# UNIVERSITY OF MAINEPOLICIES AND PROCEDURES FOR RESEARCHINVOLVING RECOMBINANT OR SYNTHETIC NUCLEIC ACID MOLECULES OR INFECTIOUS AGENTS

University of Maine
Office of the Vice President for Research and Dean of the Graduate School

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## ****Preamble****

The University of Maine acknowledges and accepts responsibility for ensuring that research using recombinant or synthetic nucleic acid molecules (including plants), biological materials/biospecimens (human and animal blood, bodily fluids, and/or tissues), infectious agents[[1]](#footnote-1) or select agents/toxins is carried out in a safe and responsible manner. For the purpose of this Policy, the term “biohazard” refers to all of the preceding.

The University of Maine accepts and incorporates into the policy the Department of Health and Human Services, National Institutes of Health (NIH), [*Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (PDF)](https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf) (NIH Guidelines) and amendments thereafter, and applicable government regulations.

## Responsibilities of the University of Maine

### Establish, implement, and maintain policies that provide for the safe conduct of research involving biohazards, and that ensure compliance with all applicable guidelines, in particular state and federal guidelines. The University may also establish whatever additional precautionary steps it deems appropriate.

### Maintain an Institutional Biosafety Committee (IBC) that meets the requirements set forth in Section III of this Policy.

### Appoint a Biosafety Officer (BSO) who shall be a member of the IBC and carry out the duties specified in Section VI of this Policy.

### Appoint an Authorized Institutional Official (AIO) who shall carry out the duties specified in Section VII of this Policy.

### Ensure that investigators responsible for research covered by this Policy comply with the provisions of Section IV of this Policy and assist them in doing so.

### Ensure appropriate training for the IBC Chair and members, the BSO, Principal Investigators (PI), and laboratory staff regarding this Policy, its implementation, and laboratory safety. Responsibility for training IBC members is carried out through the IBC Chair. Responsibility for training laboratory staff is carried out through the PI. The University of Maine is responsible for seeing that the PI has sufficient training.

### Review and approve all Biosafety Level 3 (BSL-3) research proposals and work with the BSO to ensure users have proper proficiency and training, including a minimum of 10-15 hours of observation time by the BSO or an approved authority before approving trainees to work independently. (Note: Work with agents or materials at BSL-3 requires registration, institutional approvals, and training beyond that required for other research at UMaine as set forth by state and federal regulations, Centers for Disease Control and Prevention [CDC]/NIH Guidelines, and UMaine policy.)

## The Institutional Biosafety Committee (IBC)

### Responsibilities and Authority of the IBC

#### Provide review and approval, require modifications in, or withhold approval of new protocols or significant changes in previously approved protocols of research utilizing biohazards under NIH Guidelines.This review shall include:

##### Assessing independently, the containment levels required for the proposed research.

##### Judging whether the Principal Investigator has sufficient training to provide for the safe conduct of the proposed research.

##### Assessing the adequacy of facilities, procedures, and practices.

##### Notifying the Principal Investigator of the results of their review.

##### Protocols receiving IBC approval may be subject to further administrative review by the AIO or by another officer of the University appointed to that purpose by the President. This review may result in limitations and restrictions on the use of biohazards beyond that required by the IBC. In extreme cases, approval for the use of biohazards may be denied or revoked. Under no circumstances can the administration approve a project not approved by the IBC or ease any restrictions imposed by the IBC.

#### Review annually research approved by or reported to the Committee involving the use of biohazards, and report to the AIO any instances in which the requirements of this Policy are not being fulfilled.

#### Determine for each project, in conjunction with the University healthcare providers, the necessity for a health surveillance program for research personnel and notify the AIO if such a health surveillance program is needed.

#### Ensure Principal Investigators establish written emergency plans, in concert with existing institutional emergency planning, covering accidental spills and/or personnel contamination resulting from research with biohazards. Emergency plans will be maintained in the lab, made available to all personnel, incorporated as part of the laboratory training, and made available to the BSO upon laboratory inspection.

