



Institutional Biosafety Committee

IBC REGISTRATION FORM

Office use only

EOHSS Reg. NO.: _____ Biosafety Level: _____

| | Principal/Responsible Investigator | Alternate Contact Person |
|------------------------------|------------------------------------|--------------------------|
| Name | | |
| Phone | | |
| Email | | |
| Department | | |
| Office/ Laboratory Locations | | |
| Animal Housing Locations | | |
| Project Title | | |
| IBC Submission Date | | |

Please indicate all of the following sections for Institutional Biosafety Committee review:

 Part A: Recombinant DNA Experiments. [See page 3 for a list of indications]

 Part B: Pathogenic Microorganisms. Agents capable of causing disease in humans 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 <http://www.cdc.gov/biosafety/publications/bmb15/BMBL.pdf>. **Registration is required for BSL-2 organisms or higher.**

 Part C: Human and Non-Human Primate Blood, Cell Lines and Tissues or Other Potentially Infectious Materials (OPIM). OPIM is material with the potential for transmission of HIV, HBV, HCV, and other blood borne 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. This includes human and non-human primate cell lines obtained from commercial sources. Also included are blood and tissues from live non-human primates as they may harbor unknown zoonotic conditions. These must be handled under BSL-2 conditions. For more information, see the CDC website: <http://www.cdc.gov/biosafety/publications/bmb15/BMBL.pdf>

 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 D 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.

 Part E: Animal Use: Administration to animals of any of the above categories of biologicals including the creation of a stable germline alternative of an animal's genome (transgenic animal or the testing rDNA modified restricted agent or viable rDNA modified micro-organisms on whole animals novel transgenic animal. **If you are working with non-human primates this section must be completed for all protocols.** Note: the purchase or transfer of transgenic rodents is exempt. Administration of any of the above agents to animals also requires approval of the IACUC.

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

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

OVERVIEW:

The Newark Campus IBC reviews research protocols to ensure compliance with the CDC/NIH guidelines for biosafety and OSHA guidelines for bloodborne pathogens 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. Please be sure to complete all applicable sections of the form and contact the biosafety officers listed below with any questions/ concerns.

INSTRUCTIONS:

In some cases it is acceptable to combine multiple experiments or organisms in the same registration form. Please contact the Biosafety Officer (listed below) if you have questions about use of this form. Email the completed form to Jessica McCormick, Ph.D., Sr. Biosafety Officer, Jessica.mccormick@umdnj.edu and Tamara McNair, Biosafety Officer, mcnairta@umdnj.edu. Once the biosafety officers have performed a preliminary review, the protocol will be distributed to the IBC members. All IBC members will have one week to review the protocol and submit concerns. The biosafety officer will compile the comments and forward them to the PI. The PI will be responsible for making the appropriate revisions and re-submitting the application to the IBC for further review. Once the protocol has been approved the PI must mail a signed hard copy to the biosafety officer. The biosafety officer will prepare an approval letter that is sent to the PI. Protocol applications should be submitted as soon as possible. The IBC meets the second Tuesday of each month, and formal approval is granted at these meetings.

QUESTIONS? Contact Jessica McCormick, Ph.D., Senior Biosafety Officer, Jessica.Mccormick@umdnj.edu, 973/972-8424, or Tamara McNair, Biosafety Officer, mcnairta@umdnj.edu, 973-972-8419, fax 973/972-3694 or Marta Figueroa, Assistant Director, figuerma@umdnj.edu, 973-972-5901.

Part A: RECOMBINANT DNA

Select the category that best reflects the type of experiment that you are conducting.

Please identify the type of experiment described in this registration form by checking the appropriate category in column (D). Information listed in parenthesis in column A cites the reference located in the NIH document “Guidelines for Research Involving Recombinant DNA Molecules.” For more information, the Guidelines can be accessed at:

