Registration No.:

Date Received:

IBC Docket #:

BSL Assignment Level:

Approved by:

Supporting Documents on File:  Y or  N

Approval Date:



|  |
| --- |
| BIOLOGICAL RESEARCH REGISTRATION FORM |

Please send your completed registration form electronically to [Biosafety@uml.edu](mailto:IBC@uml.edu)

1. **PRINCIPAL INVESTIGATOR INFORMATION**

|  |  |  |  |
| --- | --- | --- | --- |
| Study Nickname |  | Study Title |  |
| PI Name |  | Office Ext |  |
| **Department** |  | Lab Ext |  |
| **Mailing Address** |  | E-mail |  |
| **Name of Designated Representative** |  | Email  **Office Ext**  **Home Phone**  **Additional Contact:** |  |

**A.1 For first time UMass Lowell faculty or staff applicants, please provide the following information about your training with biological agents:**

1. Years working with biological agents

2. Have you ever been a PI on an IBC application at another institution?

3. Please describe your relevant past research experience and any biosafety training you may have had at other institutions.**?**

**A.2 For Persons applying for IBC approval to work at M2D2 locations or incubator spaces:**

1. Company Name:

2. Location:  Wannalancit Mill,  110 Canal Street,  Other

3. Estimated Occupancy Date (please list start date and potential end date):

**Please provide the following information about your training with biological agents:**

1. Years working with biological agents

2. Have you ever been a PI on an IBC application at another institution**?**

3. Please describe your relevant past research experience and any biosafety training you may have had at other institutions.

1. **REGISTRATION TITLE**

|  |
| --- |
|  |

1. **REGISTRATION TYPE**

|  |
| --- |
|  |

1. **(*Note: To put a check in the box, double click on the box.)***

|  |
| --- |
| 1.  **New Protocol**  Research or  Classroom/Teaching Laboratory |
| 2.  **Three Year Resubmission of previously approved protocol.** Previous #        Research or  Classroom/Teaching Laboratory   * 1. Indicate if there are any substantial changes (other than personnel changes) from the previously approved registration:  Yes or  No   Please highlight those changes in **BOLD**. |

**Other Committee Review and Approvals:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Does your project involve:** | **Check One:** | **If yes, then approval also needed from:** | **Protocol No. & Approval Date** | **Contact Person** |
| Vertebrate Animals | Yes No | IACUC |  | [IACUC@uml.edu](mailto:IACUC@uml.edu) |
| Human Subjects (including stem cells) | Yes  No | IRB |  | [IRB@uml.edu](mailto:IRB@uml.edu) |
| Radiation | Yes No | Radiation Safety Officer |  | [Radiation](mailto:Radiation)\_Safety@uml.edu |

**Check the additional sections that are also to be completed for this registration:**

Section L. rDNA Technology  Section O. Animals

Section M. Infectious Agents Section P. Select Agents

Section N. Human or Non-human Primate Source Material Section Q. Classroom/Teaching Labs

1. **FUNDING INFORMATION** (Check any/all that apply)

Not funded.

Internal funding, Type:

Government/Federal funding. List agency name:

Subcontract. List organization name and include contact name, telephone no., and address:

Other:

1. **PERSONNEL AND TRAINING**

*Training certification is required for all persons (faculty, students and staff) involved in handling biohazardous materials.* The initial EHS Lab Safety and Biosafety/BBP training must be in person and renewed annually.  Work with animals or human subjects requires additional training (<http://www.uml.edu/Research/Integrity>).

|  |  |  |
| --- | --- | --- |
| **Training Type** | **Frequency Required (1st time Must be in Person)** | **Options for Refresher/Renewal Training** |
| EHS Lab Safety | Annually | EHS UML Web Apps online |
| Bloodborne Pathogen | Annually | EHS UML Web Apps online or CITI online |
| EHS Biosafety | Every 3 years | Refresher CITI Biosafety modules online |
| CITI rDNA | As needed | CITI online |

NOTES: EHS BBP/Biosafety in person trainings are combined into a single session

\*For EHS Lab Safety and BBP/Biosafety in person training schedule see: <http://www.uml.edu/EEM/EHS/ehs-training/>. (No pre-registration required.). Inquiries at EHS Office 978-934-2618.

