University of Rochester Institutional Biosafety Committee

# *Registration Form for new Principal Investigators*

### [UR’s Institutional Biosafety Committee](http://www.safety.rochester.edu/homepages/ibchome.html) (IBC) reviews and approves all research protocols at the University that:

* require IBC approval under the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules
* use or produce biohazardous organisms or materials handled at Biosafety Level 2 or higher.

1. Regardless of funding source, use this form to register in vitro and in vivo experiments involving:
2. Grants or projects involving recombinant or synthetic nucleic acids that are **NOT** exempt from the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (for covered experiments, see <http://www.safety.rochester.edu/ibc/pdf/NewHireInformationalPacket.pdf> on the IBC webpage)

**NOTE:** For Program Projects with multiple Principal Investigators, **each PI** will need to submit this form with specificity to the work being done in their laboratory or in another laboratory on their behalf.

1. Non-recombinant biohazards including pathogens (human, animal or plant), or cells/cell lines that may contain an infectious agent
2. Human or nonhuman primate blood, body fluids, tissues or cells (including cell lines)
3. UR’s IBC uses a multi-form system. For new Principal Investigators, these forms are provided as a single registration document. After the initial registration, each form will be provided as a separate document for easier updating.

* The LAB/L form, one per Principal Investigator, provides the IBC and Environmental Health & Safety (EH&S) lab-level information about where biological agents and materials are used and stored, engineering controls (aerosol containment equipment), and work practice controls (disinfection practices, medical surveillance).
* The G Form describes experiments. After the initial registration, Principal Investigators may choose to have one G Form for each grant/project or UCAR (animal protocol), or consolidate their projects onto a single G Form, whichever works best for the researcher.
* The VV Form provides additional information for viral vectors and recombinant viruses, with each virus type on a separate form [i.e. one for all adenovirus vectors (rAdV-), a separate one for all lentivirus vectors (rLV-), etc.] If you are using more than one virus type, additional VV forms are available on the IBC web page.
* Human Subjects studies may require an HS or HSP form.

1. **No abbreviations, please.** If they are used, they **MUST** be defined.
2. Complete and submit this form electronically as a Word e-mail attachment to the IBC Administrative Assistant [ddouglass@safety.rochester.edu](mailto:ddouglass@safety.rochester.edu). For the signature pages, if you do not use an electronic signature, please submit a copy of the signature page by fax (274-0001), e-mail, or mail (RC Box 278878).

Useful references:

* + - * [IBC web pages](http://www.safety.rochester.edu/homepages/ibchome.html)
      * [IBC Registration Forms](http://www.safety.rochester.edu/ibc/ibcmainmenu.html)
      * [UR Biosafety Requirements and Resources](http://www.safety.rochester.edu/labbiosafe/biosftyrequireresource.html)
      * [NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules](http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines)
      * [6th edition of CDC/NIH “Biosafety in Microbiological and Biomedical Laboratories”](https://www.cdc.gov/labs/BMBL.html)

Bio-containment and safety questions can be referred to the Biosafety Officer (5-3014 or [srosen22@safety.rochester.edu](mailto:srosen22@safety.rochester.edu)).

Revision Date: 1/20/23

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 (assigned by the IBC)

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 (8/8/2018 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 (lentivirus vectors, 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) |
|  |  |  |  |

* **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?

L Form Revision Date: 1/26/22

University of Rochester Institutional Biosafety Committee

# *Grant or Project Registration Form*

Form

### G

Principal Investigator: Dept: Phone:

Co-Principal Investigator: Dept: Phone:

Technician or Alternative Contact: Dept: Phone:

Project or Grant Title:

Box #: Award #: Grant Registration #: GNT-(to be assigned by the IBC)

* Declaration of Confidentiality:

***Other than HIPAA restrictions, are any of the declared experiments subject to a confidentiality agreement with the sponsor?***  ***no***  ***yes***

The Institutional Biosafety Committee’s meeting minutes may be made public upon request. Answering this question helps protect proprietary information.

