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University of Rochester Institutional Biosafety Committee
Laboratory Registration Form

Each Principal Investigator must register all biologicals in their possession that fall under the IBC "registration umbrella". When completing this document you must answer the questions relative to the biologicals possessed by you and those individuals in your lab. These biologicals include recombinant DNA; pathogens affecting animals, humans, and plants; mammalian cell and cell lines; human blood, other fluids, and tissues; and select agents. The Laboratory Registration form is completed once and updated periodically.

1. Complete this document relative to your laboratory operations, and to the biologicals that are possessed by the laboratory. **Agents that are possessed are considered those actively used or in storage.**

2. For YES / NO questions, place "X" in the box next to the correct answer and complete corresponding question subparts.

3. Many questions have several subparts. Check carefully to ensure that all question subparts are answered.

4. Please do not use abbreviations. The IBC does not always know what you mean when you abbreviate.

5. If applicable, laboratory registrations of senior Principal Investigators may be used by "junior" Principal Investigators of the same laboratory.

6. This document will be used to support your requests for IBC approval and is provided to Environmental Health and Safety for emergency response purposes.

7. Submit this document with supporting attachments (see Section IX for list) electronically as PDF or Word email attachment to the IBC Program Coordinator ddouglass@safety.rochester.edu . Fax (274-0001) or mail (RC Box 278878) a signed copy to the IBC.

8. All labs seeking IBC approval must have a Lab Registration on file. If you are unsure if one has been submitted for your lab OR if you need to modify your Lab Registration, contact the IBC Program Coordinator ddouglass@safety.rochester.edu for an electronic copy.

Useful Resources

- UR Biosafety Requirements and Resources http://www.safety.rochester.edu/labbiosafe/biosftyrequireresource.html
- IBC web pages http://www.safety.rochester.edu/homepages/ibchome.html
- NIH Guidelines http://oba.od.nih.gov/oba/rac/Guidelines/NIH_Guidelines.htm
- 5th edition of CDC/NIH "Biosafety in Microbiological and Biomedical Laboratories" http://www.cdc.gov/biosafety/publications/bmbl5/BMBL.pdf

Bio-containment and safety questions can be referred to the Biosafety Officer srosen22@safety.rochester.edu .

Revision date: 1/3/14

Form

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Laboratory Registration Form

Principal Investigator: Dept: Phone:

Technician or Alternative Contact: Phone:

➢ Section I: Recombinant DNA (rDNA)

Question 1. Do you possess an infectious recombinant mammalian virus, which will be used as a vector system or as a vehicle to transfer genetic material (**Mammalian Virus Vector**)?

	No	***Skip to Question 2 of this section.***
	Yes	***If yes, provide a completed Mammalian Viral Vector Registration for each vector system or list its registration number in the text box below. Contact the IBC Program Coordinator if you have questions.*** *University Specific Guidelines: http://www.safety.rochester.edu/ibc/extendedhelp.html* *IBC Forms: http://www.safety.rochester.edu/ibc/ibcmainmenu.html*

Viral Vector Registration Numbers

Question 2. Do you possess recombinant DNA other than Mammalian Virus Vectors? Examples include plasmid DNA and recombinant DNA modified organisms or genetically engineered organisms.

	No	***Skip to Section II.***
	Yes	***If yes, complete Question 3of this section and all subparts.*** *Use NIH Guidelines Section I-B as reference:* http://oba.od.nih.gov/oba/rac/Guidelines/NIH_Guidelines.htm#_Toc7261549

Question 3. Are your constructs capable of and/or will your experiments involve any of the following?

Question 3.a. Formation of recombinant DNA containing genes for biosynthesis of toxins

	No	***Skip to question 3.b. of this section.***
	Yes	***If yes, complete Table 3.a below. Expand as necessary.*** *Use NIH Guidelines Section III-B-1 as reference:* http://oba.od.nih.gov/oba/rac/Guidelines/NIH_Guidelines.htm#_Toc7261563

Table 3.a.

Specify organism from which the toxin genes originate	Specify the toxin

Question 3.b. Construct contains full-length genes for drug resistance that, if expressed in disease agents of humans, animals, or plants, could compromise control of infection by those agents. (This does NOT refer to drug resistance markers used for selection during routine cloning in non-pathogenic *E. coli*.)

