THE UNIVERSITY OF WESTERN ONTARIO
BIOHAZARDOUS AGENTS REGISTRY FORM
Approved Biohazards Subcommittee: September 25, 2009
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 or in charge of a laboratory/facility where the use of Level 1, 2 or 3 biohazardous 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 biohazards 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 Biohazard 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: Kevin Shoemaker
SIGNATURE:
DEPARTMENT: Health Sciences
ADDRESS: Rm 3110 TH + Rm 402 HSB
PHONE NUMBER: 88526 + 88085
EMERGENCY PHONE NUMBER(S): Dr K Shoemaker office 85759 (519) 639-6316 (cell)
EMAIL: Kshoemak@uwo.ca

Location of experimental work to be carried out: Building(s) TH + HSB Room(s) 3110 + 402

*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 12.0, Approvals).

FUNDING AGENCY/AGENCIES: CDA, CIHR, HSFO
GRANT TITLE(S):

PLEASE ATTACH A BRIEF DESCRIPTION OF YOUR WORK THAT EXPLAINS THE BIOHAZARDS USED AND HOW THEY WILL BE USED. PROJECTS SUBMITTED WITHOUT A SUMMARY WILL NOT BE REVIEWED. A GRANT SUMMARY PAGE MAYBE ADEQUATE IF IT PROVIDES SUFFICIENT DETAIL ABOUT EACH BIOHAZARD USED.

Names of all personnel working under Principal Investigators supervision in this location:

Arlene Fleischhauer
Chantelle Nielson
Craig Steinback
Gary Hodges
Jasna Jurusovic
Udunna Anazodo
Patricia Scott
Katelyn Norton
Janet McMordie
Louis Mattar
Maria Flamengo
Meghan Thorne
Ruma Goswami
Tim Hartley
Carol Wamsley
Charlotte Usselman

*** DESCRIPTION MUST BE ATTACHED TO THIS FORM OR PROJECT WILL NOT BE REVIEWED***

The biohazard agent is human blood, in the labs in TH, Rm 3110 and HSB, Rm 402. Attach is an section from REB #15170, outlining why we are collecting the blood and how the samples are obtained

7.2a	Describe what specimens will be taken and what they will be used for. In the case of blood samples also provide the total amount of blood that will be taken.
⇒ The blood samples obtained will be used to analyze blood sugar, total cholesterol levels, catecholamines, hematocrit, plasma rennin activity, brain-derived neurotrophic factor and angiotensin II. No more than 60 ml will be drawn at each session. Biohazard training is taken by all investigators in this study.	
7.2b	Indicate how and when the specimen will be collected and by whom. Describe facilities and procedures to protect the ***physical*** comfort and safety of the participants from whom samples will be taken. In the case of invasive sampling e.g. taking blood, biopsies indicate who will take the sample and give their qualifications to do so.
⇒ The blood samples will be obtained by the venapuncture method at the beginning of our study, and will be done by Arlene Fleischhauer R.N. The blood will be collected in our research lab. The participants will be seated comfortably, or offered the option of lying down on our research table, while the blood is being obtained.	
7.2c	Explain who will control or own the specimens?
⇒ The samples will be controlled and cared for by Arlene Fleischhauer R.N.	
7.2d	Explain how and where the specimens will be stored.
⇒ 5 mL will not be frozen but taken directly to Gamma-Dynacare for testing of clinical variables (lipids, triglycerides, glucose, hsCRP). The remaining blood will be centrifuged and the serum or plasma frozen in our –70 freezer for later analysis of hormones, endothelial markers, etc. Five mL of this serum will be sent (still frozen) to the University of Waterloo for analysis of catecholamines.	
7.2e	Describe how long the specimens will be retained and how they will be destroyed.
⇒ Gamma Dynacare: No storage. Other blood samples will be stored up to nine months before analysis. The specimens will be subsequently destroyed according to the biohazardous waster disposal guidelines set out at Gamma-Dynacare, the University of Waterloo, and The University of Western Ontario.	

7.3.a	What was the **original** purpose or use of the tissue or specimens?	Collected specifically for research purposes	X
		Originally collected for diagnostic purposes	
		No purpose or use - unwanted or discarded tissue or biomaterials	
7.3b	The subsequent use of tissue or biomaterials (except blood) **originally collected for diagnostic purposes** must, be approved by the Department of Pathology Tissue Use Committee prior to submission to the HSREB and a copy of their approval appended to this form. If the Tissue Committee approval is not available at the time of submission to the HSREB, ethics approval will be withheld until a copy of Tissue Committee approval is received.		
		Tissue Use Committee approval	Not applicable X