* Summary of Experiments:

***Question A. The purpose of the section is to give the IBC a clear understanding of how the declared agent(s) will be used experimentally. Please include all research experiments the Principal Investigator is directing, even if some or all of the experiments will be performed in another laboratory.***

1. *Provide a brief summary paragraph stating the goals of your studies. DO NOT cut and paste your entire grant, UCAR or RSRB abstract.*
2. *List the in vitro and in vivo experiments done with each agent (i.e. bacteria, fungi, viruses, viral vectors, cells, recombinant or synthetic nucleic acids, and if used in vertebrate or invertebrate animals, including Drosophila). Failure to provide information summarizing how each agent will be used in both in vitro and in vivo studies will result in a SIGNIFICANT delay in your approval.*

* Declaration of Pathogens:

Question B.1. Will this grant or project involve the use of any NON-VIRAL mammalian or plant pathogens including non-recombinant and recombinant pathogens? [List any plasmids used to construct non-viral pathogens under Question E. Also use Question E for nonpathogenic species such as E. coli cloning strains and Saccharomyces cerevisiae.]

|  |  |  |
| --- | --- | --- |
|  | No | ***Skip to Question C.1.*** |
|  | Yes | If yes, complete Table B.1.a. Expand the table as necessary. Use [University Specific Guidelines](http://www.safety.rochester.edu/ibc/SAResource.html)  or contact the Biosafety Officer at 275-3014. |

***Table B.1.a.***

|  |  |
| --- | --- |
| **List pathogens (Genus, species, strain)** | **Biosafety level** |
|  |  |
|  |  |
|  |  |

***Question C.1. Will this grant or project involve the use of any VIRAL mammalian or plant pathogens including non-recombinant and recombinant pathogens or VIRAL VECTORS (packaged infectious virions used to deliver or transport desired inserts to cells for the purposes of insert expression)?***

|  |  |  |
| --- | --- | --- |
|  | No | ***Skip to Question D.1.*** |
|  | Yes | ***If yes, complete Table C.1.a. Expand tables as necessary.***  ***VIRAL VECTORS***  ***\* Submit your Mammalian Viral Vector Registration for each viral vector system declared below.*** [*Viral Vector Registration*](http://www.safety.rochester.edu/ibc/ibcmainmenu.html) *Contact the* [*IBC Program Coordinator*](mailto:ddouglass@safety.rochester.edu) *if you have questions about your Mammalian Viral Vector Registration(s).* [*University Specific Guidelines*](http://www.safety.rochester.edu/ibc/extendedhelp.html)  ***\* If you are building new plasmids that will be used to develop infectious virions, then you must also answer Questions E.1 through E.3 and complete Tables E.3.a and E.3.b relative to those constructs (not required if you are purchasing vectors or obtaining them from collaborators – ensure to include vector source on VV form).*** |

Table C.1.a. List the virus(es) or vector system(s) proposed for use in these experiments and provide the corresponding information.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **List virus(es) or**  **viral vector system(s)** | **If recombinant virus, what does your insert encode?**  **(e.g. name of gene product or nature of regulatory region)** | **If applicable, list corresponding viral vector registration number (only for viral vectors)** | **List cells transduced or infected with virus or viral vector or write “NONE”. These cells should be described in Question D.**  For viral vectors, include:  1. Packaging cells  2. E. coli strains to generate plasmids | **List biosafety level(s) for packaging, propagation, and infection.** | **Replication- competent? (yes/no)** |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

* Declaration of Eukaryotic Materials:

Question D.1. Will this grant or project involve the use of eukaryotic cells or fluids, eukaryotic cell lines, or eukaryotic unfixed tissues? (Use this section to declare human fluids such as blood and sera.)

|  |  |  |
| --- | --- | --- |
|  | No | ***Skip to Question E.1.*** |
|  | Yes | If yes, complete Table D.1.a. Expand the table as necessary. Use [University Specific Guidelines](http://www.safety.rochester.edu/ibc/SAResource.html)  or contact the Biosafety Officer at 275-3014. |

Table D.1.a. Eukaryotic cells or fluids, eukaryotic cell lines, or eukaryotic unfixed tissues description

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **List cells, fluids, tissues, cell lines** | **Organism of origin** | **From whom or where did you obtain these cells, fluids, or tissues** | **If you are using cells, fluids, or tissues from vertebrate animals, provide corresponding UCAR # or write “NA”** | **If KNOWN to harbor pathogens, specify the pathogen or write “UNKNOWN”** | **If using human materials, indicate patient population from which materials are derived or write “UNKNOWN”. Also add RSRB # if known.** | **Biosafety level** |
|  |  |  |  |  |  |  |
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|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

* Declaration of Nucleic Acids:

