July 2011

Biosafety Permit Amendment/Renewal Form

The safety of UPEI personnel and students, the public at large, animals and the environment are important to the University of Prince Edward Island. This Application for a Permit Amendment will be reviewed and the Permit Amendment 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.**

Project Information

Principal Investigator			
Name			
Department			
Campus address		Phone	
Email			
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, please provide the name and contact information of the individual, and the dates this will be in effect.			
Name			
Department			
Campus address		Phone	
Email			

Project title and original protocol number:

This application is a

- ☐ Renewal with **NO** changes. Please go to **Principal Investigator Statement** and complete this section only.
- ☐ Renewal with amendment(s) (changes at time of renewal). Complete form as indicated.
- ☐ Amendment (changes before time of renewal). Complete form as indicated.

Area(s) where amendment(s) is/are requested: Please indicate if area is applicable, and if so, provide the necessary information.

1. **Change(s) to Personnel/Teaching Assistants handling the material**

☐ **Yes If yes, please complete table below.**
☐ **No**

Name	Faculty/Dept	Phone	Biosafety resume
			Attached ☐
			On file ☐
			Attached ☐
			On file ☐

2. **Has the funding of this project changed?**

☐ Yes Please indicate new source_____
☐ No

3. **Has the use of material changed?** (teaching or research)

☐ Yes Provide details _____
☐ No

4. **Has the location where the Biohazardous Material (BHM)will be used changed?**

☐ Yes If yes, fill in the table below
☐ No

Location(s)s where the BHM will be used							
Room Number	**Room description (lab, animal facility, etc)**	**Laboratory Containment**		**Certifying Agency**		**Certification Expiry date**	**Is this a shared Space?**
		CL1	**CL2**	**CFIA**	**PHAC**		

5. Has the location where the BHM will be stored changed?

☐ Yes. If yes, please complete table below.
☐ No

Location(s)s where the BHM will be stored							
Room Number	**Room description (lab, animal facility, etc)**	**Laboratory Containment**		**Certifying Agency**		**Certification Expiry date**	**Security measures (locked room, locked freezer, etc.)**
		CL1	**CL2**	**CFIA**	**PHAC**		

6. Will you now be keeping the BHM in long term (archival) storage?

☐ Yes Please provide storage information in table below
☐ 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)**

7. Are there any changes to the Biological Safety Cabinets you are using?

☐ Yes *Please provide details* ☐ No

8. Are there changes to the Biological Materials (BHM)?

☐ Yes *Please indicate any changes to the BHM you plan to work with in the appropriate table(s) below. Attach MSDS shets, or equivalent*
☐ No proceed to Question 9

Microorganisms ☐ **Not Applicable**

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

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

Primary Cell Cultures ☐ **Not Applicable**

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

Established Cell Culture. ☐ **Not Applicable**

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

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

Substance	Species	Source	Risk Group	Proposed Containment Level

3.4 Potentially Infectious Animal Source Material. ☐ **Not Applicable**

Substance	Species	Source	Risk Group	Proposed Containment Level

Biological Toxins. ☐ **Not Applicable**

Toxin	Form (Liquid, granules, etc.)	Species from which derived	Source	Amount *(To be obtained)*	Risk Group	Proposed Containment Level

Recombinant DNA.
Genetic Modification involving Plasmids ☐ **Not Applicable**

Bacteria used for Cloning	Plasmid	Source of Plasmid	Gene(s) to be cloned or expressed	Proposed Containment Level

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)**	**Proposed Containment Level**

Genetically Modified Animals ☐ Not Applicable	
Species	**Nature of Genetic modifcation**

9. For BHMs already in use, has the source changed?

☐ Yes if yes, provide new source information in table below.

☐ No

9 .1 If new BHM are to be used, please indicate the source by completing the table below.

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** ☐

10. Will there be changes to experimental procedures from that indicated on the original application?

☐ Yes If yes, please outline the proposed changes, giving a clear description of the new procedures. Please provide enough information to allow the Biosafety Committee to assess the biocontainment/biosecurity risk in the box below and complete the table.

☐ No

Project revisions affecting biosafety:

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 preceeding 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

11. Will there be changes to the PPE worn on this project?

☐ Yes *Please describe changes*: ☐ No

12. Will there be changes to the areas in which undecontaminated materials will be transported?

Yes *Please describe areas* ☐ ☐ No

13. Will there be changes in the decontamination procedures, the disinfectant used, and/or contact time?

Yes *Please give details* ☐ ☐ No

14. Are there changes to the medical surveillance aspects of this project?

Yes *Give details* ☐ ☐ No

15. Do the changes in the project require changes in the Exposure Control Plan?

Yes *Outline changes* ☐ ☐ No

[NOTE: these changes must be shown to all personnel involved in the project, and appended to the copy of the ECP stored in the laboratory(s)]

16. Are there changes to the list of authorized users of the lab?

☐ Yes *Has this information been provided to UPEI* ☐ No

Security	

Principal Investigator Statement

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/CFIA 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.

Principal Investigator

Name (print)		**Signature**	

Chair, PI Department

Name (print)		**Signature**	

Central Services

Name (print)		**Signature**	

Comments of the UPEI Biosafety Committee:

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