BIOSAFETY PROTOCOL SUBMISSION FORM

Office use only	Start Date:
Project Number:	Completion Date:

Please complete this form and submit all documentation to Research Services, 200 Kelley Building
Please send one electronic version to reb@upei.ca.

SECTION 1. ADMINISTRATIVE INFORMATION (If different from grant title, please include the grant title as well)

1.1 Project Title

1.2 Project Summary (50 Words or less)

1.3 Principal Investigator (s)

Name			
Department			
Campus Address		**Phone**	
Email		**UPEI ID#**	

Biosafety Resume attached ☐ **Yes** ☐ **On File**

If the PI will be away for more than 30 days, someone must be designated to fill this position until the PI returns. If this is the case for this project, please fill out the Temporary Transfer of Biosafety Due to Sabbatical or Extended Leave Form.

Submissions are regarded by the Biosafety Committee as strictly CONFIDENTIAL.
The safety of UPEI personnel and students, the public at large, animals and the environment are important to the University of Prince Edward Island. Therefore all principal investigators/researchers using biological materials are required to submit the following Application for a Biosafety Permit. The Application will be reviewed and a Permit will be issued if the Application meets health, safety and environmental standards as laid out in Health Canada Laboratory Biosafety Guidelines (3rd edition, 2004), CFIA Containment Standards for Veterinary Facilities (1st edition, 1996), and UPEI policies and procedures. All information submitted will be treated as confidential.

1.3 Principal Investigator (s) Continued			
Name			
Department			
Campus Address		**Phone**	
Email		**UPEI ID#**	
Biosafety Resume attached? ☐ **Yes** ☐ **On File**			
Name			
Department			
Campus Address		**Phone**	
Email		**UPEI ID#**	
Biosafety Resume attached? ☐ **Yes** ☐ **On File**			

1.4 Personnel/Teaching assistants handling the material			
NAME	**Faculty/DEPT**	**Phone**	**Biosafety RESUME**
			☐ Yes ☐ On File
			☐ Yes ☐ On File
			☐ Yes ☐ On File
			☐ Yes ☐ On File

1.5 Project funding and certifications				
Has this protocol been approved at another institution?			☐ **Yes** ☐ **No**	***If yes, please attach the approval certificate.***
Is this project funded? ☐ **Yes** ☐ **No**			**Funding Source and ORD file # :**	
Does the project involve the use of animals?			☐ **Yes** ☐ **No**	
If Yes :	**Has an Animal Utilization Protocol been submitted?**		☐ **Yes** ☐ **No**	
	Title of Protocol:			
	Has Animal Care Committee approval been obtained?		☐ **Yes** ☐ **No**	**AUP#**
	Are the animals genetically modified?		☐ **Yes** ☐ **No**	***If yes, explain nature of the modification in section 3.6.3.***
Does the project involve human participants?			☐ **Yes** ☐ **No**	**Permit #**

1.6 Use of Materials			
This Material will be used for	☐ **Research**	☐ **Teaching**	
Course Name		**Course Number**	
Anticipated date(s) of use			
Material will be used	☐ **in vitro**	☐ **in vivo**	

SECTION 2. PROJECT LOCATION

2.1 Location(s) where the biohazardous material (BHM)(s) will be used.

Room Number	Room Description (Lab, animal facility, diagnostic services.)	Laboratory Containment Level		Certifying Agency		Certification Expiry Date	Is laboratory a shared space?
		CL 1	CL2	CFIA	PHAC		

2.2 Location(s) where the BHM(s) will be stored during the study period.

Room Number	Room Description (Lab, animal facility, diagnostic services.)	Laboratory Containment Level		Certifying Agency		Certification Expiry Date	Security measures (locked room, locked freezer, etc.)
		CL 1	CL2	CFIA	PHAC		

2.3 Will any of these BHMs be kept in long term storage, beyond the study period? ☐ Yes ☐ No

If yes, please provide the following information:

Organism	Risk Group	Condition under which material will be stored (lyophilized, frozen,…)	Location (room number and location within room)

2.4 Biological Safety Cabinets

Location (Room Number)	Class		Type				Date of latest inspection testing
	I	II	A1	A2	B1	B2	

2.5 Fume Hood		
Is a fume hood present in the location(s) identified in Section 2.1?	☐ **Yes**	☐ **No**

SECTION 3. BIOHAZARDOUS MATERIAL INFORMATION

Please attach supporting documents (eg. MSDS or equlivant) to your application. Please indicate biological materials for which the permit is required (bacteria, viruses, prions, phages, plasmids, fungi, parasites, cell lines/tissue cultures, animal tissues, genetically modified organisms, bio-toxins) by completing the appropriate sections below. If required, attach an additional page. If you are unsure of the Risk Level please contact the Biosafety Officer for assistance or see the following link. http://www.upei.ca/humanres/files/humanres/UPEI08RADefinitionsandMatrix.pdf

3.1 Microorganisms ☐ Not Applicable

Microorganisms include bacteria, fungi, protozoa, algae, viruses, mycoplasma, rickettsia, chlamydia, parasites, and prions.

Microorganism (Genus, species, strain (geographical isolates) as appropriate)	Quantity (units)	Does this organism have drug esistance? YES or NO	Host Range for Organism		Risk Group	Proposed Containment Level
			Animal Pathogen	Human Pathogen		

3.2 Primary Cell Cultures ☐ Not Applicable

Cell type (human, mouse, etc.)	Source of Cell (kidney, liver, etc.)	Potential Pathogens	Risk Group	Containment Level

3.3 Established Cell Culture. ☐ Not Applicable

Cell type (human, mouse, etc.)	Specific cell Line (Attach MSDS)	Supplier	Known Pathogens	Risk Group	Containment Level

3.4 Human and Non-Human Primate Source Material. ☐ Not Applicable

Substance	Species	Source	Risk Group	Containment Level

3.5 Potentially Infectious Animal Source Material ☐ Not Applicable				
Substance	**Species**	**Source**	**Risk Group**	**Containment Level**

3.6 Biological Toxins. ☐ Not Applicable						
Toxin	**Form (Liquid, granules, etc.)**	**Species from which derived**	**Source**	**Amount (To be obtained)**	**Risk Group**	**Containment Level**

Recombinant DNA.

3.7 Genetic Modification involving Plasmids ☐ Not Applicable				
Bacteria used for Cloning	**Plasmid**	**Source of Plasmid**	**Gene(s) to be cloned or expressed**	**Containment Level**

3.8 Genetic Modification involving Viral Vectors ☐ Not Applicable				
Virus used for Vector Construction	**Vector**	**Source of Vector**	**Gene(s) Transduced (or genes to be cloned or expressed)**	**Containment Level**

3.9 Genetically modified animals ☐ Not Applicable	
Species	**Nature of Modification**

3.10 SOURCE OF MATERIAL (Please Specify)	
Commercial (ex. ATCC, Cedar Lane)	
Field Sample	
Clinical Sample	

Other – Explain (Colleagues etc.) *[If the material is a transfer, please indicate location material is received from.]*

Was material obtained under an importation permit? *If yes, attach a photocopy of your importation permit(s).*	☐ Yes ☐ No

3. 11 List those organisms that are not currently known to be in Canada or on Prince Edward Island		
Organism	**NOT currently found in (check all that apply)**	
	☐ Canada	☐ Prince Edward Island
	☐ Canada	☐ Prince Edward Island
	☐ Canada	☐ Prince Edward Island

4.0 Please indicate whether the following items/procedures will be used involving the BHM(s) in this project:								
Needles	☐	YES	**Other sharps**	☐	YES	**Centrifugation**	☐	YES
	☐	NO		☐	NO		☐	NO
Surgical blades	☐	YES	**Glassware**	☐	YES	**Dissection**	☐	YES
	☐	NO		☐	NO		☐	NO
Pipetting	☐	YES	**Sonication**	☐	YES	**Blending/mixing/vortexing/ opening samples/aerosol creation via other means**	☐	YES
	☐	NO		☐	NO		☐	NO
All of the preceding activities can increase risk of exposure/release. Please indicate how this risk will be minimized for those procedures you will be performing (ex – use of sharps minimized, needles are not recapped, safety scalpels will be used, etc.								

4.1 Indicate the Personal Protective Equipment to be worn on this project:			
☐ Lab Coat ☐ Gloves	☐ Gown ☐ Boots/shoe covers	☐ Eye Protection ☐ Respirator	☐ Face Shield ☐ Other
If other, please describe:			
If respirator to be worn, describe type and date of fit test if applicable			
Type		Date of fit test	

4.2 Project Details

Please outline the project you intend to undertake, including a clear description of the procedures that will involve the biohazardous material(s) you have indicated. Please address where the risks of exposure and release exist, and include the means by which these will be prevented. Please provide as much information as necessary for the Biosafety Committee to complete a risk assessment. If the BHM(s) is to be used in live animals, include the animal species, method of infection, anticipated excretion of the organism into the environment (e.g. will the bedding be a risk to workers or the environment) and containment practices.

5.0 Transportation

In the process of the work performed, will it be necessary to transport un-decontaminated biohazardous materials between laboratory areas? (e.g. from a research laboratory at AVC to the incubators or centrifuges in the Central Services area	☐ Yes ☐ No

If yes, between which areas will the transport be?

Describe procedures taken to minimize risks associated with this transport.

