Rochester Institute of Technology Institutional Biosafety Committee
Project Registration Form

Name(s) of PI(s):_____ **Lab Location:** _____

Project Title: _____

1. Use this form to:
   a) Register new or modified projects involving recombinant DNA constructs. Note: There are NO projects exempt from the NIH Guidelines for Research Involving Recombinant DNA Molecules as RIT receives NIH funding.
   b) Declare non-recombinant biohazards including pathogens (mammalian or plant); and eukaryotic cells, fluids, cell lines, and unfixed tissue for new or modified projects.
   c) Register the use of biologicals noted above in animals.
   d) Register the generation of *de novo* transgenic animals using recombinant DNA technology.
   e) Register interbreeding or cross breeding of animals that were originally created using recombinant DNA technology **AND** are genetically different from each other; **AND** if you intend to administer agents listed above to these animals.
2. Contact the Chair of the Institutional Biosafety Committee (475-7961 or cbwsbi@rit.edu) directly if you intend to generate transgenic plants.
3. Please do not use abbreviations without defining them. Failure to do so will delay the review of your protocol.
4. Please e-mail your completed and signed form electronically, as a PDF or Word document, to ibc@rit.edu .
5. Is your project funded by the NIH? (PI to complete this question) Yes No

Prior to Submission to the IBC:

1. Obtain the Material Safety Data Sheet/Safety Data Sheet for the associated biological agent(s). Yes No
2. Ensure all individuals working on this project have:
   a. Reviewed the RIT EH&S Biosafety webpage: https://www.rit.edu/fa/grms/ehs/content/biosafety Yes No
   b. Taken all necessary training course(s):
      i. Biosafety Awareness (found on the biosafety webpage) Yes No
      ii. Lab Safety: https://www.rit.edu/fa/grms/ehs/content/labstudio-safety Yes No
      iii. Gas Cylinder: (if working with compressed gases). Also on the Lab Safety webpage. Yes No NA
      iv. Bloodborne Pathogens: (if working with human or non-human primate cells or tissues). File paperwork. Yes No NA
      https://www.rit.edu/fa/grms/ehs/content/bloodborne-pathogens
3. Write a project specific standard operating procedure (SOP) for the biological agent(s) you will be using. Yes No
4. Ensure the availability of all necessary safety devices (e.g. certified biosafety cabinets). Yes No NA

IBC Committee Reviewer: _____ **Date:** _____
(Signature)

IBC Committee Project Approval: _____ **Date:** _____
(Signature)

IBC Project Number: _____ **Assigned BSL:** _____

Rochester Institute of Technology Institutional Biosafety Committee
Project Registration Form

Biological Agent(s) of concern:_____

Campus Address#:

Question A.1. ***Will this project involve the use of mammalian or plant pathogens including non-recombinant and recombinant pathogens? (List infectious Mammalian Viral Vectors under Question D.)***

	No	***Skip to Question B.1.***
	Yes	***If yes, complete Table A.1.a. Expand the table as necessary.***

Table A.1.a.

List pathogens (Genus, species, strain)	Biosafety level

Question B.1. ***Will this 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 C.1.***
	Yes	***If yes, complete Table B.1.a. Expand the table as necessary.*** ** NOTE: **ATCC Biosafety levels refer to frozen cells (as shipped) only. CDC recommends that all human and non-human primate cells be handled as Biosafety Level 2.**

Table B.1.a. Eukaryotic cells or fluids, eukaryotic cell lines, or eukaryotic unfixed tissues description. List all other organisms associated with project.