#### Report suspensions of research activity, significant problems with or violations of this Policy, and any significant research-related accidents or illnesses to the AIO immediately.

#### Review suspensions of research activity ordered by the BSO and determine whether the activity shall:

##### proceed without changes; or

##### proceed only with changes; or

##### terminate.

#### Perform additional functions as may be assigned to the IBC.

### Membership of the IBC

#### The IBC shall recommend to the AIO, and the President of the University (or designee) shall appoint, members of the IBC to three-year terms. Members may be reappointed to further terms. The President (or designee) may also appoint alternates when desirable. Such alternates shall have the same voting privileges as the member for whom they substitute.

#### The President (or designee) shall appoint one member of the IBC to serve as Chair for a term of two years; the member may be reappointed to additional terms. The Chair shall normally be a member of the University’s tenured faculty who engages in research with biohazards and who has substantial experience in the review of research with biohazards.

#### The IBC shall comprise no fewer than five members, so selected that they collectively have sufficient experience, expertise, and technical capability to assess the safety of research experiments involving the biohazards and to identify any potential risk to public health or the environment. The IBC shall include:

##### At least two members who are not affiliated with the University (apart from their membership on the IBC) shall represent the interest of the surrounding community with respect to health and protection of the environment. Members meet this requirement if, for example, they are academic experts from other institutions, officials of State or local public health or environmental protection agencies, members of other local governmental bodies, or persons active in medical, occupational health, or environmental concerns in the community.

##### The BSO of the University. The BSO will be an ex-officio member with voting rights.

##### Persons with expertise in the technology, biological safety, and physical containment of biohazards, in order to ensure the competence necessary to review research activities involving biohazards.

##### The IBC may require the inclusion of experts on an ad hoc basis (e.g., plant, plant pathogen, or plant pest containment expert, animal containment expert) when University has research using biohazards involving plants or animals requiring IBC approval.

##### An individual who meets the requirements of more than one of these categories may fulfill more than one requirement. However, the IBC may not consist of fewer than five members.

##### In addition, the AIO, to whom this committee reports, shall be available as a consultant in matters concerning institutional commitments, policies, applicable law, standards of professional conduct and practice, community attitudes, and the environment.

#### No member of an IBC may be involved (except to provide information requested by the IBC) in the review or approval of a project in which he or she has been or expects to be engaged or has a direct financial interest.

## Responsibilities of the Principal Investigator (PI)

On behalf of the University of Maine, the Principal Investigator (PI) is responsible for complying fully with this Policy and the NIH Guidelines in the conduct of research involving biohazards.

For the purposes of this policy, the definition of PI is to include PIs, lab managers, research supervisors, instructors, or any individuals responsible for work to be conducted.

### General Responsibilities of the PI

#### a) Abstain from initiation or modification of research or other scholarly activity involving biohazards (herein referred to as “research”) until that research or the proposed modification has been approved by the IBC and all other requirements of this Policy have been met;b) Ensure that reporting requirements are fulfilled and is accountable for any reporting lapses.

#### Determine whether experiments involving biohazards are covered by Section III-E of the NIH Guidelines, Experiments that Require IBC Notice Simultaneous with Initiation and follow the appropriate procedures.

#### Report immediately any significant problems, violations of the NIH Guidelines, or any significant research-related accidents and illnesses to the Biosafety Officer and the IBC Chair. Faculty, staff, and students are encouraged to report ‘near misses’ in support of continuous improvement of the program.

##### Report laboratory acquired infections (LAIs) to University of Maine System (UMS) Risk Management (RM) through the appropriate incident reporting software.