For CITI online training, go to [www.CITIProgram.org](http://www.CITIProgram.org), create a username and password, and add module(s) needed.

Provide names, title, and applicable training type(s) as described above for all personnel involved:

|  |  |  |
| --- | --- | --- |
| **Name and Title** | **Email Address** | **Training Completed and Date for Each** |
| **PI:** |  | EHS Lab Safety: Date:  EHS Biosafety/BBP: Date:  CITI Basic: Date:        CITI BBP: Date:  CITI rDNA: Date:        CITI Animal: Date: |
|  |  | EHS Lab Safety: Date:  EHS Biosafety/BBP: Date:  CITI Basic: Date:        CITI BBP: Date:  CITI rDNA: Date:        CITI Animal: Date: |
|  |  | EHS Lab Safety: Date:  EHS Biosafety/BBP: Date:  CITI Basic: Date:        CITI BBP: Date:  CITI rDNA: Date:        CITI Animal: Date: |
|  |  | EHS Lab Safety: Date:  EHS Biosafety/BBP: Date:  CITI Basic: Date:        CITI BBP: Date:  CITI rDNA: Date:        CITI Animal: Date: |
|  |  | EHS Lab Safety: Date:  EHS Biosafety/BBP: Date:  CITI Basic: Date:        CITI BBP: Date:  CITI rDNA: Date:        CITI Animal: Date: |
|  |  | EHS Lab Safety: Date:  EHS Biosafety/BBP: Date:  CITI Basic: Date:        CITI BBP: Date:  CITI rDNA: Date:        CITI Animal: Date: |
|  |  | EHS Lab Safety: Date:  EHS Biosafety/BBP: Date:  CITI Basic: Date:        CITI BBP: Date:  CITI rDNA: Date:        CITI Animal: Date: |

Enter names of additional personnel and training information here, if necessary:

1. **Description of Project.**

Briefly describe the proposed work in lay terms (terms that an average newspaper reader could understand). Please fill out the following sections:

Project Overview:

Project Objectives:

Experimental Methods:

Explain briefly what is being transported and between which rooms and the steps performed in each location:

Biological Waste Handling Procedures: (State which SOPs are being followed (<https://www.uml.edu/EEM/EHS/Biosafety/default.aspx#sops>) and clearly describe decontamination procedures

1. **BIOLOGICAL MATERIALS** (This includes cell lines, recombinant DNA and biological toxins)

Identify each biological material and its source (i.e. where the material was obtained, purchased, or collected). *Note: Biohazardous materials imported from outside the US may require a USDA permit and it may take up to 80 days to get a determination.*

|  |  |  |  |
| --- | --- | --- | --- |
| **Biological Material** | **Source/Catalog Number** | **Risk Group** | **Biosafety Level** |
|  |  |  |  |
|  |  |  |  |
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|  |  |  |  |
|  |  |  |  |

Enter additional biological materials and source information here if applicable:

1. **LABORATORY INFORMATION**
   * + 1. List **ALL UMass Lowell labs/facilities** where work will be conducted (*be sure to include all satellite rooms such as autoclave rooms*).

Location of Project (Building Name):

Project Room(s):

1. **TRANSPORT OF MATERIALS**
2. Will you ship or receive biological agents/infectious substances as part of this project

Yes  No

a. If Yes,

I agree to comply with UML procurement and shipment procedures for biohazardous materials and recombinant DNA. I have contacted EHS to answer any questions I had.

1. Will you have to transport samples between rooms/building on campus as part of this project

Yes  No

* + - * 1. If yes, check the box below indicating you understand and agree to comply with the following:

All materials will be transported in closed and unbreakable secondary containers.

1. **GENERAL SAFETY INFORMATION**

1. Describe the **potential risks** associated with exposure to the material or organism(s) used. Where appropriate, group material(s) and organism(s) together by risk group to describe potential illnesses and symptoms: (*almost all materials pose some risk if ingested by or accidentally injected into humans*).

* 1. I will be using *E. coli* K12 and/or derivatives.

