



Institutional Biosafety Committee

RENEWAL/AMENDMENT DOCUMENT FOR PREVIOUSLY APPROVED IBC PROTOCOLS

Please complete and email to: Jessica McCormick, Ph.D. Senior Bio-safety Officer, EOHSS, jessica.mccormick@umdnj.edu, or Tamara McNair, Biosafety Officer, mcnairta@umdnj.edu, Stanley S. Bergen Building Room 443, Newark, 973-972-8424 and 973-972-8419.

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

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

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

Laboratory Location(s): _____ Department: _____

Project Title: _____ Date: _____

2. EOHSS or PHRI Registration No. of Previously Approved Protocol: _____

This protocol was approved for the use of:

- rDNA
- Pathogens
- Human/primate cell lines
- Human/primate material
- Select agents
- Other:

3. Please select one of the following options.	YES	NO
a. This protocol is no longer in use.		
i. If the protocol is no longer in use, have the recombinants, human cells, pathogens or select agents been destroyed?		
If destroyed, how?		
ii. If the protocol is no longer in use, are the recombinant, human cells, pathogens or select agents being stored on site?		
If yes, please indicate the building and room of storage.		
b. Renew this protocol without changes.		
c. Renew this protocol with changes		
Personnel changes:		

Please list the personnel being added or deleted:

Briefly describe what changes have been made to the protocol listed above since the IBC last approved it. 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:

4. Biosafety Cabinet Information

a. Date of last biosafety cabinet certification (mo/yr)	
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5. Animal Care and Use

YES

NO

a. Will biohazardous or recombinant materials be used in animals?		
b. State the Institutional Animal Care and Use Committee (IACUC) active or pending protocol number.		

6. Please provide a current abstract or project summary:

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7.		YES	NO
	a. Has there been any data, or finding, which would indicate an increase in the hazard or risk presented by the agents used in this study since the last renewal/ amendment of this protocol? If yes, please explain:		

8. Dual Use Research

<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". All research performed at UMDNJ will be assessed for dual use potential. Please read the following and acknowledge that you understand the definition of dual use experiments. If you have any questions you can contact Jessica McCormick, Senior Biosafety Officer at 973-972-8424 or Nancy Connell, IBC Chair, at 973-972-3759.</p> <p>Do you understand that dual use research includes the following:</p>	Yes	No
a. Disrupting immunity or the effectiveness of an immunization? (This applies to both human and animal vaccines)		
b. Enhancing the harmful consequences of a biological agent or toxin (i.e. increase virulence, pathogenicity)?		
c. Conferring to a biological agent or toxin, resistance to clinically and/ or agriculturally prophylactic or therapeutic interventions?		
d. Conferring the ability of a biological agent to evade detection methodologies?		
e. Increasing the stability, transmissibility, or the ability to disseminate a biological agent or toxin? This includes the environmental stabilization of pathogens.		
f. Altering the host range and/ or tropism for a biological agent?		
g. Enhancing the susceptibility of a host population to illness by a biological agent or toxin?		
h. Generating a novel pathogenic agent or toxin, or reconstitute an eradicated biological agent?		

9. Use the following table to list all personnel (including any students) who handle or may otherwise be exposed to any of the microorganisms, cells or rDNA listed in this protocol. Please attach additional sheets if necessary. *Principal investigators must be included on this table, but please specify as to whether they will be performing experiments for this protocol.*

Will the PI be performing experiments included in this protocol? Yes _____ No _____

Name	Title	Date of Last Bloodborne Pathogen Training	Date of Last Lab Safety Training	Handling of human or non human primate cell lines, blood or tissues? (Yes/ No)**	BSL3 Approved User? (yes/ no/ in training) <i>Applicable for BSL3 protocols only</i>	Signature*

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

** If no, then the person is not required to receive the Hepatitis B vaccination. If this changes, then they need to receive the vaccination from Occupational Medicine Services or Student Health Services and the PI must notify the IBC prior to starting work.

8. 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:

i. IACUC approval required	YES	<input type="checkbox"/>	NO	<input type="checkbox"/>
ii. IRB approval required	YES	<input type="checkbox"/>	NO	<input type="checkbox"/>
a. IRB pending	YES	<input type="checkbox"/>	NO	<input type="checkbox"/>
b. IRB approved	YES	<input type="checkbox"/>	NO	<input type="checkbox"/>
c. IRB # _____	YES	<input type="checkbox"/>	NO	<input type="checkbox"/>
iii. Other:				