University of Rochester Institutional Biosafety Committee

Form

**L**

# *Laboratory Form*

Cover/updates page, then sections:

1 Agents – location, activity, BSL

2 NIH Guidelines, viral vectors

3 Pathogens – spp., max quantity

4 Select Agents and Toxins

5 Aerosol Containment/Equipment

6 Sharps Plan

7 Shipping and Receiving

8 Waste, Disinfection

9 Personal Protective Equipment

10 Occupational Health

LAB-PI last name-YY

Principal Investigator: Dept:

Phone:

Alternative Contact: Phone:

|  |
| --- |
| MM/DD/YYYY by XX |

* EH&S Lab Inspection - Last done
* Biological Safety Cabinets (For biohazards, BSCs must be certified every 12 months.)

|  |  |  |
| --- | --- | --- |
| **Certification Date** | **Certifier** | **Location** |
|  | B&V |  |
|  | Danforth |  |

* Training dates
* EHS Lab Safety Training (LST)\* – every year

**C**hemical – all labs, includes OSHA Bloodborne Pathogens - human blood, body fluids, tissues

+ **B**iological – labs that work with pathogens and/or experiments covered by the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules

+ **A**nimal – labs that work with animals

* Shipping Biologicals and Dry Ice/BS009 training – every 2 years (if yes for Question 1, Section VII)

Complete the table below or cut/paste your lab’s MyPath transcript:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Name** | **Title/Role** | **LST Course (C/B/A)** | **LST Date** | **Shipping Biologicals and Dry Ice Date** |
|  | Principal Investigator |  |  |  |
|  | Lab Supervisor |  |  |  |
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To document site-specific training, personnel also need to sign the Lab/Site-Specific Compliance Checklist every year.

\* The IBC requires annual EHS Lab Safety Training for (for all others, the PI determines the training required for their lab):

* All personnel with reasonably anticipated exposure to biological materials that require IBC approval
* Lab directors and PIs (even if they don’t perform lab work) should take the same LST as their lab personnel (6/7/2017 IBC.)
* Section I: Research Location and Biosafety Levels

List agent, location (including another PI’s lab, Vivarium, etc.), what’s being done with the agent in that 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 STORE your biologicals.**

|  |  |  |  |
| --- | --- | --- | --- |
| **Biological Used or Stored**  (e.g. adenoviral vector, human serum, human cells, *E. coli* K-12 strains containing plasmids, 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** |
| **Example: Human blood** | **MC 3.9624, tissue culture** | **centrifugation** | **2** |
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\* BSL2+ is Biosafety Level 3 work practices in a Biosafety Level 2 lab.

\* Cells do not require IBC approval unless they are transfected, transduced, contain human pathogens, or are of human or non-human primate origin.

* **Section II: Recombinant or Synthetic Nucleic Acid Molecules (rDNA, RNA, etc.)**

**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***](http://www.safety.rochester.edu/ibc/ibcmainmenu.html) ***or list the registration number(s) below.*** |

|  |  |
| --- | --- |
| Viral Vector Registration Numbers |  |

**Question 2.** Do you possess recombinant or synthetic nucleic acid molecules other than Mammalian Virus Vectors? Examples include plasmid DNA and recombinant or genetically-engineered organisms.

|  |  |  |
| --- | --- | --- |
|  | No | ***Skip to Section III.*** |
|  | Yes | ***If yes, complete the remainder of this section and all subparts.*** *Use* [*NIH Guidelines*](http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines) *Section I-B as reference.* |

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

**Question 2.a.** Formation of recombinant or synthetic nucleic acids containing genes for biosynthesis of toxins

|  |  |  |
| --- | --- | --- |
|  | No | ***Skip to question 2.b. of this section.*** |
|  | Yes | ***If yes, complete Table 2.a below. Expand as necessary.*** *Use* [*NIH Guidelines*](http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines) *Section III-B-1 as reference.* |

**Table 2.a.**

|  |  |
| --- | --- |
| **Specify organism from which the toxin genes originate** | **Specify the toxin** |
|  |  |