http://oba.od.nih.gov/oba/rac/guidelines_02/NIH_Guidelines_Apr_02.htm

| (A) If your experiment involves: | (B) Registration w/NIH required? | (C) IBC Approval Required ? | (D) 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 (ref. III-B-1) | Yes | Yes | |
| Human gene therapy (ref. III-C-1) | Yes | Yes | |
| 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 (ref. III-A-1-a) | Yes | Yes | |
| Risk Group 2, 3, or 4 agents as host-vector systems (ref. III-D-1) | No | Yes | |
| Cloning of DNA from risk group 2, 3, or 4 microorganisms into nonpathogenic prokaryotic or lower eukaryotic host-vector systems (ref. III-D-2) | No | Yes | |
| More than 10 liters of culture (ref. III-D-6) | No | Yes | |
| DNA entirely from a prokaryotic host when propagated only in that host (ref. III-F-3) | No | No | |
| DNA entirely from a prokaryotic host when transferred to another host by well established physiological means (ref. III-F-3) | No | No | |
| DNA from a eukaryotic host when propagated only in that host or a closely related strain of the same species (ref. III-F-4) | No | No | |
| DNA segments from different species that exchange DNA by known physiological processes (ref. III-F-5) | No | No | |
| DNA segments from a single non-chromosomal or viral DNA source (ref. III-F-2) | No | No | |
| rDNA that is not in an organism or virus (ref. III-F-1) | No | Yes | |
| <u>VIRUSES</u> | No | Yes | |
| Use of infectious DNA or RNA viruses or defective DNA or RNA viruses in the presence of helper virus in tissue culture systems (ref. III-D-3) | No | Yes | |
| Propagation and maintenance in tissue culture of r-DNA containing a virus that has been established to be non-replicating (ref. III-D-3) | No | Yes | |
| 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 (ref. III-E-1) | No | Yes | |
| Formation of rDNA containing no more than 2/3 the genome of any eukaryotic virus (ref. III-E-1) | No | Yes | |
| <u>ANIMALS</u> | No | Yes | |
| Creation of transgenic animals at the UMDNJ Transgenic Core Facility (ref. III-D-4) | No | Yes | |
| Breeding of transgenic rodents from two transgenic strains requiring BL2 and higher containment (ref. III-D-4-b) | No | Yes | |
| Use of viable rDNA-modified microorganisms involving whole animals or whole plants (ref. III-D-4 and III-D-5) | No | Yes | |
| Administration of rDNA to animals (ref. III-D-4) | No | Yes | |
| Use of transgenic animals at BL-2, 3 or 4 (ref. III-E-3) | No | Yes | |
| Use/ Breeding/ Creation of transgenic animals with incorporation of more than 50% of an exogenous eukaryotic virus from a single family of viruses (Appendix C-VII) | No | Yes | |
| Use/ Breeding/ Creation of a Transgenic animal in which the transgene is under the control of a functional gammaretroviral long terminal repeat (LTR) (Appendix C-VII) | No | Yes | |
| Use of transgenic animals at BL-1 (ref. III-E-3) | No | No | |
| Existing transgenic animal purchased or transferred from another institution requiring BL2 and higher containment (Material Transfer Agreement required) (ref. III-D-4) | No | Yes | |
| Existing transgenic animal purchased or transferred from another institution requiring BL1 (Material Transfer Agreement required) | No | No | |

| <p>Please complete the following sections to describe your experiment. Indicate the possible adverse effects of the DNA, quantity of culture, and a description of the experiment. Also, provide detailed information regarding the DNA inserts, vectors and host cells being used in your rDNA system. (Vector maps are also helpful)</p> | <p>YES</p> | <p>NO</p> |
|--|-------------------|------------------|
| <p>Specify the organism name (with the specific designation, if applicable): VIRAL VECTORS: If your research involves the use of a viral expression vector, check the corresponding box below for the vector and download the corresponding EOHSS standard operating procedure (SOP) found at the given link. Answer questions #2-19 and Part F of this form, using the SOP as a guide. The Principle/ Responsible Investigator MUST return a signed copy of the fact sheet when submitting this form. Include a DETAILED description of the packaging system in answer #19, below:</p> | | |
| <p>Adenovirus: http://www.umdnj.edu/eohssweb/documents/Adenovirus_AdenoviralVectorsSOPFinal5.2011.pdf</p> <p>Adeno-associated virus: http://www.umdnj.edu/eohssweb/documents/AdenoassociatedvirusSOPFinal5.2011.pdf</p> <p>Herpes-1 Virus: http://www.umdnj.edu/eohssweb/documents/HerpesVirusSOPFinal5.2011.pdf</p> <p>Vaccinia virus: http://www.umdnj.edu/eohssweb/documents/VacciniaVirusVectorSOPFinal5.2011.pdf</p> <p>Retrovirus: http://www.umdnj.edu/eohssweb/documents/RetroviralVectorsSOPFinal5.2011.pdf</p> <p>Indicate type: Amphotropic Ecotropic Lentiviral: Other: (please include information upon submission):</p> <p>Will VSV (Vesticular Stomatitis Virus) G protein be included in the viral packaging system?</p> | | |
| <p>1. Specify source and nature of the DNA sequence(s) to be inserted (genus, species, gene name):</p> | | |
| <p>a. Will the inserted gene(s) be expressed?</p> | | |
| <p>b. If yes, what are the gene product effects? Specifically identify its toxicity, physiological activity, allergenicity, oncogenic potential or ability to alter cell cycle:</p> | | |
| <p>2. Location in which the rDNA research is to be conducted (building and room number)</p> | | |

