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.]

|  |  |  |
| --- | --- | --- |
| X | No | ***Skip to Question C.1.*** |

***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)?***

|  |  |  |
| --- | --- | --- |
| X | No | ***Skip to Question D.1.*** |

* 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.*** |
| X | 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.)***

|  |  |  |
| --- | --- | --- |
| X | 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*  |

* 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)

|  |  |  |
| --- | --- | --- |
| X | No | ***Skip to Question G.1.*** |

* 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)?***

|  |  |  |
| --- | --- | --- |
| X | No | ***Skip to Question H.1.*** |

* 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?*

|  |  |  |
| --- | --- | --- |
| X | No | ***Skip to Question I.1.*** |

* 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)?*

|  |  |  |
| --- | --- | --- |
| X | No | ***Skip to Question J.1.*** |

* 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)***

|  |  |  |
| --- | --- | --- |
| X | No | ***Proceed to Question J.2.*** |

***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.***

|  |  |  |
| --- | --- | --- |
| X | No | ***Skip to Question J.1.*** |

* 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)** |
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***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)** |
|  |  |  |  |  |  |
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* 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.***

***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 Program Coordinator** **ddouglass@safety.rochester.edu****. Also submit a copy of the signature page (last page) by fax (274-0001), e-mail, or mail (RC Box 278878).**

Revision Date: 12/14/16