Registration No.:

Date Received:

BSL Assignment Level:

Exempt Category: Approved by:

Supporting Documents on File: ( )Y or ( )N

Approval Date:



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

Please send your completed registration form electronically to IBC@uml.edu

1. **PRINCIPAL INVESTIGATOR INFORMATION**

|  |  |  |  |
| --- | --- | --- | --- |
| PI Name |       | Office Ext |       |
| **Department** |       | Lab Ext |       |
| **Mailing Address** |       | E-mail |        |
| **Name of Designated Representative**  |       | Email**Office Ext****Home Phone** |                 |

**A.1 For first time UMass Lowell faculty or staff applicants, please provide an overview of your education, training and experience in regards to handling biohazardous material:**

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

 **Company Name**:

 **Location** (check one): [ ]  Wannalancit MIL or [ ]  110 Canal Street

 **Estimated Occupancy Date**:

 **Please provide an overview of your education, training and experience in regards to handling biohazardous materials**:

1. **REGISTRATION TITLE**

|  |
| --- |
|       |

1. **REGISTRATION TYPE**

***Note: To put a check in the box, double click on the box and under Default value, select Checked and hit OK.***

|  |
| --- |
| 1. [ ]  **New Protocol** [ ]  Research or [ ]  Classroom/Teaching Laboratory |
| 2. [ ]  **Three Year Resubmission** of previously approved protocol. Previous #       [ ]  Research or [ ]  Classroom/Teaching Laboratory* 1. Indicate whether there are any changes from the previously approved registration: [ ]  Yes or [ ]  No
	2. If yes, please explain briefly the changes here (but also include them in the appropriate sections of the form:

  |

**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 |       | Amy\_Finneral@uml.edu |
| Human Subjects (including stem cells) | [ ] Yes [ ]  No | IRB |       | Emily\_Sousa@uml.edu |
| Radiation | [ ] Yes [ ]  No | Radiation Safety Officer |       | Steven\_Snay@uml.edu |

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

[ ]  Section O. rDNA Technology [ ]  Section R. Animals

[ ]  Section P. Infectious Agents [ ]  Section S. Select Agents

[ ]  Section Q. Human or Non-human Primate Source Material [ ]  Section T. Classroom/Teaching Laboratories

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/OIC/default.aspx>).

|  |  |  |
| --- | --- | --- |
| **Training Type** | **Frequency Required (1st time Must be in Person)** | **Options for Refresher/Renewal Training** |
| EHS Lab Safety | Annually | EHS Lab Safety or ResourceNow online  |
| Blood Borne Pathogen | Annually | EHS in person, CITI BBP online, or Resource Now online course |
| EHS Biosafety | Every 3 yrs | EHS in person or CITI Biosafety Refresher online |
| CITI rDNA | As needed | CITI |

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/Training-schedule/Training-Schedule-EHS.aspx>. (No pre-registration required.)

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

 For EHS Lab Safety or Resource Now online training, please contact EHS 978-934-2618.

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. **STUDY OBJECTIVES**

 In one paragraph describe the goals of this project and, in **lay language**, what experimental methods you will be using to try to achieve this purpose. This should be a description that can be understood by average newspaper readers and not focused on the technical aspects of the project.

1. **EXPERIMENTS AND TECHNIQUES**

For each aim or goal of the project that involves biological materials, describe the agents used and the experimental methods and techniques that will be applied. Be sure to include specifics about where tasks will be conducted, especially any tasks involving a BSC. (The IBC is looking for information to understand the specific materials used, how they are used and risks with each material and process.):

1. **BIOLOGICAL MATERIALS**

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** |
|       |       |
|       |       |
|       |       |
|       |       |
|       |       |
|       |       |
|       |       |
|       |       |
|       |       |
|       |       |

Enter additional biological materials and source information here if applicable:

1. **COLLECTION AND TRANSPORT OF MATERIALS**
2. Are the materials listed in this registration being purchased? [ ] Yes [ ] No
3. If not purchased, from where and how are the biological materials obtained?
	* + - 1. How are the materials transported to campus?

 b. How are the materials transported once on campus?

1. The maximum total volume transported is:       (include units).
2. The maximum container size and type of container used during transport is:       (include units).
3. **RISK GROUP AND BIOSAFETY LEVEL**

Identify the risk group and highest biosafety level required for the project (*for guidance, refer to* [*http://oba.od.nih.gov/rdna/nih\_guidelines\_oba.html*](http://oba.od.nih.gov/rdna/nih_guidelines_oba.html) *and/or* [*http://www.cdc.gov/biosafety/publications/bmbl5/BMBL.pdf*](http://www.cdc.gov/biosafety/publications/bmbl5/BMBL.pdf)). *NOTE: OSHA regulations require any human derived cell lines or primary tissues to be designated as RG-2 and BSL-2.*

**Check the highest Risk Group for this Registration:**

[ ]  RG-1: agents that are well characterized and not associated with disease in healthy adult humans.

[ ]  RG-2: agents that are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are *often* available

[ ]  RG-3: agents are associated with serious or lethal human disease for which preventive or therapeutic interventions *may be* available

**Check the reason for the biosafety level requirement:**

[ ]  BSL-1, agents used are of minimal threat to workers and environment and normally do not cause disease in healthy adults. Work with these agents can generally be performed on standard open laboratory benches without containment equipment with use of standard microbiology practices. (Examples include several kinds of bacteria and viruses.)

[ ]  BSL-2, agents normally associated with human disease so pathogenic or infectious organisms posing a moderate hazard. Work generally must be conducted in biosafety cabinets and additional standard practices followed to protect workers. Immunocompromised persons with increased risk for infection may be denied to work with these materials. (Examples includes human blood, viruses, pathogenic bacteria, human cell lines, and fungi.)

[ ]  BSL-3, agents that are indigenous or exotic that may cause serious or lethal disease via aerosol transmission. Must only be used in a very controlled environment. *UMass Lowell has no labs at this time that will allow work with these materials.*

1. **LABORATORY INFORMATION**
	* + 1. List **ALL UMass Lowell labs/facilities** where work will be conducted (*check all that apply*).

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Building**  | **Room Number** | **Biological Safety Cabinet** | **Sharps Container** | **Autoclave** | **Biological Waste Disposal Box** | **EHS Authorized Sink Disposal** | **Satellite Waste Area** | **Storage** |
|       |       | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
|       |       | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
|       |       | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
|       |       | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |

2. List **ALL areas at M2D2 labs/facilities** where work will be conducted (*check all that apply*)

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Location**  | **Area or Room No.** | **Biological Safety Cabinet** | **Sharps Container** | **Autoclave** | **Biological Waste Disposal Box** | **EHS Authorized Sink Disposal** | **Satellite Waste Area** | **Storage** |
| Wannalancit |       | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
| 110 Canal St |       | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
| Other:  |       | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |

1. Will the materials be transferred between the buildings and/or rooms? [ ] Yes [ ]  No

 (If yes, all buildings and rooms should be noted in the table above.)

* + - * 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. Explain briefly what is being transported and steps performed in each location:

1. **STANDARD OPERATING PROCEDURES**

UMass Lowell, Environmental Health and Safety has specific Standard Operating Procedures (SOPs) for handling, cleaning, decontamination and disinfection of anything used with biohazardous materials. If you have any questions about the specific SOPs, contact the Biosafety Officer at biosafety@uml.edu, call 978-934-2618 or go to <http://www.uml.edu/EEM/EHS/Biosafety/default.aspx#sops>

**1. Routine Cleaning and Decontamination**

Check below all SOPs applicable to cleaning and decontamination of work surfaces, instruments, equipment and reusable glassware:

[ ]  **SOP-BIO-005** – *Decontamination of Reusable Labware, Work Surfaces and Equipment.*

[ ]  **SOP-BIO-007** – *Cleaning Biological Spill inside the Centrifuge*.

[ ]  **SOP-BIO-008** – *Cleaning and Decontamination of Small Spills in the Lab or inside the Biosafety Cabinet.*

[ ]  **SOP-BIO-009** – *Cleaning Instruments and Materials Used for Handling Potentially Prion Infected Neural Tissue.*

[ ]  **SOP-BIO-010** – *Usage and Cleaning of the Biosafety Cabinet.*

[ ]  **N/A -** describe here other procedures to be followed for cleaning and decontamination or explain why none are required:

**2. Waste Generation and Disposal**

Check below all SOPs applicable to waste generation and disposal:

[ ]  **SOP-BIO-001** – *Lab Glassware and Disposal*.

[ ]  **SOP-BIO-002** – *Sharps Usage and Disposal* (includes needles, blades, syringes, scalpels, lancets and only broken glassware contaminated with blood or infectious material).

[ ]  **SOP-BIO-003** – *Disposal of Solid Biohazardous Waste* (includes plastic lab ware such as culture flasks, plates, petri dishes, pipette tips, plastic pipettes and tubes used with materials and may include agar).

[ ]  **SOP-BIO-004** –*Decontamination of Liquid Biohazardous Waste* (includes culture media, effluents or supernatant collected after centrifugation or filtration).

[ ]  **N/A** – describe here other procedures to be followed for waste generation and disposal:

**3. Will any radioactive biological waste be generated?** [ ]  Yes [ ]  No

a. If yes, estimate the amount generated per week?

b. Has radiation safety approved this? [ ]  Yes [ ]  No If Yes, add date of approval:

c. Describe how waste will be transported and to where, if applicable. (For example, include procedure for transport to autoclave):

**4. PI Assurances**

[ ]  I will be submitting a Non-Hazard Waste Determination Form for liquid waste sink disposal.

<https://www.uml.edu/docs/Non%20Hazardous%20Waste%20Determination%20Form%202018_3_19_18_tcm18-289071.pdf>

[ ]  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 agree to abide by all of the SOPs that are checked above for this registration.

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 these organisms 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. Describe **laboratory procedures that pose a risk of exposure** to the biohazardous material(s), for example plating, injection, use of sharps, transfer, and/or counting of cells:

1. Describe **procedures** that will be used to prevent these potential exposures:

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. Will sharps be used during the study (needles, blades, glass slides, etc.)? [ ]  Yes [ ]  No

*NOTE: Plastic pipette tips are not considered sharps.*

1. Indicate in the table below all types of personal protective equipment (PPE) required at any time for handling or manipulating the biological materials.

|  |  |  |
| --- | --- | --- |
|   **Type of PPE** | **Check all that apply** | **Specific Procedure Used For** |
| Gloves | [ ]  |       |
| Safety glasses | [ ]  |       |
| Closed-front gown | [ ]  |       |
| Lab coat | [ ]  |       |
| Shoe covers | [ ]  |       |
| Face shield | [ ]  |       |
| Respirator type:       | [ ]  |       |
| Other:       |  [ ]  |       |

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

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

1. **ACCIDENTAL EXPOSURE AND SPILLS**

*NOTES:*

1. *Any time someone is uncomfortable cleaning up a spill, regardless of volume, call 978-934-4911 for assistance.*
2. *Any time a spill occurs in a common area, call 978-934-4911for assistance.*
3. *For questions 1, 4 and 5, check all of the boxes to indicate you understand the recommended procedures to follow.*
4. If **someone is exposed to biohazardous materials or organisms**, I understand the action plan will be as follows (the first 3 are required by the UMass Lowell BBP Exposure Control Plan):

|  |
| --- |
| [ ]  If personnel are exposed to potentially infectious materials, the person should immediately wash the affected area with soap and water then follow the reporting procedures outlined in the UML Bloodborne Pathogen Exposure Control Plan. |
| [ ]  Arrangements will be made for the appropriate medical treatment and follow-up. |
| [ ]  An incident report will be completed by the exposed person and filed with EHS. |
| [ ]  If other, indicate here:       |

1. Indicate how staff/personnel will be educated and trained to handle the materials safely, prevention of spills and exposure, handling of spills and exposure and potential symptoms and illnesses that may result from exposure (*check all that apply*).

|  |
| --- |
| [ ]  Chemical Hygiene Plan (which includes chemical materials) |
| [ ]  UMass Lowell Biosafety Guide / Exposure Control Plan (BBP) |
| [ ]  Agent specific training provided by the PI |
| [ ]  Standard Operating Procedures available in laboratory. |
| [ ]  Other:       |

1. For spill planning, what is the maximum volume of the registered materials that will be used at any time?
2. **Small** (20 mL or less) accidental, low hazard spills and/or releases of the biohazardous material or organism will be handled as follows:

|  |
| --- |
| [ ]  Wearing PPE (at a minimum, lab coat, gloves and safety glasses), surround the spill with paper towels and cover the small spill with freshly prepared 10% bleach, and let sit for 20 minutes. Removed the soaked paper towels and dispose them in the biohazard bag for routine EHS pickup. |
| [ ]  Wearing PPE (at a minimum, lab coat, gloves and safety glasses), if the small **spill includes broken glass**, surround the spill with paper towels, pour freshly prepared 10% bleach over the spill and let sit for 20 minutes. Pick up the broken glass with tongs or using two dust pans and place the broken glass in a sharps container or discard in a broken glass receptacle. Dust pans or tools such as tongs can be treated with 10% bleach after use. Do not pick up glass with gloved hands. |
| [ ] When all of the debris has been removed, the area should again be decontaminated with freshly prepared 10% bleach as above. |
| [ ]  Other:       |