| | | |
|--|--|--|
| 3. 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: | | |
| b. If no, please provide a reference to support your conclusion: | | |
| 4. Quantity of Material to be used: | | |
| a. < 1 Liter | | |
| b. 1-10 Liter | | |
| c. > 10 Liters | | |
| 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? | | |
| 9. Are any viral component(s)/sequence(s) present? | | |
| If yes , specify the nature of the viral component(s): | | |
| 10. Does the insert contain >2/3 of a eukaryotic viral genome? | | |
| 11. Is helper virus used? | | |
| If yes , specify type | | |

| | | |
|--|--|--|
| 12. Is it a retrovirus? | | |
| 13. What cells, cell lines, tissues, animals, humans, insects or plants will be exposed to the recombinant? Indicate type and species: | | |
| 14. Will rDNA be used to create a novel transgenic animal? | | |
| 15. Will breeding between 2 strains of transgenic animals(housed at BSL-2) be performed? | | |
| If yes, please describe the strains that will be bred. | | |
| 16. Will this experiment include human gene therapy? | | |
| 19. Provide a flow sheet to describe your experiment. Provide enough information to describe project's specific aims, the packaging vector, cell lines used, and the function of the rDNA in the context of the overall project. | | |

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*. <http://www.cdc.gov/biosafety/publications/bmb15/BMBL.pdf>

| | | |
|---|------------|-----------|
| 1. Name of organism (genus, species, strain description): | | |
| | YES | NO |
| 2. Is the organism attenuated? | | |
| 3. Is there a toxin produced? | | |
| A) Will you work with the toxin? | | |
| 4. Is drug resistance expressed? | | |
| A) If yes, indicate to which drugs. | | |

| | YES | NO |
|--|-----|----|
| 5. Where is the organism stored? Bldg _____ Room _____ Are biohazard labels in use? | | |
| 6. Is a stock culture prepared? | | |
| <p>If yes, please indicate:</p> <p>a) Maximum volume of stock culture that will be prepared:</p> <p>b) Volume aliquotted per individual vial:</p> <p>c) Concentration/ mL per individual vial:</p> <p>d) Maximum volume used in an experiment:</p> | | |
| 7. Is the organism inactivated prior to use? If yes, what is the method of inactivation: | | |
| 8. Do you concentrate the organism in your protocol? If yes please indicate which method is used: Centrifugation: Precipitation: Filtration: Other: | | |
| 9. Are cultures, stocks, and contaminated items decontaminated prior to disposal? If yes, please indicate which method(s) is/ are used: Autoclave Chemical Disinfectant: Other (specify): | | |
| 10. Previously approved SOP number (for BSL3 projects only): If not using a preapproved SOP, be sure to include a copy of your SOP submitted to the appropriate risk assessment committee | | |
| 11. Does this protocol involve work with human blood or blood products, unfixed human tissue, or human/nonhuman primate cell lines? If yes complete Part C below: | | |
| 11. 12. Provide a flow sheet to describe your experiment. Include enough information to describe the project's specific aims and the role of the pathogen in the context of the overall project. | | |

Part C – HUMAN and Non-HUMAN PRIMATE CELLS AND TISSUES

Please list the cell lines, body fluids and tissues that you will be using from humans and/ or non-human primates. Attach additional sheets if needed. Include established human or primate ATCC cell lines.

Note: Use of human cell lines or human source materials may require registration with the Institutional Review Board (IRB). Please fill out the form available at: if you require further guidance on IRB applicability.

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

12. Provide a flow sheet to describe your experiment. Include enough information to describe the project’s specific aims and the role of the human/ non-human primate cell line, human body fluid or tissue in the context of the overall project.

