



Institutional Biosafety Committee Troy, NY

IBC Reg. NO.: _____ Biosafety Level: _____

Principal Investigator (PI): _____ Department: _____

phone: _____ e-mail: _____ office: _____

Alternate Contact Person: _____ Department: _____

phone: _____ e-mail: _____ office: _____

Laboratory Location(s): _____

Project Title: _____

Date of submission: _____

Please check all that apply:

rDNA / RNA Pathogen Select Agents / Toxins Human cells / tissues Viruses

GENERAL INSTRUCTIONS: The intent of this form is to ensure compliance with the CDC/NIH guidelines for biosafety in research laboratories. In completing this form you must convey to the Institutional Biosafety Committee (IBC) that you: understand the potential hazards of the proposed research, have designed the experiments to minimize potential hazards, and have communicated potential hazards to others who may come in contact with the products you propose to use or generate.

In some cases, it is acceptable to combine multiple experiments or organisms onto the same registration form. If the form can be clearly understood when more than one organism/experiment is listed, then a PI may combine. Please contact the IBC if you have questions about this form.

SUBMITTING THIS FORM TO THE IBC: Submit the completed form to the IBC. The IBC will submit comments and questions to the PI for a response. The PI's response will be sent to the IBC for further review.

After all comments have been addressed, the protocol will be voted on at the next available IBC meeting. The IBC meets bi-monthly to review protocols. After the protocol has passed the IBC's vote, the PI must mail a signed hard copy to the IBC, which then will provide an approval letter for the PI.

Please mark which of the following sections you will be completing:

Part A: Recombinant DNA Experiments. Select the category that best reflects the type of experiment that you are conducting. Indicate the possible adverse effects of the DNA, quantity of culture used, and a description of the experiment. Also, provide detailed information regarding the DNA inserts, vectors and host cells being used in your rDNA system.

Part B: Pathogenic Microorganisms. Agents capable of causing disease in immune-normal, healthy adults must be registered in Part B. These agents include organisms classified as biosafety level 2 (BSL-2) or higher in the latest edition of the CDC Biosafety in Microbiological and Biomedical Laboratories (BMBL) publication. **Registration is required for BSL-2 organisms or higher.**

Part C: Human Blood, Human Cell Lines and Tissues or Other Potentially Infectious Materials (OPIM). These items, including established human/primate cell lines must be listed in Part C. Human and primate cell lines obtained from commercial sources are also included in this requirement. OPIM is material with the potential for transmission of HIV, HBV, HCV, and other bloodborne diseases, including tissue from animals known to be infected with any of these agents, microbial stocks and cultures, certain body fluids, unfixed human tissue, primary tissue/cell cultures and must also be registered in Part B. These must be handled under BSL-2 conditions as if they were primary cells or tissues. For further information, please visit the CDC website: <http://www.cdc.gov/od/ohs/biosfty/bmbl4/b4ah.htm>

Part D: Possession, Use and Transfer of Select Agents, Toxins, High Consequence Livestock or Plant Pathogens. The use of these agents, toxins or pathogens is regulated by the [CDC Select Agent Regulation, 42 CFR 73](#), and the [USDA Select Agent Rule 7 CFR 331/9 CFR 121](#). Facility Registration is required and is administered by the [Centers for Disease Control](#), and/or the [USDA](#). If you anticipate using these materials complete Part C of this form. Additional requirements of the "USA Patriot Act" and the "Public Health Security, Bioterrorism and Response Act of 2002" also must be satisfied.

Part E: Administration to animals of any of the above selections. Administration of any of the above agents to animals requires approval of the IACUC and may also require that the animals be housed in specialty cages and handled under BSL-2 or BSL-3 conditions.

Part F: Safety Measures. This section must be completed for all registrations.

Part G: Affirmation. This section must be completed for all registrations.

Part A: RECOMBINANT DNA

Please identify the type of experiment described in this registration form by checking the appropriate category in column (E).

