk Group 3, Risk Group 4, or Restricted Agents as Host-Vector Systems. 2. Involves DNA from Risk Group 2/3/4, or Agents Cloned into Nonpathogenic Prokaryotic/Lower Eukaryotic Host-Vector Systems. 3. Involves Infectious DNA/RNA Viruses or Defective DNA/RNA Viruses in the Presence of Helper Virus in Tissue Culture Systems. 4. Involves Whole Animals. 5. Involves Whole Plants. 6. Involves More than 10 Liters of Culture. 7. Involves Influenza Viruses. 8. Involves Gene Drive Modified Organisms.
III-E	**Experiments that require IBC Notification at project initiation and require IBC Approval ****	1. Formation of rDNA Molecules or Synthetic Nucleic Acid Molecules with No More than Two-Thirds of the Genome of any Eukaryotic Virus. 2. Involves Whole Plants (see NIH guidelines for experiments that fall under category D vs E) 3. Involves Transgenic Rodents

III-F	Exempt Experiments that require IBC Notification at project initiation and require IBC Approval **
Sec III-F-1	Involve synthetic nucleic acids that: (1) can neither replicate nor generate nucleic acids that can replicate in any living cell (e.g. oligonucleotides or other synthetic nucleic acids that do not contain an origin of replication or contain elements known to interact with either DNA or RNA polymerase), and (2) are not designed to integrate into DNA, and (3) do not produce a toxin that is lethal for vertebrates at an LD50 of less than 100 nanograms per kilogram body weight. If a synthetic nucleic acid is deliberately transferred into one or more human research participants and meets the criteria of Section III-C, it is not exempt under this Section.
Sec III-F-2	Involve organisms, cells, or viruses and that have not been modified or manipulated (e.g., encapsulated into synthetic or natural vehicles) to render them capable of penetrating cellular membranes.
Sec III-F-3	Consist solely of the exact recombinant or synthetic nucleic acid sequence from a single source that exists contemporaneously in nature.
Sec III-F-4	Consist entirely of nucleic acids from a prokaryotic host including its indigenous plasmids or viruses when propagated only in that host (or a closely related strain or the same species), or when transferred to another host by well-established physiological means.
Sec III-F-5	Consist entirely of nucleic acids from a eukaryotic host including its chloroplasts, mitochondria, or plasmids (but excluding viruses) when propagated only in that host (or a closely related strain of the same species.
Sec III-F-6	Consist entirely of DNA segments from different species that exchange DNA by known physiological processes, though one or more of these segments may be synthetic equivalent.
Sec III-F-7	Involve genomic DNA molecules that have acquired a transposable element, provided the transposable element does not contain any recombinant and/or synthetic DNA.
Sec III-F-8	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, following appropriate notice and opportunity for public comment.
Appendix C	C-I: Molecules in Tissue Cultures C-II: E. coli K-12 Host-Nucleic Acid Vector Systems C-III: Saccharomyces Host-Vector Systems C-IV: Kluyveromyces Host-Vector Systems C-V: Bacillus subtilis or Bacillus Licheniformis Host-Vector Systems C-VI: Extrachromosomal Elements of Gram-Positive Organisms C-VII: The Purchase or Transfer of Transgenic Rodents C-VIII: Generation of BL1 Transgenic Rodents via Breeding

All Other Biohazardous Materials: Experiments that Require IBC Approval Before Initiation*