THE UNIVERSITY OF WESTERN ONTARIO
BIOLOGICAL AGENTS REGISTRY FORM
Approved Biohazards Subcommittee: October 14, 2010
Biosafety Website: www.uwo.ca/humanresources/biosafety/

This form must be completed by each Principal Investigator holding a grant administered by the University of Western Ontario (UWO) or in charge of a laboratory/facility where the use of Level 1, 2 or 3 biological agents is described in the laboratory or animal work proposed. The form must also be completed if any work is proposed involving animals carrying zoonotic agents infectious to humans or involving plants, fungi, or insects that require Public Health Agency of Canada (PHAC) or Canadian Food Inspection Agency (CFIA) permits.

This form must be updated at least every 3 years or when there are changes to the biological agents being used.

Containment Levels will be established in accordance with Laboratory Biosafety Guidelines, 3rd edition, 2004, Public Health Agency of Canada (PHAC) or Containment Standards for Veterinary Facilities, 1st edition 1996, Canadian Food Inspection Agency (CFIA).

Completed forms are to be returned to Occupational Health and Safety, (OHS), (Support Services Building, Room 4190) for distribution to the Biohazards Subcommittee. For questions regarding this form, please contact the Biosafety Officer at extension 81135 or biosafety@uwo.ca. If there are changes to the information on this form (excluding grant title and funding agencies), contact Occupational Health and Safety for a modification form. See website: www.uwo.ca/humanresources/biosafety

PRINCIPAL INVESTIGATOR	Sanjay Mehta
DEPARTMENT	Medicine
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EMERGENCY PHONE NUMBER(S)	519-439-1421, 519-679-8782
EMAIL	Sanjay.Mehta@lhsc.on.ca

Location of experimental work to be carried out: Building(s) LHSC,VRL, 6 th fl.
Room(s) A6-114,118

*For work being performed at Institutions affiliated with the University of Western Ontario, the Safety Officer for the Institution where experiments will take place must sign the form prior to its being sent to the University of Western Ontario Biosafety Officer (See Section 15.0, Approvals).

FUNDING AGENCY/AGENCIES: HSFO
GRANT TITLE(S): Complex Regulation Of Microvascular Endothelial Cell Function In Sepsis

List all personnel working under Principal Investigators supervision in this location:

Name	UWO E-mail Address	Date of Biosafety Training
Le Feng Wang	Lefengw@hotmail.com	Feb. 2008
Marta Rohan	Marta.rohan@lhsc.on.ca	Feb 2008

Please explain the biological agents and/or biohazardous substances used and how they will be stored, used and disposed of. Projects without this description will not be reviewed.

Pseudomonas aeruginosa is Gram-negative bacterium that is the most common pathogen in ICU, and 3rd most commonly isolated nosocomial organism.

P.Aeruginosa suspension is obtained from Dept. Of Microbiology, LHSC – Victoria Hosp. There is no storage of this suspension in my lab.

Intratracheal Pseudomonas aeruginosa pneumonia model – mice/rats - animals are allowed to recover, and followed over time between 4-24 hrs after induction of pneumonia before euthanasia.

The experimental animals are anesthetized with Isoflurane/Oxygen. Under aseptic conditions the trachea is exposed via anterior cervical dissection and an anterior tracheotomy is performed with a 24-gauge angiocatheter (mouse) or a 22-gauge angiocatheter (rat). Angiocatheter is introduced into the trachea just above the carina. Pneumonia is induced by intratracheal instillation of a 50ul (mouse) or 200ul (rat) aliquot of a homogeneous suspension of Pseudomonas aeruginosa at a 2 McFarland density standard, followed by a 200ul (mouse) or 500ul (rat) bolus of air in order to optimize peripheral delivery of bacteria. The angiocatheter is removed and the puncture side sealed with Gelfoam and the neck area is sutured (4-0 silk). Regular analgesics and saline are injected s.c. as per ethics protocol for 2-24hrs.

Following induction of active infection, animals are specially housed in room # A6-114, under conditions equivalent to level 2 biohazard containment: this includes in an operational fume hood, and with barrier HEPA filter-fitted cage housing.

After animal sacrifice, and harvesting of relevant biological samples (eg. blood, tissues), the carcass is disposed of freezer box provided by Animal Care and Vet. Serv. VRL, 7 th fl., LHSC.