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 D 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) | √ | Viruses (HHS and USDA) | √ | Toxins (HHS and USDA) | √ |
|---|---|---|---|--|---|
| Akabane virus | | Swine vesicular disease virus | | Abrin | |
| African swine fever virus | | Tick-borne encephalitis complex (flavi) viruses | | Botulinum neurotoxins | |
| African horse sickness virus | | Central European Tick-borne encephalitis | | Conotoxins | |
| Avian influenza virus (highly pathogenic) | | Far Eastern tick-borne encephalitis | | <i>Clostridium perfringens</i> epsilon toxin | |
| Blue tongue virus (Exotic) | | Russian Spring and Summer encephalitis | | Diacetoxyscirpenol | |
| Bovine spongiform encephalopathy agent | | Kyasanur Forest disease | | Ricin | |
| Camel pox virus | | Omsk Hemorrhagic Fever | | Saxitoxin | |
| Classical swine fever virus | | Variola major virus (Smallpox virus) | | Shigatoxin | |

| | | | |
|---|---|--|---|
| Crimean-Congo hemorrhagic fever virus | Variola minor virus (Alastrim) | Shiga-like ribosome inactivating proteins | |
| Eastern Equine Encephalitis virus | Venezuelan Equine Encephalitis virus | Staphylococcal enterotoxins | |
| Ebola viruses | Vesicular stomatitis virus (Exotic) | T-2 toxin | |
| Foot and mouth disease virus | | Tetrodotoxin | |
| Goat pox virus | Bacteria (HHS and USDA) | √ | |
| Cercopithecine herpesvirus 1 (Herpes B) | Bacillus anthracis | USDA Plant Pathogens | √ |
| Japanese encephalitis virus | <i>Brucella abortus</i> | <i>Liberobacter africanus</i> | |
| Lassa fever virus | <i>Brucella melitensis</i> | <i>Liberobacter asiaticus</i> | |
| Lumpy skin disease virus | <i>Brucella suis</i> | <i>Peronosclerospora philippinensis</i> | |
| Malignant catarrhal fever virus (Exotic) | <i>Burkholderia mallei</i> (formerly <i>Pseudomona mallei</i>) | <i>Phakopsora pachyrhizi</i> | |
| Marburg virus | <i>Burkholderia pseudomallei</i> | Plum Pox Potyvirus | |
| Menangle virus | <i>Botulinum neurotoxin producing species Clostridium</i> | <i>Ralstonia solanacearum</i> race 3, biovar 2 | |
| Monkeypox virus | <i>Cowdria ruminantium</i> (Heartwater) | <i>Schlerophthora rayssiae</i> var <i>zeae</i> | |
| Newcastle disease virus (VVND) | <i>Coxiella burnetti</i> | <i>Synchytrium endobioticum</i> | |
| Nipah and Hendra Complex viruses | <i>Francisella tularensis</i> | <i>Xanthomonas oryzae</i> | |
| Peste Des Petits Ruminants virus | <i>Mycoplasma capricolum/ M.F38/M. mycoides capri</i> | <i>Xylella fastidiosa</i> (citrus variegated chlorosis strain) | |
| Rift Valley fever virus | <i>Mycoplasma mycoides mycoides</i> | <i>Synchytrium endobioticum</i> | |
| Rinderpest virus | <i>Rickettsia prowazekii</i> | <i>Xanthomonas oryzae</i> | |
| Sheep pox virus | <i>Rickettsia rickettsii</i> | <i>Xylella fastidiosa</i> (citrus variegated chlorosis strain) | |
| <i>South American Hemorrhagic fever viruses</i> | <i>Yersinia pestis</i> | | |
| Junin | | | |
| Machupo | Fungi | √ | |
| Sabia | <i>Coccidioides immitis</i> | | |
| Flexal | <i>Coccidioides posadasii</i> | | |
| Guanarito | | | |
| 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. | | | |

Part E: ANIMAL USE

Complete this section if biohazardous materials will be administered to animals or if you will be working/ handling non-human primates.