(A)	(B)	(C)	(D)	(E)
If your experiment involves:	Registration w/NIH required?	Registration w/IBC required?	IBC must receive registration	Experiment described on this form involves
Cloning of DNA encoding toxin molecules lethal to vertebrates at an LD ₅₀ of less than 100 ng/kg	Yes	Yes	Prior to initiation	<input type="checkbox"/>
Human gene therapy	Yes	Yes	Prior to initiation	<input type="checkbox"/>
Transfer of drug resistance to organisms not known to naturally acquire the trait, if such acquisition could compromise use of the drug to control disease in humans, veterinary medicine, or agriculture	Yes	Yes	Prior to initiation	<input type="checkbox"/>
Risk Group 2, 3, or 4 agents as host-vector systems	No	Yes	Prior to initiation	<input type="checkbox"/>
Cloning of DNA from risk group 2, 3, or 4 microorganisms into nonpathogenic prokaryotic or lower eukaryotic host-vector systems	No	Yes	Prior to initiation	<input type="checkbox"/>
Use of infectious DNA or RNA viruses or defective DNA or RNA viruses in the presence of helper virus in tissue culture systems	No	Yes	Prior to initiation	<input type="checkbox"/>
Production of transgenic animals at the UMDNJ Transgenic Core Facility	No	Yes	Prior to initiation	<input type="checkbox"/>
Use of transgenic animals at BL-2, 3 or 4	No	Yes	Prior to initiation	<input type="checkbox"/>
Use of viable rDNA-modified microorganisms involving whole animals or whole plants	No	Yes	Prior to initiation	<input type="checkbox"/>
Administration of rDNA to animals	No	Yes	Prior to initiation	<input type="checkbox"/>
More than 10 liters of culture	No	Yes	Prior to initiation	<input type="checkbox"/>
Propagation and maintenance in tissue culture of r-DNA containing <2/3 of the genome of any eukaryotic virus in the demonstrable absence of helper virus, or of a virus that has been established to be non-replicating	No	Yes	At initiation	<input type="checkbox"/>
Propagation and maintenance in tissue culture of r-DNA containing a virus that has been established to be non-replicating	No	Yes	At initiation	<input type="checkbox"/>
Formation of rDNA containing no more than 2/3 the genome of any eukaryotic virus	No	Yes	At initiation	<input type="checkbox"/>
Use of transgenic animals at BL-1	No	No	n/a	<input type="checkbox"/>
rDNA that is not in an organism or virus	No	No	n/a	<input type="checkbox"/>
DNA segments from a single non-chromosomal or viral DNA source	No	No	n/a	<input type="checkbox"/>
DNA entirely from a prokaryotic host when propagated only in that host	No	No	n/a	<input type="checkbox"/>
DNA entirely from a prokaryotic host when transferred to another host by well established physiological means	No	No	n/a	<input type="checkbox"/>
DNA from a eukaryotic host when propagated only in that host or a closely related strain of the same species	No	No	n/a	<input type="checkbox"/>
DNA segments from different species that exchange DNA by known physiological processes	No	No	n/a	<input type="checkbox"/>

Please complete the following sections to describe your experiment.

1. Does the donor rDNA, RNA, cDNA source or its vector have any recognized or anticipated pathogenic, toxigenic or virulence potential for animals, plants or humans?
 - a. If yes, explain:

YES NO

a. If no, please provide a reference to support your conclusion:

2. Quantity of Material to be used:

- a. < 1 Liter
- b. 1-10 Liter
- c. > 10 Liters

3. Location in which rDNA research is to be conducted (building and room #):

4. Specify source and nature of the DNA sequence(s) to be inserted (genus, species, gene name):

- a. Will the inserted gene(s) be expressed?
- b. If yes, what are the gene product effects? Specifically identify its toxicity, physiological activity, allergenicity, oncogenic potential or ability to alter cell cycle:

YES NO

5. Describe the virus, phage and/or plasmid used for constructing your recombinants (prokaryotic, eukaryotic):

6. If possible, provide a diagram or map illustrating the construct. If appropriate, include Entrez Gene nomenclature (<http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?db=gene>).

