

**The University of Western Ontario**  
**BIOLOGICAL AGENTS REGISTRY FORM**  
**Approved Biohazards Subcommittee: July 8, 2011**  
**Biosafety Website: [www.uwo.ca/humanresources/biosafety/](http://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, 1<sup>st</sup> edition 1996, Canadian Food Inspection Agency (CFIA).

Electronically completed forms are to be submitted to Occupational Health and Safety, (OHS), (Support Services Building, Room 4190 or to [jstanle2@uwo.ca](mailto:jstanle2@uwo.ca)) for distribution to the Biohazards Subcommittee. For questions regarding this form, please contact the Biosafety Officer at extension 81135 or [biosafety@uwo.ca](mailto: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/](http://www.uwo.ca/humanresources/biosafety/).

Please ensure that all questions are fully and clearly answered. Failure to do so will lead to the form being returned, which will cause delays in your approval and frustration for you and your colleagues on the Committee.

**If you are re-submitting this form as requested by the Biohazards Subcommittee, please make modifications to the form in bold print, highlighted in yellow. Please re-submit forms electronically.**

PRINCIPAL INVESTIGATOR:	<b>Dr. Andreana Butter</b>
DEPARTMENT:	<b>Surgery (Division of Pediatric Surgery)</b>
ADDRESS:	<b>Children's Hospital, 800 Commissioners Rd East, Rm B1-188</b>
PHONE NUMBER:	<b>519-685-8401</b>
EMERGENCY PHONE NUMBER(S):	<b>519-685-8500 pager 19188</b>
EMAIL:	<b><a href="mailto:andreana.butter@lhsc.on.ca">andreana.butter@lhsc.on.ca</a></b>

Location of experimental work to be carried out :

Building :	<b>ACVS</b>	Room(s):	<b>Sheep unit</b>
Building :	_____	Room(s):	_____
Building :	_____	Room(s):	_____

**\*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: Division of Pediatric Surgery

GRANT TITLE(S): The effects of congenital diaphragmatic hernia on molecular markers of lung growth

UNDERGRADUATE COURSE NAME(IF APPLICABLE): \_\_\_\_\_

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

<u>Name</u>	<u>UWO E-mail Address</u>	<u>Date of Biosafety Training</u>
<b>Dr. Tim Regnault (co-PI)</b>	<b><a href="mailto:tim.regnault@uwo.ca">tim.regnault@uwo.ca</a></b>	_____
<b>Brad Matuszewski</b>	<b><a href="mailto:bjmatush@uwo.ca">bjmatush@uwo.ca</a></b>	_____

Dr. Leslie Scott

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[leslie.scott@lhsc.on.ca](mailto:leslie.scott@lhsc.on.ca)

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Please explain how the biological agents are used in your project and how they are stored and disposed of. The BARF without this description will not be reviewed.

The only biological agents in this project are the pregnant ewes themselves which may carry Q fever. The animals are appropriately stored in the sheep containment unit at ACVS during the experiments. After euthanasia, the sheep will be appropriately disposed of as per AUS protocol ie. double bagged, sprayed etc.

**Please include a ONE page research summary or teaching protocol in lay terms.  
Forms with summaries more than one page will not be reviewed.**

**BRIEF DESCRIPTION OF BIOHAZARDS TO BE USED**

Project title: The effects of congenital diaphragmatic hernia on molecular markers of lung growth in sheep  
PI: Dr. Andreana Bütter, Division of Pediatric Surgery

The only biohazard to be used in this project are the sheep themselves. Sheep may carry a virus which may result in Q fever, a flu-like illness, in humans. For this reason, any experiments in sheep must be carried in a specialized facility, such as the new animal care facility at UWO (ACVS). Appropriate attire must be worn and all personnel involved with the sheep must shower prior to leaving the facility.

After autopsy of the lambs, only the lungs will be removed for molecular analysis in Dr. Regnault's lab. They will be placed in formaldehyde and placed in sealed packaging prior to transport. Once in the lab, there are no known biohazards to be used.

## 1.0 Microorganisms

1.1 Does your work involve the use of biological agents? YES X 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? YES 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:

Full Scientific 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
	Yes No	Yes No	Yes No			1 2 2+ 3
	Yes No	Yes No	Yes No			1 2 2+ 3
	Yes No	Yes No	Yes No			1 2 2+ 3
	Yes No	Yes No	Yes No			1 2 2+ 3
	Yes No	Yes No	Yes No			1 2 2+ 3
	Yes No	Yes No	Yes No			1 2 2+ 3
	Yes No	Yes No	Yes No			1 2 2+ 3
	Yes No	Yes No	Yes No			1 2 2+ 3

*\*Please attach a Material Safety Data Sheet or equivalent from the supplier if the bacterium used is not on this link:*  
[http://www.uwo.ca/humanresources/docandform/docs/ohs/CFIA\\_Ecoli\\_list.pdf](http://www.uwo.ca/humanresources/docandform/docs/ohs/CFIA_Ecoli_list.pdf)

Additional Comments: \_\_\_\_\_

## 2.0 Cell Culture

2.1 Does your work involve the use of cell cultures? YES  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	Yes No		Not applicable
Rodent	Yes No		
Non-human primate	Yes No		
Other (specify)	Yes No		

1.3 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	Yes No			
Rodent	Yes No			
Non-human primate	Yes No			
Other (specify)	Yes No			

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

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

Additional Comments: \_\_\_\_\_

## 3.0 Use of Human Source Materials

3.1 Does your work involve the use of human source materials? YES  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) or other Body Fluid		Yes Unknown		1 2 2+ 3
Human Blood (fraction) or other Body Fluid		Yes Unknown		1 2 2+ 3
Human Organs or Tissues (unpreserved)		Yes Unknown		1 2 2+ 3
Human Organs or Tissues (preserved)		Not Applicable		Not Applicable

Additional Comments: \_\_\_\_\_

#### 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?      YES      X NO      If **NO**, please proceed to Section 5.0

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

Bacteria Used for Cloning *	Plasmid(s) **	Source of Plasmid	Gene Transformed or Transfected	Will there be a change due to transformation of the bacteria?	Will there be a change in the pathogenicity of the bacteria after the genetic modification?	What are the consequences due to the transformation of the bacteria?

*\* Please attach a Material Safety Data Sheet or equivalent if available.*

*\*\* Please attach a plasmid map.*

*\*\*\*No Material Safety Data Sheet is required for the following strains of E. coli:*

[http://www.uwo.ca/humanresources/docandform/docs/ohs/CFIA\\_Ecoli\\_list.pdf](http://www.uwo.ca/humanresources/docandform/docs/ohs/CFIA_Ecoli_list.pdf)

4.3 Will genetic modification(s) of bacteria and/or cells involving viral vectors be made?      YES, complete table below      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.*

4.3.1 Will virus be replication defective?      YES      NO

4.3.2 Will virus be infectious to humans or animals?      YES      NO

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

#### 5.0 Will genetic sequences from the following be involved?

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

5.1 Is any work being conducted with prions or prion sequences?      X NO YES

Additional Comments: \_\_\_\_\_

## 6.0 Human Gene Therapy Trials

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

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

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

1.4 How will the biological agent be administered?

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

6.6 Has human ethics approval been obtained? YES, number: NO PENDING

## 7.0 Animal Experiments

7.1 Will live animals be used? X YES NO If **NO**, please proceed to section 7.0

7.2 Name of animal species to be used **pregnant ewes**

7.3 AUS protocol # **2008-093**

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

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

## 8.0 Use of Animal species with Zoonotic Hazards

8.1 Will any animals with zoonotic hazards or their organs, tissues, lavages or other body fluids including blood be used (see list below)? X YES NO - If **NO**, please proceed to section 8.0

8.2 Will live animals be used? X YES NO

8.3 If **YES**, please specify the animal(s) used:

- |                             |                                     |      |
|-----------------------------|-------------------------------------|------|
| ◆ Pound source dogs         | YES                                 | X NO |
| ◆ Pound source cats         | YES                                 | X NO |
| ◆ Cattle, sheep or goats    | X YES, species <b>pregnant ewes</b> | NO   |
| ◆ Non-human primates        | YES, species                        | X NO |
| ◆ Wild caught animals       | YES, species & colony #             | NO   |
| ◆ Birds                     | YES, species                        | X NO |
| ◆ Others (wild or domestic) | YES, specify                        | X NO |

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

## 9.0 Biological Toxins and Hormones

9.1 Will toxins or hormones of biological origin be used? YES X NO If no, please proceed to Section 9.0

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

1.3 What is the LD<sub>50</sub> (specify species) of the toxin or hormone

9.4 How much of the toxin or hormone is handled at one time\*?

9.5 How much of the toxin or hormone is stored\*?

9.6 Will any biological toxins or hormones be used in live animals? YES NO

If YES, Please provide details:

\*For information on biosecurity requirements, please see:

[http://www.uwo.ca/humanresources/docandform/docs/healthandsafety/biosafety/Biosecurity\\_Requirements.pdf](http://www.uwo.ca/humanresources/docandform/docs/healthandsafety/biosafety/Biosecurity_Requirements.pdf)

Additional Comments: \_\_\_\_\_

## 10.0 Insects

10.1 Do you use insects? YES X NO - If NO, please proceed to Section 10.0

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

10.3 What is the origin of the insect?

10.4 What is the life stage of the insect?

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

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

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

## 11.0 Plants

- 1.1 Do you use plants? YES  NO - If **NO**, please proceed to Section 11.0
- 1.2 If YES, please give the name of the species.
- 1.3 What is the origin of the plant?
- 11.4 What is the form of the plant (seed, seedling, plant, tree...)?
- 11.5 What is your intention?      Grow and maintain a crop      "One-time" use
- 11.6 Do you do any modifications to the plant?      YES      NO  
If yes, please describe:
- 11.7 Please describe the risk (if any) of loss of the material from the lab and how this will be mitigated:
- 11.8 Is the CFIA permit attached?      YES      NO  
If **YES**, Please attach the CFIA permit & describe any CFIA permit conditions:

## 12.0 Import Requirements

- 12.1 Will any of the above agents be imported? YES, country of origin       NO  
If **NO**, please proceed to Section 12.0
- 12.2 Has an Import Permit been obtained from HC for human pathogens?      YES      NO
- 12.3 Has an import permit been obtained from CFIA for animal or plant pathogens?      YES      NO
- 12.4 Has the import permit been sent to OHS?      YES, please provide permit #      NO

## 13.0 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.

***An X in the check box indicates you agree with the above statement... X***

***Enter Your Name*** Andreana Butter      ***Date:*** Sept 5, 2011