I understand that *E. coli* K12 and/or derivatives are enfeebled and will not cause human health effects.

*Note: For manipulations of these cells for rDNA technology, also complete Section O.*

* 1. I will be using human or non-human primate cell lines or human cells or samples.

I understand that even if purchased from commercial vendors, these cell lines are considered by OSHA to be a risk for blood borne pathogens (i.e., HIV, hepatitis, etc.). *Also complete Section Q.*

* 1. I will be using other potentially biohazardous materials. Describe the potential symptoms associated with exposure to the material or organism(s) used:

1. Discuss the Hazard/Risks associated with this protocol (e.g. potential exposure risks such as needle sticks, aerosolization risks, etc.) and steps that will be taken to prevent potential exposure.

Potential Exposure Risk:

PPE to be used:

Procedures to be used to prevent exposure:

1. Identify in the table below all equipment used during the study that could potentially aerosolize the material and describe measures implemented to prevent aerosol exposure.

|  |  |  |
| --- | --- | --- |
| **Equipment** | **Check all that apply** | **Aerosol exposure prevention plan** |
| Not Applicable |  | Not Applicable, no potential for aerosolization. |
| Blender |  |  |
| Tissue Grinder |  |  |
| Cell sorter |  |  |
| Centrifuge |  |  |
| Vortex |  |  |
| Ultrasonicator |  |  |
| Homogenizer |  |  |
| Other: |  |  |

1. Identify below any immunizations/vaccinations **recommended** for personnel working with the materials:

|  |
| --- |
| Tetanus |
| Rabies |
| Hepatitis B |
| Other: Click here to enter text. |

Has everyone listed in the registration been offered the Hepatitis B vaccine?  Yes  No

*(For more information, contact the Biosafety Officer at* - *978-934-2618.)*

1. **RECOMBINANT DNA TECHNOLOGY**  Yes  No

* *The CITI module on NIH Guidelines for Research Involving Recombinant and Synthetic Nucleic Acid Molecules is required for this work. Refer to Section E.*

*For guidance, refer to* <https://osp.od.nih.gov/policies/biosafety-and-biosecurity-policy#tab2/>

1. Describe inserted/altered genetic elements (include origin and biological function):

* + - * 1. The inserted genetic material encodes (*check all that apply*):

Oncogene  Tumor suppressor inhibitors

Immuno-modulator  Toxin

Anti-apoptotic factors

Other, Explain:

* + - * 1. Indicate the source of DNA/RNA sequences (include genus, species, gene name, abbreviation):
        2. Are you cloning >2/3 of the genome?  Yes  No

If yes, you need to speak to the BSO regarding your work.

* + - * 1. What are the potential biohazards of the product produced by this gene (*if you have references to support your assessment, please include*)?
        2. Recombinant plasmid(s)/vector(s) used to manipulate and/or express the gene (check those that apply):

|  |  |  |
| --- | --- | --- |
| Bacterial Plasmid | Adenovirus | Herpes virus |
| Retrovirus or Retroviral vector | Adeno-associated virus | Other mammalian virus (specify): |
| Lentivirus | Poxvirus |  |

2. Will this project, at some point, require the release of organisms containing recombinant molecules into the environment?  Yes  No. If yes, explain:

3. Will there be any attempt to transfer rDNA molecules in vivo to plant or animal systems (other than tissue culture)?  Yes  No. If yes, explain:

4. Will this project require large-scale fermentation (>10 liters) of organisms containing recombinant DNA molecules?  Yes  No. If yes, explain:

1. **INFECTIOUS AGENTS**  Yes  No

(This section is **NOT** for using human tissue or body fluids; see Section N.)

As the PI, check here to indicate you understand that you will be responsible to train personnel to safely handle these materials in the laboratory.

1. Agent Identification. List biohazardous agent risk group:

2. Hazards: Is the agent infectious to humans?  Yes  No

Is the agent infectious to non-human animals?  Yes  No

Is the agent infectious to plants?  Yes  No

If yes, answer the following questions:

a. Susceptible hosts:

b. Infectious dose information (*if you have references to support your assessment please include*):

c. Describe any known antibiotic resistance:

d. Describe any known antibiotic susceptibility:

e. Does the agent synthesize a toxic molecule that may be lethal for vertebrates?