#### Report to the IBC new information bearing on this Policy.

#### Be adequately trained in good microbiological techniques and laboratory safety.

#### Adhere to approved emergency plans for dealing with accidental spills and personnel contamination (this includes having appropriate spill kit materials on hand); and

#### Comply with shipping and permitting requirements for biohazards. (See Appendix H of the NIH Guidelines.)

### Responsibilities of the PI to the IBC

#### Make the initial determination of the required levels of physical and biological containment in accordance with this Policy.

#### Select appropriate microbiological practices and laboratory techniques to be used in the research.

#### Submit an initial IBC registration form to provide a basic summary of all biological work (including Biosafety Level 1 [BSL-1] or higher, DNA [deoxyribonucleic acid], and/or infectious agents).

#### Submit, if needed (depending on work, including Biosafety Level 2 [BSL-2] or higher, recombinant DNA, and/or as directed by BSO), a protocol form to the IBC for review and approval or disapproval prior to initiating the research. Do not initiate research for the protocol prior to receiving IBC approval.

#### Remain in communication with the IBC about any changes throughout the conduct of the research:

##### Submit promptly any changes to an existing registration (e.g., changes in personnel or location). Important note: if changes to scope of research on a registration form could newly qualify the work to require a protocol submission and IBC approval, please do not initiate the amended research prior to determining the need for a protocol submission and, if applicable, gaining IBC approval.

##### Submit a protocol amendment for proposed changes to existing protocols (e.g., changes in the source of or synthetic nucleic acid or host-vector system) to the IBC for review and approval or disapproval. Do not initiate amendments to protocols prior to receiving IBC approval.

#### Submit annually to the IBC an updated registration form, and protocol amendments as appropriate, to indicate whether:

##### Research is occurring as-is with no modification

##### Research has been amended or modified (e.g., personnel transition or location change)

##### Research has been suspended or terminated

##### Research has ended

##### If a PI does not submit an updated registration form as requested on an annual basis, research may be suspended.

#### Submit a renewal for each protocol to the IBC every three years if work is to continue. Do not continue work for an existing protocol beyond three years from its last approval date until the IBC approves the renewal.

### Responsibilities of the PI Prior to Initiating Research or Laboratory Teaching Activities Involving Biohazardous Materials

#### Be adequately trained in good microbiological techniques and laboratory safety to provide for the safe conduct of the proposed research.

#### Make available to the laboratory staff the protocols that describe the potential biohazards and the precautions to be taken.

#### Instruct and train staff in the practices and techniques required to ensure safety and in the procedures for dealing with accidents and maintain copies of training records (it is recommended that training records be signed by both parties).

#### Inform the staff of the reasons and provisions for any precautionary medical practices advised or requested, such as vaccinations or serum collection.

### Responsibilities of the PI During the Conduct of the Research

#### Supervise the safety performance of the staff to ensure that the required safety practices and techniques are employed.

#### Investigate and report in writing to the IBC and BSO any significant problems pertaining to the operation and implementation of containment practices and procedures.

#### Correct work errors and conditions that may result in the release of biohazards.

#### Ensure the integrity of the physical containment (e.g., biological safety cabinets) and the biological containment (e.g., purity and genotypic and phenotypic characteristics).

### Responsibilities of a PI Leaving the University

#### Notify ORC and BSO to initiate registration/protocol transfer or closure.

#### Work with BSO and UMS Risk and Safety Management (RSM) to decommission lab (dispose of materials and decontaminate as needed).

## Responsibilities of the Department Chair or Unit Director

The chair of any department or director of any unit in which research using biohazards is conducted shall be familiar with this policy and shall exercise the following responsibilities:

### Assure compliance with this policy.

### Provide appropriate resources to adequately support infrastructure, equipment, and staffing needs.

### Assure proper management of the laboratory facilities and allow only those research projects to be conducted for which the facilities are adequate and safe.

### Assure proper supervision of research personnel.

### Nominate, at the request of the AIO (from among members of the department or unit), representatives to serve on the IBC.