6.0 Disposal Methods
What methods will be used for decontamination and disposal of BHM(s)? Include disinfectant to be used & required contact time.

7.0 Medical Surveillance	
Do personnel working with these materials require special medical precautions or health monitoring?	☐ Yes ☐ No
If Yes: Has immunization been recommended/offered to staff? ☐ Yes ☐ No If yes, outline recommendations:	
If immunization is recommended: Have they been given? ☐ Yes ☐ No Are records kept of vaccination as well as vaccination refusals/waivers? ☐ Yes ☐ No	
Are there other considerations besides vaccination that need to be communicated to workers - such as the exclusion of highly susceptible individuals from hazardous lab work? ☐ Yes ☐ No	
Are laboratory personnel educated on the signs/symptoms of a possible exposure, to facilitate the early detection of laboratory acquired infections? ☐ Yes ☐ No	

8.0 Incidents and Spills
Outline steps to be taken in the event an accident, incident or spill (safety issues, containment, disinfection, reporting and prevention of re-occurrence)

9.0 Biosecurity	
Are BHM(s) safely secured from unauthorized access and theft? Please describe means by which this is obtained (e.g., locked freezer, locked lab, authorized access..)	☐ Yes ☐ No
Please describe means by which this is obtained (e.g., locked freezer, locked lab, authorized access.)	
Are all workers trained in the Biosecurity Plan?	☐ Yes ☐ No
Have you submitted a list of authorized users of your lab(s) to UPEI Security?	☐ Yes ☐ No
Have you entered the BHM into the UPEI electronic inventory if you currently possess them, or will they be entered as soon as obtained?	☐ Yes ☐ No

9.1 Identification of Dual Use potential in Life Sciences Research

Dual use potential is described in the CBS as "Qualities of a pathogen or toxin that allow it to be either used for legitimate scientific applications (e.g., commercial, medical, or research purposes), or intentionally misused as a biological weapon to cause disease (e.g., bioterrorism)". The following questions are present to identify potential dual use research at UPEI, as required by the PHAC (Plan for Administrative Oversight for Pathogens and Toxins in a Research Setting – Required Elements and Guidance (2015)).

Are you creating, re-creating or modifying a new or existing pathogen?	☐ Yes	☐ No
Will the pathogen(s) to be used acquire any of the following potential hazards, to the best of your knowledge?		
1. Increased virulence?	☐ Yes	☐ No
2. Production of a novel toxin?	☐ Yes	☐ No
3. Enhanced communicability or transmissibility?	☐ Yes	☐ No
4. Altered host range?	☐ Yes	☐ No
5. The ability to interfere, by-pass or diminish the effectiveness of diagnostic tools, and therapeutic or prophylactic antimicrobial or antiviral treatments?	☐ Yes	☐ No
6. Enhanced capacity for spreading or for easy release or for making them "weapons grade"?	☐ Yes	☐ No
Is there a potential for research knowledge (e.g., data, methodology, results), technology, intermediate and final products (e.g., toxins) to be misused?	☐ Yes	☐ No
If released, will the pathogen or research information pose a threat to:		
1. Aquatic animals or invertebrates?	☐ Yes	☐ No
2. Terrestrial animals?	☐ Yes	☐ No
3. Humans?	☐ Yes	☐ No
4. Public safety?	☐ Yes	☐ No
5. National security?	☐ Yes	☐ No

If you answered yes to any of the above, please provide details:

10.0 Signatures

I accept responsibility for the accuracy of the information included in this application. I will ensure that all work carried out under this permit will be conducted in accordance with the policies and procedures of the University of Prince Edward Island, and in compliance with the Health Canada Laboratory Safety Guidelines, 3rd Edition 2004, and/or the CFIA Containment Standards for Veterinary Facilities. I have discussed the risks associated with this work with all personnel who may be affected. Any changes to this permit (as listed in the UPEI Biosafety in Research and Teaching Policy) that may arise will be forwarded to the Biosafety Committee as an amendment to the permit.

PI Name	**PI Signature**	**Date**

Chair, PI Department	**Chair, Signature**	**Date**

This Protocol has been reviewed by Central Services ☐ Yes ☐ No

Central Services, Authority Name	**Authority Signature**	**Date**

Please ensure the following are included in your application:

- ☐ **Biosafety Application** (1 signed original)
- ☐ **Biosafety Resume** (if not on file)
- ☐ **Exposure Control Form** (if the proposed work uses biohazardous (Risk Factor > 1) organisms, attach a copy that will be inserted in the Laboratory Safety Manual in each laboratory/area where the organism will be present.
- ☐ **Risk Assessment table** can be found at: http://hr.upei.ca/files/hr/upei08radefinitionsandmatrix.pdf