**Question 2.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 question 3 of this section.*** |
|  | Yes | ***If yes, complete Table 2.b below. Expand as necessary.*** *Use* [*NIH Guidelines*](http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines) *Section III-A-1-a as reference.* |

**Table 2.b.**

|  |  |  |
| --- | --- | --- |
| **Specify Organism** | **Specify Drug** | **Specify gene** |
|  |  |  |

**Question 3.** Do you possess recombinant or synthetic nucleic acid molecules that create gene drives or selfish genetic elements (i.e. a higher chance of a gene being inherited than by Mendelian genetics)?

|  |  |  |
| --- | --- | --- |
|  | No | ***Skip to Section III.*** |
|  | Yes | ***If yes,******provide a description:*** |

* **Section III: Pathogens (recombinant and non-recombinant)** – do not include viral vectors

Do you possess pathogens affecting humans, animals, or plants?

|  |  |  |
| --- | --- | --- |
|  | No | ***Skip to Section IV.*** |
|  | Yes | ***If yes, complete the table below; expand as necessary.***  If this information is already in another format (e.g. Excel), attach and note “see attached” in the table. |

|  |  |  |
| --- | --- | --- |
| **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.** |
|  |  |  |
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### Section IV: Select Agents and Toxins, or Botox®

Do you possess CDC/USDA regulated Select Agents ([www.selectagents.gov](http://www.selectagents.gov)), or Botox®?

|  |  |  |
| --- | --- | --- |
|  | No | ***Skip to Section V.*** |
|  | Yes | ***If yes, describe briefly:*** |

* Section V: Aerosol Containment Equipment (Engineering Controls)

**Question 1.** Is a Class II biological safety cabinet used for opening containers, pipetting, animal administration, etc.?

|  |  |  |
| --- | --- | --- |
|  | Not Applicable | ***Explain in the text box below why a Class II cabinet is not applicable for your experiments.*** |
|  | Yes | ***If yes, complete the table on page 1; expand table as necessary.*** |

|  |  |
| --- | --- |
| Explanation for “Not Applicable” |  |

|  |  |
| --- | --- |
| When working at BSL2, which procedures are performed on the bench top? Are shields used? |  |

**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:*** |  | Sealed rotors \* |  | Sealed Centrifuge Safety cups |
|  | ***NA*** | ***No centrifugation*** | | | | |

*\* “Sealed rotors” means the rotor can be removed from the spindle without taking off the lid, to be opened in a biological safety cabinet for aerosol containment in the event of a tube failure or spill.*

**Question 3.** How are aerosols controlled when working at BSL2 (or above) when blending, grinding, sonicating or shaking?

|  |  |
| --- | --- |
| Aerosol control description |  |

**Question 4.** When using syringes at BSL2 (or above), do the syringes have luer locks?

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | No | ***If not, please explain why:*** | | | | |
|  | Yes | ***If yes, check all that apply:*** |  | Always used |  | Used for selected experiments (list): |
|  | NA | ***Syringes are not used at BSL2.*** | | | | |

* Section VI: Sharps (Engineering Controls)

OSHA’s hierarchy of controls for sharps and how they’re implemented at UR are in the ‘Lab-Specific Sharps Safety Plan for nonhazardous or chemical-contaminated sharps’. Additional precautions for biohazards follow.

**Question 1.** Are sharps (any object that could cut or pierce skin, e.g. needles, blades) used with materials assigned BSL2 or above?

|  |  |  |
| --- | --- | --- |
|  | No | ***Your ‘Lab-Specific Sharps Safety Plan for nonhazardous or chemical-contaminated sharps’ still applies.*** |
|  | Yes | ***If yes, complete the questions below.*** |

**Question 2.** What sharps are used, and how is the risk mitigated? - Include sharps in both lab and Vivarium spaces.

Sharps safety devices have an integral, engineered device that blunts or covers the sharp immediately following use and prior to disposal.