	No	***Skip to Section II.***
	Yes	***If yes, complete Table 3.b below. Expand as necessary.*** *Use NIH Guidelines Section III-A-1-a as reference:* http://oba.od.nih.gov/oba/rac/Guidelines/NIH_Guidelines.htm#_Toc7261561

Table 3.b.

Specify Organism	Specify Drug	Specify gene

➢ Section II: Pathogens including non-recombinant and recombinant pathogens

(Mammalian viral vectors should be declared under Section I question 1.)

Question 1. Do you possess pathogens affecting humans, animals, or plants?

	No	***Skip to Section III.***
	Yes	***If yes, complete Table 1 below by listing your pathogens and providing the information requested for each listed pathogen. Expand the table as necessary. If your pathogens are already tabulated with the requested information in another format, attach your document and note "see attached" in the table.*** *University Specific Guidelines: http://www.safety.rochester.edu/ibc/extendedhelp.html*

Table 1.

Pathogens (genus, species, strain)	**Indicate which your agent is pathogenic for. List all that apply. (Human, animal - other than human, plant)**	**Indicate the maximum quantity produced or worked with at any one time.**

➢ Section III: Mammalian Cells, Cell lines, and Unfixed Tissues

Question 1. Do you possess mammalian cells or fluids, mammalian cell lines, or mammalian unfixed tissues? Use this section to declare human fluids such as blood and sera.

	No	***Skip to Section IV.***
	Yes	***If yes, complete Question 2 of this section.*** *University Specific Guidelines: http://www.safety.rochester.edu/ibc/extendedhelp.html*

Question 2. What is the maximum quantity cultured or worked with at any one time? Check one box.

	< 1 liter
	1-10 liters
	> 10 liters
	Not Applicable (i.e. tissues)

➢ Section IV: Select Agents

Question 1. Do you possess select agents (pathogens, recombinant DNA, or toxins of biological origin) as outlined in 42 CFR 73, 9 CFR 121, or 7 CFR 331?

	No	***Skip to Section V.***
	Yes	***If yes, describe briefly in the text box below.*** *University Specific Guidelines:* http://www.safety.rochester.edu/restricted/labbiosafe/selectagent.html *or contact the Biosafety Officer at 275-3014.*

Select Agent Description

➢ Section V: Employee Medical Surveillance

All labs must complete this section. Check all that apply.

	Hepatitis B Vaccine Series: This vaccine series must be offered to all lab employees who work with human blood, body fluids, and tissues; primary human cells; and human cell lines (including established lines). Contact University Health Services (x54955) for assistance in formally offering (or declining) the vaccine as well as for vaccine administration, and record keeping.
	Vaccinia Virus Vaccine: This vaccine must be offered to laboratory employees working with vaccinia virus. Contact University Health Services (x54955) for assistance in formally offering and declining the vaccine, vaccine administration, and record keeping.
	BSL-3 Medical Surveillance Program: subject to change. Contact Biosafety Officer (x53014) or BSL-3 Director (x54670) for details. Applies to BSL3 and ABSL3 facility users only.
	Serum Banking: This option is offered to lab employees working with certain human pathogens. Refer to http://www.safety.rochester.edu/ibc/ibcserum.html for additional information. Note that serum banking is NOT recommended or supported for routine work with HIV, HCV and HBV (common bloodborne pathogens). It is recommended only in limited, specific instances described at the above web site.
	Seasonal Influenza Vaccine: This vaccine series is highly recommended for laboratories working with any influenza virus. The vaccine can be obtained during seasonal offering. The seasonal influenza vaccine may not prevent infection with strains used in laboratory research, but may help eliminate potential sources of viral culture contamination from laboratory workers by preventing community-acquired influenza.
	Not Applicable. Please note that if you check this box and are using human cell lines, you will be asked to provide certification that the lines have been found to be free of human pathogens.
	Other: Describe briefly in this box. Note that all medical surveillance must be pre-approved by University Health Services.

➢ Section VI: Additional Questions

All labs must complete this section.

Question 1. Is a Class II biosafety cabinet available for use? Include cabinets in both lab and Vivarium spaces.

	Not Applicable	***Explain in the text box below why a Class II cabinet is not applicable for your experiments.***
	Yes	***If yes, complete Table 1 below relative to the biosafety cabinets that are available for your use. Expand table as necessary*** *University Specific Guidelines: http://www.safety.rochester.edu/ibc/doc/class2BSCrequire.doc*

Explanation for "Not Applicable"

Table 1.

