The University *of* Western Ontario
BIOLOGICAL AGENTS REGISTRY FORM
Approved Biohazards Subcommittee: July 8, 2011
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).

Electronically completed forms are to be submitted to Occupational Health and Safety, (OHS), (Support Services Building, Room 4190 or to 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. 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.

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:	**Dr Eric Savory (PI at Western)**
DEPARTMENT:	**Mechanical and Materials Engineering**
ADDRESS:	**Room 3085, Spencer Engineering Building**
PHONE NUMBER:	**ext 88256**
EMERGENCY PHONE NUMBER(S):	**Mike Gaylard (ext 88292, cell 519 617 0958)**
EMAIL:	**esavory@eng.uwo.ca**

Location of experimental work to be carried out :

Building :	**Thompson Engineering Building**	Room(s):	**306**
Building :	**Thompson Engineering Buidling**	Room(s):	**308/308A**
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: **NSERC (Collaborative Health Research Project, CHRP)**

GRANT TITLE(S): **Characterization of infectious bioaerosols generated by subjects inoculated with respiratory viruses (grant to be applied for in Fall 2011, NOI has been accepted)**

UNDERGRADUATE COURSE NAME(IF APPLICABLE): **None**

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

Name	UWO E-mail Address	Date of Biosafety Training
TBA on award of grant	--	--
(probably 1 graduate student)		

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.

Biological agents are not used in this project.

Human subjects presenting influenza symptoms, specifically coughing, will either sit or stand in a fixed location in the laboratory whilst the airflow and particle (presumably containing influenza virus) distribution associated with each cough are measured. The equipment used in the experiments will be wiped down with disinfectant at the end of each day when experiments have been carried out.

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

BACKGROUND OF THE OVERALL PROJECT:

Aerosol transmission plays an important role in seasonal as well as pandemic spread of influenza viruses. Limited data are available regarding the characteristics of infectious bioaerosols generated by virus-infected hosts. Using a guinea pig model, the importance of temperature and relative humidity on influenza virus transmission have been demonstrated, but the mechanism has not been established. Furthermore, host determinants for transmission remain largely unexplored. An understanding of the characteristics and behaviour of infectious bioaerosols will help the development of interventions designed to mitigate the spread of influenza virus.
The primary objective is to characterize virus-laden bioaerosols generated by guinea pigs and humans. It is proposed to initially examine influenza virus-laden bioaerosols generated by experimentally-infected guinea pigs (work to be carried out in Toronto) based upon the following variables:
a) Environmental factors including temperature and percent relative humidity. Currently influenza virus transmission experiments are conducted using unadapted human strains of influenza and the guinea pig model. Aerosol transmission experiments are conducted in an environmental chamber which maintains temperature and %relative humidity (%RH). These environmental variables can be changed to examine the aerosols generated under a range of controlled temperatures and %RH. This equipment has been acquired and is functioning within a biobubble housed in a biohazard suite at Sunnybrook Research Centre (Toronto).
b) Host determinants such as age, immune-status, and bacterial colonization status. The effects of host immune status will be examined using the a guinea pig models of immunosuppression (cyclophosphamide-treated animals); susceptibility (non-immunized); and immunity (vaccinated) animals, to examine the effects of immunesuppression and immune-protection on bioaerosol generation and transmission. Guinea pig models for Staphylococcus aureus colonization and infection are currently being developed in the Sunnybrook laboratory and it is intended to apply these models to study the impact of bacterial colonization on the aerobiology of influenza virus.
The work to be carried out at Western (outlined below) will involve human subjects who have been naturally infected by an influenza virus, with the focus being on the fluid dynamics of the aerosol jet produced by coughing.

WORK TO BE CARRIED OUT AT WESTERN:

It is proposed to engage paid volunteers (Western students recruited on campus) who are exhibiting influenza symptons during the regular flu season, notably coughing. The paid volunteers will come to the fluid mechanics laboratory (either TEB 306 or TEB 308/308A) and will either sit or stand in a marked location in front of the particle image velocimetry (PIV) instrumentation. Upon coughing, the airflow velocity time history will be measured by PIV and aerosol samples taken for analysis of their distribution and virus content, using a Coriolis sampler (Bertin Technologies). These data will be used to assess the physics of the transient jet and its penetration into the environment. The investigators carrying out the experiments will use a fit-tested N-95 respirator and gloves. No additional protection is envisaged since the subjects are presenting with everyday flu symptoms as would be encountered in any workplace. No-one else will be allowed in the laboratory during the experiments and the laboratory air will be re-cycled via the building's existing HVAC system.

1.0 Microorganisms

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

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:
None. Risk of transmission of the virus from the host to any nearby person would be the same as in any other environment (classroom, workplace, home, public transit etc). Those conducting the experiments will use a fit-tested N-95 respirator and gloves.

Please attach the CFIA permit.