***Question E.1. Will this grant or project involve the use of recombinant or synthetic nucleic acid molecules? (Do not list oligonucleotides.)***

|  |  |  |
| --- | --- | --- |
|  | No | ***Skip to Question F.1.*** |
|  | Yes | ***If yes, describe your recombinant and synthetic nucleic acids by answering questions E.2 – E.3 and by completing Table E.3.a and Table E.3.b. Expand tables as necessary.***   * *Use* [*NIH Guidelines Section I-B*](http://osp.od.nih.gov/sites/default/files/NIH_Guidelines.html#_Toc351276218)  *as reference* * *If you are creating transgenic animals, using recombinant DNA, then declare the construct under this question and complete Question I.* * *List under Question C any infectious Mammalian Viral Vectors that are already packaged and that will be used as part of these experiments.*   ***If you are building new plasmids that will be used to develop a viral vector, then you must answer Question E.1 – E.3 and complete Table E.3.a and Table E.3.b. relative to those plasmids (not required if you are purchasing vectors or obtaining them from collaborators – ensure to include vector source on VV form).*** |

***Question E.2. What is the nature of the inserts? Check all that apply. IBC approval is required before initiation of studies involving constructs having these inserts.***

|  |  |
| --- | --- |
|  | ***Insert contains full-length genes for toxins*** |
|  | ***Insert 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, e.g. ampicillin.)*** |
|  | ***Insert contains genetic material from a BSL-2 (or higher) MICROORGANISM (e.g. pathogenic bacteria, viruses, fungi, etc).*** |
|  | ***Not applicable: None of the above categories describe the inserts proposed for use in these studies.*** |

***Question E.3. Describe all the recombinant and synthetic nucleic acid constructs used in these studies by completing Tables E.3.a and E.3.b. Expand tables as necessary.***

***Table E.3.a. Insert Description***

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Insert number** | **What does your insert encode?**  **(e.g. name/gene ID and description of gene product or nature of regulatory region)** | **List DNA type**  **(e.g. genomic, cDNA, antisense, shRNA, siRNA, sgRNA for CRISPR, etc.)** | **List organism or species of origin (or species homology for sgRNA)** | **Does the insert / gene contain its original promoter?**  **(Yes, no, unknown)** | **Will you INTENTIONALLY express the product of the insert?**  **(Yes, no)** |
| 1 |  |  |  |  |  |
| 2 |  |  |  |  |  |
| 3 |  |  |  |  |  |
| 4 |  |  |  |  |  |

***Table E.3.b. Vector and Host Information. Correlate insert number from Table E.3.a. to information requested below.***

|  |  |  |  |
| --- | --- | --- | --- |
| **Insert number from E.3.a.**  **(Use this column to match your insert(s) with its vector(s))** | **List vector name(s) and describe** | * 1. **List all bacterial and/or fungal agents in which this construct will be placed. Provide specific strain.**   2. **List potential adverse effects of expression (e.g. pathogenic conversion, toxin, etc).**   3. **If no bacterial and/or fungal agents are used, write “NONE”.**   4. **Be sure to organize this information so it is CLEAR which construct you are referring to.** | 1. **List all eukaryotic cells (or cell lines) in which this construct will be placed. These cells should be described in Question D.** 2. **List potential adverse effects of expression.** 3. **If no eukaryotic cells are used, write “NONE”.** 4. **Be sure to organize this information so it is CLEAR which construct you are referring to.** |
| Example: 1-4 | pUC | *E. coli* DH5-alpha (K-12) | Any of the cell lines listed in Table D.1.a. |
| 1 |  |  |  |
| 2 |  |  |  |
| 3 |  |  |  |
| 4 |  |  |  |

* Declaration of Select Agents or Botox®:

***Question F.1. Will the grant or project involve the use of SELECT AGENTS or BOTOX®? (Select Agents are highly regulated pathogens, toxins or specific genetic elements and recombinant or synthetic nucleic acids that have the potential to be used as biowarfare agents.)*** [www.selectagents.gov](http://www.selectagents.gov)

|  |  |  |
| --- | --- | --- |
|  | No | ***Skip to Question G.1.*** |
|  | Yes | ***If yes, describe briefly in the text box below.*** *Use*[*University Specific Guidelines*](http://www.safety.rochester.edu/ibc/SAResource.html) *or contact the Biosafety Officer at 275-3014.* |

|  |  |
| --- | --- |
| *Description* |  |

* Declaration of Gain of Function experiments:

***Question G.1. Per NSABB (National Science Advisory Board for Biosecurity) criteria, will the grant or project generate a pathogen that is either 1) highly transmissible and likely capable of wide and uncontrollable spread in human populations, or 2) highly virulent and likely to cause significant morbidity and/or mortality in humans (i.e. will you be lowering the infectious dose of the pathogen, or will you be increasing the pathogenesis of the pathogen)?***

|  |  |  |
| --- | --- | --- |
|  | No | ***Skip to Question H.1.*** |
|  | Yes | ***If yes, describe briefly in the text box below.*** *Use*[*University Specific Guidelines*](http://www.safety.rochester.edu/ibc/SAResource.html), [*NSABB report*](http://osp.od.nih.gov/sites/default/files/NSABB_Final_Report_Recommendations_Evaluation_Oversight_Proposed_Gain_of_Function_Research.pdf)*, or contact the Biosafety Officer at 275-3014.* |

|  |  |
| --- | --- |
| *Description* |  |

* Large Scale Experiments:

## *Question H.1. Will any of the experiments covered by this registration ever involve more than 10 liters of culture at any one time?*

|  |  |  |
| --- | --- | --- |
|  | No | ***Skip to Question I.1.*** |
|  | Yes | ***If yes, describe briefly in the text box below.*** *Use*[*NIH Guidelines*](http://osp.od.nih.gov/sites/default/files/NIH_Guidelines.html#_Toc351276242) *or contact the Biosafety Officer at 275-3014.* |

|  |  |
| --- | --- |
| *Description* |  |

* Experiments Involving Live Animals:

*Question I.1. Will this project or grant involve the administration of any biological, declared above, to LIVE animals (e.g. vertebrates, invertebrates)?*

|  |  |  |
| --- | --- | --- |
|  | No | ***Skip to Question J.1.*** |
|  | Yes | ***If yes, complete Questions I.1 – I.4 (and the associated tables) relative to the biologicals declared above AND which will be administered to LIVE animals. Expand tables as necessary.*** *Generation of transgenic animals should be declared and described under Question J.1 and J.2.* |

***Table I.1.a.***

|  |  |  |
| --- | --- | --- |
| **List animal species (one per line) or strain(s)** | **Is this species transgenic? (Yes or No)** | **List corresponding UCAR number or write “NONE” if no UCAR is required.** |
|  |  |  |
|  |  |  |
|  |  |  |

***Table I.1.b. Cut and paste this table for each species or strain to ensure clarity when using multiple agents in multiple species or strains.***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **List agent administered to animals**  **For cells, indicate if modified (transfected or transduced).** | **What is the number of doses?** | **What is the concentration of dose?** | **Describe administration method and potential risk to experimenter (e.g. needlestick risk). Indicate Biosafety Level (ABSL1, ABSL2)** | **List type of animal housing necessary (ABSL1, ABSL2)** |
|  |  |  |  |  |
|  |  |  |  |  |

Note: Mammalian cells do not require IBC approval unless they are transfected, transduced, contain human pathogens, or are of human or non-human primate origin.

***Question I.2. Will you be collecting tissues, cells, or fluids from these animals?***

|  |  |  |
| --- | --- | --- |
|  | No | ***Skip to Question I.3.*** |
|  | Yes | ***If yes, complete Table I.2. Expand table as necessary.*** |

***Table I.2.a. Expand table as necessary.***

|  |  |  |  |
| --- | --- | --- | --- |
| **List animal species or strain** | **List the potentially hazardous agents that were administered** | **List fluids, cells, or tissues collected** | **If the collected cells, tissues or fluids are KNOWN to harbor pathogens or toxins, specify the pathogens or toxins or write “UNKNOWN”** |
|  |  |  |  |
|  |  |  |  |

***Question I.3. Will the animals produce, secrete, or shed a toxic or infectious agent as a result of these experiments? Note: if you are using transgenic animals, you must also consider whether the animal is more susceptible to the agent making the agent more likely to be shed.***

|  |  |  |
| --- | --- | --- |
|  | No | ***Skip to Question I.4.*** |
|  | Yes | ***If yes, complete Table I.3.a describing how your biological may be transmitted to humans or to other animals.***  *Please remember that the biological(s) (e.g. replication-defective virus, cell lines, human cells) administered to your animals may carry pathogens that could cause an infection, which could then be transmitted to humans or perhaps other animals.* |