Certification Date	Certifier	Location

Question 2. Do you have access to sealed rotors or sealed centrifuge safety cups?

	No	***If no, ensure that you have a spill plan posted.***
	Yes	***If yes, check all that apply in Table 2.***
	NA	***No centrifugation***

Table 2.

Sealed rotors *	
Sealed Centrifuge Safety cups	

** "Sealed rotors" means the rotor can be removed from the spindle without taking off the lid, to be opened in a biosafety cabinet for aerosol containment in the event of a tube failure or spill. These are available for many newer centrifuges but may not be available for older ultracentrifuges.*

Question 3. Please explain how you control aerosols from BSL2 (BSL2+, and BSL3, if applicable) agents when blending, grinding, sonicating, shaking, or opening containers. ?

Aerosol control description

➢ Section VII: Waste Handling and Disinfection

All labs must complete this section. Check all that apply.

Laboratory waste must be segregated and treated separately from regular garbage. Additional information regarding laboratory waste disposal is available at http://www.safety.rochester.edu/restricted/labwastetable.pdf .

Question 1. Complete the table. If you do NOT chemically decontaminate your liquid waste, specify your method below. Expand table as needed.

	Specify the decontaminant	Specify the final concentration of the decontaminant	Specify the contact time
Liquid Waste Treatment			
E.P.A. Registered Decontaminant for work surfaces / equipment <u>AFTER</u> experiments. (Note: Ethanol is not EPA registered)			
Decontaminant for FLOOR Spills, if different from above			

Describe method of decontaminating liquid waste: (Other than chemical decontamination- i.e. autoclaving, etc.)

➢ Section VIII: Research Location and Biosafety Levels

All labs must complete this section relative to the research performed by the lab members. Therefore, if research is being done in space that is allocated to someone else and your staff is using it, the space and corresponding agents and activities must be noted below.

Correlate the information declared in each section with the agent, a location, what is being done with the agent in the particular location, and your assessment of the necessary biological containment. An example is provided in shaded area. Expand table as necessary.

Be sure to list where you <u>STORE</u> your biologicals and list your Vivarium space.

Biological Used or Stored (e.g. adenoviral vector, human serum, human cells, plasmid DNA, etc.)	**Building, Room Number, Lab Type** (e.g. main lab, tissue culture, animal surgery, etc.)	**General Tasks Performed with Agent in Room** (e.g. tissue culture, centrifugation, sonication, animal administration, animal necropsy, vector construction, storage, etc.)	**Biosafety Level**
<u>Example:</u> Human blood	**MC, 3.9624, tissue culture**	**centrifugation**	**2**

➢ Section IX: Attachments that Must Accompany this Document

1. IF APPLICABLE, the Mammalian Virus Vector Registration Form.
   http://www.safety.rochester.edu/ibc/ibcmainmenu.html

2. In a separate Word document, please list all of the laboratory personnel, including the Principal Investigator, for whom this document applies. Please use full names.

Principal Investigator Affirmation

By signing below, I certify that I have read the following statements and agree that all the listed participants and I will abide by them.

1. All research involving biologicals (e.g., recombinant DNA, non-recombinant infectious agents, human blood, sera and cell lines) performed in my laboratory will comply with the University's requirements for the applicable biosafety level.

2. All personnel have completed the University's Laboratory Safety Training Program. **Required annually.**

3. All personnel have received training regarding your laboratory and agent specific guidelines **prior to working at the bench.** All individuals handling BSL2 (or higher) materials have demonstrated competency prior to working with such materials. The lab's training is documented including date of training, summary of training, signature of trainee, initials or signature of trainer. Safety information is available in the laboratory for referral or upon request by the Biosafety Officer.

4. All exposures, accidents and illnesses relative to the agents declared through this document will be reported to the IBC immediately.

5. All employee injuries and/or exposures are reported to the University through the University's Employee Incident Report Form http://www.safety.rochester.edu/SMH115.html

6. The Principal Investigator is responsible for rapidly communicating new information or data to the IBC if that new information or data should reveal or strongly suggest that the anticipated safety or biohazard potential of the approved experiments or vector systems diverge significantly from what was originally anticipated. (For example, it may be determined that a replication-incompetent viral vector system in fact contains substantial levels of a replication-competent revertant virus, with the potential for human infection of transmission.)

Principal Investigator: _____ Date: _____

Please Sign & Date Above

If applicable:
Secondary PI: _____ Date: _____

Revision: 1/3/14