IBC No.:
Date Received:
BSL Assignment Level:
III-F Exempt, Approved by:
Supporting Documents on File: ☐Yes ☐No
Approval Date:

IBC RESEARCH REGISTRATION FORM

Please send your completed registration form electronically to orsp@umb.edu and umbehs@umb.edu

A. PRINCIPAL INVESTIGATOR INFORMATION

PI Name		**Office Ext.**	
Department		**Lab Ext.**	
Mailing Address		**Email**	

B. PROJECT TITLE

C. TYPE

1. ☐ **New Protocol** ☐ **Amendment** ☐ **Three Year Review/Update** **Previous #:**
2. **Project Period:** to
3. ☐ **Research or** ☐ **Classroom Laboratory**

Other Committee Review and Approvals:

Does your project involve:	Check One:	If yes, then you also need approval from:	Protocol Number & Approval Date (MM/DD/YYYY):	Contact Person:
Animal	☐ Yes ☐ No	IACUC	No.: Date:	orsp@umb.edu
Human Subjects (Including stem cells)	☐ Yes ☐ No	IRB	No.: Date:	orsp@umb.edu
Radiation	☐ Yes ☐ No	Radiation Safety Office	No.: Date:	umbehs@umb.edu

D. FUNDING INFORMATION

☐ Funded ☐ Non-Funded

If funded, list funding source and grant or contract number:

PERSONNEL AND TRAINING

Provide names, title, and applicable training for all personnel involved. EHS Lab Safety and Biosafety/BBP training is required for all PIs, as well as any faculty, students, or staff involved in handling biological materials.

Name and Title	Email Address	Training Completed (MM/DD/YY)
Name: Position:		☐ EHS Lab Safety Date: ☐ EHS Biosafety Date:

Name: Position:		☐ EHS Lab Safety Date: ☐ EHS Biosafety Date:
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Name: Position:		☐ EHS Lab Safety Date: ☐ EHS Biosafety Date:
Name: Position:		☐ EHS Lab Safety Date: ☐ EHS Biosafety Date:

Enter additional personnel and training information here if applicable. Attach additional pages if needed.

E. PROJECT(S) OVERVIEW

In one paragraph, provide a project description in lay language (i.e. language that could be understood by students or community members).

F. PROJECT DESCRIPTION

Provide a detailed description of all procedures involving biological materials. Provide enough detail so that the techniques and purposes of the experiments with the biological materials are clear. If using vertebrate animals, describe what biological materials will be introduced into the animals. Submit a separate attachment if your response is greater than 300 words.

G. BIOLOGICAL MATERIALS

Identify all biological materials by category and its source.

Biological Category	Source (Vendor/Collaborator)
☐ rDNA ☐Human/Non-human Primate Materials (e.g. cells, tissue) ☐ Microorganisms ☐Viral Vectors ☐Biological Toxins	
☐ rDNA ☐Human/Non-human Primate Materials ☐ Microorganisms ☐Viral Vectors ☐Biological Toxins	
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☐ rDNA ☐Human/Non-human Primate Materials ☐ Microorganisms ☐Viral Vectors ☐Biological Toxins	

H. COLLECTION AND TRANSPORT OF MATERIALS

1. Are the materials present in the lab? ☐ Yes ☐No
   a) Were they ☐created or ☐acquired?
2. Are the materials listed in the registration being purchased? ☐Yes ☐No
3. How are the materials transported?
4. The maximum total volume transported is (included units):
5. The maximum container size used during transport is (include units):

I. RISK GROUP AND BIOSAFETY LEVEL

Identify the risk group (RG) for the biological materials to be used and biosafety level(s) (BSL) required for the project (for guidance, refer to *https://osp.od.nih.gov/biotechnology/nih-guidelines/* and/or *http://www.cdc.gov/biosafety/publications/bmbl5/BMBL.pdf*).

Check One:	Check One:
RG-1 ☐	BSL-1 ☐
RG-2 ☐	BSL-2 ☐
RG-3 ☐	BSL-3 ☐

Explain the rationale for biosafety level requirements:

J. LABORATORY INFORMATION

List **ALL** labs/facilities where work will be conducted. Check all that apply.

Building	Room Number	Biological Safety Cabinet	Sharp Container	Autoclave	Biological Waste Disposal Box
		☐	☐	☐	☐
		☐	☐	☐	☐
		☐	☐	☐	☐
		☐	☐	☐	☐
		☐	☐	☐	☐

Will the materials be transferred between the buildings and/or rooms? ☐ Yes ☐ No
(All buildings and rooms should be noted in the table above.)

If YES, check the box below indicating you understand and comply with the following:
☐ All materials will be transported in closed and unbreakable secondary containers.

K. GENERAL SAFETY INFORMATION

1. If BSL-2, identify equipment used during the study that could potentially aerosolize the material and describe measures implemented to prevent aerosol exposure.