***Table I.3.a.***

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Transmission potential. Check all that apply.** | | | | | | |
| **List agent likely produced or shed** | **Transmission from animal to animal? (Please be aware that some agents may be harmless to humans but could be pathogenic in animals and damaging to our animal colony.)** | **Transmission from animal to humans?** | **Environmental transmission (to feral populations)?** | **Transmission via urine?** | **Transmission via feces?** | **Transmission via saliva?** | **Transmission via natural vector? *Specify vector:*** |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |

***Question I.4. Are there any mitigating factors that may modify (raise or lower) the biological containment level for these experiments?***

|  |  |  |
| --- | --- | --- |
|  | No | ***Skip to Question J.1.*** |
|  | Yes | ***If yes, describe briefly in text box below.*** |

|  |  |
| --- | --- |
| *Description* |  |

* Transgenic Animal Generation:

***Question J.1. Will you be generating transgenic animals through recombinant or synthetic nucleic acid technology? (e.g. mice, Drosophila, C. elegans, or other members of the Kingdom Animalia)***

|  |  |  |
| --- | --- | --- |
|  | No | ***Proceed to Question J.2.*** |
|  | Yes | ***If yes, complete Table J.1.a. If the construct will be generated in the lab, then Question E and its subparts must also be completed.***  *Examples of recombinant or synthetic nucleic acid technology include (1) Direct microinjection of a chosen gene construct from another member of the same species or a different species into the pronucleus of a fertilized ovum; (2) Insertion of the desired DNA sequence by homologous recombination into an in vitro culture of embryonic stems and cells; (3) Use of a plasmid or virus to transfer the genetic material into germ cells; (4) Gene ablation if recombinant techniques are used to knock out the gene.*  *Use* [*NIH FAQs for Transgenic Animals*](http://osp.od.nih.gov/office-biotechnology-activities/biosafety/biosafety-guidance/faq) *and* [*NIH Guidelines*](http://osp.od.nih.gov/sites/default/files/NIH_Guidelines.html#_Toc351276240) *as references.* |

|  |  |
| --- | --- |
| *Construct description* |  |

***Table J.1.a.***

|  |  |
| --- | --- |
|  | **Constructs** |
| **List corresponding UCAR number or write “NONE” if no UCAR is required.** |  |
| **If the inserted genetic material is from a Risk Group 2 (or higher) microorganism, list the organism or write “NONE”.** |  |
| **If inserted genetic material is from a virus, how much of the total viral genome will be inserted. Write “less than ½” or “greater than ½” or write “None”.** |  |
| **If inserted genetic material encodes for a functional toxin or a fraction of a toxin gene, list the toxin and percentage of toxin gene or write “NONE”.** |  |
| **Will animals secrete or shed a toxic or infectious agent? List infectious agent or toxin or write “NONE”.** |  |
| **List route of secretion or shedding (e.g. urine, saliva, feces) or write “NONE”.** |  |
| **Will the animals that are generated have an increased propensity for infections with pathogens, either human or animal? Write “Yes” and explain or write “No”.** |  |
| **Does the technique used result in the creation of a gene drive or selfish genetic element (i.e. a higher chance of a gene being inherited than by Mendelian genetics)? Write “Yes” and explain or write “No”.** |  |

***Question J.2. Will you be interbreeding or cross breeding transgenic animals (those originally created using recombinant or synthetic nucleic acid technology) AND which are genetically different from each other? This question also covers backcrossing transgenic animals with wild type.***

|  |  |  |
| --- | --- | --- |
|  | No | ***Skip to Question K.1.*** |
|  | Yes | ***If yes, answer Question J.2.a. For non-rodent animals and for rodents which are NOT EXEMPT from the NIH Guidelines (determined in Question J.2.a.), complete Questions J.3 through J.7 relative to the progeny.*** *Use* [*NIH FAQs for Transgenic Animals*](http://osp.od.nih.gov/sites/default/files/Animals_NA_0.pdf) *and the* [*NIH Guidelines*](http://osp.od.nih.gov/sites/default/files/NIH_Guidelines.html#_Toc351276247) *as reference.* |