7. Identify host cell(s) or packaging cell line in which recombinant vector will be amplified:

8. Is the vector replication competent?

YES NO

9. Are any viral component(s)/sequence(s) present?

YES NO

- a. If yes, specify the nature of the viral component(s):

10. Does the insert contain >2/3 of a eukaryotic viral genome?

YES NO

11. Is helper virus used?

YES NO

- a. Specify type:

12. Is it a retrovirus?

YES NO

12. What cells, tissues, animals, humans, insects or plants will be exposed to the recombinant? Indicate type of cell line and species:

13. Will you work with transgenic animals?

YES NO

14. Will human subjects be exposed to rDNA?

YES NO

15. Brief description of proposed research (please include enough information to describe project's specific aims):

Part B - PATHOGENIC MICROORGANISMS

To be completed by the Principal Investigator for all laboratories handling or storing pathogenic microorganisms (agents capable of causing disease in immune-normal, healthy adults and includes organisms classified as requiring work at BSL-2 or higher in the latest edition of either the CDC/NIH publication, *Biosafety in Microbiological and Biomedical Laboratories* or the NIH's *Guidelines for Research Involving Recombinant DNA Molecules*.

1. Name of Organism (genus, species, strain description):

a. Is organism attenuated?

YES NO

2. Is a toxin produced?

YES NO

a. Work with toxin?

YES NO

3. Is drug resistance expressed?

YES NO

A. If yes, indicate to which drugs:

4. Where is organism stored? Bldg: _____ Room: _____

a. Are Biohazard Warning Labels in use?

YES NO

5. Building and room where organism is used? Bldg: _____ Room: _____

6. Is a stock culture prepared?

YES NO

If yes, indicate:

a. Total volume of stock culture _____

b. Volume aliquoted per individual vial _____

c. Concentration /ml individual vial _____

d. Maximum volume used in an experiment _____

7. Is organism inactivated prior to use?

YES NO

a. Specify Method: _____

8. Do you concentrate the organism in your protocol?

YES NO

a. Specify method: centrifugation

precipitation

filtration

other: _____

9. Does the laboratory work with human blood or blood products, unfixed human tissue, or human or other primate cells? **If yes, fill out Part B below.**

YES NO

10. Are cultures, stocks, and contaminated items decontaminated prior to disposal?

YES NO

a. Method:

autoclave

chemical disinfectant

other (specify): _____

Brief description of proposed research (please include enough information to describe project's specific aims):

Part C - HUMAN CELLS AND TISSUES

Please list the cell lines and tissues that you will be using, attach additional sheets if needed. Include established human or primate ATCC cell lines and any other potentially infectious materials.

Note: Use of human cell lines or human source materials may require registration with the Institutional Review Board (IRB). Please contact the IRB to determine if your protocol will require review.

1.	2.	3.
4.	5.	6.
7.	8.	9.

Brief description of proposed research (please include enough information to describe projects's specific aims):

Part D: POSSESSION, USE OR TRANSFER OF SELECT AGENTS, TOXINS, HIGH CONSEQUENCE LIVESTOCK PATHOGENS, AND PLANT PATHOGENS.

The University is required to register with the CDC or USDA for possession, use or transfer of any of these agents, toxins or pathogens. These agents are regulated by [Select Agent Regulation, 42 CFR 73.0](#) and the [Agricultural Bioterrorism Protection Act of 2002](#). If you anticipate obtaining these materials complete Part C of this form. Additional requirements of the "USA Patriot Act" and the "Public Health Security, Bioterrorism and Response Act of 2002" must also be satisfied.

Are, or will, any of the following agents, toxins or pathogens be used in your laboratory: Yes No.