2. Do your procedures require handling or manipulation of the biological materials that need personal protective equipment (PPE) other than: gloves, safety glasses, lab coat? ☐ Yes ☐ No
   If Yes, please list and explain:

3. Disinfectants used for decontamination of surfaces and equipment

L. RECOMBINANT DNA TECHNOLOGY

1. Describe inserted/altered genetic elements (include origin and biological function):
   a. Indicate the source of DNA/RNA sequences (include genus, species) **to be cloned**:
   b. If the source is a microorganism (bacteria, fungi, virus, etc.), do you have the microorganism in your laboratory? ☐ Yes ☐ No
      If Yes, list:
   c. Recombinant plasmid(s)/vector(s) used to manipulate and/or express gene(s) (check those that apply):
      ☐ Bacterial Plasmid ☐ Adenoviral ☐ Herpes viral
      ☐ Retroviral ☐ Adeno-associated viral ☐ Lent viral
      ☐ Pox viral
      ☐ Other mammalian virus, specify:

2. If using a viral vector, provide the following information (transfer vector and insert, packaging constructs, cell lines, source and function of the insert, host range of packaged viral vector, virus titer):

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

4. 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:

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

6. Will this project produce transgenic animals? ☐ Yes ☐ No
If Yes, explain:

7. Will this project transfer recombinant material in vivo to plants or animals? ☐ Yes ☐ No
If Yes, explain:

8. For experiments involving rDNA, the Principal Investigator must identify the appropriate NIH Guideline category/categories under which your experiments fall:
☐ Section III-D ☐ Section III-E ☐ Section III-F

NIH Guidelines Information:
Section III-D: Using Risk Group (RG) 2, 3, or 4 or Restricted Agents as host-vector systems; cloning DNA from RG 2, 3, or 4 or Restricted Agents into nonpathogenic or lower eukaryotic host-vector systems; using infectious DNA or RNA viruses or defective DNA or RNA viruses plus helper virus in tissue culture systems; experiments to genetically engineer plants requiring BSL2 or higher containment; experiments involving >10 liters of culture; experiments involving influenza viruses. This also includes experiments involving whole animals in which the animal's genome has been altered by stable introduction of recombinant or synthetic nucleic acid molecules, into the germ-line (transgenic animals) and experiments involving viable recombinant or synthetic nucleic acid molecule-modified microorganisms tested on whole animals.

Section III-E: Using components derived from nonpathogenic prokaryotes and nonpathogenic lower eukaryotes; creation of rDNA molecules containing no more than 2/3 of genome of any
eukaryotic virus; generating transgenic rodents that require BSL-1 containment.

Section III-F: Experiments involving rDNA that are not in organisms or viruses; experiments which consist entirely of DNA from a prokaryotic or eukaryotic host when propagated in the same host; breeding of BSL-1 transgenic rodents

For more information see the NIH Guidelines: *https://osp.od.nih.gov/biotechnology/nih-guidelines/*. If you believe your use of rDNA does not fall into Sections IIII- E, or III-F, or if you have questions, please contact umbehs@umb.edu.

M. SELECT AGENTS

Do you currently use or plan on using Select Agents (Bioterrorism Agents) http://www.selectagents.gov/? If yes, please contact umbehs@umb.edu. ☐ Yes ☐ No
If Yes, list agent and/or toxin and explain use:

N. EXPORT CONTROL COMPLIANCE

Material leaving your laboratory must be reviewed by the Export Control Compliance manager, Matthew.Meyer@umb.edu.

1. ☐ This material is not on the Commerce Control List (CCL) and the registration may proceed for IBC approval.
2. ☐ 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.

O. CLASSROOM/TEACHING LABORATORIES

List the course name, number, and location of where biological materials are being used:

Course Name	Course Number	Location

P. PRINCIPAL INVESTIGATOR ASSURANCE AND SIGNATURE

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.***

1. ☐ I will not initiate Recombinant DNA 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.
2. ☐ I have reviewed the UMass Boston Laboratory Safety Policies and Procedures, UMass Boston Biosafety Manual, and applicable Standard Operating Procedures and agree to abide by the requirements of the current NIH and CDC Guidelines and other specific regulations pertaining to the proposed research.
3. ☐ I understand that an amended registration must be submitted to the IBC for review if there is any change in the Biosafety Risk levels for any proposed research.
4. ☐ I understand I am responsible for the overall safety and health of personnel indicated on this registration.
5. ☐ I understand and agree to follow routine cleaning and decontamination procedures for work surfaces, instruments, equipment, and reusable glassware.
6. ☐ I agree to follow the waste management requirement set out in the EHS/Chem plan for solid and liquid biological waste as well as sharps and broken glassware contaminated with bio hazardous materials.

PI Printed Name:	**Date:**

Provide any additional information if necessary: