**Fitchburg State University - IBC Registration Form**

**Registration for the Use of Recombinant DNA and Synthetic Nucleic Acids, Human and Non-Human Primate Materials, and Biological Agents and Toxins**

**SECTION 1 – GENERAL INFORMATION**

|  |
| --- |
|   |
| Date |  |
| Principle Investigator Name |  |
| Email  |  |
| Project Title |  |
|  |  |
| Department |  |
| Proposed Biosafety Level |  |
| (BSL1 or BSL2) |  |
| IBC Registration Number |   |
|  |  |

**SECTION 2 – LOCATION AND PERSONNEL INFORMATION**

List ALL Laboratories/Facilities where work is to be conducted and the corresponding biosafety level: include cold rooms, equipment rooms, storage rooms, and vivarium spaces as appropriate. Please indicate room(s) where biosafety cabinets (BSCs) are located. Specify the cabinet and shelf identification number.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |
| Building | Room | Biosafety Level (BSL1 or BSL2) | Biosafety Cabinets in Room | Equipment Room | Shared Room |
|  |   | **BSL 1 [ ] BSL 2 [ ]** | Yes **[ ]**No **[ ]** | Yes **[ ]**No **[ ]** | Yes **[X]**No **[ ]** |
|   |   | **BSL 1 [ ] BSL 2 [ ]**  | Yes **[ ]**No **[ ]**  | Yes **[ ]**No **[ ]** | Yes **[X]**No **[ ]** |
|   |   | **BSL 1 [ ] BSL 2 [ ]** | Yes **[ ]**No **[ ]** | Yes **[ ]**No **[ ]** | Yes **[X]**No **[ ]**  |
|   |   | **BSL 1 [ ] BSL 2 [ ]** | Yes **[ ]**No **[ ]** | Yes **[ ]**No **[ ]** | Yes **[X]**No **[ ]**  |
|   |   | **BSL 1 [ ] BSL 2 [ ]**  | Yes **[ ]**No **[ ]** | Yes **[ ]**No **[ ]** | Yes **[X]**No **[ ]** |
|   |   | **BSL 1 [ ] BSL 2 [ ]**  | Yes **[ ]**No **[ ]** | Yes **[ ]**No **[ ]** | Yes **[X]**No **[ ]** |
|   |   | **BSL 1 [ ] BSL 2 [ ]**  | Yes **[ ]**No **[ ]** | Yes **[ ]**No **[ ]**  | Yes **[X]**No **[ ]** |
|   |   | **BSL 1 [ ] BSL 2 [ ]**  | Yes **[ ]**No **[ ]** | Yes **[ ]**No **[ ]** | Yes **[X]**No **[ ]** |
|  |  |  |  |  |  |

**Is the Cold Room (Science 114) being used?** Yes **[ ]** No **[ ]**

**Is the Vivarium (Science 101A-101H) being used?** Yes **[ ]** No **[ ]**

**In the utilized rooms, specify any biosafety cabinet and shelf identification numbers.**

**List all personnel working with materials described in this registration:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| First Name | Last Name | Works with Human Materials | Completed CITI Biosafety Training | Completed Responsible Conduct of Research Training |
|  |   | Yes **[ ]** No **[ ]** | Yes **[ ]** No **[ ]** | Yes **[ ]**  No **[ ]** |
|   |   | Yes **[ ]** No **[ ]** | Yes **[ ]** No **[ ]** | Yes **[ ]** No **[ ]** |
|   |   | Yes **[ ]** No **[ ]** | Yes **[ ]** No **[ ]** | Yes **[ ]** No **[ ]** |
|   |   | Yes **[ ]** No **[ ]** | Yes **[ ]** No **[ ]** | Yes **[ ]** No **[ ]** |
|   |  | Yes **[ ]** No **[ ]** | Yes **[ ]** No **[ ]** | Yes **[ ]** No **[ ]** |
|   |   | Yes **[ ]** No **[ ]** | Yes **[ ]** No **[ ]** | Yes **[ ]** No **[ ]** |
|   |   | Yes **[ ]** No **[ ]** | Yes **[ ]** No **[ ]** | Yes **[ ]** No **[ ]** |
|   |  | Yes **[ ]** No **[ ]** | Yes **[ ]** No **[ ]** | Yes **[ ]** No **[ ]** |

**Registration is not complete until all researchers have fulfilled the training requirements.**

**Are students from a course involved in the registered research? Yes** **[ ]** **No [ ]**

**If yes, provide the course catalog number and name:**

**If individual training is required, what is the anticipated date for completion of training?**

**If students have not been fully trained, state how you intend to have students complete the CITI biosafety and the responsible conduct of research training prior to starting the research project? Name any additional CITI biosafety modules that students should complete?**

**SECTION 3 – NON-TECHNICAL SUMMARY**

Include a non-technical summary written at a level that a non-scientist committee member will understand. Include information regarding the overall goal(s) of the project. Clearly describe the purpose of the work and the techniques that will be used. Clarity and brevity should be considered for the purpose of this non-technical summary.