Other animal models of sepsis (CLP, LPS injection) – No exposure to biohazards during the actual experiments. Animal carcasses are disposed of as above.

Isolated cell culture work (human and mouse) – No specific/greater biohazard risks other than expected during such cell culture work.

Please include a one page research summary or teaching protocol.

5. Summary of Research Proposal

Title. Complex Regulation of Microvascular Endothelial Cell Function in Sepsis

Background. Sepsis is a common and serious clinical problem, with significant morbidity and mortality. A central role for activation/injury of microvascular endothelial cells (MVEC) in systemic organs, such as the lung, has been proposed in the pathogenesis of septic multiple organ dysfunction. For example, septic acute lung injury (ALI) is characterized by activation, injury, and dysfunction of lung MVEC. This results in the key pathophysiologic features of septic organ injury: high-protein edema, leukocyte infiltration, and subsequent organ dysfunction. MVEC in vivo do not exist in isolation, but interact critically with several other key cells, including circulating blood neutrophils (PMN), local tissue macrophages (MAC), as well as subjacent epithelial cells (EpC; eg. intestinal EpC in the gut, alveolar EpC in the lung). We have recently shown that PMN and MAC individually and directly contribute to MVEC injury in simple co-culture systems *in vitro* as well as in septic mice *in vivo* (**Shelton et al, Microvasc Res 2007; Farley et al, Am J Physiol Lung**

2006). However, there is little work defining the complex effects of multiple cellular influences, namely PMN/MAC/EpC on MVEC biology and function in sepsis.

Hypothesis & Aims. The **hypothesis** of the current proposal is that epithelial cells (EpC) protect against PMN/MAC-dependent MVEC injury in sepsis. We will pursue this hypothesis in parallel ***murine*** models, including isolated ***murine*** MVEC *in vitro* and an *in vivo* mouse model, as well as subsequently confirm important findings in isolated ***human*** MVEC *in vitro*. We will address **4 major aims:**

1) To characterize the effects of ***murine*** MAC on ***murine*** MVEC injury under septic conditions *in vitro* and *in vivo*.
2) To define the complex, interactive effects of ***murine*** PMN and MAC on ***murine*** MVEC injury under septic conditions *in vitro* and in septic mice *in vivo*.
3) To investigate the protective effects of ***murine*** EpC on PMN/MAC-dependent ***murine*** MVEC injury under septic conditions *in vitro* and in septic mice *in vivo*.
4) To define the effects of ***human*** EpC on PMN/MAC-dependent ***human*** MVEC injury under septic conditions *in vitro*.

Research Approach. The proposed experiments will focus on the mechanisms of septic MVEC injury (i.e. cells and soluble factors involved in MVEC activation/injury) and the consequences thereof (i.e. induction of MVEC oxidant stress, upregulation of pro-adhesive phenotype, neutrophil adhesion/migration across MVEC, and changes in MVEC permeability). We will use state-of-the-art techniques: (1) isolation of MVEC from mouse lung, and the innovative *in vitro* co-culture of these MVEC with multiple, relevant cellular influences (eg. PMN, MAC, and EpC, using cells from multiple different genetic backgrounds (eg. wild-type, $iNOS^{-/-}$, $p47^{phox-/-}$); (2) our established *in vivo* clinically-relevant mouse model of cecal ligation/perforation-induced sepsis, with selective PMN- and MAC-specific depletion-reconstitution strategies to dissect out the discrete effects of individual cells in the complex *in vivo* situation; (3) isolation of MVEC from septic vs sham mice and FACS assessment of MVEC activation/injury; (4) isolation and co-culture of human lung MVEC with human PMN, MAC, and EpC.

Feasibility / Future Directions. Over the past few years, through our ongoing work and publications on septic MVEC injury *in vivo* and *in vitro*, we have demonstrated our extensive experience with *in vivo* murine sepsis models, selective cell (eg. PMN, MAC) manipulation via depletion-reconstitution, isolation of MVEC from mouse and human lung, and co-culture of MVEC with PMN and MAC. Most exciting is that direct studies on mechanisms of human sepsis can be carried out using human MVEC *in vitro*. Improved therapy for human sepsis will depend upon a clear understanding of MVEC activation/dysfunction and of the specific, complex role of other critical, multiple cellular influences.

1.0 Microorganisms

1.1 Does your work involve the use of biological agents? X YES O NO
(non-pathogenic and pathogenic biological agents including but not limited to bacteria and other microorganisms, viruses, prions, parasites or pathogens of plant or animal origin)? If no, please proceed to Section 2.0

Do you use microorganisms that require a permit from the CFIA? O YES X NO
If YES, please give the name of the species. _____
What is the origin of the microorganism(s)? _____
Please describe the risk (if any) of escape and how this will be mitigated:
_____
_____
_____
Please attach the CFIA permit.
Please describe any CFIA permit conditions:
_____
_____
_____

1.2 Please complete the table below:

Name of Biological Agent(s)* (Be specific)	Is it known to be a human pathogen? YES/NO	Is it known to be an animal pathogen? YES/NO	Is it known to be a zoonotic agent? YES/NO	Maximum quantity to be cultured at one time? (in Litres)	Source/ Supplier	PHAC or CFIA Containment Level
Pseudomonas aeruginosa	X Yes O No	X Yes O No	O Yes X No	1 mL #	LHSC Microbiology lab	O 1 X 2 O 2+ O 3
	O Yes O No	O Yes O No	O Yes O No			O 1 O 2 O 2+ O 3
	O Yes O No	O Yes O No	O Yes O No			O 1 O 2 O 2+ O 3
	O Yes O No	O Yes O No	O Yes O No			O 1 O 2 O 2+ O 3

*Please attach a Material Safety Data Sheet or equivalent from the supplier.
Pls note: this is grown in the LHSC clinical microbiology lab, over which we have no control; we are simply provided 1mL suspension at the appropriate concentration of 2McF (6 x 10E8).

2.0 Cell Culture

2.1 Does your work involve the use of cell cultures? X YES O NO
If no, please proceed to Section 3.0

2.2 Please indicate the type of primary cells (i.e. derived from fresh tissue) that will be grown in culture:

Cell Type	Is this cell type used in your work?	Source of Primary Cell Culture Tissue	AUS Protocol Number
Human	X Yes O No	Human Lung Tissue	Not applicable
Rodent	X Yes O No	Mouse Lung Tissue	2007-002-06
Non-human primate	O Yes X No		
Other (specify)	O Yes X No		

2.3 Please indicate the type of established cells that will be grown in culture in:

Cell Type	Is this cell type used in your work?	Specific cell line(s)*	Containment Level of each cell line	Supplier / Source of cell line(s)
Human	X Yes O No	N/A	2	LHSC Resp. Clin. Services
Rodent	X Yes O No	N/A	2	Commercial Animal Vendors
Non-human primate	O Yes X No			
Other (specify)	O Yes X No			

*Please attach a Material Safety Data Sheet or equivalent from the supplier. (For more information, see www.atcc.org)

2.4 For above named cell types(s) indicate PHAC or CFIA containment level required O 1 X 2 O 2+ O 3

3.0 Use of Human Source Materials

3.1 Does your work involve the use of human source materials? X YES O NO
If no, please proceed to Section 4.0

3.2 Indicate in the table below the Human Source Material to be used.

Human Source Material	**Source/Supplier /Company Name**	**Is Human Source Material Infected With An Infectious Agent? YES/UNKNOWN**	**Name of Infectious Agent (If applicable)**	**PHAC or CFIA Containment Level (Select one)**
Human Blood (whole): used to isolate blood neutrophils	LHSC	O Yes X Unknown		O 1 X 2 O 2+ O 3
Human Organs or Tissues (unpreserved): human lung tissue obtained directly from surgery on patients with lung cancer having their lung resected; tissue used for isolation of MVEC for cell culture	LHSC	O Yes X Unknown		O 1 X 2 O 2+ O 3
Human Organs or Tissues (preserved)		Not Applicable		Not Applicable

4.0 Genetically Modified Organisms and Cell lines

4.1 Will genetic modifications be made to the microorganisms, biological agents, or cells described in Sections 1.0 and 2.0? O YES X NO If no, please proceed to Section 5.0

4.2 Will genetic modification(s) involving plasmids be done? O YES, complete table below O NO

Bacteria Used for Cloning *	Plasmid(s) **	Source of Plasmid	Gene Transfected	Describe the change that results from transformation or tranfection
				.

* Please attach a Material Data Sheet or equivalent if available.
** Please attach a plasmid map.

4.3 Will genetic modification(s) of bacteria and/or cells involving viral vectors be made?
O YES, complete table below O NO

Virus Used for Vector Construction	Vector(s) *	Source of Vector	Gene(s) Transduced	Describe the change that results from transduction

* Please attach a Material Safety Data Sheet or equivalent.

4.4 Will genetic sequences from the following be involved?

- HIV O YES, please specify _____ O NO
- HTLV 1 or 2 or genes from any Level 1 or Level 2 pathogens O YES, specify _____ O NO
- SV 40 Large T antigen O YES O NO
- E1A oncogene O YES O NO
- Known oncogenes O YES, please specify _____ O NO
- Other human or animal pathogen and or their toxins O YES, please specify _____ O NO

4.5 Will virus be replication defective? O YES O NO

4.6 Will virus be infectious to humans or animals? O YES O NO

4.7 Will this be expected to increase the containment level required? O YES O NO

5.0 Human Gene Therapy Trials

5.1 Will human clinical trials be conducted involving a biological agent? O YES XNO
(including but not limited to microorganisms, viruses, prions, parasites or pathogens of plant or animal origin)
If no, please proceed to Section 6.0

5.2 If YES, please specify which biological agent will be used: _____
Please attach a full description of the biological agent.

5.2 Will the biological agent be able to replicate in the host? O YES O NO

5.3 How will the biological agent be administered? _____

5.4 Please give the Health Care Facility where the clinical trial will be conducted:_____

5.5 Has human ethics approval been obtained? O YES, number: _____ O NO O PENDING

6.0 Animal Experiments

6.1 Will live animals be used? X YES O NO If no, please proceed to section 7.0

6.2 Name of animal species to be used__Mice_____

6.3 AUS protocol # _____2007-002-06 (renewal currently pending) _____

6.4 Will any of the agents listed in section 4.0 be used in live animals O YES, specify: _____ X NO

6.5 Will the agent(s) be shed by the animal: O YES X NO, please justify:

_____

_____

7.0 Use of Animal species with Zoonotic Hazards

7.1 Will any animals with zoonotic hazards or their organs, tissues, lavages or other body fluids including blood be used (see list below)? O YES x No If no, please proceed to section 8.0

7.2 Will live animals be used? O YES x No

7.3 If yes, please specify the animal(s) used:

- Pound source dogs O YES X NO
- Pound source cats O YES X NO
- Cattle, sheep or goats O YES, please specify species _____ X NO
- Non-human primates O YES, please specify species _____ X NO
- Wild caught animals O YES, please specify species & colony # _____ X NO
- Birds O YES, please specify species _____ X NO
- Others (wild or domestic) O YES, please specify _____ X NO

7.4 If no live animals are used, please specify the source of the specimens:

_____

8.0 Biological Toxins

8.1 Will toxins of biological origin be used? O YES X NO If no, please proceed to Section 9.0

8.2 If YES, please name the toxin(s)_____
Please attach information, such as a Material Safety Data Sheet, for the toxin(s) used.

8.3 What is the LD_{50} (specify species) of the toxin_____

8.4 How much of the toxin is handled at one time*? _____

8.5 How much of the toxin is stored*? _____

8.6 Will any biological toxins be used in live animals? O YES, Please provide details:_____ O NO

*For information on biosecurity requirements, please see:
http://www.uwo.ca/humanresources/docandform/docs/healthandsafety/biosafety/Biosecurity_Requirements.pdf

9.0 Insects

9.1 Do you use insects? O YES X NO If no, please proceed to Section 10.0

9.2 If YES, please give the name of the species. _____

9.3 What is the origin of the insect? _____

9.4 What is the life stage of the insect? _____

9.5 What is your intention? O Initiate and maintain colony, give location: _____
O "One-time" use, give location: _____

9.6 Please describe the risk (if any) of escape and how this will be mitigated:

_____

_____

9.7 Do you use insects that require a permit from the CFIA permit? O YES O NO
If YES, Please attach the CFIA permit & describe any CFIA permit conditions:

_____

_____

10.0 Plants

10.1 Do you use plants? O YES X NO If no, please proceed to Section 11.0

10.2 If YES, please give the name of the species. _____

10.3 What is the origin of the plant? _____

10.4 What is the form of the plant (seed, seedling, plant, tree…)? _____

10.5 What is your intention? O Grow and maintain a crop O "One-time" use

10.6 Do you do any modifications to the plant? O YES O NO
If yes, please describe: _____

_____

10.7 Please describe the risk (if any) of loss of the material from the lab and how this will be mitigated:

_____

_____

10.8 Is the CFIA permit attached? O YES O NO
If YES, Please attach the CFIA permit & describe any CFIA permit conditions:

_____

_____

11.0 Import Requirements

11.1 Will any of the above agents be imported? O YES, please give country of origin_____ X NO
If no, please proceed to Section 12.0

11.2 Has an Import Permit been obtained from HC for human pathogens? O YES O NO

11.3 Has an import permit been obtained from CFIA for animal or plant pathogens? O YES O NO

11.4 Has the import permit been sent to OHS? O YES, please provide permit # _____ O NO

12.0 Training Requirements for Personnel Named on Form

All personnel named on the above form who will be using any of the above named agents are required to attend the following training courses given by OHS:

- Biosafety
- Laboratory and Environmental/Waste Management Safety
- WHMIS (Western or equivalent)
- Employee Health and Safety Orientation

As the Principal Investigator, I have ensured that all of the personnel named on the form who will be using any of the biological agents in Sections 1.0 to 9.0 have been trained.

SIGNATURE S Mehta _____

13.0 Containment Levels

13.1 For the work described in sections 1.0 to 9.0, please indicate the highest HC or CFIA Containment Level required. O 1 X 2 O 2+ O 3

13.2 Has the facility been certified by OHS for this level of containment?

X YES, date of most recent biosafety inspection: __March 29,2011_____

O NO, please certify

O NOT REQUIRED for Level 1 containment

13.3 Please indicate permit number (not applicable for first time applicants): _R-06-000599_____

14.0 Procedures to be Followed

14.1 Please describe additional risk reduction measures will be taken beyond containment level 1, 2, 2+ or 3 measures, that are unique to this agent.

Use a 10% bleach solution to wipe down laboratory bench work areas before and after using bacteria solution.

14.2 Please outline what will be done if there is an exposure to the biological agents listed, such as a needlestick injury or an accidental splash:

Visit the Occupational Health and Safety for professional help

14.3 As the Principal Investigator, I will ensure that this project will follow the Western Biosafety Guidelines and Procedures Manual for Containment Level 1 & 2 Laboratories (and the Level 3 Facilities Manual for Level 3 projects). I will ensure that UWO faculty, staff and students working in my laboratory have an up-to-date Hazard Communication Form, found at http://www.wph.uwo.ca/

SIGNATURE _____ Date:_____July 20th, 2011_____

15.0 Approvals

1) UWO Biohazards Subcommittee: SIGNATURE: _____
Date: _____

2) Safety Officer for the University of Western Ontario
SIGNATURE:_____
Date:_____

3) Safety Officer for Institution where experiments will take place (if not UWO):
SIGNATURE:_____
Date:July 25, 2011

Approval Number: _____ Expiry Date (3 years from Approval): _____

Special Conditions of Approval:

New Info

Hi Jen

Sorry for the delay. We have modified the form as requested. See specific answers as below:

1 In Section 1.2 the form should indicate the volume of *Pseudomonas aeruginosa* grown in the lab instead of the density.

This has been modified as per the volume we receive; note the clinical laboratory grows the bacteria, and we have no control or knowledge of their volumes.

2 The form should say that the bacteria are in a ?suspension? instead of a solution.

Done.

3 The Committee requires clarification on the use of human blood or body fluid (re: isolation of neutrophils).

This has been specified for both whole blood used for neutrophils, as well as lung tissue for isolation of MVEC.

4 The form also mentions doing work in a fumehood, it should be a biological safety cabinet.

Materials (eg chemicals) are stored in a safety cabinet. However, all work with pathogens and potential biological or other hazards is done in an actual fume hood, with continuous flow to exhaust all toxins/exposures to the filter system instead of into the room, thus eliminating any exposure of personnel. Pls advise if we should simply change the terminology. Gail Ryder, our local Safety Inspector is fully aware of our procedures and approves of all of our approaches to minimize exposure to these potential hazards.

Best Regards

Sanjay

AUP 2011-026

11.12.1B - Agent/Material/Drug/Device Information

Species Name	Mouse

1. Agent/Material/Drug/Device Name
Pseudomonas Aeruginosa
2. Agent/Material/Drug/Device Category
Biological
3. Agent/Material/Drug/Device Class
Biolev2

AGENT/MATERIAL/DRUG/DEVICE RELATED QUESTIONS

1. Source of Biological Agent (Please provide website and attach an MSDS or equivalent)	LHSC Microbiology Lab
2. Biosafety Approval number:	BIO-LHRI-0041 (note rewewal pending)
3. Is this biological agent on your current Biosafety approval? If not, please submit a protocol modification (See www.uwo.ca/humanresources/biosafety for information.	Yes
4. Dose\Volume administered, Routes of administration and Frequency of administration:	1McF, 50ul, intratracheal, once
5. Are you creating genetic modifications using plasmids or viral vectors?	No
5.1. If Q.5 is 'Yes', has the Biosafety permit been updated to reflect this modified agent? If 'No', please complete a protocol modification (See www.uwo.ca/humanresources/biosafety for more information).	
5.2. If Q.5.1. is 'Yes', please describe the expected increase in invasiveness, toxicity or tumourgenicity of the agent in the animal.	
6. Will the biological agent be used according to the Occupational Health and Safety Standard Operating Procedures (SOP) for Use of Biological, Chemical,Radiation and/or	Yes

other Physical agents with live animals? (please link to http://www.uwo.ca/animal/website/VS/Content/SOPs.htm)	
6.1. If Q.6 is 'No', please explain what section(s) will not be followed and why.	
7. Do animals require housing after exposure to the biological agent(s)?	Yes
7.1. If Q.7 is 'Yes', please list all housing and/or imaging facilities.	VRL room # A6-114
8. Are animals transported between buildings after exposure to the biological agent(s)?	No
8.1. If Q.8 is 'Yes', please describe the precautions taken during transportation.	N/A
9. Will the agent/material or metabolite be excreted or shed by the animal?	No
9.1. If Q.9 is 'Yes', describe the route(s) and duration of shedding. (Please note that bedding will need to be treated as biohazardous by personnel and for disposal. Cages will need to be decontaminated)	
9.2. If Q.9 is 'No', please explain (Provide documentation if possible).	Bacteria in the lung are not shed by pneumonia mice.
10. PLEASE INDICATE THE CONTROL MEASURES TO BE TAKEN TO MINIMIZE THE RISK OF EXPOSURE TO ANIMAL FACILITY STAFF:	
10.1. Level 1 Precautions	Yes
10.2. Level 2 Precautions	Yes
10.3. Level 2 Plus Precautions	
10.4. Level 3 Precautions	
10.5. Other - Please provide clarification:	Following induction of active infection, animals are specially housed in room # A6-114, under conditions equivalent to level 2 biohazard containment: this includes in an operational fume hood, and with barrier HEPA filter-fitted ~~cage~~ **cage.Induction of the active infection is done in a certified fume hood in a certified Class II biosafety Room A6-114.** housing.
11. PLEASE INDICATE THE SOPS THAT WILL BE FOLLOWED: (For more information, please see	

http://www.uwo.ca/humanresources/facultystaff/h_and_s/biosafety/biosafety_policies.htm)	
11.1. ACVS Level 2 Policy (MANDATORY FOR LEVEL 2 PROJECTS.)	Yes
11.2. UWO Biosafety Guidelines and Procedural Manual for Containment Level 1 & 2 Laboratories, see www.uwo.ca/humanresources/biosafety (MANDATORY FOR ALL PROJECTS).	Yes
11.3. UWO Level 3 Manual (MANDATORY FOR LEVEL 3 PROJECTS)	
11.4. Viral Vector Policy (MANDATORY FOR PROJECTS INVOLVING VIRAL VECTORS)	
11.5. Biosafety Requirements for in vivo and in vitro work (MANDATORY FOR PROJECTS INVOLVING IMAGING AND THE USE OF BIOLOGICAL AGENTS)	
11.6. Other - Please provide clarification:	
12. Please list and describe any additional precautions to be taken.	Use a 10% bleach solution to wipe down laboratory bench work areas before and and after using bacteria solution._

Attachments List

File Spec	Description	Created

Reviewer(s) Notes

Revision Number	Name	Recommendation Notes	Private	Reviewer Deadline
0000000001	AUS	Question 1: please answer Question 2: please answer Question 14: please answer	No	/ /
0000000002	Harding, Martha	I would think that the infected mice could aerosolize Pseudomonas, so we should consider them infectious, ie #12 should be yes - - Biosafety should review....	Yes	/ /
0000000003	Stanley, Jennifer J	August 8, 2011 - Several questions not addressed ie 3, 6, 7, 8, 11, 12(?)	No	10/26/2011
0000000004	AUS	OH&S Review - Pseudomonas Aeruginosa: Several questions not addressed ie 3, 6, 7, 8, 11, 12(?)	No	/ /
0000000007	Ryder, Gail	October 18, 2011 - Not approved until clarification: Room A6-114 has a certified fume hood in it. There is no BSC in the room. However, the VRL has a dedicated Adenovirus room therefore we need clarification where he is doing the actual induction of the active infection.	No	10/26/2011
0000000007	Stanley, Jennifer J	August 22, 2011 - For question 10.5: does the room have a biosafety cabinet or a fumehood or both? Please note that this work should be done in a certified Class II biosafety cabinet. Please clarify.	No	10/26/2011
0000000007	AUS	OH&S Review - Pseudomonas Aeruginosa: For question 10.5: does the room have a biosafety cabinet or a fumehood or both? Please note that this work should be done in a certified Class II biosafety cabinet. Please clarify. Room A6-114 has a certified fume hood in it. There is no BSC in the room. However, the VRL has a dedicated Adenovirus room therefore we need clarification where he is doing the actual induction of the active infection.	No	/ /
0000000008	Stanley, Jennifer J	Oct 24, 2011 - Question 2 - The application for the use of this agent is on the agenda for the November Biohazards Subcommittee meeting (as a revisit).	Yes	10/26/2011
0000000008	Ryder, Gail	October 19, 2011 - Sorry, I said Adenovirus when I meant to say Pseudomonas, therefore fume hood is suitable to avoid exposure. Approved.	No	10/26/2011
0000000008	AUS	10.19.11 Jennifer Stanley and Gail Ryder - please review	No	/ /

Recommendation Notes

-------- Original Message --------
Subject: Re: Biological Agents Registry Form (Mehta)
Date: Fri, 05 Aug 2011 12:27:29 -0400
From: Sanjay Mehta <Sanjay.Mehta@LHSC.ON.CA>
To:jstanle2@uwo.ca
CC: Sanjay Mehta <Sanjay.Mehta@LHSC.ON.CA>

Hi Jen

Animals are bought from the vendor in animal ethics protocol, but many are locally bred as well

I have checked, and although we previously bought cells from atcc, we are currently not planning on buying any more cells right now. As such, pls disregard the atcc msds

Thanks
Sanjay
Sent from Sanjay's Blackberry
-----Original Message-----
From: Jennifer Stanley <jstanle2@uwo.ca>
To: Mehta, Sanjay <Sanjay.Mehta@lhsc.on.ca>

Sent: 8/4/2011 5:16:43 PM
Subject: Biological Agents Registry Form (Mehta)

Hi there

I have two questions about your recently submitted Biological Agents Registry Form.

For the rodent cells in Table 2.3, can I assume that the source of these
cells are the animals purchased (from "Commercial animal vendors"), used
in AUS protocol 2007-002-06?

Can you confirm that you do not purchase any cells from ATCC (I only ask
because an MSDS from ATCC was included in the submission).

Regards,
Jennifer

MSDs'

Pseudomonas spp. (excluding B. mallei, B. pseudomallei) - Material Safety Data Sheets (MSDS)

MATERIAL SAFETY DATA SHEET - INFECTIOUS SUBSTANCES

SECTION I - INFECTIOUS AGENT

NAME: *Pseudomonas* spp. (excluding *B. mallei, B. pseudomallei*)

SYNONYM OR CROSS REFERENCE: *P. aeruginosa, P. cepacia*

CHARACTERISTICS: Family Pseudomonadaceae, gram negative bacillus, aerobic, non-spore forming, some pigmented (pyocyanin, fluorescein), motile by polar flagella, variety of toxins produced

SECTION II - HEALTH HAZARD

PATHOGENICITY: Opportunistic pathogen, greatest risk of disease in the immunocompromised; most medical conditions arise from colonization of pathogen in the respiratory and urinary tracts or due to deep disseminated infections leading to pneumonia and bacteremia; chronic respiratory infections among cystic fibrosis patients; eye infections (especially in contact lens wearers); nosocomial infections causing severe and often fatal infections (case fatality in susceptible populations is 30%), increasingly associated with bacterial meningitis, abscesses, endocarditis

EPIDEMIOLOGY: Worldwide; increasing in frequency in recent years; commonly a nosocomial infection associated with contaminated instruments; 16% of nosocomial pneumonia, 12% of hospital acquired urinary-tract infections; rarely causes community acquired infections in immunocompetent patients

HOST RANGE: Humans, animals, plants

INFECTIOUS DOSE: Not known

MODE OF TRANSMISSION: Direct contact with contaminated water, aerosols or aspirations, by contact of mucous membranes with discharges from infected conjunctivae or upper respiratory tract of infected persons through contaminated objects (improperly sterilized medical equipment, contaminated IV fluids) or fingers;

INCUBATION PERIOD: Variable depending on infection; eye infection - 24 to 72 hours

COMMUNICABILITY: Can be transmitted during course of active infection

SECTION III - DISSEMINATION

RESERVOIR: Saprophyte - soil, water, decomposing matter; infected animals and humans; infected solutions - I.V., soaps, eye drops, humidifiers; organism thrives in moist conditions

ZOONOSIS: None

VECTORS: None

SECTION IV - VIABILITY

DRUG SUSCEPTIBILITY: Sensitive to extended spectrum penicillins, aminoglycosides, cephalosporins, fluroquinolones, polymixins and monobactams; aminoglycoside with a beta-lactam penicillin is the first line of treatment

DRUG RESISTANCE: Multidrug resistant strains are on the rise

SUSCEPTIBILITY TO DISINFECTANTS: Susceptible to many disinfectants - 1% sodium hypochlorite, 70% ethanol, 2% glutaraldehyde, formaldehyde; few reports of this bacteria growing in disinfectant solutions; alcohol-containing disinfectants recommended for resistant strains

PHYSICAL INACTIVATION: Inactivated by moist heat (121° C for at least 15 min) and dry heat (160-170° C for at least 1 hour)

SURVIVAL OUTSIDE HOST: Survives for several months in water with minimal nutrients

SECTION V - MEDICAL

SURVEILLANCE: Bacteriological identification of infection

FIRST AID/TREATMENT: Antibiotic therapy - aggressive treatment is necessary to avoid chronic infections; drainage of wounds; local application of antibiotic ointment or drops

IMMUNIZATION: None

PROPHYLAXIS: Antibiotic prophylaxis, not usually administered

SECTION VI - LABORATORY HAZARDS

LABORATORY-ACQUIRED INFECTIONS: No reported infections to date

SOURCES/SPECIMENS: Clinical specimens - respiratory secretions, wound exudates, blood, urine; environmental specimens - water, infected solutions (IV, disinfectants, soap)

PRIMARY HAZARDS: Accidental parenteral inoculation; direct contact of mucous membranes with infected materials; inhalation of infectious aerosols and ingestion also present a hazard

SPECIAL HAZARDS: None

SECTION VII - RECOMMENDED PRECAUTIONS

CONTAINMENT REQUIREMENTS: Biosafety level 2 practices, containment equipment and facilities for activities involving suspected or known infectious specimens and cultures

PROTECTIVE CLOTHING: Laboratory coat, gloves when direct contact with infectious materials is unavoidable

OTHER PRECAUTIONS: Good personal hygiene, frequent hand washing and the avoidance of rubbing eyes as a precautionary measure against eye infections

SECTION VIII - HANDLING INFORMATION

SPILLS: Allow aerosols to settle; wearing protective clothing, gently cover spill with paper towels and apply 1% sodium hypochlorite, starting at perimeter and working towards the centre; allow sufficient contact time before clean up and disposal (30 min)

DISPOSAL: Decontaminate before disposal - steam sterilization, chemical disinfection, incineration

STORAGE: In sealed containers that are appropriately labelled

SECTION IX - MISCELLANEOUS INFORMATION

Date prepared: March, 2001

Prepared by: Office of Laboratory Security, PHAC

Although the information, opinions and recommendations contained in this Material Safety Data Sheet are compiled from sources believed to be reliable, we accept no responsibility for the accuracy, sufficiency, or reliability or for any loss or injury resulting from the use of the information. Newly discovered hazards are frequent and this information may not be completely up to date.

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