1.0 Microorganisms

1.1 Does your work involve the use of biological agents? O YES ⊘ NO
(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 O 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 3
	O Yes O No	O Yes O No	O Yes O No			O 1 O 2 O 3
	O Yes O No	O Yes O No	O Yes O No			O 1 O 2 O 3
	O Yes O No	O Yes O No	O Yes O No			O 1 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		

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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)*	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 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	research participants	O Yes O No ⊗Unknown		O 1 O 2 O 3
Human Blood (fraction) or other Body Fluid	" "	O Yes O No ⊗Unknown		O 1 O 2 O 3
Human Organs or Tissues (unpreserved)		O Yes O No O Unknown		O 1 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

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

4.3 Will genetic modification(s) 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

* 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 Animals are studied & housed in TH 2170 (Earl Noble's lab)

6.1 Will live animals be used? ☒ YES NOT here in TH or HSB O NO If no, please proceed to section 7.0

6.2 Name of animal species to be used Sprague - Dawley, SHR

6.3 AUS protocol # 2006 - 109 - 10 2007 - 046 - 05

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

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

_____

_____

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7.0 Use of Animal species with Zoonotic Hazards

7.1 Will any of the following animals or their organs, tissues, lavages or other body fluids including blood be used?

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

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

9.0 Insects Requiring CFIA Permits

9.1 Do you use insects that require a permit from the CFIA? 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 Please attach the CFIA permit.

9.8 Please describe any CFIA permit conditions:
_____
_____

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10.0 Plants Requiring CFIA Permits

10.1 Do you use plants that require a permit from the CFIA? 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 NO, please forward the permit to he Biosafety Officer when available.

10.9 Please 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_____
If no, please proceed to Section 12.0 X NO

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 biohazardous agents in Sections 1.0 to 9.0 have been trained.

SIGNATURE _____

P. Scott & C. Wamsley have not completed Biosafety course - yet.

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13.0 Containment Levels

11.1 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 3

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

☒ YES, permit # if on-campus B10-UWO-0146
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: Oct 29/09

14.2 Please describe additional risk reduction measures will be taken beyond containment level 1, 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 biohazards listed, such as a needlestick injury:

_____
_____

15.0 Approvals

UWO Biohazard Subcommittee: SIGNATURE: _____
Date: _____

Safety Officer for Institution where experiments will take place: SIGNATURE: _____
Date: _____

Safety Officer for University of Western Ontario (if different from above): SIGNATURE: _____
Date: _____

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

Special Conditions of Approval:

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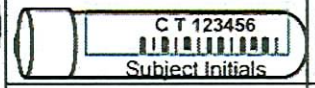
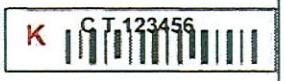
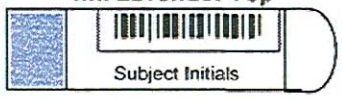
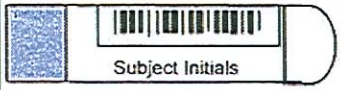
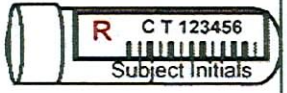
University of Western ON. ARTEMIS

Gamma-Dynacare Medical Laboratories

SPECIMEN COLLECTION AND LABELING PROCEDURE

Tests	Collection Procedures	Tube (Not Provided)	Labels	Transfer Tube & Volume required	Shipments
Chemistry (Serum) **Estradiol hsCRP Glucose (f)**	Invert 10-15 times to mix blood tube, Allow to stand - 30 min. Then Centrifuge 1100-1300g - 15 min. and aliquot serum.	**1X 8.5 ml Tiger Top** 	**1ml in Pour-off Tube** 	**"H" Letter CT barcode Serum label** 	**Ambient** (Shipped daily refrigerated)
Insulin			**1ml in Pour-off Tube** 	**No Letter barcode** 	Frozen Shipped daily on Dry Ice)
Lipid Panel: (Serum) **Cholesterol LDL-Cholesterol HDL-Cholesterol Triglycerides**			**2ml in Pour-off Tube** 	**"k" Letter CT barcode Serum Label** 	Ambient Shipped daily refrigerated)
HbA1c (Whole blood)	Invert gently 10-15 times to mix blood with tube additive.	**4ml Lavender Top** 	**No Transfer Tube. Freeze and send in original container**	**No Letter barcode + Green CT sticker** 	Ambient Shipped daily refrigerated)
Catecholamines (Plasma)	Invert gently 10-15 times to mix, **Centrifuge & Aliquot 3ml Plasma in to pour off tube for 2ml for catechol. Freeze within 30min.**	**4ml Lavender Tube** 	**2ml to Transfer Tube** 	**"R" CT barcode with Black label** 	Ambient (Shipped daily)

Label containers with 2 identifiers -- Subject Initials and Barcode Number