UMass | Dartmouth
Institutional Biosafety Committee (IBC)

For Internal IBC Use
IBC Registration #: _____
Biosafety Level: _____
Risk Group: _____
Action: _____

IBC Registration Form for Use of Biohazardous Materials

UMass Dartmouth (UMassD) requires all educational use and research of biohazardous materials (recombinant DNA or Synthetic Nucleic Acid Molecules, Infectious or Pathogenic Agents (Viral, Bacterial, Fungal, Parasitic, and Prions), Vectors, Biological Toxins, Allergens, and/or Human/ Animal Tissues) conducted at or supported by UMassD be registered and approved by the Institutional Biosafety Committee (IBC) prior to initial use.

Instructions:

1. For guidance, consult the NIH Guidelines for Research Involving Recombinant DNA or Synthetic Nucleic Acid Molecules, Biosafety in Microbiological and Biomedical Laboratories, 6th Edition, CDC Diseases and Conditions Page, American Biological Safety Association Risk Group Database, and American Type Culture Collection Website for information needed to complete this form. Please provide complete information for every item; blank/incomplete items may delay the processing.
2. For more information and to submit completed forms, please email Stephanie Peña at ibc.research@umassd.edu.

Part A – Basic Information:

Principal Investigator:		**Academic Title:**	
Department:		**E-mail:**	
Building:		**Office Phone #:**	
Office Room#:		**Lab Phone #:**	
Laboratory Location(s): (*if multiple components, list all locations*)**:**			

1. Type of Registration: *(see Appendix A for definitions)* ☐ **Single Project** ☐ **Multiple Projects**

2. Project Title(s): *(if multi-project, include umbrella title, then list titles of each project and assign a number to each)*

_____
_____
_____

3. Sponsor(s): *(specify source and grant number)*

_____
_____

4. Principal Investigator Assurance:

☐ I attest that the information provided is accurate and complete to the best of my knowledge. I agree to submit an amendment if there are changes that alter the approved registration or a new registration to the IBC if there are changes that alter the Biosafety levels, or introduce new rDNA, or biohazardous materials for any proposed research.

☐ I have reviewed the *NIH Guidelines for Research Involving Recombinant DNA Molecules* and the *Biosafety in Microbiological and Biomedical Laboratories, 6th Edition,* agree to abide by the requirements of the current NIH Guidelines, CDC, USDA, or APHIS Biocontainment or Biosecurity Guidelines, and all Federal, State and Local regulations pertaining to the proposed research, shipment, and transfer of biohazardous materials.

☐ I agree to conduct these experiments in accordance with all *UMassD IBC Standard Operating Procedures (SOPs)* and relevant policies and use the corresponding Biosafety Level containment practices with all registration work.

☐ I have the knowledge and training required to safely handle the materials described. I understand that I bear the responsibility for ensuring that all personnel and possible co-occupants are adequately trained and informed of any risks with the research activity. I have or will have appropriately trained and advised my staff and possible co-occupants of the requirements outlined in the NIH Guidelines and/or CDC requirements prior to initiation of the project.

☐ I understand the risks associated with use of biological hazard materials (human pathogens, human blood, body fluids or tissues, animal pathogens, blood, body fluids or tissues, plant pathogens), and imported biological materials. I acknowledge my responsibility to secure and control the biological agents used in this project. Entry doors to the laboratory will be closed and locked when the laboratory is unattended.

☐ I agree to treat and render non-infectious, all potentially infectious materials using an IBC-approved method prior to disposal.

☐ I agree to provide written reports and to notify the IBC immediately should related activity produce an unanticipated product that increases virulence or toxicity, or otherwise confers a phenotypic change that could be biologically hazardous. I agree to comply with all reporting requirements:

- Reporting of all personnel exposures of regulated biological material, any accident or illness as the result of inoculation, ingestion, and inhalation of biohazardous materials or recombinant DNA; any incident causing serious exposure of personnel or danger of environmental contamination.
- Reporting any transgenic/knockout/knock-in/ biological material release/escape. Transport/transfer of for import/export of biological commodities. Any problems pertaining to operation and implementation of biological and physical containment safety procedures or equipment or facility failure.