**SECTION 4 – RECOMBINANT OR SYNTHETIC NUCLEIC ACID**

Do you use or generate recombinant microorganisms, cells, or animals?

 Yes **[ ]** No **[ ]**

***If no, proceed to Section 5. If yes, please complete the following:***

What section(s) of the NIH Guidelines for Research Involving Recombinant or Synthetic DNA Molecules apply to this project? If you are unsure, contact the Biosafety Officer or check <http://oba.od.nih.gov/rdna/nih_guidelines_oba.html>. Note that work that is exempt under Section III-F or Appendix C of the NIH Guidelines must still be registered.

 **[ ]** Section III-A

 **[ ]** Section III-B

 **[ ]** Section III-C

 **[ ]** Section III-D

 **[ ]** Section III-E

 **[ ]** Section III-F

Specify the DNA/RNA source (or probe), nature of insert, is a protein expressed, and percent of any viral genome in the construct. If any sequences code for toxins, please specify.

Is the DNA source from a USDA-regulated plant, animal or insect?

 Yes **[ ]** No **[ ]**

Identify cloning/expression/transfection vectors, recipient bacterial strains, and recipient host cell lines (human, mouse, etc). List the vendor, laboratory or other source from which each material was obtained. Describe the location and type of promoters and other control sequences, and percent of any viral genome in the construct.

If using viral vectors, indicate packaging cell lines and whether replication competent virus (RCV) is produced. If available, provide a vector map. Describe the assay system to measure helper virus titer or titer of replication competent virus generated. Include host range of packaged viral vector.

**SECTION 5 – HUMAN AND NON-HUMAN PRIMATE MATERIALS**

Do you work with human or non-human primate materials (cell lines, tissues, blood)?

 Yes **[ ]** No **[ ]**

***If yes, please complete the following:***

List materials and the source of the materials (e.g. field collection, another Fitchburg State laboratory, an external collaborator, ATCC, etc.).

**SECTION 6 – BIOLOGICAL AGENTS**

Do you work with microbes (viruses, bacteria, fungi, rickettsia, prions)? Yes No

 Yes **[ ]** No **[ ]**

***If yes, please complete the following:***

List biological agent(s) including microorganism genus/species/strain, host range, any antibiotic resistance, recommended biosafety level, and the source of the agent (e.g. a lab within Fitchburg State, an external collaborator, ATCC, etc.).

Describe experiment and procedures involving use of the agent(s). Indicate culture volume, maximum concentration. How and at what stage of the work is the biological agent inactivated or lysed?

Will this work result in the acquisition of new characteristics such as enhanced virulence, drug or antibiotic resistance, or change in host range? If so, explain.

**SECTION 7 – BIOLOGICAL TOXINS**

Will biological toxins (microbial and/or non-microbial) be used?

 Yes **[ ]** No **[ ]**

***If yes, please complete the following:***

|  |  |  |  |
| --- | --- | --- | --- |
|  |  |  |  |
| **HHS & USDA Select Agent Toxins** | **Max. qty. in lab (mg)** | **Working Dilution** | **Use in Animals** |
| Abrin  |   |   | Yes **[ ]** No **[ ]** |
| Conotoxins |   |   | Yes **[ ]** No **[ ]**  |
| Diacetoxyscirpenol (DAS) |   |   | Yes **[ ]** No **[ ]** |
| Ricin |   |   | Yes **[ ]** No **[ ]**  |
| Saxitoxin |   |   | Yes **[ ]** No **[ ]**  |
| Tetrodotoxin |   |   | Yes **[ ]** No **[ ]** |
| Shiga-like ribosome inactivating proteins |   |   | Yes **[ ]** No **[ ]**  |
| Botulinum neurotoxins |   |   | Yes **[ ]** No **[ ]**  |
| Clostridium perfringens epsilon toxin |   |   | Yes **[ ]** No **[ ]**  |
| Shigatoxin |   |   | Yes **[ ]** No **[ ]** |
| Staphylococcal enterotoxins |   |   | Yes **[ ]** No **[ ]**  |
| T2-toxin |   |   | Yes **[ ]** No **[ ]**  |
| **Other Toxins of Biological Origins** |   |   | Yes **[ ]** No **[ ]**  |
| Diphtheria toxin |   |   | Yes **[ ]** No **[ ]**  |
| Vibrio cholera, Subunit A |   |   | Yes **[ ]** No **[ ]**  |
| Pertussis toxin |   |   | Yes **[ ]** No **[ ]**  |
| Cholera toxin |   |   | Yes **[ ]** No **[ ]**  |
| OTHER (please list) |   |   | Yes **[ ]** No **[ ]**  |
|  |  |  |  |

Please describe the overall use of toxins of biological origins including Select Agent Toxins.

**SECTION 8 – USE OF ANIMALS**

**Are vertebrate animals being used in this research? Yes [ ] No [ ]**

If yes, contact the Institutional Animal Care and Use Committee to register your animal research.

IACUC Protocol Number(s):

Will microorganisms, recombinant or synthetic nucleic acid molecules, human materials or biological toxins be used in **vertebrate or invertebrate** animals?