Please describe any CFIA permit conditions:
N/A

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
Influenza virus	☒ Yes ☐ No	☒ Yes ☐ No	☒ Yes ☐ No	**None**	**Infected volunteer**	☒ 1 ☐ 2 ☐ 2+ ☐ 3
	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No			
	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No			
	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No			☐ 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

See E-mail

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

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		

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	☐ 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)

2.4 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	**Infected volunteer**	☒ Yes ☐ Unknown	**Influenza virus**	☒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 ☒ 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

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

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

Additional Comments: _____

6.0 Human Gene Therapy Trials

6.1 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

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

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

6.4 How will the biological agent be administered? **It will not be administered**

6.5 Please give the Health Care Facility where the clinical trial will be conducted: **None**

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

7.0 Animal Experiments

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

7.2 Name of animal species to be used

7.3 AUS protocol #

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

7.5 Will the agent(s) be shed by the animal:
☐ YES ☒ 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)? ☐ YES ☒ NO - If **NO**, please proceed to section 8.0

8.2 Will live animals be used? ☐ YES ☒ NO

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

♦ Pound source dogs	☐ YES	☐ NO
♦ Pound source cats	☐ YES	☐ NO
♦ Cattle, sheep or goats	☐ YES, species	☐ NO
♦ Non-human primates	☐ YES, species	☐ NO
♦ Wild caught animals	☐ YES, species & colony #	☐ NO
♦ Birds	☐ YES, species	☐ NO
♦ Others (wild or domestic)	☐ YES, specify	☐ 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 ☒ NO If no, please proceed to Section 9.0

9.2 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.

9.3 What is the LD_{50} (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

Additional Comments: _____

10.0 Insects

10.1 Do you use insects? ☐ YES ☒ 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

11.1 Do you use plants? ☐ YES ☒ NO - If **NO**, please proceed to Section 11.0

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

11.3 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... ☒
Enter Your Name Dr Eric Savory ***Date:*** 6th December 2011

14.0 Containment Levels

14.1 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

14.2 Has the facility been certified by OHS for this level of containment?
- ☐ YES, location and date of most recent biosafety inspection:
- ☐ NO, please certify
- ☒ NOT REQUIRED for Level 1 containment

14.3 Please indicate permit number (not applicable for first time applicants):

15.0 Procedures to be Followed

15.1 Are additional risk reduction measures necessary beyond containment level 1, 2, 2+ or 3 measures that are unique to these agents? ☒ YES ☒ NO

If **YES** please describe:

Gloves and a fit-tested N-95 respirator will be used

15.2 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:

Should large droplets resulting from the subject coughing (that may contain the influenza virus) land on any bare skin of the person carrying out the experiments, that area of skin shall be immediately and thoroughly washed using soap and water.

15.3 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.shs.uwo.ca/workplace/newposition.htm

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

Enter Your Name **Dr Eric Savory** ***Date:*** **6th December 2011**

15.4 Additional Comments: _____

16.0 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:

E-mail

------- Original Message --------
Subject:RE: Influenza study (Savory lab)
Date: Mon, 09 Jan 2012 15:46:48 -0500
From: Eric Savory <esavory@eng.uwo.ca>
To: Jennifer Stanley <jstanle2@uwo.ca>
CC: Dr. Sidney Siu <srscons@on.aibn.com>

Dear Jennifer

The plaque assays will be carried out at Sunnybrook Hospital in Toronto in the PIs (Samira Mubareka's) lab. The sample will be put on ice immediately after collection and stored at -80 deg C in a freezer until they are shipped to Sunnybrook on dry ice (we'll ship them in batches).

Best wishes

Eric

From: Jennifer Stanley [mailto:jstanle2@uwo.ca]
Sent: Monday, January 09, 2012 10:34 AM
To: Eric Savory
Cc: Dr. Sidney Siu
Subject: Re: Influenza study (Savory lab)

Thanks for the information Dr. Savory

Will the *in vitro* work using plaque assay be done here or at U of T?

Regards
Jennifer

On 1/6/2012 6:26 PM, Eric Savory wrote:
Dear Jennifer

Thanks for this. I am happy for you to change the containment level to "2" if that better reflects the statements we have made in the BARF document.

We will be using samplers to collect the droplets to be analyzed for viral content. The Coriolis Micro (made by Bertin Technologies) is a sampler based upon wet cyclone technology, which allows sampling of pathogens into a liquid media. This prevents desiccation of pathogens and allows for concentration of the pathogens, improving sensitivity. With sampling flow rates of up to 300L/minute, large volumes of air can be sampled and particles of 0.5-10 µm can be collected into a sterile cone containing liquid media. The vortex formed during collection generates a centrifugal force separating particles from the air and concentrating them into the liquid media, which is then spun down on a filter membrane for concentration. The samples will then be analyzed using plaque assay for *in vitro* infectiousness.

I hope that is the information you were looking for.

Best wishes

Eric