_____ _____
Signature of Principal Investigator **Date**

_____ _____
Signature of Co-Investigator **Date**

Part B – Classifications/Confirmations:

B. 1 Level of Oversight Category: *Select the highest level of oversight required per the NIH Guidelines.*

☐ **Section III-A: Experiments that Require IBC Approval, RAC Review, 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 it could compromise use of the drug to control disease agents in humans, veterinary medicine or agriculture.

☐ **Section 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.

☐ **Section III-C: Experiments Involving Human Gene Transfer.**

☐ **Section III-D: Experiments that Require IBC Approval.**

☐ **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.

☐ **Section III-E: Experiments that Require IBC Notification.**

☐ **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

☐ **4.** Other:_____

☐ **Section III-F: Exempt Experiments.**

☐ **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.

☐ **2.** Involve recombinant or synthetic nucleic acid molecules that are not in 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.

☐ **3.** Involve recombinant or synthetic nucleic acid molecules that consist solely of the exact recombinant or synthetic nucleic acid sequence from a single source that exists contemporaneously in nature.

☐ **4.** Involve rDNA molecules that 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 of the same species), or when transferred to another host by well-established physiological means.

☐ **5.** Involve rDNA molecules that 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).

☐ **6.** Involve rDNA molecules that consist entirely of DNA segments from different species that exchange DNA by known physiological processes, though one or more of the segments may be a synthetic equivalent. A list of such exchangers will be prepared and periodically revised by the NIH Director with advice of the RAC after appropriate notice and opportunity for public comment (see Section IV-C-1-b-(1)-(c), Major Actions). See Appendices A-I through A-VI, Exemptions under Section III-F-6- Sublists of Natural Exchangers, for a list of natural exchangers that are exempt from the NIH Guidelines.

☐ **7.** Involve genomic DNA molecules that have acquired a transposable element, provided the transposable element does not contain any recombinant and/or synthetic DNA.

☐ **8.** Involve recombinant or synthetic nucleic acid molecules that do not present a significant risk to health or the environment (see Section IV-C-1-b-(1)-(c), Major Actions), as determined by the NIH Director, with the advice of the RAC, and following appropriate notice and opportunity for public comment. For other classes of experiments which are exempt from the NIH Guidelines, See **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

☐ **Section UMassD: All Other Biohazardous Materials:**

_____

B.2 Exempt Confirmations: *If the answer to any of the following is **Yes**, then this registration **requires Committee Review.***

1. Do any procedures involve viral DNA constructs that represents more than 2/3 of any eukaryotic viral genome?
   ☐ No. ☐ Yes. This registration requires Committee Review.

2. Do any procedures involve viral constructs from DNA of Risk Group 3, 4, or restricted agents?
   ☐ No. ☐ Yes. This registration requires Committee Review.

3. Do any procedures involve the deliberate transfer of rDNA into one or more human subjects?
   ☐ No. ☐ Yes. This registration requires Committee Review.

4. Do any procedures involve generation of transgenic animals or plants?
   ☐ No. ☐ Yes. This registration requires Committee Review.

5. Do any procedures involve the generation of toxin molecules lethal for vertebrates at an LD50 of less than 100 ng per kilogram body weight?
   ☐ No. ☐ Yes. This registration requires Committee Review.

6. Do any procedures involve the generation of more than 10 liters of culture?
   ☐ No. ☐ Yes. This registration requires Committee Review.

7. Do any procedures involve the deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally and if so, could this acquisition compromise the use of the drug to control disease agents in hu-mans, animals, and/or plants?
   ☐ No. ☐ Yes. This registration requires Committee Review.