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 IACUC # 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"	Biosafety level**

Question C.1. ***Will this project involve the use of recombinant DNA (e.g. plasmids, non-pathogenic or pathogenic genetically engineered microorganisms)?***

	No	***Skip to Question D.1.***
	Yes	***If yes, describe your recombinant DNA by answering questions C.2. - C.3 and by completing Table C.3.a. and Table C.3.b . Expand tables as necessary.*** *Use NIH Guidelines Section I-B as reference* *If you are creating transgenic animals, complete Question H.* *List under Question D. 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 C.1 – C.3 and complete Table C.3.a and Table C.3.b. relative to those plasmids.*

Question C.2. ***What is the nature of the DNA 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).
	Insert contains genetic material that likely codes for an oncogene
	Not applicable: None of the above categories describe the inserts proposed for use in these studies.

Question C.3. ***Describe all the recombinant DNA constructs used in these studies by completing Tables C.3.a. and C.3.b. Expand tables as necessary.***

Table C.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 insert contain promoter? (Yes, no, unknown)	Will you INTENTIALLY express the product of the insert? (Yes, no)
1					
2					
3					
4					

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

Insert number (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 B. 2. List potential adverse effects of expression (e.g. oncogenic potential, etc). 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.**
1			
2			
3			
4			

<u>Question D.1.</u> Will this project involve the use of Mammalian Viral Vectors?

	No	***Skip to Question E.1.***
	Yes	***If yes, complete Table D.1.a. Expand tables as necessary. Also submit your Mammalian Viral Vector Registration completed for each viral system declared below.*** *Contact the IBC Chair if you have questions about your Mammalian Viral Vector Registrations.*

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

List viral vector system (e.g. adenoviral, lentiviral, retroviral, adeno-associated, etc.)	**List corresponding viral vector registration number**	**List cells transduced or infected with viral vector or write "NONE". These cells should be described in Question B.**	**List biosafety level(s) for packaging, propagation, and infection.**

<u>Question E.1.</u> Will project involve the use of select agents (pathogens, recombinant DNA, or toxins of biological origin)?

	No	***Skip to Question F.1.***
	Yes	***If yes, describe briefly in the text box below. Hint: Cut & paste from your Lab Registration, if applicable.***

<u>Select Agent Description</u>	

Question F.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 G.1.***
	Yes	***If yes, describe briefly in the text box below.***

Brief description of 10L experiments	

Question G.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 H.1.***
	Yes	***If yes, complete Questions G.1 – G.4 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 H .1. and H.2.*

Table G.1.a.

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

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

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

Table G.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 G.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 G.4.***
	Yes	***If yes, complete Table G.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 G.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 G.4. ***Are there any mitigating factors that may modify (raise or lower) the biological containment level for these experiments?***

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

Brief description of mitigating factors	

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

	No	***Proceed to Question H.2.***
	Yes	***If yes, describe recombinant construct (vector, gene, gene function) in text box below and complete Table H.1.a.*** *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* *Use NIH Guidelines as reference: http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html*

Construct description	

Table H.1.a.

	Construct 1	**Construct 2**	**Construct 3**
List corresponding IACUC number or write "NONE" if no IACUC 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 H.2. ***Will you be interbreeding or cross breeding transgenic animals (those originally created using recombinant DNA technology) AND 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, complete Table H.2.a. and questions H.3. through H.6.*** *Use the NIH Guidelines as reference*

Table H.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.		
List corresponding IACUC number or write "NONE" if no IACUC is required.		

Question H.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 H.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 H.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 H.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.1. ***Will any portion of this project take place in other labs that are not controlled by the listed Principal Investigator or Co-Principal Investigator?***

	No	***Skip to Question J.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 J.2. ***List full name of lab personnel involved in the experiments declared through this registration document, including all Principal Investigators, Co-Principal Investigators, Student Employees, and Students.***

Question K. ***Please provide a brief summary (2-3 paragraphs maximum) stating the goals of your studies and describing the nature of the experiments done with each agent declared in Questions A-E. (i.e. cells, DNA, viruses, bacteria). Described each aspect of the project including: acquisition, use/handling, storage, and disposal.***

DO NOT cut and paste your grant abstract or your IACUC abstract, as it will not provide enough detail for the IBC review. Providing the specific aims of the project may be useful to provide perspective to the committee, however, submitting the aims without providing a summary of what you intend to do with each agent is no longer acceptable.

Failure to provide information detailing how each agent will be used will result in a SIGNIFICANT delay in your approval.

Question L. ***Criteria for review from the Fink Committee Report – The IBC will, as part of its protocol review process, consider whether experiments being proposed fall into any of the seven categories of experiments of concern, those with legitimate scientific purpose, but which could be misused to pose a biological threat to public health and/or national security (Dual Use Technology). PIs are responsible for the initial assessment of their experiments in light of the Fink Report. For more information, please visit http://www.nap.edu/books/0309089778/html.***

Please check the appropriate answer:

The Fink Committee identified seven classes of experiments that it believes 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.		
1. Would this experiment demonstrate how to render a vaccine ineffective? This would apply to both human and animal vaccines. Creation of a vaccine-resistant smallpox virus would fall into this class of experiments.	***Yes***	
	No	
If Yes, please explain:		
2. Would this experiment confer resistance to therapeutically useful antibiotics or antiviral agents? This would apply to therapeutic agents that are used to control disease agents in humans, animals, or crops. Introduction of ciprofloxacin resistance in Bacillus anthracis would fall in this class.	***Yes***	
	No	
If Yes, please explain:		
3. Would this experiment enhance the virulence of a pathogen or render a nonpathogen virulent? This would apply to plant, animal, and human pathogens. Introduction of cereolysin toxin gene into Bacillus anthracis would fall into this class.	***Yes***	
	No	
If Yes, please explain:		
4. Would this experiment increase transmissibility of a pathogen? This would include enhancing transmission within or between species. Altering vector competence to enhance disease transmission would also fall into this class.	***Yes***	
	No	
If Yes, please explain:		
5. Would this experiment alter the host range of a pathogen? This would include making nonzoonotics into zoonotic agents. Altering the tropism of viruses would fit into this class.	***Yes***	
	No	
If Yes, please explain:		
6. Would this experiment enable the evasion of diagnostic/detection modalities? This could include microencapsulation to avoid antibody-based detection and/or the alteration of gene sequences to avoid detection by established molecular methods.	***Yes***	
	No	
If Yes, please explain:		
7. Would this experiment enable the weaponization of a biological agent or toxin? This would include the environmental stabilization of pathogens. Synthesis of smallpox virus would fall into this class of experiments.	***Yes***	
	No	
If Yes, please explain:		

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 every academic year.**

3. All personnel have received training regarding your laboratory and agent specific guidelines **prior to working at the bench. Any new individuals assigned to the project must also receive the appropriate training.** 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 significant laboratory-related accidents and illnesses 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.

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: _____

If applicable:
Secondary PI: _____ Date: _____

Please submit a signed copy of this form electronically to ibc@rit.edu .

Environmental Health & Safety – Laboratory Review

Inspection items to be verified after IBC review:

1. Ensure proper maintenance/certification of all equipment (e.g. certified biosafety cabinets). ☐ Yes ☐ No ☐ NA
2. Ensure all required signage is posted in laboratory areas. ☐ Yes ☐ No
3. Compile a lab notebook consisting of items 1-3 from page 1. (SDS, training certificates, SOP) ☐ Yes ☐ No
4. Ensure no decorative plants or animals (e.g. pets) in the laboratories. ☐ Yes ☐ No
5. Ensure any autoclaves have appropriate, up-to-date operation and validation logs, and are validated every 40 operating hours. ☐ Yes ☐ No ☐ NA

COMMENTS:

PI Signature _____ Date _____

EH&S Signature _____ Date _____

Retain a copy of this completed checklist with your project documentation. For questions, contact Cindy White at (585) 475-4980 or clwehs@rit.edu.
NOTE: Any comments or non-compliance with guidelines require a written response/notification of action to Cindy White within 14 days of checklist receipt.