***Question J.2.a. Check any of the following that apply to your proposed RODENT crossing(s). All NON-RODENT crossings must be described in Table J.2.a***

|  |  |
| --- | --- |
|  | ***One or both parental rodent strains must be housed at ABSL2 or above (see NIH Guidelines section III-D-4). If yes, describe these crossings in Table J.2.a below. Use one table for each crossing, copy/paste more tables as needed. Complete Questions J.3 through J.7 relative to the progeny.*** |
|  | ***The parental and/or progeny rodent strains contain more than one half of the genome of an exogenous eukaryotic virus from a single family of viruses. If yes, describe these crossings in Table J.2.a below. Use one table for each crossing, copy/paste more tables as needed. Complete Questions J.3 through J.7 relative to the progeny.*** |
|  | ***Either of the parental transgenic rodent strains of a particular cross contains a transgene that is under the control of a gammaretroviral long terminal repeat (e.g. LTR from Moloney Murine Leukemia Virus). If yes, describe these crossings in Table J.2.a below. Use one table for each crossing, copy/paste more tables as needed Complete Questions J.3 through J.7 relative to the progeny.*** |
|  | ***None of the above – This RODENT crossing is exempt from the NIH guidelines. Skip to Question K.1.*** |

***Table J.2.a. Describe the existing genetics of each parental transgenic animal by completing the appropriate tables. Cut and paste this table to describe more than one cross.***

|  |  |  |
| --- | --- | --- |
|  | Parent 1 | **Parent 2** |
| **Specify species & strain(s)**  e.g. BALBc mouse; *Drosophila melanogaster; C. elegans* |  |  |
| **What does your insert encode** (e.g. name of gene product or nature of regulatory region)**?** **Write NA if not applicable.** |  |  |
| **What was deleted** (e.g. name of gene product or nature of regulatory region)**?** **Write NA if not applicable.** |  |  |
| **Specify source of inserted sequence** (e.g. mouse, human, etc.) |  |  |
| **Specify any potentially hazardous agent that may be encoded in INSERTED sequence** (e.g. toxin, pathogens, oncogene)**.**  **Write NA if not applicable.** |  |  |
| If the genome of an exogenous eukaryotic virus (from a single family of viruses) has been incorporated into either parent, **what is the percentage of the viral genome and what is the virus? Write NA if not applicable.** |  |  |
| **List corresponding UCAR number or write “NONE” if no UCAR is required.** |  | |

***Question J.3. Will the progeny likely be selectively vulnerable to specific pathogens? (e.g. Consider pathogens that may be present in their immediate environment or that you may administer to these animals which may be transmissible to humans or to other animals.)***

|  |  |  |
| --- | --- | --- |
|  | ***No*** |  |
|  | ***Yes*** | ***Explain briefly in this box.*** |

***Question J.4. Will the progeny likely have a survival advantage that could be genetically transmitted to feral populations? (e.g. If the animal escapes, how likely will it die fairly quickly or how likely is it to reproduce with feral animals to produce viable offspring?)***

|  |  |  |
| --- | --- | --- |
|  | ***No*** |  |
|  | ***Yes*** | ***Explain briefly in this box.*** |

***Question J.5. Will the progeny likely shed a pathogen that is transmissible to humans or a toxin that may affect humans?***

|  |  |  |
| --- | --- | --- |
|  | ***No*** |  |
|  | ***Yes*** | ***Explain briefly in this box. Be sure to list the pathogen or toxin and how the agent may be shed from the animal.*** |

***Question J.6. Will the resultant progeny result in the expression of transgenes or the disregulation of endogenous gene-products?***

|  |  |  |
| --- | --- | --- |
|  | ***No*** |  |
|  | ***Yes*** | ***Explain briefly in this box.*** |

***Question J.7. Will the resultant progeny contain ½ or less of exogenous viral genome from a single family of viruses?***

|  |  |  |
| --- | --- | --- |
|  | ***No*** |  |
|  | ***Yes*** | ***Explain briefly in this box (i.e. percentage of virus and virus).*** |

* Flow Cytometric Experiments:

***Question K.1. Will this grant or project involve flow cytometry, either for high speed sorting or analysis of cells?***

|  |  |  |
| --- | --- | --- |
|  | No | ***Skip to Question L.1.*** |
|  | Yes | ***If yes, describe under Table K.1.a and Table K.1.b as applicable.*** *Use*[*University Specific Guidelines*](http://www.safety.rochester.edu/ibc/SAResource.html)  *or contact the Biosafety Officer at 275-3014.* |

***Table K.1.a. High Speed Sorting***

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **List the Cell Type** | **List organism or species of origin** | **List fixative and concentration or write “NONE” if not fixed** | **Are there known human pathogens in sample? Write “YES” or “NO”.** | **List instrument name**  **(e.g. FACSAria)** | **List location of instrument**  **(e.g. URMC Flow Core)** |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

***Table K.1.b. Analytical Flow Cytometry***

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **List the Cell Type** | **List organism or species of origin** | **List fixative and concentration or write “NONE” if not fixed** | **Are there known human pathogens in sample? Write “YES” or “NO”.** | **List instrument name**  **(e.g. LSRII)** | **List location of instrument**  **(e.g. URMC Flow Core)** |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

* Facilities and Personnel:

***Question L.1. Will any portion of this grant or project take place in other UR research labs that are not controlled by the listed Principal Investigator(s) or Co-Principal Investigator(s)?*** *Please include core labs (not required for the Confocal and Conventional Microscopy Core or URMC Flow Core).*

|  |  |  |  |
| --- | --- | --- | --- |
|  | No | ***Skip to Question L.2.*** | |
|  | Yes | ***If yes, list the names of the Principal Investigators responsible for the labs and briefly describe the activities performed by each group relative to the declared agents in the text box below.***  *Note: Program projects frequently involve vastly different experiments for each investigator involved. Therefore each Principal Investigator should submit their own Grant / Project Registration representing their portion of the research. If you are registering a program project, list the other Principal Investigators and Co-Principal Investigators; and note “Program Project” under “Activity”. Questions should be directed to the IBC Program Coordinator.* | |
| **Principal Investigator** | | | **Activity (brief description – 1-2 sentences)** |
|  | | |  |
|  | | |  |

***Question L.2. List full name of lab personnel involved in the experiments declared through this registration document, including all Principal Investigators and Co-Principal Investigators.***

G Form Revision Date: 12/14/2016

**University of Rochester Institutional Biosafety Committee**

#### Form

VV

# *Mammalian Viral Vector System Registration Form*

rVV-PI last name-YY(assigned by the IBC)

Principal Investigator: Dept: Phone:

Co-Principal Investigator: Dept: Phone:

Technician or Alternate Contact: Phone:

***Complete this document for the infectious, recombinant viruses you possess which were constructed to deliver or transport desired inserts into cells for the purposes of insert expression.***

***This document*** *must be completed individually* ***for each viral base*** *(i.e. adenovirus, lentivirus, etc.) even if more than one is proposed for one project.*

The Mammalian Virus Vector Registration Form provides supplemental information to the IBC to help determine the appropriate biosafety precautions for your particular viral construct(s). Do not submit this form by itself; it must be accompanied by a Grant/Project registration (G-form).

Complete and submit this form electronically as a Word e-mail attachment to the IBC Administrative Assistant [ddouglass@safety.rochester.edu](mailto:ddouglass@safety.rochester.edu).

Useful references:

* + - * [IBC web pages](http://www.safety.rochester.edu/homepages/ibchome.html)
      * [Additional guidance for virus vectors](http://www.safety.rochester.edu/ibc/pdf/ibcvirus.pdf)
      * [NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules](http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines)
      * Biosafety Officer (275-3014 or [srosen22@safety.rochester.edu](mailto:srosen22@safety.rochester.edu))
      * IBC Coordinator (275-2402 or [ddouglass@safety.rochester.edu](mailto:ddouglass@safety.rochester.edu))

VV1. What vector system are you registering with this document?

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Adenovirus Vector |  | Adeno-associated virus vector |  | Retrovirus vector |
|  | Herpes vector (Amplicon-type) |  | Herpesvirus vector (Standard) |  | Lentivirus vector |
|  | Poxvirus vector |  | Other mammalian virus, specify: | | |

VV2. Will your lab play any part in constructing and producing the infectious virus? (e.g., cloning insert, transfecting plasmids into packaging cells, purification or isolation of virus)

|  |  |  |  |
| --- | --- | --- | --- |
| YES |  | NO |  |

If you will be receiving the infectious virus from someone, please indicate source:

VV3. Virus vector characteristics and production:

1. List the **name and source** of all vector backbone(s), packaging plasmid(s). Include if VSV-G pseudotyped.
2. If you are using the vector for gene ablation (e.g. CRISPR/Cas9), will the construct result in the creation of a **gene drive** or selfish genetic element (i.e. a higher chance of a gene being inherited than by Mendelian genetics)? Explain why or why not.
3. Describe your **production methods**, including packaging or producer cell lines and *E. coli* strains for plasmid propagation. Will production involve centrifugation or filtration (indicate whether syringe or vacuum based filtration)? Needles or other sharps?
4. Does your vector system include a **helper virus** (e.g., some AAV systems, herpes virus amplicons)? If so, is this helper virus inactivated or attenuated? How much infectious helper virus remains in your vector inoculum?
5. What genes are deleted from your vector and/or its helper virus (e.g. E1A/E1B/E3/E4 for adenovirus; IE/TK for herpes; gag/pol/env/tat/rev for lentivirus; TK for pox; HA for pox; gag/pol/env for retrovirus)? Is your vector system **replication defective**? Is your vector system **self-inactivating** (i.e. truncated 3’ LTR)?
6. What is the **potential that wild-type virus will be produced** during the *in vitro* generation of virus stocks? Provide any evidence that supports your estimate (published or otherwise). Will you monitor production of wild-type virus and if so, how? **If you do not know what the frequency of virus reversion is, you must state this clearly in your lab operating procedure and anyone handling the virus in your lab must be apprised of this risk.** Please think carefully about additional aspects of the recombinant virus, particularly as they may relate to (i) potential for regeneration of infectious virus, (ii) pre-existing presence of such virus in your starting material, (iii) recombination with wild-type virus (if present in the environment).
7. What **experience** do you have working with this virus? If you have none, will you collaborate with someone who is experienced? If so, who?

VV4. Questions relating to the nature of recombinant DNA sequences transduced by the virus:

Questions in the following table must be answered for each distinct gene/construct. Add rows to the table as needed for additional constructs.

NOTE: It is forbidden to insert any variola sequence into any pox-based vector. Also, individuals working with variola virus sequences must be physically separated from experiments involving other poxviruses (i.e., if the sequences are being expressed in *E. coli*, other experiments with poxviruses must not occur in the same room or equipment).

Please also note this list of questions is incomplete; think carefully about the specifics of your gene. Remember that although your recombinant may not be able to replicate on its own, many viruses (e.g., adenoviruses, herpes viruses, AAV) are common in the environment and contagious, and co-infection with a wild-type virus will result in the spread of the recombinant through aerosols and/or feces.

Comments:

**(to e in the following table) What adverse effects might result from inhaling or otherwise ingesting the recombinant virus containing your cloned genes?** *For example: adenovirus can replicate in the respiratory tract and the gut; AAV may survive passage through the GI tract.* If this would result in the expression of your gene in tissue(s) where it normally is not expressed, what effects might this have? Explain in detail below.

**(to f in the following table) Is your gene involved in cell growth control (i.e., oncogene, tumor suppressor, cytokine)?** Might this result in tumor induction? Is there a risk of oncogenesis as a result of viral insertion into the host chromosome?

**(VV4. Questions relating to the nature of recombinant or synthetic nucleic acid sequences transduced by the virus, continued):**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| (a) | (b) | (c) | (d) | (e) | (f) | (g) |
| Insert | Nucleic acid type | Species of origin | Expression (Promoter) | Insert name  Potentially adverse effects? | Involved in cell control? | Pathogenic conversion? |
| Expression | | | | | | |
| Gene symbol, preferably in alphabetic order | *ex.* genomic, cDNA, microRNA, etc. |  |  | Insert name, then list potentially adverse effects (*ex*: oncogenic potential, toxic, pro-inflammatory) | *ex*: proliferation, cell survival |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
| Insert | Nucleic acid type | Species of origin | Expression (Promoter) | Insert name  Potentially adverse effects? | Involved in cell control? | Pathogenic conversion? |
| Antisense or Knockout | | | | | | |
| Gene symbol, preferably in alphabetic order | *ex:* shRNA, siRNA, sgRNA for CRISPR, etc. | or, species homology for sgRNA |  | Insert name, then list potentially adverse effects (*ex*: oncogenic potential, toxic, pro-inflammatory) | *ex*: proliferation, cell survival |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

VV Form Revision Date: 12/14/2016

**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 my 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 registration 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**

**Please submit this form electronically as a Word e-mail attachment to the IBC Administrative Assistant** [**ddouglass@safety.rochester.edu**](mailto:ddouglass@safety.rochester.edu)**.**

* New protocols or 5 year updates: Submit a copy of the signature page (last page) by fax (274-0001), e-mail, or mail (RC Box 278878)
* Modifications: PI’s email serves as signature.

New PI Template Revision Date: 8/23/2021