

**EOHSS USE ONLY)**  
**EOHSS Reg. No.:** \_\_\_\_\_  
**Biosafety Level:** \_\_\_\_\_



## REGISTRATION FORM FOR RECOMBINANT DNA EXPERIMENTS

### GENERAL INFORMATION:

The intent of this form is to ensure compliance with the NIH Guidelines for research involving recombinant DNA molecules. In completing this form you must convey to the committee 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.

It is important to complete all sections of the form, to read the NIH Guidelines and to sign the statement indicating you understand the guidelines. The most recent and complete NIH Guidelines for Research Involving Recombinant DNA can be found at: [NIH Guidelines for Research Involving Recombinant DNA Molecules](#).

**Please send completed form via interoffice mail to:  
Tracy Pfromm, MPH, Biosafety Officer, EOHSS, Liberty Plaza, Suite 2250, New Brunswick Campus**

Principal/Responsible Investigator (print): \_\_\_\_\_ Department: \_\_\_\_\_

Alternate Contact Person (print): \_\_\_\_\_ Phone (PI): \_\_\_\_\_ Phone (Alt. Contact): \_\_\_\_\_

Email (PI): \_\_\_\_\_ Email (Alt. Contact): \_\_\_\_\_

Laboratory Location(s): \_\_\_\_\_

Project Title: \_\_\_\_\_ Date: \_\_\_\_\_

**Researcher's assessment of approval class: Indicate by checking A, B, C or D.** The following categorization is not all-inclusive; it covers the most common activities. If you need further assistance in determining the appropriate category for your activities, refer to the links above or contact EOHSS.

- A.** Experiments requiring NIH and Institutional Biosafety Committee **approval prior to initiation**.
- Cloning of DNA encoding toxin molecules lethal to vertebrates at an LD<sub>50</sub> of less than 100 ng/kg.
  - Human Gene Therapy. (IRB approval also required.)
  - 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.
- B.** Experiments requiring Institutional Biosafety Committee **approval prior to initiation**.
- Experiments using Risk Group 2, 3, or 4 agents as host-vector systems.
  - Experiments in which DNA from Risk group 2, 3, or 4 microorganisms is cloned into nonpathogenic prokaryotic or lower eukaryotic host-vector systems.
  - Experiments involving the use of infectious DNA or RNA viruses or defective DNA or RNA viruses in the presence of helper virus in tissue culture systems
  - Experiments involving transgenic animals and experiments involving viable r-DNA-modified microorganisms involving whole animals or whole plants.
- C.** Experiments requiring **notification** of the IBC at the time of initiation.
- 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.
- D.** Exempt Experiments - registration with the Institutional Biosafety Committee is not required
- The generation of transgenic rodents requiring BL-1 containment (the lowest risk level).

**DETAILS OF PROPOSAL:**

1. Provide a brief description of the proposed r-DNA research. (Please attach a copy of a grant abstract, if available.)

**2. DNA INSERT(S):**

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

b. Will the inserted gene(s) be expressed?  Yes  No

c. If yes, what are the gene product effects? (Specifically, its toxicity, physiological activity, allergenicity, oncogenic potential or ability to alter cell cycle.)

**3. VECTOR(S):**

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

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

c. Is the vector replication competent?  Yes  No

d. Are any viral component(s)/sequence(s) present?  Yes  No

e. Specify the nature of the viral component(s):

f. Does the insert contain >2/3 of a eukaryotic viral genome?  Yes  No

g. Is helper virus used?  Yes  No Specify type: \_\_\_\_\_

h. Is it a retrovirus?  Yes  No

**4. HOST(S):** Provide information below as to what cells, tissues, animals, humans, insects or plants will be exposed to the recombinant.

a. Indicate type of cell line and species:

b. Will animal(s) be exposed to rDNA?  Yes  No, If yes, specify: \_\_\_\_\_

c. Will you work with transgenic animals?  Yes  No

d. Will human subjects be exposed to rDNA:  Yes  No

**5.** 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.  Yes  No

b. If yes, explain: \_\_\_\_\_

**6.** Quantity of material to be used?  < 1 Liter  1-10 Liter  > 10 Liters

**7.** Location in which rDNA research is to be conducted (building, room #'s): \_\_\_\_\_, \_\_\_\_\_

8. Please use the following table to list all project personnel in your laboratory who handle or may otherwise be exposed to any of these materials. Use the Personnel Update Form on page 6 to update names as necessary.

Name	Title	Lab Person's Initials <sup>#</sup>

<sup>#</sup> indicates person who initialed this form has been informed of potential hazards and safe work practices)

9. **Safety Measures:** Experiments requiring BL2 or higher containment, the use of the equipment items and/or engineering controls listed below may be required. Place a check in front of items that are available.

- Certified Biosafety Cabinets (indicate building/room location) \_\_\_\_\_
- Last date of BSC certification (Month/Year) \_\_\_\_\_
- Centrifuge-Are sealed safety cups available and used?       Yes     No
- Autoclave (infectious waste, rDNA materials are to be inactivated prior to disposal)
- Personal protective equipment (lab coat, safety glasses/goggles/face shield)
- Gloves:  nitrile     non-powdered latex (powdered latex not recommended)     vinyl
- Micro-isolator cages (for BL2 animal experiments)
- HEPA-filtered ventilated cage racks
- BSL-3 Containment suite

10. Provide a statement of any additional measures (attach additional pages if necessary) that will be taken to prevent dissemination of the rDNA or any potentially infectious virus or microorganisms involved, include measures and materials necessary and available to decontaminate and control spills: (for Decontamination/Disinfection, see the EOHSS Fact sheet <http://www2.umdj.edu/eohssweb/publications/disinfection.pdf>.)

