# THE UNIVERSITY OF WESTERN ONTARIO
# BIOLOGICAL AGENTS REGISTRY FORM
**Approved Biohazards Subcommittee: July 9, 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 | Dr. Douglas Fraser |
| DEPARTMENT | Paediatrics |
| ADDRESS | Victoria Research Labs, 800 Commissioner's Rd E |
| PHONE NUMBER | 519-685-8500 ext 55728 (lab), ext 52767 (office) |
| EMERGENCY PHONE NUMBER(S) | 519-868-0762 (Tech Cell) |
| EMAIL | Douglas.fraser@lhsc.on.ca |

Location of experimental work to be carried out: Building(s) _____VRL, VH_____ Room(s)_A5-137_____

*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:_____Children's Health Foundation_____
GRANT TITLE(S): _Translational Research Centre_____

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

| Name | UWO E-mail Address | Date of Biosafety Training |
|---|---|---|
| Alayne Brisson | abrisso@uwo.ca | 11-JAN-2010 |

**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.**

Human Blood: Blood is collected in hemoguard vacutainers by registered nurses and transported to the lab in A5-137. The samples are spun in a sealed bucket centrifuge and then the plasma or serum and buffy coat are aliquoted into cryovials and frozen ay -80. This is done using PPE including lab coat, gloves and goggles. Samples are transferred to other labs for analysis and any leftover samples are stored indefinitely. When there is a suspected organism (i.e. the patient has MRSA Sepsis, necrotizing fasciitis or meningitis), the samples are handled in a biological safety cabinet using the PPE mentioned above.

Human Saliva: Saliva is collected in a container designed for that purpose that contains a DNA preserving mixture (ORAgene DNA Saliva Kit- commercially available). The saliva is aliquoted into cryovials and frozen at -80. Samples are then transferred to other labs for analysis and any leftover samples are stored indefinitely.

Human Urine & Stool: Urine and stool samples are collected in sterile containers at patient areas in the hospital and then transported to the lab in A5-137. Urine may be tested (dip stick) or aliquoted and frozen. Lab coat, gloves and goggles are worn. Stool is simply frozen in the container it was supplied in and is not handled in the lab.

Other Samples: The lab also collects cerebrospinal fluid, bronchoalveolar lavage fluid (fluid that is suctioned from the lungs of patients), bone marrow, and solid tissues. All fluid samples are handled using a similar protocol as that of human blood. Solid tissues are generally from biopsies and are divided with half being frozen and the other half being placed in culture media. All samples are shipped to other labs and any leftover samples are stored indefinitely.

Disposal: Any excess samples or products from processing are disposed of as biological waste in the yellow waste stream.

**Please include a one page research summary or teaching protocol.**

The Translational Research Centre (TRC) is a facility designed to aid clinicians and scientists in the collection of humans samples for research purposes. The TRC offers a number of services including:

- Assistance with Bioethics - working with the University of Western Ontario's Office of Research Ethics, the TRC has created a research consent form that gives broad consent for sample and patient data collection and storage for use in future academic research projects. For projects involving intensive care units, a 24 hour waiver of consent has been obtained to ensure the most relevant specimens are being collected.
- Patient Consent – the TRC can assist investigators with patient consent.
- Secure database – meeting all of the Personal Health Information Privacy Act requirements, the TRC database allows for transfer of de-identified patient and sample information to investigators. This database was designed in collaboration with *I-THINK* Research at Lawson. Investigators have remote access to clinical information matching their samples.
- Standardized Specimen Collection and Processing – use of standard operating procedures (SOPs) ensures optimal recovery of research data from specimens. The SOPs were created in collaboration with the Canadian Critical Care Trials Group and the Ontario Cancer Biomarker Network. To serve a greater number of projects, many types of biological specimens are collected. TRC SOPs are updated regularly.
- Specimen Storage – all samples are securely stored at ultra-low temperatures to preserve sample quality. Two freezers are used with samples split between them to prevent loss due to equipment failure. Freezers are locked at all times and accessible only to TRC Staff.
- Specimen Transfer – the TRC is able to ship specimens world-wide.
- Specimen Repository – excess samples are retained indefinitely for use in future research projects. This reduces future costs and time to discovery.
- Healthy Control Specimens – the TRC has created a protocol to collect different specimens from healthy volunteers that allows multiple projects to take advantage of this resource.

The TRC provides services at no cost to academic projects and charges industry-sponsored clinical trials a cost-recovery fee.

SOPs that have been created are:
SOP I: Labeling of Specimens
SOP II: Blood Sample Collection and Processing – PLASMA
SOP III: Blood Sample Collection and Processing – SERUM
SOP IV: CSF Collection and Processing
SOP V: Bronchoalveolar Lavage Fluid Collection and Processing
SOP VI: Mononuclear Cell Isolation – BLOOD or BONE MARROW
SOP VII: Clinical Data Collection
SOP VIII: Specimen Shipment
SOP IX: DNA Isolation from Whole Blood
SOP X: Blood Collection and Processing for Isolation of RNA
SOP XI: Saliva Collection and Processing using ORAgene Kits

## 1.0 Microorganisms

1.1 Does your work involve the use of biological agents? O 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

Do you use microorganisms that require a permit from the CFIA? O 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:

| 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 |
|---|---|---|---|---|---|---|
| | 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 |
| | 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.

## 2.0 Cell Culture

2.1 Does your work involve the use of cell cultures? O 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 | O Yes O No | | Not applicable |
| Rodent | O Yes O No | | |
| Non-human primate | O Yes O No | | |
| Other (specify) | O Yes O 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)* | Supplier / Source |
|---|---|---|---|
| Human | O Yes O No | | |
| Rodent | O Yes O No | | |
| Non-human primate | O Yes O No | | |
| Other (specify) | O Yes O 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 O 2 O 2+ O 3

**3.0 Use of Human Source Materials**

3.1 Does your work involve the use of human source materials? ☒ 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/NO** | **Name of Infectious Agent (If applicable)** | **PHAC or CFIA Containment Level (Select one)** |
|---|---|---|---|---|
| Human Blood (whole) or other Body Fluid | Patient Samples | O Yes ☒ Unknown | Risk group 2 | O 1 ☒ 2 O 2+ O 3 |
| Human Blood (fraction) or other Body Fluid | | O Yes O Unknown | | O 1 O 2 O 2+ O 3 |
| Human Organs or Tissues (unpreserved) | | O Yes O Unknown | | O 1 O 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 ☒ 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) involving viral vectors be made? O 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.

4.4 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 ☒ 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? 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? O 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 O YES, specify: _____ O NO

6.5 Will the agent(s) be shed by the animal: O YES O 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 ☒ No If no, please proceed to section 8.0

7.2 Please specify the animal(s) used:

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

## 8.0 Biological Toxins

8.1 Will toxins of biological origin be used? O 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 $LD_{50}$ (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 ☒ 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 ⊗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_____ ⊗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 _____

## 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 ☒ 2 O 2+ O 3

13.2 Has the facility been certified by OHS for this level of containment?
☒ YES, permit # if on-campus (LHSC - Gail Ryder) Certified on November 10, 2009 Gail Ryder
O NO, please certify
O 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: Nov 2/10

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:

for a blood/body fluid exposure, we would follow the LHSC protocol which includes irrigating the exposed area, the patient would be consented to give a sample for hepatitis & HIV testing & it would be reported to OHSS.

## 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: Gail Ryder
Date: November 5, 2010

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

Special Conditions of Approval: