

**(EOHSS USE ONLY)**

**EOHSS Reg. No.:** \_\_\_\_\_

**Biosafety Level:** \_\_\_\_\_



## REGISTRATION FORM FOR PATHOGEN, SELECT AGENTS and HUMAN CELLS/TISSUES

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: \_\_\_\_\_

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

**Please check off the Parts being completed:**

**Part A: 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 the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5<sup>th</sup> Edition. See EOHSS website, <http://www2.umdj.edu/eohssweb/publications/external.htm#Microbiological>, for a complete listing of pathogenic microorganisms.

**Registration is required for BL 2 organisms or higher.**

**Part B: Human Blood, Human Cell Lines and Tissues or Other Potentially Infectious Materials (OPIM):**

Includes established cell lines of human/primate origin (including those obtained from commercial sources) and OPIM (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). These must be handled under BSL-2 conditions as if they were primary cells or tissues. <http://www.cdc.gov/od/OHS/biosfty/bmb15/bmb15toc.htm>

**Part C: "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 [Select Agent Regulation, 42 CFR 73.0](#), and the [Agricultural Bioterrorism Protection Act of 2002](#). Facility Registration is required and is administered by the [Centers for Disease Control](#), and/or the [USDA](#). 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.

**Part D: 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 microisolator or filtered, ventilated cages and handled under BSL-2 conditions.

**Part E: Safety Measures: THIS SECTION MUST BE COMPLETED FOR ALL REGISTRATIONS.**

**Part F: Affirmation: THIS SECTION MUST BE COMPLETED FOR ALL REGISTRATIONS.**

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

**Part A - Pathogenic Micro-organisms**

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*. Complete Part A for each organism used in the lab.

1. Name of Organism (genus, species, strain description)  Is organism attenuated?      Yes      No	2. Is a toxin produced? <input type="checkbox"/> Yes <input type="checkbox"/> No  Work with toxin? <input type="checkbox"/> Yes <input type="checkbox"/> No
3. Is drug resistance expressed? <input type="checkbox"/> Yes <input type="checkbox"/> No	4. Where is organism stored? Room/location _____  Are Biohazard Warning Labels in use? <input type="checkbox"/> Yes <input type="checkbox"/> No
5. Largest volume used: _____ liter(s)	6. Is organism inactivated prior to use? <input type="checkbox"/> Yes <input type="checkbox"/> No  Specify Method: _____
7a. Do you concentrate the organism in your protocol? <input type="checkbox"/> Yes <input type="checkbox"/> No	7b. Specify method: <input type="checkbox"/> centrifugation <input type="checkbox"/> precipitation <input type="checkbox"/> filtration <input type="checkbox"/> other
8a. Building and room where organism is used? _____	9. Does the laboratory work with human blood or blood products, unfixed human tissue, or human or other primate cells?  <input type="checkbox"/> No <input type="checkbox"/> Yes <b>(if yes, fill out Part B below)</b>
8b. Source of Organism: _____	
8c. CDC Shipping permit #: _____	
10. Are cultures, stocks, and items contaminated items decontaminated prior to disposal? <input type="checkbox"/> No <input type="checkbox"/> Yes Method: <input type="checkbox"/> autoclave <input type="checkbox"/> chemical disinfectant <input type="checkbox"/> other (specify): _____	

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

\_\_\_\_\_

**Part B - Human Cells and Tissues:** (includes ATCC established cell lines of human/primate origin or OPIM)

1.	2.	
4.	5.	
7.	8.	

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

\_\_\_\_\_

**Part C: Possession, Use or Transfer of "Select Agents, Toxins, High Consequence Livestock/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".

**SELECT AGENTS, TOXINS, HIGH CONSEQUENCE LIVESTOCK/PLANT PATHOGENS**

<b>Viruses (HHS and USDA)</b>	√	<b>Bacteria (HHS and USDA)</b>	√
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		<b>Fungi</b>	√
Lumpy skin disease virus		Coccidioides immitis	
Malignant catarrhal fever virus (Exotic)		Coccidioides posadasii	
Marburg virus		<b>Toxins (HHS and USDA)</b>	√
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		<b>USDA Plant Pathogens</b>	√
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 zaeae	
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)			
<b>Genetic Elements, Recombinant Nucleic Acids, and Recombinant Organisms:</b>			√
* If your research involves rDNA, you must submit a registration form with the IBC. 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 D: Animal Use**

Will biohazardous materials be administered to animals?  Yes  No

If yes, what species: \_\_\_\_\_

Is the material an animal pathogen?  Yes  No

Is the material a human pathogen?  Yes  No

Will the material or organism be inactivated prior to use in animals?  Yes  No

Experimental administration route, volume, titer: \_\_\_\_\_

Caging: microisolator cages?  Yes  No Other? \_\_\_\_\_

Special procedures needed for containment: \_\_\_\_\_

Work in biosafety cabinet?  Yes  No Other? \_\_\_\_\_

Animal Biosafety level requested: \_\_\_\_\_

IACUC #: \_\_\_\_\_ IACUC Approval date: \_\_\_\_\_

IACUC Approval Pending?

(Attach detailed procedure if biohazards do not fit conventional Animal Biosafety Level 1 or 2 work practices)

Reference CDC/NIH BMBL Animal Biosafety Levels: <http://www.cdc.gov/od/ohs/biosfty/bmbl5/bmbl5toc.htm>

**Part E: Safety Measures**

Research will be conducted at **Biosafety Level** \_\_\_\_\_

(Contact EOHSS if you need assistance in determining the appropriate classification).

Reference CDC/NIH BMBL5<sup>th</sup> Edition. Web address: <http://www.cdc.gov/od/ohs/biosfty/bmbl5/bmbl5toc.htm>

**Engineering controls:** available to control significant aerosol generating steps for work requiring BL-2 containment or higher (e.g., centrifugation, vortexing, sonication, egg harvesting), check all that apply:

- Biological Safety Cabinet (BSC): Class I \_\_\_\_\_ Class II \_\_\_\_\_ Last date of BSC Certification (Mo/Yr) \_\_\_\_\_
- Centrifuge Are centrifuge safety cups available and used?  Yes  No
- Containment suite
- Other: \_\_\_\_\_

**Sharps:** (e.g., syringes, scalpels, glass) used with BSL-2 and higher organisms must be minimized.

Will (syringes, scalpels, glass) be used?  Yes  No

Has the research protocol been reviewed to minimize the use of sharps where possible?  Yes  No

Are sharps with integrated safety devices available?  Yes  No

If yes, please describe device (Type, Model, Brand): \_\_\_\_\_

**Personal protective equipment:** check all that are recommended and available for your work:

- Lab coat
- Gloves:  nitrile  non-powdered latex (powdered latex not recommended)  vinyl
- Safety glasses with side shields
- Other: \_\_\_\_\_

**Decontamination/Disinfection:** See the EOHSS Fact Sheet <http://www2.umdj.edu/eohssweb/publications/disinfection.pdf>.

**Disinfectant(s)** which will be used for routine cleaning & spills:  1/10 bleach  70% ethanol  povidone-iodine  
 other: \_\_\_\_\_

**Describe 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).**

Solids - Disinfection method:  autoclave  1/10 bleach  povidone-iodine  70% ethanol  other: \_\_\_\_\_

Liquids - Disinfection method:  autoclave  1/10 bleach  povidone-iodine  70% ethanol  other: \_\_\_\_\_

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

- 1) No medical surveillance necessary.
- 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. (Basic OSHA BBP compliance adequate for BL-2 work.)
- 3) Additional vaccination/surveillance required for work on this project. Must be approved by 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 Employee Health Services (732-445-0123) for counseling.

**Project Personnel:** Principal Investigators, use the following table to list all personnel in your laboratory who handle or may otherwise be exposed to any of the microorganisms. Please print (attach sheet if necessary).

Name	Title	Lab Person's Initials*

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

Use the Pathogen Registry Personnel Update Form on page 6 of this document, to list new personnel.

**Part F –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: \_\_\_\_\_