* Safety sharps should be used whenever needles or blades are used at Biosafety Level 2.
* This ‘should’ becomes a ‘must’ for all work covered under OSHA’s Bloodborne Pathogens Standard [HIV, HBV, HCV, and human cells (including cell lines), tissues, blood or body fluids]. If it is not possible to use safety sharps, then the reasons must be documented on an evaluation form, e.g. <https://tdict.org/tools/medical-device-evaluation-forms/>.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Sharp**  (Be specific - type, brand, gauge, length) | **Safety Device?**  (yes or no) | | **Procedure** | **BSL2 (or above) Material(s)** |
|  |  | |  |  |
|  |  | |  |  |
|  |  | |  |  |
| If sharps safety devices are not available, how are sharps risks mitigated? | | |  | | | |

* **Section VII: Shipping and Receiving** (Engineering and Work Practice Controls)

\* Reference: EHS Shipping Biologicals and Dry Ice (BS009) [www.safety.rochester.edu/labbiosafe/shipping/SOPShippingBiologicialMaterials.html](http://www.safety.rochester.edu/labbiosafe/shipping/SOPShippingBiologicialMaterials.html)

**Is ‘Shipping Biological Materials and Dry Ice’ training required?** Yes, if your lab plans to send (ship) or transport on a public road a) dry ice, b) any pathogens in Section III of this form or c) any material that may contain human, livestock or poultry pathogens.

|  |  |  |
| --- | --- | --- |
|  | No | ***Note: For some materials (e.g. genetic elements), a permit or license may be required even if training is not.*** |
|  | Yes | ***If yes, anyone who packages, marks or ships needs ‘Shipping Biological Materials and Dry Ice’ training.*** |

**Federal or state permits or licenses may be required to ship or receive materials in this LAB form.**

* EH&S (or the lab) – completion of the table below helps lab personnel prepare and plan for shipments.
* Lab - Before shipping or receiving pathogens, cells, genetic elements (DNA, RNA) or any material obtained from livestock or poultry, always double-check Import/Export in EHS Shipping Biologicals and Dry Ice (BS009).

|  |  |  |  |
| --- | --- | --- | --- |
| **Materials in this LAB form that require federal or state permits or licenses for shipping/receiving** | **Shipping** | | **Receiving** |
| **To other countries, including Canada** | **To other states in the US** | **From other countries, including Canada** |
| Example: VSV-G (rLV plasmid) | Export license  (Submit MTA through IORA) | Follow [USDA Guideline 1125](https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-and-animal-product-import-information/organisms-vectors/ct_organisms_and_vectors) | [USDA permit](https://efile.aphis.usda.gov/s/vs-permitting-assistant) |
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* Section VIII: Waste Handling and Disinfection (Work Practice Controls)

Note: For checkboxes , double-click and then select Default Value – Checked or Not Checked. Or, use an X adjacent.

Laboratory waste must be segregated and treated separately from regular garbage. For additional information regarding laboratory waste disposal, see the Hazardous Waste Unit/Environmental Compliance website and their [Learner’s Guide](https://www.safety.rochester.edu/envcompliance/pdf/HazardousMaterialsManagement.pdf).

\* Only New York State-registered pesticides can be used as disinfectants. Therefore, lab-made 70% ethanol, Microcide SQ™ and other disinfectants commonly used elsewhere cannot be used at UR.

- For NYS: <https://www.dec.ny.gov/chemical/27354.html>, click Look Up Products/NYSPAD (New York State Pesticide Administration Database), and search database. All listed are EPA-registered (general).

