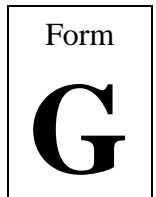


University of Rochester Institutional Biosafety Committee
Grant or Project Registration Form



1. Use this form to register:
 - A. New 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

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.
 - B. Non-recombinant biohazards including pathogens (mammalian or plant); and eukaryotic cells, fluids, cell lines, and unfixed tissue for new grants or projects.
 - C. The use of biologicals noted in numbers 1 and 2 (see above) in animals.
 - D. The generation of de novo transgenic animals using recombinant or synthetic nucleic acid technology.
 - E. Interbreeding or cross breeding of animals that were originally created using recombinant or synthetic nucleic acid technology **AND** are genetically different from each other; **AND** if you intend to administer agents (listed above under numbers 1 and 2) to these animals.
 - F. Contact the Biosafety Officer (275-3014 or rosen22@safety.rochester.edu.) directly if you intend to generate transgenic plants.
2. **No abbreviations, please.** If they are used, they **MUST** be defined. Failure to do so will delay the review of your protocol.
3. Complete and submit this form electronically as PDF or Word e-mail attachment to the IBC Program Coordinator ddouglass@safety.rochester.edu . Fax (274-0001) or mail (RC Box 278878) a signed copy of this form to the IBC.
4. A **LAB registration** for the space(s) in which the work is being done must be on file with the IBC. (<http://www.safety.rochester.edu/homepages/ibchome.html> under “IBC Registration Forms”) Please contact the IBC program Coordinator ddouglass@safety.rochester.edu if unsure.
5. **Changes to existing registrations must be approved by the IBC.** Modify Form G to include all the changes. Make sure those changes (and only those changes) are in **RED** type or are highlighted **YELLOW**. Make sure to update Question A giving a brief description of your work with these agents. Submit it with supporting documents, as applicable (Form VV, Lab Registration) to the IBC Program Coordinator at ddouglass@safety.rochester.edu.

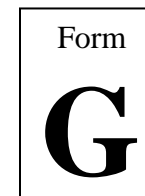
Useful references:

- [UR Biosafety Requirements and Resources](#)
- [IBC web pages](#)
- [NIH Guidelines](#)
- [5th edition of CDC/NIH “Biosafety in Microbiological and Biomedical Laboratories”](#)

Bio-containment and safety questions can be referred to the Biosafety Officer rosen22@safety.rochester.edu.

Revised: 3/21/14

University of Rochester Institutional Biosafety Committee
Grant or Project Registration Form



Principal Investigator:

Dept:

Phone:

Co-Principal Investigator:

Dept:

Phone:

Technician or Alternative Contact:

Dept:

Phone:

Project or Grant Title:

Box #:

Award #:

Grant Registration #: GNT-

➤ **Declaration of Confidentiality:**

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

➤ **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 provide a brief summary stating the goals of your studies. Describe the nature of the in vitro and in vivo experiments done with the agent(s) declared in Questions B - J (e.g., cells, DNA, viruses, bacteria, animals).*

DO NOT cut and paste your grant abstract or your UCAR abstract, as it will not provide appropriate experimental detail for the IBC review. Failure to provide information summarizing how each agent will be used 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 the plasmids used to construct the non-viral pathogens under Question E. Do not declare cloning bacteria here.]

No	Skip to <u>Question C.1.</u>
Yes	If yes, complete <u>Table B.1.a.</u> Expand the table as necessary. University Specific Guidelines

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)? [List the plasmids used to construct the viruses under Question E.]

No	Skip to <u>Question D.1.</u>
Yes	If yes, complete <u>Table C.1.a.</u> Expand tables as necessary. <u>VIRAL VECTORS</u> * Submit your Mammalian Viral Vector Registration for each viral vector system declared below. Viral Vector Registration . Contact the IBC Program Coordinator if you have questions about your Mammalian Viral Vector Registration(s). University Specific Guidelines * 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.

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	List cells transduced or infected with virus or viral vector or write "NONE".	List biosafety level(s) for packaging,	Replication-competent? (yes/no)

		registration number (only for viral vectors)	These cells should be described in Question D.	propagation, and infection.	

➤ **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. University Specific Guidelines

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

➤ **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 oligos.)