- a. Indicate Disinfectant(s) which will be used for routine cleaning & spills:  
 1/10 bleach     70% ethanol     povidone-iodine     other: \_\_\_\_\_
- b. Indicate the Infectious Waste Handling procedures to be used (note, all laboratory ware and culture media that contacts BL2 organisms or recombinant materials are to be inactivated prior to disposal).
  - i. Solids – identify disinfection method:  
 autoclave     1/10 bleach     povidone-iodine     70% ethanol     other: \_\_\_\_\_
  - ii. Liquids – identify disinfection method:  
 autoclave     1/10 bleach     povidone-iodine     70% ethanol     other: \_\_\_\_\_
- c. Will radioactive infectious waste be generated?     Yes       No

11. The use of **Sharps** - (e.g., syringes, scalpels, glass) with BSL-2 and higher organisms must be minimized.

- a. Are sharps (syringes, scalpels, glass) going to be used?       Yes     No
- b. Has the research protocol been reviewed to minimize the use of sharps where possible?     Yes     No
- c. Are sharps with integrated safety devices available?       Yes     No
- d. If yes, please describe device (Type, Model, Brand): \_\_\_\_\_

## 12. Dual Use Research Issues:

<p>According to the 2007 Fink Report (<a href="http://www.nap.edu/books/0309089778/html">http://www.nap.edu/books/0309089778/html</a>) and the National Science Advisory Board for Biosecurity (<a href="http://oba.od.nih.gov/biosecurity/biosecurity.html">http://oba.od.nih.gov/biosecurity/biosecurity.html</a>), research with a legitimate scientific purpose that could be misused to pose a biological threat to public health and/or national security is considered “dual use research”. Please answer the following questions to the best of your current knowledge. A yes response will be evaluated by the committee and follow up with the laboratory may occur to address any additional biosafety and/or biosecurity concerns.</p> <p><b>Please describe your experiment.</b></p>	Yes				No	
	Experimental goal	Very likely	Possible	Very unlikely		
a. Could these experiments disrupt immunity or the effectiveness of an immunization? (This applies to both human and animal vaccines) <i>If yes, please explain:</i>						
b. Could these experiments enhance the harmful consequences of a biological agent or toxin (i.e. increase virulence, pathogenicity)? <i>If yes, please explain:</i>						
c. Could these experiments confer to a biological agent or toxin, resistance to clinically and/ or agriculturally prophylactic or therapeutic interventions? <i>If yes, please explain:</i>						
Could these experiments confer the ability of a biological agent to evade detection methodologies? <i>If yes, please explain:</i>						
e. Could these experiments increase the stability, transmissibility, or the ability to disseminate a biological agent or toxin? This includes the environmental stabilization of pathogens. <i>If yes, please explain:</i>						
Could these experiments alter the host range and/ or tropism for a biological agent? <i>If yes, please explain:</i>						
g. Could these experiments enhance the susceptibility of a host population to illness by a biological agent or toxin? <i>If yes, please explain:</i>						
h. Could these experiments generate a novel pathogenic agent or toxin, or reconstitute an eradicated biological agent? <i>If yes, please explain:</i>						

13. Check the required level of Medical Surveillance for this work and the conditions that apply:

- 1) No medical surveillance necessary. This option requires that you be able to provide certification that the human cell lines have been found to be free of pathogens.
- 2) Employees have been provided Bloodborne Pathogens (BBP) training within the past year. All potentially exposed employees have received Hepatitis B vaccine or proven immunity. (OSHA BBP compliance is adequate for BSL-2 work.)
- 3) Additional vaccination/surveillance required for work on this project. Must be approved by RWJMS Employee Health Services (EOHSI - 732-445-0123). 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 RWJMS Employee Health Services (732-445-0123) for counseling.

**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 EOHSS 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 #: \_\_\_\_\_

**FOR COMMITTEE USE:**

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

**Committee Determination of Required Biological Containment -Biosafety Level:** \_\_\_\_

**Signatures:**

IBC Chairman / Representative: \_\_\_\_\_ Date: \_\_\_\_\_

Biological Safety Officer (EOHSS): \_\_\_\_\_ Date: \_\_\_\_\_

Department Chairperson: \_\_\_\_\_ Date: \_\_\_\_\_

Employee Health Physician (as appropriate): \_\_\_\_\_ Date \_\_\_\_\_

Veterinarian (if animals will be used): \_\_\_\_\_ Date \_\_\_\_\_

**\* Modifications:**

IRB approval required       IRB approval: IRB #: \_\_\_\_\_       IRB pending

IACUC approved required

Other Describe: \_\_\_\_\_

\_\_\_\_\_  
**For further infomation, contact Tracy Pfromm, MPH, Biosafety Officer, EOHSS**  
**Phone: (732) 235-8376, Fax: (732) 235-5270, e-mail [pfrommtr@umdnj.edu](mailto:pfrommtr@umdnj.edu)**