1. **Large** (greater than 20 mL) accidental spills and/or release of any biohazardous material or organism will be handled as follows:

|  |
| --- |
| [ ]  Call 978-934-4911 Identify your name, building location, material, quantity and if anyone was hurt. |
| [ ]  Other:       |

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* [*http://oba.od.nih.gov/rdna/nih\_guidelines\_oba.html*](http://oba.od.nih.gov/rdna/nih_guidelines_oba.html)

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
				3. What are the potential biohazards of the product produced by this gene (*if you have references to support your assessment, please include*)?
				4. 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 Q.)

[ ]  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. List the source of the infectious agent: [ ]  Purchased or [ ]  Obtained from another laboratory

 Explain:

f. 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 experiments 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.*

* *The CITI module on OSHA Bloodborne Pathogens is required for this work. Refer to Section E.*
* *NOTE: BSL-2 practices are required for this work; refer to* [*http://www.cdc.gov/biosafety/publications/bmbl5/BMBL.pdf*](http://www.cdc.gov/biosafety/publications/bmbl5/BMBL.pdf) *or* [*www.uml.edu/ehs*](http://www.uml.edu/ehs) *for guidance.*

**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. Has everyone listed in the registration been offered the Hepatitis B vaccine? [ ] Yes [ ] No

*(For more information, contact the Biosafety Officer at* *biosafety@uml.edu* *or call 978-934-2618.)*

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 Elaine Major at 978-934-3452.*

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. For each agent, provide the following information (copy and insert table to include more agents if needed.):

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Agent 1** | **Agent 2** | **Agent 3** | **Agent 4** |
| Hazardous Biological Agent |       |       |       |       |
| Dose administered |       |       |       |       |
| Exposure route | [ ]  Intraperitoneal[ ]  Intramuscular[ ]  Intravenous[ ]  Subcutaneous[ ]  Intracerebral[ ]  Intranasal[ ]  Inhalation[ ]  Gavage[ ]  Other:  | [ ]  Intraperitoneal[ ]  Intramuscular[ ]  Intravenous[ ]  Subcutaneous[ ]  Intracerebral[ ]  Intranasal[ ]  Inhalation[ ]  Gavage[ ]  Other:  | [ ]  Intraperitoneal[ ]  Intramuscular[ ]  Intravenous[ ]  Subcutaneous[ ]  Intracerebral[ ]  Intranasal[ ]  Inhalation[ ]  Gavage[ ]  Other:  | [ ]  Intraperitoneal[ ]  Intramuscular[ ]  Intravenous[ ]  Subcutaneous[ ]  Intracerebral[ ]  Intranasal[ ]  Inhalation[ ]  Gavage[ ]  Other:  |
| Animal facility room no.  |       |       |       |       |
| Length of time animals are housed in facility |       |       |       |       |

*NOTE: The use of hazardous chemicals in animals will require**a standard operating procedure (SOP)**approved by EHS, since the use and disposal of all hazardous chemicals requires overview by EHS.*

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 | [ ]  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 M? [ ] 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 will you dispose of biological materials used in the animal facility:

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

**S. 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, <http://www.selectagents.gov/SelectAgentsandToxinsList.html>, be aware that these agents are controlled by the U.S. Department of Commerce and approval from the Export Control Compliance Manager is required before the registration may be approved. Contact Thomas\_Porro@uml.edu or call 978-934-3207 for assistance.

The possession, use, shipping or receiving of Select Agents also requires that the facility be registered with the Centers for Disease Control and Prevention. Special containment and controlled access to facilities that contain Select Agents is also required for these substances. To comply with federal law, PIs are required to register the possession of Select Agents with the IBC. Failure to comply may result in criminal penalties.

Please contact the Biosafety Officer (biosafety@uml.edu) for information about how to proceed for a project that requires the use of Select Agents and how to complete the form “Research Using Select Agents” before submitting it to the IBC for review.

1. **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.*

**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/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 Standard Operating Procedures for routine cleaning and decontamination as well as waste generation, disposal and transportation.

[ ]  I understand that written reports will be submitted to EHS (Ruth\_Medina@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.

[ ]  I understand I am responsible for the overall safety and health of personnel indicated on this registration.

|  |
| --- |
| 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.