No	Skip to Question F.1.
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Yes	<p><i>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.</i></p> <p><i>Use NIH Guidelines Section I-B as reference</i></p> <p><i>If you are creating transgenic animals, using recombinant DNA, then declare the construct under this question and complete Question I.</i></p> <p><i>List under Question C any infectious Mammalian Viral Vectors that are already packaged and that will be used as part of these experiments.</i></p> <p><i>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.</i></p>
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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.*

	<i>Insert contains full-length genes for toxins</i>
	<i>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.)</i>
	<i>Insert contains genetic material from a BSL-2 (or higher) <u>MICROORGANISM</u> (e.g. pathogenic bacteria, viruses, fungi, etc).</i>
	<i>Insert contains genetic material that likely codes for an oncogene</i>
	<i>Not applicable: None of the above categories describe the inserts proposed for use in these studies.</i>

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 (Use this column to match your insert with its vector)	What does your insert encode? (e.g. name of gene product or nature of regulatory region)	List DNA type (e.g. genomic, cDNA, antisense, etc.)	List organism or species of origin	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	List vector name(s) and describe	1. List all bacterial and/or fungal agents in which this	1. List all eukaryotic cells (or cell lines) in which this
---------------	----------------------------------	--	--

(Use this column to match your insert (s) with its vector(s))		<p>construct will be placed. Provide specific strain.</p> <p>2. List potential adverse effects of expression (e.g. pathogenic conversion, toxin, etc).</p> <p>3. If no bacterial and/or fungal agents are used, write "NONE".</p> <p>4. Be sure to organize this information so it is CLEAR which construct you are referring to.</p>	<p>construct will be placed. These cells should be described in Question D.</p> <p>2. List potential adverse effects of expression (e.g. oncogenic potential, etc).</p> <p>3. If no eukaryotic cells are used, write "NONE".</p> <p>4. Be sure to organize this information so it is CLEAR which construct you are referring to.</p>
1			
2			
3			
4			

➤ **Declaration of Select Agents:**

Question F.1. Will the grant or project involve the use of **SELECT AGENTS**? (Select Agents are highly regulated pathogens, DNA encoding for functional select agent toxins, and toxins of biological origin that have the potential to be used as biowarfare agents.)
<http://www.selectagents.gov/Select%20Agents%20and%20Toxins%20List.html>

No	Skip to Question G.1.
Yes	<p>If yes, describe briefly in the text box below and complete question F.2.</p> <p>University Specific Guidelines or contact the Biosafety Officer at 275-3014.</p>

Select Agent Description

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Question F.2. Does this study involve Tier 1 Select Agents (or materials derived therefrom)?

No	Skip to Question G.1.
Yes	<p>If yes, complete Table F.2.a.</p> <p>University Specific Guidelines or contact the Biosafety Officer at 275-3014.</p>

Table F.2.a.

The US government has identified seven classes of experiments believed to illustrate the types of endeavors or discoveries that will require review and discussion by informed members of the scientific and medical community before they are undertaken or, if carried out, before they are published in full detail.

Experiments, which involve Tier 1 select agents and fall into one or more of the categories listed below, are considered Dual Use Research of Concern. Such experiments are subject to further institutional approval. [Dual Use Research of Concern](#)

1. Would this experiment enhance the harmful consequences of the agent or toxin?	<i>Yes</i>	
	<i>No</i>	

If Yes, please explain:

2. Would this experiment confer to the agent or toxin resistance to clinically or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin, or facilitates their ability to evade detection methodologies.	<i>Yes</i>	
	<i>No</i>	

If Yes, please explain:

3. Would this experiment disrupt the immunity or the effectiveness of an immunization against the agent or toxin without clinical or agricultural justification?	<i>Yes</i>	
	<i>No</i>	

If Yes, please explain:

4. Would this experiment increase stability, transmissibility, or the ability to disseminate the agent or toxin?	<i>Yes</i>	
	<i>No</i>	

If Yes, please explain:

5. Would this experiment alter the host range or tropism of the agent or toxin?	<i>Yes</i>	
	<i>No</i>	

If Yes, please explain:

6. Would this experiment enhance the susceptibility of a host population to the agent or toxin?	<i>Yes</i>	
	<i>No</i>	

If Yes, please explain:

7. Would this experiment generate or reconstitute an eradicated or extinct agent or toxin?	<i>Yes</i>	
	<i>No</i>	

If Yes, please explain:

➤ **Large Scale Experiments:**

Question G.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 H.1.
Yes	If yes, describe briefly in the text box below. NIH Guidelines or contact the Biosafety Officer at 275-3014.