## ****Responsibilities of the Biosafety Officer (BSO)****

### Ensure through periodic inspections that laboratory standards are rigorously followed.

### Suspend any research activity if he/she determines that the activity is not being conducted in a safe and responsible manner.

### Report to the IBC Chair significant problems with and violations of this Policy and any significant research-related accidents and illnesses of which the BSO becomes aware unless the BSO determines that report has already been filed by the PI.

### Develop emergency plans for dealing with accidental spills and personnel contamination and investigating research laboratory accidents involving biohazards.

### Provide technical advice on laboratory security and safety.

### Provide technical advice to PI and IBC on research safety procedures.

### Liaise with University System or UMaine occupational safety representation on non-biosafety related concerns.

### Encourage PIs to report LAIs to RM through the appropriate incident reporting software. Follow up with RM as necessary and as requested by the IBC Chair.

### Liaise with local emergency responders to include technical hazardous material responders (i.e., Orono Fire Department) and UMS Risk and Safety Management staff, as needed.

## ****Responsibilities of the Authorized Institutional Official (AIO)****

### Provide administrative oversight and serve as the institutional representative responsible for reporting to the National Institutes of Health and other cognizant federal agencies.

### Report within 30 days to the National Institutes of Health Office of Biotechnology Activities any significant problems with and violations of the NIH Guidelines and significant research-related accidents and illnesses.

### Take appropriate, corrective action to remedy reported safety problems or Policy violations and report that action to the IBC.

### Forward the names of individuals to be appointed to the IBC by the President (or designee). In addition, the AIO forwards the name of one member to be appointed by the President (or designee) to serve as Chair for a term of two years.

### Maintain official files of the IBC.

### Make available to the public, upon request, all minutes of IBC meetings and any documents submitted to or received from funding agencies which the latter are required to make available to the public. If comments are made by members of the public on IBC actions, the University shall forward to NIH both the comments and the IBCs response.

## Required Training

All personnel who work with biohazards are required to complete biosafety/biosecurity training through the university’s Collaborative Institutional Training Initiative (CITI) subscription. Some research may involve additional hazards requiring additional training(s) (e.g., respiratory training for research involving a respirator, etc.). Note: Significant in-person training, including a minimum of 10-15 hours of observation by the BSO or an approved authority, is required for personnel who will be involved in BSL-3 research. A BSL-3 Biosafety Manual describing all procedures that must be followed by researchers in the BSL-3 facility is made available during training.

## Export Control Regulations

Some biohazards are also controlled by U.S. Export Control regulations (ECR). 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. ([See the Office of Research Compliance Export Control Regulations Overview](https://umaine.edu/research-compliance/export-control/overview-export-control/).)

## Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential

Dual use research of concern (DURC) and pathogens with enhanced pandemic potential (PEPP) are types of life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops, and other plants, animals, the environment, material, or national security.

Investigators at the University of Maine wishing to conduct or sponsor life sciences research that involves one or more of the agents or toxins listed, and produces, aims to produce, or is reasonably anticipated to produce one or more of the effects listed in the “categories of experiments” below are required to contact the IBC. The research will be evaluated by the IBC for DURC and/or PEPP.

Life sciences research that raises dual use concerns will be reviewed by the IBC, acting as the Institutional Review Entity, in accordance with the *United States Government Policy (USG) for Oversight of Life Sciences Dual Use Research of Concern and Pathogens with Pandemic Potential (*[*USG Policy [PDF]*](https://www.bidenwhitehouse.gov/wp-content/uploads/2024/05/USG-Policy-for-Oversight-of-DURC-and-PEPP.pdf)*).* The IBC will maintain records of DURC reviews and risk mitigation plans in accordance with USG Policy.