B.3 Dual Use Research Concern: Dual Use Research of Concern (DURC) is defined as: life sciences research that 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.

*If the answer to any of the following is **Yes**, then this registration requires **Committee Review**.*

1. Do any procedures demonstrate how to render a vaccine ineffective?
   ☐ No. ☐ Yes. This registration requires Committee Review.

2. Do any procedures render a pathogen (≥ risk group 2) resistant to antibiotics or antivirals?
   ☐ No. ☐ Yes. This registration requires Committee Review.

3. Do any procedures enhance a pathogen's virulence or render a non-pathogen virulent?
   ☐ No. ☐ Yes. This registration requires Committee Review.

4. Do any procedures increase a replication competent pathogen's transmissibility?
   ☐ No. ☐ Yes. This registration requires Committee Review.

5. Do any procedures alter a replication competent pathogen's host range?
   ☐ No. ☐ Yes. This registration requires Committee Review.

6. Do any procedures enable a pathogen to evade diagnostic tests?
   ☐ No. ☐ Yes. This registration requires Committee Review.

7. Do any procedures enable weaponization of pathogens and toxins?
   ☐ No. ☐ Yes. This registration requires Committee Review.

Part C – Material Information:

C.1 Biohazardous Material(s): *Identify all biohazardous materials by name (attach all material safety data sheets and maps).*

Select Agent/Organism:	Select Biosafety Level.	Select Risk Level.
☐ E. coli. K-12	☐ BSL-1 ☐ BSL-2	☐ RG1 ☐ RG2 ☐ RG3 ☐ RG4
☐ Other Bacteria:	☐ BSL-1 ☐ BSL-2	☐ RG1 ☐ RG2 ☐ RG3 ☐ RG4
☐ Virus:	☐ BSL-1 ☐ BSL-2	☐ RG1 ☐ RG2 ☐ RG3 ☐ RG4
☐ Fungi/Yeast/YAC:	☐ BSL-1 ☐ BSL-2	☐ RG1 ☐ RG2 ☐ RG3 ☐ RG4
☐ Parasite:	☐ BSL-1 ☐ BSL-2	☐ RG1 ☐ RG2 ☐ RG3 ☐ RG4
☐ Toxin:	☐ BSL-1 ☐ BSL-2	☐ RG1 ☐ RG2 ☐ RG3 ☐ RG4
☐ Prion:	☐ BSL-1 ☐ BSL-2	☐ RG1 ☐ RG2 ☐ RG3 ☐ RG4
☐ Plant:	☐ BSL-1 ☐ BSL-2	☐ RG1 ☐ RG2 ☐ RG3 ☐ RG4
☐ Other:	☐ BSL-1 ☐ BSL-2	☐ RG1 ☐ RG2 ☐ RG3 ☐ RG4

☐ **Human Subject/Tissue/Cell Use:** IRB Protocol #: _____ Approval Date: _____
** Must attach IBC Appendix for Human Subject Use*

☐ **Lab Animal/Tissue/Cell Use:** IACUC Protocol #: _____ Approval Date: _____
** Must attach IBC Appendix for Animal Use*

C.2 Source/Origin of Material(s): *Identify where will biological materials be procured from (attach documentation).*

Company: _____
Collaborator: _____
Other:

C.3 Select Study Characteristic(s):

	Impacts Biosafety Level? If yes, elaborate under Materials/Methods.
☐ Vector(s):	☐ Yes ☐ No
Identify: ☐ **Bacterial** ☐ **Adeno** ☐ **Retro** ☐ **Lenti** ☐ **Pox** ☐ **Herpes** ☐ **Other:**	
☐ Cell line:	☐ Yes ☐ No
☐ rDNA/synthetic nucleic acids:	☐ Yes ☐ No
☐ Artificial Chromosomes:	☐ Yes ☐ No
☐ Plasmid:	☐ Yes ☐ No
☐ Cosmid:	☐ Yes ☐ No
☐ Specific Phage:	☐ Yes ☐ No
☐ Drug Resistance Gene:	☐ Yes ☐ No
☐ Oncogenic Gene:	☐ Yes ☐ No
☐ Parasitic Gene:	☐ Yes ☐ No
☐ Marker/Reporter Gene:	☐ Yes ☐ No
☐ Supplementary Gene:	☐ Yes ☐ No
☐ Sex-linked Gene:	☐ Yes ☐ No
☐ Defective Vector:	☐ Yes ☐ No
☐ Replication Vector:	☐ Yes ☐ No
☐ Gene Fragment:	☐ Yes ☐ No
☐ Other:	☐ Yes ☐ No

C.4 Publications Support for Intended Use of Material(s): *(attach relevant publications for reference).*

Part D – Protocol Details:

D.1 Material Information: *If using recombinant DNA molecules, please refer to Appendix B for example descriptions.*

Materials: Name, Source, and Nature; (inserted DNA Sequence/Expressed gene)	Host(s)	Vector(s)	Function and Intended Use

D2. Background, Study Design, & Intended Use of Material(s): *Outline the research question, rationale, experimental approach, and potential in lay terms. Ensure to address the nature, purpose, and biological function of the biohazardous materials proposed for use.*

D.3 Materials/Methods: *Outline procedures and techniques to be performed (e.g., cloning, DNA or RNA synthesis, expression, cell culture, etc).Identify bacteria (e.g. E. coli K12) and/or mammalian cell lines (e.g. HeLa cells) that will serve as the host for the recombinant DNA, cells used for amplification of recombinant DNA, source of the cells, and attach corresponding detailed vector maps. If applicable, include recombinant DNA gene manipulations/gene editing, ensure to identify the gene product (protein) you wish to express, and any key features of the material(s) proposed for use. If using viruses, identify the viral vector(s), marker genes, and foreign insert genes. Clarify replication features, replication defi-cient or replication competent. If not replication competent, clarify what tests will be performed to verify their incompetence to replicate.Address if viral vectors can be complimented or recombine and if any procedures could potentially extend the host range or enhance the pathogenicity of the vector. Identify any helper viruses or packaging/producer cell lines to be used and outline essential genes deleted from the vector. If using lentiviral vectors, clarify the generation and proposed testing to determine replication competence.*

D.4 Risks: *Address potential risks associated with the use of and exposure to biohazardous material to researchers, environment, or public and clarify if any materials are infectious to human, animals, and/or plants. Address the potential for accidental exposure and clarify how exposure might occur (e.g. needlestick, eye exposure, aerosol/inhalation, splash, ingestion, animal bite). Explain the repercussion of human exposure, clarify available treatment options (therapies or vaccination) and plans for administration. Note, studies which use a BSL2 agent must provide a separate Biological Hazards Material Standard Operating Protocols (BHMSOP) to facilitate delivery of care and address prevention of spread in the event of an accidental exposure to agents used in this project, or onset of an illness that is unexplained and potentially related to lab activities. Additionally, clarify if UMD should have an executed Memorandum of Understanding (MOU) with South Coast Medical to cover an accidental exposure.*

D.5 Management of Biohazards: *Describe the equipment, locations, and safety practices to be employed. Outline the training the PI will implement to protect staff from hazards and to minimize an accidental release or exposure event. Detail response plan for handling accidental exposure(s) (eye washing, hand washing, etc), and plan to notify IBC and EHS. Describe the biosecurity measures in place to minimize access to this lab facility (i.e. locked doors at all times, agents in locked freezers, restricted access, key card access, etc.). Describe methods and procedures for storage (include maximum anticipated titer/concentration/volume of the agent/preparation), transport, decontamination, and inactivation of/disposal of the material and any associated contaminated materials generated from the experiments (clarify procedures for decontamination prior to disposal and disposal of after decontamination). Note, Management of Biohazards can be addressed in the separate BHMSOP.*