- For specific pathogens: also check if EPA-registered [effective for that pathogen](https://www.epa.gov/pesticide-registration/selected-epa-registered-disinfectants), e.g. *C. difficile* (spores), HIV-1, HBV, HCV, influenza (avian), MRSA, norovirus, SARS-CoV-2, TB, and VRE.

|  |  |  |
| --- | --- | --- |
|  | Specify the NYS registered decontaminant and final concentration | Specify the contact time/ time left wet |
| Liquid Waste Treatment | Household bleach (1 part bleach:9 parts liquid waste)  Other | 30 minutes |
| Work surfaces / equipment AFTER experiments (and spills)  - if more than one, specify if for surfaces or spills | Household bleach (1 part bleach:9 parts water, or spill)  Vesphene IIse®  Virex® II 256  REScue®/PeroxigardTM, per manufacturer (Vivarium)  Other (put NYSPAD info below): | Surfaces: 10 minutes  Spills: 30 minutes |

* **Section IX: Personal Protective Equipment (PPE) -** provided by the PI

|  |  |  |  |
| --- | --- | --- | --- |
|  | **PPE** | **Tasks** | **Types** |
|  | Gloves | Worn when opening containers of infectious agents, performing work with open containers or touching potentially contaminated surfaces | Nitrile  Latex  Double gloves for: |
|  | Lab coat | * Worn in compliance with CDC/NIH and the NIH Guidelines. * Worn to protect street clothes when working at the bench or in a biological safety cabinet. | Cloth (laundered by UR)  Closed front disposable (mandatory for BSL2+) |
| safety glasses with s#51569 | Eye/Face protection  (splash) | Worn when splashes or sprays are not contained by engineering controls (e.g. biological safety cabinet sash, splash shield for bench top work). | Safety glasses  gasketed (or goggles)  Surgical mask  fluid-resistant  Chin-length face shield |
|  | Additional |  |  |

* **Section X: Employee Occupational Health**

|  |  |
| --- | --- |
|  | **Hepatitis B Vaccine Series:** All individuals with a reasonably anticipated risk of exposure to human blood, body fluids, tissues (unfixed), cells or cell lines must be offered the Hepatitis B vaccine series and either:  (a) receive three doses of vaccine, or  (b) sign a declination form and file it with their department and, if applicable, with their medical record at University Health Service. [www.safety.rochester.edu/ibc/BBPResource.html](file:///\\its-fp3\ehs_home$\srosen22\UofR%20IBC\Form%20revisions\www.safety.rochester.edu\ibc\BBPResource.html). |
|  | **Seasonal Influenza Vaccine:** The seasonal influenza vaccine is recommended for all individuals working with influenza or inoculated animals. 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.** Must be in line with current CDC recommendation or pre-approved by University Health Service. |

Biosafety Manual

All labs working at ≥ BSL2 must have a lab-specific Biosafety Manual - paper or electronic.

1. Labs may write their own manual, or
2. Use the LAB/L form, additional IBC documents, and relevant resources:

IBC forms/documents:

* LAB/L form Note: If you use an electronic biosafety manual, always keep a separate copy of the LAB/L form IBC submissions.
* IBC approval/UCAR Protocol Review for Hazardous Substances – Biohazards, ‘NIH Guidelines’
* G/project form
* VV/viral vector forms

Resources:

* Biological agent overview, transmission routes, clinical signs, strains resistant to treatment, etc. Options:
* Research articles
* [www.cdc.gov](http://www.cdc.gov)
* Carroll’s Manual of Clinical Microbiology 2019 <https://www.urmc.rochester.edu/libraries/miner/mdl.aspx?redirect=2000000320>
* Public Health Agency of Canada Safety Data Sheets <https://www.canada.ca/en/public-health/services/laboratory-biosafety-biosecurity/pathogen-safety-data-sheets-risk-assessment.html>
* EH&S Policy/Procedures:
* Biosafety Level Requirements for BSL1, ABSL1, BSL2, ASBL2, BSL2+ or ABSL2+ (BS020)
* Emergency Procedures for Biological Spills in BSL1, BSL2 and BSL2+ Labs (BS017)
* Requirements for Biological Safety Cabinets Used in Laboratories for Biohazard Containment (BS010)
* Viral Vector Requirements for Laboratories (BS014)
* Shipping Biological Materials and Dry Ice (BS009)
* EH&S Guidance Document: How do I transport a Hazardous Sample?

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 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 or Laboratory Safety Unit inspector.
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:

**Signature Print**

**If applicable:**

Secondary PI: / Date:

**Signature Print**

Form template revised: 1/26/2022