| | |
|--|--|
| 1. What species of animal will be exposed? | |
| 2. State the Institutional Animal Care and Use Committee (IACUC) active or pending | |
| 3. State the maximum dose volume to be administered per animal | |

| | | |
|--|------------|-----------|
| 4. State the maximum dose concentration to be administered per animal | | |
| 5. State the total amount of animals that will be dosed per experiment | | |
| 6. State the total amount of animals that will be dosed in the duration of this study | | |
| 7. State the Animal Biosafety Level Requested <i>(attach detailed procedure if biohazards do not fit conventional Animal BSL2 or 3 work practices. Reference CDC/NIH BMBL Animal Biosafety Levels: http://www.cdc.gov/od/ohs/biosfty/bmb15/bmb15toc.htm)</i> | | |
| 8. Indicate the proposed route of administration | YES | NO |
| Aerosol | | |
| Indwelling catheter or cannula | | |
| | YES | NO |
| Intranasal | | |
| Parenteral (e.g., IV, IM, IP) | | |
| Other | | |
| 9. Will the animal be anesthetized or tranquilized during administration? | | |
| Indicate the route of anesthesia | | |
| Indicate the chemical and the dosage used: | | |
| 10. Is the agent(s) an animal pathogen? | | |
| 11. Is the agent(s) a human pathogen? | | |
| 12. Is the agent transmitted from animal to animal? | | |
| 13. Is the agent transmitted from animal to human? | | |
| 14. Will the agent be inactivated prior to use in animals? | | |
| 15. Will the animals be house in microisolator (shoebox cage with a filter-top bonnet) cages? | | |
| If yes, will the cages be ventilated? | | |
| 16. Will there be any special procedures or containment needed? | | |
| If yes, please describe | | |
| 17. Will work with animals be performed in the biological safety cabinet? | | |

Part F: SAFETY MEASURES

Research will be conducted at **Biosafety Level** _____. Contact EOHSS if you need assistance in determining the appropriate classification. Reference the CDC/NIH BMBL4th Edition available at: <http://www.cdc.gov/od/ohs/biosfty/bmb15/bmb15toc.htm>.

| | | |
|---|------------|-----------|
| 1. Engineering controls: The following facilities or devices are available to minimize exposure to aerosol generating steps for work requiring BL-2 containment or higher (e.g., centrifugation, vortexing, sonication, egg harvesting.) Check all that will be utilized in your research: | | |
| | YES | NO |
| a. Containment suite (e.g., BSL-3) | | |
| b. Biocontainment animal housing (if applicable) | | |
| c. Class II biological Safety Cabinet | | |
| Type A (A1 or A2) | | |
| Type B (B1 or B2) | | |
| Most Recent Certification Date (Mo/Yr) | | |
| d. Centrifuge Safety Cups | | |

| | | |
|--|--|--|
| e. Other | | |
| 2. Sharps: (e.g., syringes, scalpels, glass) used with BSL-2 and higher organisms must be minimized. | | |
| a. Will syringes, scalpels, glass or other sharps be used? | | |
| b. Has the research been reviewed to eliminate or minimize the use of sharps where possible? | | |
| c. Which sharps with integrated safety devices/mechanisms are available and used? (<i>Examples of safety sharps can be found at http://www2.umdj.edu/eohssweb/publications/safety_sharps_examples.doc</i>) | | |
| If yes, please describe the safety device (Type, Model and Brand): | | |
| d. Has training been given to the staff on this safety device? | | |
| Who has administered this training? | | |

3. **Personal protective equipment** Indicate the personal protective equipment required for your work (check all that apply):

| | Laboratory Use | | | | Animal Facility Use (if applicable) | | | |
|--|------------------------|--|----|--|--|--|----|--|
| a. Tyvek® suit or coverall | YES | | NO | | YES | | NO | |
| b. Lab coat | YES | | NO | | YES | | NO | |
| c. Apron or rear-fastening gown with sleeves | YES | | NO | | YES | | NO | |
| d. Apron or rear fastening gown w/o sleeves | YES | | NO | | YES | | NO | |
| e. Bonnet or hair cover | YES | | NO | | YES | | NO | |
| f. Powered Air Purifying Respirator (PAPR) | YES | | NO | | YES | | NO | |
| g. N-95 respirator | YES | | NO | | YES | | NO | |
| h. N-100 respirator | YES | | NO | | YES | | NO | |
| i. Surgical mask | YES | | NO | | YES | | NO | |
| j. Shoe covers | YES | | NO | | YES | | NO | |
| k. Cover sleeves | YES | | NO | | YES | | NO | |
| l. Safety glasses | YES | | NO | | YES | | NO | |
| m. Gloves | YES | | NO | | YES | | NO | |
| | (check all that apply) | | | | (check all that apply) | | | |
| | | nitrile <input type="checkbox"/> | | | | nitrile <input type="checkbox"/> | | |
| | | nonpowdered latex <input type="checkbox"/> | | | | nonpowdered latex <input type="checkbox"/> | | |
| | | vinyl <input type="checkbox"/> | | | | vinyl <input type="checkbox"/> | | |
| | | other: | | | | other: | | |
| n. Other (please list): | | | | | | | | |