 **Yes [ ] No [ ]**

**If yes, please describe the objective of the research.** Include recipient species and describe how the biological materials will be administered.

Will transgenic animals (e.g. knockouts) be generated? **Yes [ ] No [ ]**

**If yes, please provide information on the transgene and vector used as well as the expected phenotype of the recombinant animal.**

**SECTION 9 –PRACTICES AND PROCEDURES**

The clarity of this section to the reviewer is of utmost importance to the review process. Please be appropriately descriptive, and whenever possible limit the scope of the responses.

1. Identify and discuss the health and safety risks associated with the use of biological materials described in this protocol.

2. Describe the signs and symptoms of exposure, the mode(s) of transmission, and availability of vaccine or therapeutic treatment, providing appropriate references when available.

3. What procedures create the greatest risk of exposure or infection (e.g. aerosolization of materials), and how will this risk be minimized during the course of the research:

4. Outline protective equipment required to minimize exposure of laboratory personnel during all procedures requiring handling or manipulation of biological agent e.g. use of gloves, lab coats, safety glasses, etc.

5. Outline decontamination procedures and disinfectant(s) to be used for work surfaces, instruments, equipment, liquid containing biological materials and glassware:

6. Outline disposal/decontamination procedures for contaminated sharps, contaminated solid waste, tissues, pipette tips, etc.

7. If mixed waste will be generated (radioactive/biological or chemical/biological), indicate how you will inactivate the biological component of the mixed waste.

**SECTION 10 – DUAL-USE ASSESSMENT**

**Does the research proposal qualify as dual use? Yes [ ] No [ ]**

**(Carefully read and answer the below questions)**

Please read the following questions and check the appropriate box.

1. Will the experiment(s) result in acquisition of new characteristics such enhanced virulence, infectivity, stability, transmissibility, or the ability to be disseminated? If so, explain:

2. Will the experiment(s) result in resistance to useful prophylactic or therapeutic interventions? If so, explain:

3. Will the experiment(s) result in the biological agent being able to evade detection methodologies as such that the capacity to identify or provide treatment for the agent? If so, explain:

4. Will the experiment(s) enhance the susceptibility of a host to the biological agent? If so, explain.

5. Will the experiment(s) cause disruption in the immunity of the host or the effective next of an immunization or change the host range? If so, explain:

6. Will the experiment(s) generate or reconstitute a biological agent for which there are no known or widely available prophylactic or therapeutic interventions? If so, explain.

7. Will your research result in the development of materials or technologies with “dual use” potential?

 **Yes [ ] No [ ]**

If so please explain:

If yes, please indicate which question number(s) and your corresponding answer below.

**SECTION 11 – CERTIFICATION**

The information contained in this registration is accurate and complete. I am familiar with and agree to abide by all guidelines and regulations pertaining to this research. These guidelines and regulations include the current NIH Guidelines for Research Involving Recombinant and Synthetic Nucleic Acid Molecules; CDC and NIH guidance documents such as “Biosafety in Microbiological and Biomedical Laboratories”; the DHHS and USDA Select Agents and Toxin regulations; 105 CMR 480.000 Minimum Requirements for the Management of Medical or Biological Waste; as well as any Fitchburg State University Policies and Procedures and other local, state and federal regulations that may be applicable.

Specifically I agree to abide by the following requirements:

a. I will not initiate any biological research subject to the regulations and guidelines mentioned above until that research has been registered, reviewed and approved by the Institutional Biosafety Committee.

b. I will assure that personnel have received appropriate information about the biological hazards of the research outlined in this registration by making available copies of approved protocols, Biosafety Manuals, and Biological Research Registrations that describe the potential biohazards and precautions to be taken to prevent exposures or release to the laboratory or the environment. I will assure that all policies outlined in the Biosafety Manual will be followed.

c. I am familiar with and will ensure use of appropriate biosafety level laboratory practices and procedures in the conduct of this research.

d. I certify that project personnel have been trained in appropriate technical and safety procedures.

e. I will ensure that project personnel know the procedures for dealing with incidents and spills of biological materials, and know the appropriate waste management procedures.

f. I will comply with all shipping requirements for biohazardous materials.

g. I will ensure that all project personnel working with biological materials are listed on this

registration.

h. I will assure that all project personnel have completed all necessary training and that their

training records are up to date.

i. I certify that all spaces associated with the activities described in this registration are

listed.

j. I will assure adequate supervision of personnel, and will correct work errors and

conditions that could result in breaches of the guidelines and regulations pertaining to this

work as listed above.

k. I will inform the Environmental Health and Safety Office and the Dean of Health and Natural Sciences of any serious spills, potential exposures or breaches of the guidelines and regulations listed above.

l. Any intentional alteration of the embedded text within this form will result in immediate revocation of biological research privileges recognized by the Institutional Biosafety Committee and the Provost and Dean of Health and Natural Sciences will be notified.

**PI Name (print):** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_

**Department Chair (print):** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_

**Institutional Biosafety Committee Chair (print):** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_