(If "yes", please indicate which by marking the box next to the item with a check "√" or an "X".)

Viruses (HHS and USDA)	√	Bacteria (HHS and USDA)	√
Akabane virus		Bacillus anthracis	
African swine fever virus		Brucella abortus	
African horse sickness virus		Brucella melitensis	
Avian influenza virus (highly pathogenic)		Brucella suis	
Blue tongue virus (Exotic)		Burkholderia mallei (formerly Pseudomonas mallei)	
Bovine spongiform encephalopathy agent		Burkholderia pseudomallei	
Camel pox virus		Botulinum neurotoxin producing species Clostridium	
Classical swine fever virus		Cowdria ruminantium (Heartwater)	
Crimean-Congo hemorrhagic fever virus		Coxiella burnetii	
Eastern Equine Encephalitis virus		Francisella tularensis	
Ebola viruses		Mycoplasma capricolum/ M.F38/M. mycoides capri	
Foot and mouth disease virus		Mycoplasma mycoides mycoides	
Goat pox virus		Rickettsia prowazekii	
Cercopithecine herpesvirus 1 (Herpes B virus)		Rickettsia rickettsii	
Japanese encephalitis virus		Yersinia pestis	
Lassa fever virus		Fungi	√
Lumpy skin disease virus		Coccidioides immitis	
Malignant catarrhal fever virus (Exotic)		Coccidioides posadasii	
Marburg virus		Toxins (HHS and USDA)	√
Menangle virus		Abrin	
Monkeypox virus		Botulinum neurotoxins	
Newcastle disease virus (VVND)		Conotoxins	
Nipah and Hendra Complex viruses		Clostridium perfringens epsilon toxin	
Peste Des Petits Ruminants virus		Diacetoxyscirpenol	
Rift Valley fever virus		Ricin	
Rinderpest virus		Saxitoxin	
Sheep pox virus		Shigatoxin	
South American Hemorrhagic fever viruses		Shiga-like ribosome inactivating proteins	
Junin		Staphylococcal enterotoxins	
Machupo		T-2 toxin	
Sabia		Tetrodotoxin	
Flexal		USDA Plant Pathogens	√
Guanarito		Liberobacter africanus	
Swine vesicular disease virus		Liberobacter asiaticus	
Tick-borne encephalitis complex (flavi) viruses		Peronosclerospora philippinensis	
Central European Tick-borne encephalitis		Phakopsora pachyrhizi	
Far Eastern tick-borne encephalitis		Plum Pox Potyvirus	
Russian Spring and Summer encephalitis		Ralstonia solanacearum race 3, biovar 2	
Kyasanur Forest disease		Schlerophthora rayssiae var zeeae	
Omsk Hemorrhagic Fever		Synchytrium endobioticum	
Variola major virus (Smallpox virus)		Xanthomonas oryzae	
Variola minor virus (Alastrim)		Xylella fastidiosa (citrus variegated chlorosis strain)	
Venezuelan Equine Encephalitis virus			
Vesicular stomatitis virus (Exotic)			
Genetic Elements, Recombinant Nucleic Acids, and Recombinant Organisms: * If your research involves rDNA, you must complete the rDNA section of this registration form. Contact EOHSS to obtain more information.			√
(1) Select agent viral nucleic acids (synthetic or naturally derived, contiguous or fragmented, in host chromosomes or in expression vectors) that can encode infectious and/or replication competent forms of any of the select agent viruses.			
(2) Nucleic acids (synthetic or naturally derived) that encode for the functional form(s) of any of the toxins listed in if the nucleic acids: (i) are in a vector or host chromosome; (ii) can be expressed in vivo or in vitro; or (iii) are in a vector or host chromosome and can be expressed in vivo or in vitro.			
(3) Viruses, bacteria, fungi, and toxins listed that have been genetically modified.			