### **Agents and toxins**

The 15 agents and toxins listed below and in the USG Policy are subject to the select agent regulations (Code of Federal Regulations [CFR] 42 CFR Part 73, 7 CFR Part 331, and 9 CFR Part 121), which set forth the requirements for possession, use, and transfer of select agents and toxins, and have the potential to pose a severe threat to human, animal, or plant health, or to animal or plant products. It is important to note, however, that the Federal Select Agent Program does not oversee the implementation of the USG Policy or the March 2012 DURC Policy. Please also note that the below list of agents and toxins may not be comprehensive, as it is subject to updates by USG; consult the current USG Policy for the most up to date list.

1. Avian influenza virus (highly pathogenic)
2. *Bacillus anthracis*
3. Botulinum neurotoxin (For the purposes of the USG Policy, there are no exempt quantities of botulinum neurotoxin. Research involving any quantity of botulinum neurotoxin should be evaluated for DURC potential.)
4. *Burkholderia mallei*
5. *Burkholderia pseudomallei*
6. Ebola virus
7. Foot-and-mouth disease virus
8. *Francisella tularensis*
9. Marburg virus
10. Reconstructed 1918 Influenza virus
11. Rinderpest virus
12. Toxin-producing strains of *Clostridium botulinum*
13. Variola major virus
14. Variola minor virus
15. *Yersinia pestis*

### **Categories of experiments**

1. Enhances the harmful consequences of the agent or toxin
2. Disrupts immunity or the effectiveness of an immunization against the agent or toxin without clinical and/or agricultural justification
3. Confers to the agent or toxin resistance to clinically and/or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitates their ability to evade detection methodologies
4. Increases the stability, transmissibility, or the ability to disseminate the agent or toxin
5. Alters the host range or tropism of the agent or toxin
6. Enhances the susceptibility of a host population to the agent or toxin
7. Generates or reconstitutes an eradicated or extinct agent or toxin listed above

## Select Agents & Toxins

Planned work with Select Agents or Toxins, *even if not potentially DURC and/or PEPP*, (as described in Section X), should be discussed with the IBC as it requires registration with the CDC under the Federal Select Agent Program. A list of Select Agents and Toxins can be found on the [Federal Select Agent Program website](https://www.selectagents.gov/sat/list.htm).

## Resources

### Department of Health and Human Services, National Institutes of Health, [*Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (PDF)*](https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf)

### [University of Maine, Office of Research Compliance, Export Control Regulations Overview](https://umaine.edu/research-compliance/export-control/overview-export-control/)

### [The United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential (PDF)](https://www.bidenwhitehouse.gov/wp-content/uploads/2024/05/USG-Policy-for-Oversight-of-DURC-and-PEPP.pdf)

### [Federal Select Agent Program](https://www.selectagents.gov/)

## Definitions

### **Registration**

* Brief form to be completed by each PI working with biological materials, which includes basic information about the PI and their research or teaching.
	+ All researchers conducting work with biological materials of any kind (including BSL-1 or higher, DNA, and/or infectious agents) must complete.
	+ Each registration form is associated with an individual PI (thus two PIs working in the same lab would each need their own registration form).
* Changes to registration information (e.g., lab location or personnel) should be submitted promptly.
* Registration forms must be updated on an annual basis (to include changes, or to indicate no changes).

### **Protocol**

* Detailed form about specific research or teaching project that meets the criteria to necessitate IBC approval.
	+ All research that involves BSL-2 or higher, recombinant DNA, and/or has been requested by the BSO must be submitted as a protocol and approved by the IBC prior to initiating research.
	+ Protocols are for research projects, not PIs, thus a single protocol may have co-PIs, or a single PI could have multiple protocols, etc.
* Proposed changes to a protocol must be submitted and approved by the IBC prior to initiating amended research.
* All protocols must be submitted for reapproval every three years if their work is to continue (regardless of if amendments have been made or not).
1. The University of Maine has defined "infectious agents" as all bacterial, parasitic, fungal, viral, and prion, included within Class 2 or higher classes. (See Appendix B of [NIH Guidelines [PDF](https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf)].) [↑](#footnote-ref-1)