

(EOHSS Use Only)
Revised IBC Registration
Number: _____
Biosafety
Level _____



RWJMS IBC PROTOCOL RENEWAL/AMENDMENT/TERMINATION FORM (PROTOCOL RENEWAL REQUIRED EVERY 3 YEARS)

This form should be used to renew/amend/terminate approved protocols every three years. Please use this form to make **minor** changes to approved protocols, as needed. Send completed form via email or campus mail to: Tracy Pfromm, MPH, Biosafety Officer, EOHSS, pfrommtr@umdnj.edu, Liberty Plaza, Suite 2250, New Brunswick Campus, 732-235-8376

1. Principal Investigator: _____ Phone (PI): _____

Alternate Contact Person: _____ Phone (Alt Contact): _____

Email (PI): _____ Email (Alt. Contact): _____

Laboratory Location(s): _____ Department: _____

Project Title: _____ Date: _____

2. IBC Approval Number of Protocol: _____

3. Please select one of the following options:

_____ **This protocol is no longer in use.** Indicate: 1) exact location where material is being stored, or; 2) whether the recombinants, human cells, pathogens or select agents have been destroyed, and if so, how?
YOU MAY PROCEED TO SECTION 9.

_____ **Renew this protocol without changes**

_____ **Renew/Amend (circle one) this protocol with the following changes:** Briefly describe what changes have been made to the protocol listed above since last approved by the IBC. Please include changes to staff, location of experiment, gene of interest, nature of the inserted DNA, host cells, animals used, vectors, cell lines, culture size, etc. as appropriate.

NOTE: A *NEW* IBC [registration form\(s\)](#) will be required if: 1) you are adding a **pathogenic agent** *not* of the same type for which you have received previous IBC approval (e.g., adding a lentiviral vector with no previous IBC approval for lentivirus); 2) conducting previously unregistered rDNA work with the amended cells/cell lines, vectors, etc. Additionally, amendments to registrations pre-dating 2001 will require a new registration form be submitted to the IBC. Please contact Tracy Pfromm, Biosafety Officer, with any questions at 5-8376 or pfrommtr@umdnj.edu.

4. Last Date of Biosafety Cabinet certification: _____

5. Animal Care and Use

Will biohazardous or recombinant materials be used in animals? Yes No

If yes:

- state the Institutional Animal Care and Use Committee (IACUC) active or pending protocol number: _____
- Provide the date IACUC protocol last approved: _____

6. Dual Use Research Issues:

<p>According to the 2007 Fink Report (http://www.nap.edu/books/0309089778/html.) and the National Science Advisory Board for Biosecurity (http://oba.od.nih.gov/biosecurity/biosecurity.html), 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>Please describe your experiment.</p>	Yes				No	
	Experimental goal	Very likely	Possible	Very unlikely		
<p>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></p>						
<p>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></p>						
<p>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></p>						
<p>Could these experiments confer the ability of a biological agent to evade detection methodologies? <i>If yes, please explain:</i></p>						
<p>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></p>						
<p>Could these experiments alter the host range and/ or tropism for a biological agent? <i>If yes, please explain:</i></p>						
<p>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></p>						
<p>h. Could these experiments generate a novel pathogenic agent or toxin, or reconstitute an eradicated biological agent? <i>If yes, please explain:</i></p>						

7. Use the following table to list all personnel (including any students) who handle or may otherwise be exposed to any of the microorganisms. Please attach additional sheets if necessary. Principal investigators must be included

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

- 8 Please provide a brief current abstract or project summary: (You may attach additional sheets, if necessary)

9. 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, infectious agents or other potentially hazardous materials into the environment.

Principal Investigator Signature: _____ Date: _____

For Committee Use Only

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 (EOHSS): _____ Date: _____

Employee Health Physician (as appropriate): _____ Date: _____

Veterinarian (as appropriate): _____ Date: _____

Modifications: check if:

IACUC approval required

IRB approval required

IRB approval pending

IRB approved. Provide approval number: _____

Other approval