- 6. Chlorine dioxide product e.g. Clidox ®
- 7. Quaternary ammonium product e.g. Quatricide ®
- 8. Other:

b. Will radioactive infectious waste be generated?

YES NO

c. How will contaminated solid waste be disposed?

5. **Principal Investigator's Assessment of Risk**

a. What is the most serious adverse event you can foresee as a result of this experiment? (For example: recombination, employee exposure, environmental release, activation of latent virus, etc.)

b. How did you determine the appropriate biosafety level for this protocol?

c. Please list the following information about your most recent literature search on the safety of the organisms, reagents and experimental procedures used in this protocol.

- i. What is the date of your most recent search?
- ii. Which databases did you search?
- iii. What keywords did you use?
- iv. Please describe any pertinent safety or hazard analysis findings:

d. Is there potential for this material to be contaminated with an organism requiring a higher biosafety level?

YES NO

i. How would you determine if the material was contaminated with an organism requiring a higher biosafety level?

ii. Is your lab equipped to perform such an evaluation?

e. What was the source of this material (i.e., ATCC, colleague, other)?

i. Can the sender provide background information or quality control data on the material?

YES NO

ii. Have you already obtained this documentation?

YES NO

6. **Medical Surveillance** (check all that apply):

_____ 1) Personnel have attended Bloodborne Pathogens (BBP) training within the past year. Personnel have attended bi-annual Laboratory Safety training. Personnel shipping and receiving biohazard material have attended biannual IATA training. Contact EOHSS if more information on training is required.

_____ 2) All personnel who are potentially exposed to blood, body fluids or human cell lines have received Hepatitis B vaccine or proven immunity.

_____ 3) Additional vaccination/surveillance is required for work on this project.

Specify agents and special vaccination/surveillance requirements (attach sheets if necessary):

_____ 4) Individuals at increased risk of susceptibility to agent (e.g., preexisting diseases, medications, compromised immunity, pregnancy or breast feeding) have been referred to RPI Occupational Medicine Services or Employee Health Services for counseling.

_____ 5) There is a known vaccine and/or therapy

7. **Project Personnel:** Principal Investigators, use the following table to list all personnel (including any students) in your laboratory who handle or may otherwise be exposed to any of the rDNA, human cell lines, or microorganisms. Please attach additional sheets if necessary.

Name	Title	Date of Last Bloodborne Pathogen Training	Date of Last Lab Safety Training	Signature*

* indicates person who signed this form has been informed of potential hazards and safe work practices

Part G: AFFIRMATION

I accept responsibility for the safe conduct of work with this material. I accept responsibility for ensuring that all personnel associated with this work have received the appropriate training on the hazards and the level of containment required to perform this research safely. I will report to RPI EH&S any accident or incident that results in a potentially toxic exposure to personnel or any incident releasing recombinant DNA or other potentially hazardous materials into the environment.

Principal/Responsible Investigator: _____

Signature: _____

Date: _____

Grant Agency: _____

Award #: _____

COMMITTEE USE

Approval: Yes Yes, approved with modifications *(see notes below) No

Committee's Determination of Required Biological Containment-Biosafety Level: _____

Signatures

IBC Chairman / Representative: _____

Date: _____

Biological Safety Officer (optional): _____

Date: _____

Department Chairperson (as appropriate): _____

Date: _____

Occupational Medicine Physician (as appropriate): _____

Date: _____

Veterinarian (as appropriate): _____

Date: _____

Modifications:

- i. IACUC approval required
 - a. IACUC tracking #:
- ii. IRB approval required
 - a. IRB pending
 - b. IRB approved
 - c. IRB #:
- iii. Other:

YES	<input type="checkbox"/>	NO	<input type="checkbox"/>
YES	<input type="checkbox"/>	NO	<input type="checkbox"/>
YES	<input type="checkbox"/>	NO	<input type="checkbox"/>
YES	<input type="checkbox"/>	NO	<input type="checkbox"/>