D.6 Indicate the Highest Risk Group Level: (*See Appendix D*). ☐ RG1 ☐ RG2 ☐ RG3 ☐ RG4

D.7 Indicate the Highest Biosafety Containment Level: (*See Appendix C*). ☐ BSL-1 ☐ BSL-2

D.8 Personal Protective Equipment (PPE): *Select all that apply.*

☐ Safety Glasses/Goggles ☐ Gloves ☐ Lab Coat ☐ Disposable Lab Gown
☐ Hair Bonnet ☐ Surgical Mask ☐ Pipetting ☐ Disposable Booties
☐ Other: (*Describe)* _____

D.9 Engineering Controls and Laboratory Equipment: *(Provide Location and certification details, as necessary)*

☐ Bench Top: _____
☐ Biosafety Cabinet: _____
☐ Fume Hood: _____
☐ Freezer/Refrigerator: _____
☐ Autoclave: _____
☐ Centrifuge: _____
☐ Flowcytometry: _____
☐ Other: _____

Part E – Additional Appendices *Only fill out sections which apply.*

E.1 IBC Appendix for Animal Use: ☐ N/A

1. Identify the species and source *(attach procurement documentation).*

_____
_____

2. Material Type: *Select all that apply.*

☐ Whole Animals ☐ Unfixed Cells ☐ Organs ☐ Tissues
☐ Blood/Blood Products ☐ Bodily fluids ☐ Cell lines ☐ Other:

3. Animal Biosafety Level: ☐ ABSL-1 ☐ ABSL-2

4. Locations: *Identify Building and Room No.*

Animal Facility: _____
Laboratory: _____
Other: _____

5. Route of Administration: *Select all that apply.*

☐ Intraperitoneal ☐ Intramuscular ☐ Intravenous ☐ Subcutaneous ☐ Intracerebral
☐ Per Os ☐ Intranasal ☐ Inhalation ☐ Gastric lavage
☐ Other: _____

5. Does agent occur natural in the species? ☐ No ☐ Yes

6. Describe expected time course of experiments:

Number of Experiments: _____
Duration of Experiments: _____
Duration of Exposure: _____

7. Clarify if animals be exposed to human cells/ fluids/ tissues, what the known human pathogens the species may carry are, and how the cells/ fluids/ tissues will be safely handled to minimize the risk of accidental exposure to these potential pathogens that may be present. Clarify if material will be previously tested and/or certified pathogen-free of bloodborne pathogens (ensure to provide testing source information). Note: If it has not been tested for bloodborne pathogens, you are required to treat animals exposed to these tissues as also infected with bloodborne pathogens.

8. Will any cells or animals be purposely infected with human or animal pathogens? If so, please describe precautions that will be taken to minimize risk to the researcher when handling infected cells. If infecting/testing animals with a known human/animal pathogen, describe how this information will be communicated to animal care staff (cage/ tank cards, door signage, etc.) and how lab space will be routinely disinfected to minimize the risk of accidental exposure.

9. Provide the best estimate of the length of time after animal inoculation that the animal may shed the inoculated agent in a form that is potentially hazardous to humans. Indicate the route of shedding (e.g. urine, feces, saliva, from skin). Please provide any available scientific data that supports your time estimate.

10. Describe Protective Measures: *Select all that apply.*

☐ Room ventilation	☐ Standard for designated ABSL	☐ Other:
☐ Caging/ changing/ washing	☐ Standard for designated ABSL	☐ Other:
☐ Biosafety equipment	☐ Standard for designated ABSL	☐ Other:
☐ Bedding disposal	☐ Standard for designated ABSL	☐ Other:
☐ Carcass disposal	☐ Standard for designated ABSL	☐ Other:
☐ Additional measures not listed:		

E.2 IBC Appendix for Human Subject Use: ☐ N/A

1. Identify the source of materials *(attach procurement documentation).*

2. Material Type: *Select all that apply.*

☐ Whole Human	☐ Unfixed Cells	☐ Organs	☐ Tissues
☐ Blood/Blood Products	☐ Bodily fluids	☐ Cell lines	☐ Other: _____

3. If Whole Human Used, Clarify Route of Administration: *Select all that apply.*

☐ Intraperitoneal	☐ Intramuscular	☐ Intravenous	☐ Subcutaneous
☐ Per Os	☐ Intranasal	☐ Inhalation	☐ Gastric lavage
☐ Other: _____			

4. If working with human cell lines (primary or established) or bodily fluids, clarify if there are known pathogens present. Describe how the fluids will be disposed of after use in experiments.

5. Will any of the human cells be purposely infected with human pathogens? If so, please describe precautions that will be taken to minimize risk to the researcher when handling infected human cells.

E.3 IBC Appendix for Select Agent Use: ☐ N/A

1. Identify each select agent, source, and biosafety level.

2. List all permit numbers and dates obtained.

3. Storage and Security: *Clarify where agents will be kept and confirm security measures.*

4. Plans for notification in case of accidental exposure.

E.4 IBC Appendix for Select Agent Use: ☐ N/A

1. Identify each toxin, source, and biosafety level.

2. Identify LD50 for the toxin(s).

3. Identify symptoms associated with exposure to toxins and clarify how personnel will be monitored post handling

4. Describe toxin inactivation procedures, clarify how inactivation efficacy will be verified.

F ï Personnel: *Please include all personnel to be involved in the research.*

Name of the Personnel:	**Role in the Project** (*Title and job on project*)	**Experience and Relevant Details**	**Training:** (*Provide certificates)*
			☐ Biosafety Complete Training Series ☐ Lab Chemical Safety ☐ Life Sciences RCR ☐ Physical Science RCR ☐ Select Agents, Biosecurity and Bioterrorism ☐ OSHA Bloodborne Pathogens ☐ NIH Recombinant DNA (rDNA) Guidelines ☐ Lab Safety Training with EHS online
			☐ Biosafety Complete Training Series ☐ Lab Chemical Safety ☐ Life Sciences RCR ☐ Physical Science RCR ☐ Select Agents, Biosecurity and Bioterrorism ☐ OSHA Bloodborne Pathogens ☐ NIH Recombinant DNA (rDNA) Guidelines ☐ Lab Safety Training with EHS online
			☐ Biosafety Complete Training Series ☐ Lab Chemical Safety ☐ Life Sciences RCR ☐ Physical Science RCR ☐ Select Agents, Biosecurity and Bioterrorism ☐ OSHA Bloodborne Pathogens ☐ NIH Recombinant DNA (rDNA) Guidelines ☐ Lab Safety Training with EHS online
			☐ Biosafety Complete Training Series ☐ Lab Chemical Safety ☐ Life Sciences RCR ☐ Physical Science RCR ☐ Select Agents, Biosecurity and Bioterrorism ☐ OSHA Bloodborne Pathogens ☐ NIH Recombinant DNA (rDNA) Guidelines ☐ Lab Safety Training with EHS online
			☐ Biosafety Complete Training Series ☐ Lab Chemical Safety ☐ Life Sciences RCR ☐ Physical Science RCR ☐ Select Agents, Biosecurity and Bioterrorism ☐ OSHA Bloodborne Pathogens ☐ NIH Recombinant DNA (rDNA) Guidelines ☐ Lab Safety Training with EHS online

UMass | Dartmouth

Institutional Biosafety Committee (IBC)

Appendix A: Definitions from the *NIH Guidelines* for use of Exempt rDNA Molecules

Recombinant DNA:
In the context of the NIH guidelines, recombinant DNA molecules are defined as either:

1. Molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or
2. Molecules that result from the replication of those described in 1.

Multi-project registration:

- Several projects with similar overall research objectives and procedures are described in the registration form; however, this registration form must only include work with exempt recombinant DNA.
- Please include all information describing experimental procedures in multiï project registrations.

Appendix B: Example of Completed Table for Question D.1

Materials: Name, Source, and Nature; inserted DNA Sequence/Expressed gene;	**Host(s)**	**Vector(s)**	**Function and Intended Use**
Major histocompatibility complex class II (mouse)	*E. coli (K-12)* *E. coli* *Yeast*	Plasmid, Bluescript, pET21 pDHIL	Cloning, sequencing Over expression of protein in E. coli for structure/function Over expression of protein in yeast for structure/function
cDNA (human)	*E. coli*	Lambda gt10	CDNA Library, screen for clones
Heme B3-8 gene (human)	*E. coli*	pUC19	PCR amplification
Promoter of BMP2 (mouse)	*E. coli* F9 cells (mouse)	Reporter plasmid, pGL2-promoter (luciferase)	Transient infections to study promoter activity
Nitric oxide synthase (bovine)	*E. coli* Insect cells (SF9)	Plasmid, pFASTBAC. Baculovirus, AcNPV	Over expression of protein in insect cells
Galactosidase (LacZ gene), (E. coli)	*E. coli*	Plasmid, pUB110, pS194, pT127	Gene expression (northerns, attenuation studies)

Appendix C: Definitions of Biosafety Levels

Biosafety Level 1: BSL-1 is suitable for work involving well-characterized agents not known to cause disease in health adult humans, and of minimal potential hazard to laboratory personnel and the environment. **BSL-1 requires that:**

1. The laboratory is not necessarily separated from the general traffic patterns in the building.
2. Work is generally conducted on open bench tops using standard microbiological practices.
3. Special containment equipment or facility design is not required nor generally used.
4. Laboratory personnel have specific training in the laboratory procedures and are supervised by a scientist with general training in microbiology or a related science.

Biosafety Level 2: BSL-2 is similar to Level 1and is suitable for work involving agents of moderate potential hazard to personnel and the environment. **BSL-2 requires BSL-1 containment practices plus:**

1. Laboratory personnel have specific training in handling pathogenic agents and are directed by competent scientists
2. Access to the laboratory is limited when work is being conducted
3. Extreme precautions are taken with contaminated sharp items
4. Procedures with a potential for infectious aerosols or splashes are conducted in biological safety cabinets or other physical containment equipment.

There are no BSL-3 nor BSL-4 facilities at U Mass Dartmouth.

Biosafety Level 3: BSL-3 is applicable to clinical, diagnostic, teaching, research, or production facilities in which work is done with indigenous or exotic agents which may cause serious or potentially lethal disease as a result of exposure by inhalation. BSL-3 requires BSL-2 containment practices plus:

1. Laboratory personnel have specific training in handling pathogenic and potentially lethal agents and are supervised by competent scientists who are experienced in working with these agents.
2. All procedures are conducted within biological safety cabinets or other physical containment devices, or by personnel wearing appropriate personal protective clothing and equipment.
3. The laboratory has special engineering and design features.

Biosafety Level 4: BSL-4 is required for work with dangerous and exotic agents which pose a high individual risk of aerosol-trans-mitted laboratory infections and life-threatening disease. Restrictions apply to personnel training, lab accessibility and construction, and the use of protective equipment and clothing.

Appendix D: Risk Group Assessment

For a full list of Risk Agents, please see the NIH Guidelines **Appendix B - Table 1.**

Basis for the Classification of Biohazardous Agents by Risk Group (RG)

Risk Group 1 (RG1) Agents that are not associated with disease in healthy adult humans.

Risk Group 2 (RG2) Agents that are associated with human disease which is rarely serious and for which pre-ventive or therapeutic interventions are *often* available.

Risk Group 3 (RG3) Agents that are associated with serious or lethal human disease for which preventive or therapeutic interventions *may be* available (high individual risk but low community risk).

Risk Group 4 (RG4) Agents that are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are *not usually* available (high individual risk and high commu-nity risk).