Brief description of 10L experiments

➤ **Experiments Involving Live Animals:**

Question H.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 I.1.
Yes	If yes, complete Questions H.1 – H.4 (and the associated tables) relative to the biologicals <u>declared above</u> AND which will be administered to <u>LIVE</u> animals. Expand tables as necessary. Generation of transgenic animals should be declared and described under Question I.1 and I.2.

Table H.1.a.

List animal species or strain (one per line)	Is this species transgenic? (Yes or No)	List corresponding UCAR number or write "NONE" if no UCAR is required.

Table H.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	What is the number of doses?	What is the concentration of dose?	Describe exposure (administration) method and potential risk to experimenter. Indicate Biosafety Level (ABSL1, ABSL2, ABSL3)	List type of animal housing necessary (ABSL1, ABSL2, ABSL3)

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

No	Skip to Question H.3.
Yes	If yes, complete Table H.2. Expand table as necessary.

Table H.2.a. Expand table as necessary.

List animal species of 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 H.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 H.4.
Yes	If yes, complete Table H.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 H.3.a.

	Transmission potential. Check all that apply.
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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 H.4. Are there any mitigating factors that may modify (raise or lower) the biological containment level for these experiments?

No	Skip to Question I.1.
Yes	If yes, describe briefly in text box below.

Brief description of mitigating factors

➤ **Transgenic Animal Generation:**

Question I.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 I.2.
Yes	<p>If yes, complete Table I.1.a. If the construct will be generated in the lab, then Question E and its subparts must also be completed.</p> <p>Examples of recombinant DNA 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</p> <p>Use NIH FAQs for Transgenic Animals and NIH Guidelines as references</p>

Table I.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”.	

Question I.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 animals.*

No	Skip to Question J.1.
Yes	If yes, answer Question I.2.a. Complete Table I.2.a for non-rodent animals and for rodents which are NOT EXEMPT from the NIH Guidelines (determined in Question I.2.a). Then complete Questions I.3 through I.7 relative to the progeny. Use NIH FAQs for Transgenic Animals and the NIH Guidelines as reference

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

	<i>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 I.2.a below. Use one table for each crossing, copy/paste more tables as needed. Complete Questions I.3 through I.7 relative to the progeny.</i>
	<i>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 I.2.a below. Use one table for each crossing, copy/paste more tables as needed. Complete Questions I.3 through I.7 relative to the progeny.</i>
	<i>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 (LTR). If yes, describe these crossings in Table I.2.a below. Use one table for each crossing, copy/paste more tables as needed Complete Questions I.3 through I.7 relative to the progeny.</i>
	<i>None of the above – This RODENT crossing is exempt from the NIH guidelines. Skip to Question J.1.</i>

Table I.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 I.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 I.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 I.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 I.6. *Will the resultant progeny result in the expression of transgenes or the dysregulation of endogenous gene-products?*

	No	
	Yes	Explain briefly in this box.

Question I.7. *Will the resultant progeny contain 1/2 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 J.1. *Will this grant or project involve flow cytometry, either for high speed sorting (stream-in-air) or analysis of cells?*

	No	Skip to Question K.1.
	Yes	If yes, describe under Table J.1.a and Table J.1.b as applicable. University Specific Guidelines

Table J.1.a. High Speed Sorting (Stream-in-air)

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. FACS Aria)	List location of instrument

Table J.1.b. FACS Analysis

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. FACS Calibur)	List location of instrument

➤ **Facilities and Personnel:**

Question K.1. Will any portion of this grant or project take place in other UR labs that are not controlled by the listed Principal Investigator(s) or Co-Principal Investigator(s)?

If applicable, please designate the Principal Investigator in whose lab these experiments will be completed, whether or not that PI is involved in the project.

No	Skip to Question K.2.
Yes	<p>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.</p> <p><i>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.</i></p>

Principal Investigator	Activity (brief description – 1-2 sentences)

Question K.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 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 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 or transmission.)

Principal Investigator: _____ / _____
Signature Print

Date: _____

If applicable:

Secondary PI: _____ / _____
Signature Print

Date: _____

Please submit this form electronically as an e-mail attachment to the IBC Program Coordinator (ddouglass@safety.rochester.edu).

Fax (274-0001) or mail (RC Box 278878) a signed copy of this form to the IBC.