4. **Decontamination/Disinfection**

a. **Indicate the disinfection method (see columns to the right). Mark the applicable boxes with an "X."**
 For Decontamination and Disinfection information, see the EOHSS Fact sheet <http://www2.umdj.edu/eohssweb/publications/disinfection.pdf>.

1. Autoclave
2. 1/10 bleach solution
3. Povidone-iodine product e.g. Betadine ®
4. 70% ethanol
5. Phenolic product e.g. Vesphene ®
6. Chlorine dioxide product e.g. Clidox ®
7. Quaternary ammonium product e.g. Quatricide ®
8. Other:

| | Routine cleaning | Spill cleanup | Solid waste | Liquid waste | Animal Carcasses (if applicable) | Animal bedding and cages (if applicable) |
|--|------------------|---------------|-------------|--------------|----------------------------------|--|
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b. Will radioactive infectious waste be generated?

YES NO

c. How will contaminated radioactive solid waste be disposed?

d. Please list the PI radiation license number and expiration date:

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 in this protocol. *Note: Literature search must have been conducted within one month of submission to the IBC.*

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 a significant potential for this material to be contaminated with a organism requiring a higher biosafety level? (e.g., a live virus/ bacterium contaminating a preparation of dead virus/ bacteria)

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?

iii. If your lab cannot perform such an evaluation, what steps will be taken to ensure the safety of staff and student working with the material?

- e. What was the source of this material? Please indicate if the material is obtained from ATCC, colleague [*name and institution*], or another source?
- i. Can the sender provide background information or quality control data on the material? If possible, please include information on the types of infectious microorganisms screened for in these samples.
- f. What infection or disease can the rDNA, pathogens, cell lines or human materials used in this application cause?
- g. List the route(s) of exposure for the rDNA, pathogens, cell lines or human materials used in this protocol application.
- h. List the signs and symptoms of exposure to the rDNA, pathogens, cell lines or human materials listed in this protocol application.

6. Dual Use Research

| 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. | Yes | No |
|--|-----|----|
| Do you understand that dual use research includes the following: | | |
| 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? | | |

7. Medical Surveillance and Training Requirements

| | | | | |
|---|---|-----|----|----|
| a. | a. All personnel who are potentially exposed to human blood, human body fluids or human cell lines have received Hepatitis B vaccine or proven immunity (required for work with human and non human primate cell lines, blood and tissues). | YES | NO | NA |
| | b. All personnel who are potentially exposed to <i>Mycobacterium tuberculosis</i> have completed baseline TB surveillance (either TB skin test or gamma interferon release assay) and will undergo TB surveillance every 6 months for BSL3 users. | | | |
| | c. Additional vaccination/surveillance is required for work on this project. | | | |
| In Newark, these additional requirements must be approved by Occupational Medicine Services (OMS, 973-972-2900). Describe the special requirements. | | | | |
| | d. There is a known vaccine and/ or therapy. | | | |
| List the vaccine or therapy: | | | | |
| | e. Individuals at increased risk of susceptibility to the agents in this protocol (e.g., preexisting diseases, medications, compromised immunity, pregnancy or breast feeding) have been referred to Occupational Medicine Services (973-972-2900) for counseling | | | |
| Please indicate the date referred: | | | | |
| Please list the date counseling was completed: | | | | |

8. Project Personnel: 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 listed in this protocol. *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 | Shipping of biohazardous material or dry ice? (yes/ no) | 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.

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 the Biological Safety Officer any accident, incident, or adverse event 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's Determination of Required Biological Containment-Biosafety Level: _____

Signatures

IBC Chairman / Representative: _____

Date: _____

Biological Safety Officer (EOHSS): _____

Date: _____

Department Chairperson (as appropriate): _____

Date: _____

Occupational Medicine Physician (as appropriate): _____

Date: _____

Veterinarian (as appropriate): _____

Date: _____

Modifications: