

**THE UNIVERSITY OF WESTERN ONTARIO
BIOLOGICAL AGENTS REGISTRY FORM**
Approved Biohazards Subcommittee: September 10, 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 _____

DEPARTMENT _____

ADDRESS _____

PHONE NUMBER _____

EMERGENCY PHONE NUMBER(S) _____

EMAIL _____

Location of experimental work to be carried out: Building(s) _____ 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: _____

GRANT TITLE(S): _____

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>
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
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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.

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Please include a one page research summary or teaching protocol.

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

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

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

Please describe any CFIA permit conditions:

Name of Biological agent(s)*	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

2.0 Cell Culture

If no, please proceed to Section 3.0

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		

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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)*	Biosafety level(s) of each cell line(s)	Supplier / Source
Human	☐ Yes ☐ No			
Rodent	☐ Yes ☐ No			
Non-human primate	☐ Yes ☐ No			
Other (specify)	☐ Yes ☐ No			

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*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 ☐ 1 ☐ 2 ☐ 2+ ☐ 3

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/NO	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

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 ☐ 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 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.

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4.3 Will genetic modification(s) of bacteria and/or cells involving viral vectors be made?

☐ YES, complete table below ☐ NO

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

4.5 Will virus be replication defective? ☐ YES ☐ NO

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

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

5.0 Human Gene Therapy Trials

5.1 Will human clinical trials be conducted involving a biological agent? ☐ YES ☐ 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

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? ☐ YES ☐ 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? ☐ YES, number: _____ ☐ NO ☐ PENDING

6.0 Animal Experiments

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

6.2 Name of animal species to be used _____

6.3 AUS protocol # _____

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

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

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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)? ☐ YES ☐ No If no, please proceed to section 8.0

7.2 Will live animals be used? ☐ YES ☐ No

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

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

7.4 If no live animals are used, please specify the source of the specimen~~s~~:

8.0 Biological Toxins

8.1 Will toxins of biological origin be used? ☐ YES ☐ 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 LD₅₀ (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? ☐ YES, Please provide details: _____ ☐ 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? ☐ YES ☐ 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? ☐ Initiate and maintain colony, give location: _____
☐ "One-time" use, give location: _____

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

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9.7 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:

10.0 Plants

10.1 Do you use plants? ☐ YES ☐ 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? ☐ Grow and maintain a crop ☐ "One-time" use

10.6 Do you do any modifications to the plant? ☐ YES ☐ 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? ☐ YES ☐ 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? ☐ YES, please give country of origin _____ ☐ NO
If no, please proceed to Section 12.0

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

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

11.4 Has the import permit been sent to OHS? ☐ YES, please provide permit # _____ ☐ 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 _____

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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. ☐ 1 ☐ 2 ☐ 2+ ☐ 3

13.2 Has the facility been certified by OHS for this level of containment?
☐ YES, permit # if on-campus _____
☐ NO, please certify
☐ NOT REQUIRED for Level 1 containment

14.0 Procedures to be Followed

14.1 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: _____

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

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

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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: _____

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

Special Conditions of Approval:

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