Yes – Toxin:        No  Not Known

1. Additional Information.

a. How and at what stage of the experiment is the infectious agent inactivated?

b. Will any experiment result in acquisition of new characteristics such as enhanced virulence, infectivity, drug resistance, or change in host range?  Yes, explain:        No

**For OIC Use Only:**

This material has been reviewed by the Export Control Compliance Manager.  Yes  No

This material is not on the CCL and the registration may proceed for IBC approval.

This material is on the CCL and the Export Control Compliance Manager will contact the PI to evaluate the activity. IBC approval is not permitted until this is completed and materials are controlled appropriately.

1. **HUMAN OR NON-HUMAN PRIMATE SOURCE MATERIALS**  Yes  No

*NOTE: Companies, such as ATCC, that are used to purchase these materials do not complete comprehensive testing for all potential human pathogens. Precautions should be taken accordingly for all personnel working with these types of materials and appropriate training for personnel should be provided.*

* *Training on OSHA Bloodborne Pathogens is required for this work. Refer to Section E.*

*NOTE: BSL-2 practices are required for this work; Contact the Biosafety Officer at the EHS office 978-934-*2618 or refer *to EHS SOP Bio-012, Biosafety Guide (*<https://www.uml.edu/EEM/EHS/Biosafety/>) or <https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf>, or <https://www.cdc.gov/labs/BMBL.html>

**Complete this section if you work with human or non-human primate source material**(s), including bodily fluids, tissues primary cell cultures, cell lines, or immortalized cell lines.

1. List the types of primary human source material and for each type describe the source (blood, bone, sputum, cell culture) used:
2. For tissue culture, list all cell types and names:
3. Indicate which cell lines are potentially tumorigenic:

*NOTE: Handling of tumorigenic cell lines should be included in personnel training.*

1. Provide the source from where you plan to obtain the materials:
2. If not purchased, provide details about how the samples are collected or obtained:
3. If you plan to collect fluids, cells, or tissues from humans, prior approval must be granted from the IRB. Provide the IRB protocol number       and status (*i.e. pending, approved*)

*NOTE: Use of these materials as part of course work does not need IRB approval unless materials will be used for research as well.*

1. Do you have a copy of the UMass Lowell Exposure Control Plan available for all personnel in the laboratory?  Yes  No
2. Are you using human embryonic stem cells?  Yes  No

*NOTE: Use of embryonic stem cells requires special IRB approval and a license from the Commonwealth of MA. Contact Emily Sousa at 978-934-4134.*

1. **ANIMAL SUBJECTS**  Yes  No

*Note: The CITI Animal Biosafety training module is required for this work. Add training date in Section E.*

* + - 1. List the species (common name) of animals used:
      2. Will animals be infected with or exposed to pathogens or tumor cell lines  Yes  No
  1. If yes, which route of infection will be used? *Check all that apply*

Intraperitoneal  Intramuscular  Intravenous  Subcutaneous  Intracerebral

Intranasal  Inhalation  Gavage  Other:

Skip if not using

3. Will tumor cell lines be used?  Yes  No  Not Applicable

If yes, describe in detail the type of cell line:

4. Indicate any of the following which could present exposure risks to personnel *(check all that apply)*:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Urine | Feces | Saliva | Blood | Bedding | Aerosols |
| Animal bite or scratch | Contact with lesion on animal | Injury from contaminated caging | Mucous membrane contact with secretions or excretions | | Needle Sticks  Other: |

5. Describe additional handling procedures necessary for using biohazardous materials to protect animal facility personnel:

1. Are procedures the same as described in Section K?  Yes  No
2. If no, indicate types of additional PPE recommended for animal facility personnel:
3. How will animal facility personnel be informed of the risks involved and trained about appropriate handling procedures:
4. Identify protective measures to be implemented to prevent accidental exposure to researchers and staff from room ventilation, caging, biosafety equipment, cage changing, bedding disposal, cage washing, carcass disposal:

6. Describe how you will dispose of biological materials used in the animal facility:

7. Other information which you feel is pertinent to the project that the IBC should consider:

**P. SELECT AGENTS**  Yes  No

*Training certification from the CITI module on Select Agents and Biosecurity is required for this work.*

If you intend to work with any select agents or toxins (<https://www.selectagents.gov>)listed at <https://www.selectagents.gov/SelectAgentsandToxinsList.html> contact the Biosafety Officer at the EHS Office 978-934-2618 for information about how to proceed. The Institution (UMass Lowell) and PI will have to complete APHIS/CDC Form 1 to apply to possess, use, or transfer select agents and toxins (as described in 7 CFR 331, 9 CFR 121, and 42 CFR 73). This process should be completed before submitting the IBC registration for IBC review.

After Registration with APHIS/CDC and before transfer any type of Select Agent the PI needs approval of the APHIS/CDC Form2 (<https://www.selectagents.gov/form2.html>). Advice from APHIS/CDC-approved EHS professional (978-934-2618) is required for packing, labelling and shipping select agents. Approval from Export Control Compliance Manager (978-934-3207) maybe required.

**Q. CLASSROOM/ TEACHING LABORATORIES**  Yes  No

1. List the course name and number:

|  |  |
| --- | --- |
| **Course Name** | **Course Number** |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |

Additional:

2. Describe the purpose and goals of the classroom laboratory.

3. Indicate how the students will receive training about the use of biological materials (check all that apply):

|  |
| --- |
| The laboratory safety policies are outlined in the course syllabus |
| Training video is used |
| Live demonstration / discussion |
| Laboratory manual |
| Other, explain: |

*NOTE: To update changes in personnel, including Teaching Assistants and Adjunct Faculty, submit a minor amendment form (*[*https://www.uml.edu/Research/Integrity/biological-safety/forms.aspx*](https://www.uml.edu/Research/Integrity/biological-safety/forms.aspx)*).*

**PRINCIPAL INVESTIGATOR ASSURANCE AND SIGNATURE PAGE**

I attest that the information provided is accurate and complete to the best of my knowledge and that all personnel involved in this project have met training requirements and will not deviate from approved procedures.

*All boxes MUST be checked.*

I will not initiate rDNA research or research that involves the use of biological agents, human cells or tissues, or select agents and toxins until that research has been reviewed and approved in writing by the IBC.

I have reviewed the UMass Lowell IBC Policies and Procedures and agree to abide by the requirements of the current NIH and CDC Guidelines and other specific regulations pertaining to the proposed research. (These are available online at [http://www.uml.edu/Research/Integrity](http://www.uml.edu/Research/OIC/default.aspx)).

I will make available to laboratory personnel copies of the approved protocols that describe the potential biohazards and the precautions to be taken. I agree to ensure that all laboratory personnel working on this research are listed with the IBC.

I understand that I am responsible to ensure that appropriate biosafety level laboratory practices and procedures will be used in this research, including universal precautions for work with blood borne pathogens.

I agree to comply with the procurement, shipment, and transfer requirements of biohazardous materials and recombinant DNA.

I agree to abide by UMass Lowell EHS-Biosafety Standard Operating Procedures for routine cleaning and decontamination as well as waste generation, disposal and transportation.

I will be submitting a Non-Hazard Waste Determination Form for liquid waste sink disposal of non-biological waste.

<https://www.uml.edu/EEM/EHS/EHS-forms.aspx>

I will be collecting biological waste in a hazardous waste satellite area. All liquids that contain any chemical hazard must be collected in a hazardous waste satellite area (except bleach that is used for decontamination).

I understand that written reports will be submitted to EHS ([biosafety@uml.edu](mailto:biosafety@uml.edu)) concerning:

* Any accident or illness as the result of inoculation, ingestion, and inhalation of biohazardous materials or recombinant DNA
* Any incident causing exposure of personnel or danger of environmental contamination
* Any problems pertaining to operation and implementation of biological and physical containment safety procedures or equipment or facility failure

I understand that a new registration must be submitted to the IBC for any change in the biosafety risk levels for any proposed research.

|  |
| --- |
| Printed Name of PI:       Date:  **PI Signature:** |

Check here if submitted electronically from the P.I.’s email account and a signature is not required.